Policy Memorandum

To: Stakeholders and Other Interested Parties

From: Miles V. McEvoy, Deputy Administrator

Subject: Nanotechnology

Date: Approved on March, 24 2015

This memorandum clarifies the status of nanotechnology in organic production and handling under the U.S. Department of Agriculture (USDA) organic regulations at 7 C.F.R. Part 205.

Issue:

The National Organic Program (NOP) has received questions about the use of nanotechnology in organic production and handling.

Nanotechnology is science, engineering, and technology conducted at the nanoscale, which is about 1 to 100 nanometers. Nanomaterials are commonly associated with a size range (nanoscale) of 1 to 100 nanometers along at least one dimension. They may, however, exceed that size, and be defined by physical or chemical characteristics or behavior that distinguish them from bulk, or non-nanomaterial. Nanomaterials can occur naturally, for example in volcanic ash and ocean spray, and may also be incidental byproducts of human activity, such as homogenization or milling. They can also be produced intentionally with specific properties through certain chemical or physical processes. Nanomaterials have many commercial applications spanning different fields, such as medicine, electronics, and energy, as well as agricultural production and food processing. We use the term "engineered nanomaterials" to refer to substances specifically designed and manufactured to have unique properties or behavior attributable to particle size. We use the term "incidental nanomaterials" to refer to substances that are incidental byproducts of other manufacturing (e.g., homogenization, milling) or that occur naturally.

Policy:

In 2010, the National Organic Standards Board (NOSB) recommended that engineered nanomaterials[1] be considered synthetic and prohibited in organic production and processing. The NOSB proposed defining engineered nanomaterials as "substances deliberately designed, engineered, and produced by human activity to be in the nanoscale range of 1-300 nanometers, because of very specific properties or composition (e.g., shape, surface properties, chemistry)

[1] October 2010 NOSB recommendation, Guidance Document— Engineered Nanomaterials in Organic Production, Processing and Packaging.

that result only in that nanoscale." The NOSB-recommended definition would include all nanomaterials containing capping agents or other synthetic components, but not incidental particles created during traditional food processing, or naturally occurring nanomaterials.

The NOP does not consider nanotechnology to be intrinsically benign or harmful. This memorandum clarifies that the statutory framework for the review of substances intended for use in organic production and handling would also apply to engineered nanomaterials.

The Organic Foods Production Act of 1990 (OFPA) authorizes the Secretary of Agriculture to establish the National List of Allowed and Prohibited Substances. The National List specifies which synthetic substances may be used in organic production as well as any substances prohibited for use in organic production. Section 205.605 of the USDA organic regulations includes the list of synthetic and nonsynthetic substances that may be used in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

Under 7 U.S.C. 6517, the National List established by the Secretary at 7 C.F.R. 205.605 shall be based upon a proposed National List or proposed amendments to the National List developed by the NOSB. The statute further requires that any amendments to the National List must undergo a public notice and comment period before changes are made.

As with other substances, no engineered nanomaterial will be allowed for use in organic production and handling unless the substance has been: 1) petitioned for use; 2) reviewed and recommended by the NOSB; and 3) added to the National List through notice and comment rulemaking. The OFPA provides criteria that the NOSB must use to evaluate substances requested for use in organic production and handling. Individuals or organizations petitioning to add an engineered nanomaterial to the National List must provide information to address the OFPA criteria.[2]

To avoid conflicts about the presence of nanomaterials in substances regulated by other Federal agencies, the NOP is not establishing a separate definition for engineered nanomaterials, such as the definition recommended by the NOSB. The descriptions in the U.S. Food and Drug Administration's Guidance for Industry Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology[3] and the U.S. Environmental Protection Agency's policies on Regulating Pesticides that Use Nanotechnology[4] and Control of Nanoscale Materials Under the Toxic Substances Control Act[5] should be used as applicable.

[2] Refer to the NOP Guidelines on Procedures for Submitting National List Petitions, 72 FR 2167.
[3] U.S. Food and Drug Administration, Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology, http://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm.
[4] U.S. Environmental Protection Agency, Regulating Pesticides that Use Nanotechnology, http://www.epa.gov/pesticides/regulating/nanotechnology.html
[5] U.S. Environmental Protection Agency, Control of Nanoscale Materials Under the Toxic Substances Control Act, http://www.epa.gov/oppt/nano/

National Organic Standards Board
Materials/GMO Subcommittee
Request to Establish a Task Force for Seed Purity from GMOs

Introduction

For several years now the National Organic Standards Board (NOSB) has been collecting public input on the issue of Seed Purity from GMOs. After three discussion documents, a report, a collection of Prevention strategies to keep GMOs out, and an expert panel on seed purity, we are still not to the point of making a comprehensive proposal.

The obstacles are immense, and have been thoroughly vetted in our past posted documents. Suffice to say the obstacles are not shrinking with the passage of time, but the need for action is growing.

Therefore we are proposing to set up an official Task Force as a viable next step to keep working on this important issue.

Background

Most of the background was covered in the most recent Discussion Document from the Spring 2016 NOSB meeting: *Discussion Document on Next Steps for Improving Seed Purity*. After discussing all the issues, several scenarios were posed as possible next steps. The suggestion that got the most positive feedback was:

> **B. USDA Task Force**
> The NOSB could recommend that the USDA establish a Seed Purity Advisory Task Force. The task force members would be appointed by the USDA, primarily through NOP but possibly in conjunction with the AC21 FACA board.
>
> The task force would design a feasibility study based on testing that would be administered and carried out by USDA. The study would be crop specific and would evaluate what a rigorous yet realistic threshold might look like, focusing on non-organic seed. The task force would design a 3 - 5 year action plan, after which time the testing could begin and data from it could be collected.

This was also in our Discussion Document:

> We are mindful of this quote from Matthew Dillon from ClifBar in his testimony to the NOSB during the Expert Panel, "We often say that seed work is slow work. It takes seven, ten, twelve years to breed a new variety and get it into the commercial marketplace. Sometimes longer. Seed work is slow work and we have to be deliberate in our approach to seed, whether it's in breeding and production or in our decisions regarding regulations."[1]

[1] NOSB meeting transcript, Spring 2015, La Jolla, CA

Among the four ideas that were presented in the Spring 2016 Discussion Document, the one that got the most support was establishing a Seed Purity Advisory Task Force to take on the specifics and feasibility of all the ideas presented for discussion. While many stakeholders are concerned because the process of implementing a seed testing protocol is not happening fast enough, the majority felt that it is important to do this in a coordinated and comprehensive way. As one commenter stated: "The farmer needs to know that when they look at a bag of seed that has a certified organic label on it that the GMO level is low enough that they can plant the seed and then sell the corn as organic corn and not get it rejected because the seed corn had too high of GMO contamination."[2]

Goals

- The Seed Purity Advisory Task Force would be charged to develop processes to implement any or all of the suggestions regarding seed purity in organic systems.
- Develop an effective data collection process and framework, to determine how much contamination is occurring by crop and where the contamination is coming from.
- Grapple with the specific questions surrounding data collection of both organic and conventional untreated seed used in organic systems. This could include sampling method, sample size, threshold considerations, and how to compile and use such data.
- Act as experts to interpret the data being collected, looking at the impact of certain crop-specific thresholds with regard to seed industry and farmer financial risk
- Design a crop-specific feasibility study based on testing that would be administered and carried out by USDA.
- Consider organization structure of a sanctioned testing program and funding mechanisms that do not burden the organic community, but spread costs of seed contamination throughout the organic community.

Make-up of Task Force

The Seed Purity Advisory Task Force must fully represent the growers and industry affected by contamination of organic and other non-GMO seed. At the same time there needs to be expertise among participants. We suggest a maximum of 12 appointees so that scheduling and working is not too cumbersome.

The following stakeholders are appropriate appointees:

organic farmers
organic seed producers
organic seed suppliers
processors or exporters of at-risk organic crops
genetic testing experts
academic professionals who work with organic at-risk crops
organic farming and food advocacy groups
Accredited Organic Certifiers

Additionally, one or two members of the NOSB could participate in a liaison role.

[2] public comment from David Marshall, a farmer from PA.

Timeline

We request that the Task Force be appointed initially for 3 years from the date of convening the first meeting (either live or virtual). While there may need to be an extension if progress is being made but not completed, the three years should give enough time for feasibility studies and the other goals to be addressed in a significant way.

Giving a very specific timeline is not possible yet, but it is anticipated that the Task Force will report regularly to the NOSB on their progress and any proposals that come out of their efforts.

Proposal For The Organic Poultry Working Group
May 17, 2016

Background:
At the NOSB Spring 2015 meeting in La Jolla, CA, the board voted unanimously for the following resolution:

The National Organic Standards Board is committed to the phase-out of synthetic methionine for organic poultry production, and encourages aggressive industry and independent research on natural alternative sources of methionine, breeding poultry that perform well on less methionine, and management practices for improved poultry animal welfare.

Organizational Intent:
The Organic Poultry Working Group (OPWG) will be created for the purpose of identifying those issues around organic poultry production that are barriers to achieving the objective stated in the NOSB resolution.

Objective:

1. The first task of the group will be to create a "white paper" on the current status of the feeding of synthetic methionine to organic poultry on a global level. The white paper would also contain information on what practices are being carried out as alternatives to synthetic methionine or practices that eliminate the need for synthetic methionine. The paper would contain information on synthetic alternatives and alternative practices from not only the United States but globally and would also evaluate the effectiveness of those alternatives. The white paper would then be used to guide the Livestock Subcommittee in determining specific and detailed research priorities related to alternatives for synthetic methionine.

2. Identify any research areas that the Livestock Subcommittee can bring forward as research priorities for organic poultry production in the following areas:
    a. Methionine Alternatives
    b. Animal Welfare or Behavior
    c. Management Practices
    d. Poultry Breeding/Genetics

Timeline:
1. May 31, 2016 Livestock Subcommittee Submits Formal Recommendation to NOP
2. September 1, 2016 Federal register publication to call for nominations
3. October 14, 2016 Nominations Close
4. December 1, 2016 Announcement of Organic Poultry Working Group Members
5. January 1, 2017 OPWG Begins Work
6. August 1, 2017 Preliminary Draft of White Paper and research priorities due
7. October 1, 2017 Final Draft of White Paper and Research Priorities Due to Subcommittee
8. October 2017 Livestock Committee Presents White Paper at Fall Meeting and gathers feedback from full board and public on any missing work or issues not identified.
9. November 2017 OPWG is disbanded unless full NOSB board identifies any missing information.

Members:

1. Reports to NOSB Livestock subcommittee
2. 8-12 members with diverse backgrounds
    i. Poultry producers (large to small should be represented)
    ii. Consumer Group representative
    iii. Academia
    iv. Environmentalist
    v. Feed Mills
    vi. FDA/AFCO
    vii. NOSB member(s)

National Organic Standards Board
Materials/GMO Subcommittee Proposal
Excluded Methods Terminology
August 30, 2016

Introduction and Background

In April 2013 the project was started to grapple with the definition of "excluded methods" in the USDA organic regulations. This is the definition that appears in the rule (7 CFR 205.2; Terms Defined):

> Excluded methods. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture. (Federal Register / Vol. 65, No. 246 / Thursday, December 21, 2000 / Rules and Regulations p. 80639)

The definition was based on the best efforts of the NOSB in 1995 and has provided adequate guidance to prohibit the use of the most obvious genetically engineered crops such as herbicide-resistant corn and soybeans and Bt cotton, as well as prohibit processing inputs such as genetically engineered yeasts and enzymes. However, this definition is in need of re-examination and updating due to rapid advances in recombinant DNA biotechnology since 1995 that have made for gray areas for the organic standards regarding interpretation and enforcement.

In 2011 and 2012 a number of confusing issues came before the NOSB and to the NOP which made it necessary to revisit the definition. These include genetically engineered vaccines for livestock, the use of cell fusion within plant families to create male sterility in brassica hybrids, whether or not GMOs could be used in biodegradable bioplastic mulches, and the question of whether mutated algae might therefore be genetically engineered. The current definition is inadequate to clarify these issues. In the last few years the rise of gene editing with no insertion of foreign DNA, synthetic biology, and the genetically engineered insects that are starting to appear make this effort even more important.

The first NOSB Discussion Document on excluded methods in 2013,[1] discussed each of the terms in the above definition, defined and discussed other terms involved in traditional breeding, such as mutagenesis and conjugation, and brought up new terms that may be considered to be genetic engineering. No conclusions were suggested except that there is a need to do more work on the subject. The discussion questions posed asked commenters to suggest principles on which to base GE distinctions, to offer opinions on what terms were and were not excluded methods, and to bring forward new terms that may need consideration.

The second NOSB Discussion Document posted in September 2014 and in April 2015[2] analyzed the comments received and proposed several options for an updated definition, and principles and criteria to use when evaluating the various genetic modification issues. Additional terms were collected and the beginnings of some definitions were started. A structure was proposed similar to the one in use by the Research Institute of Organic Agriculture (FiBL) in Europe that involves an itemized chart with a yes/no column where the specific techniques could be itemized and evaluated. The Subcommittee made an informal recommendation, which was not voted upon, that these revisions to the definition and structure

for evaluating techniques be regulated through NOP guidance rather than additional rulemaking. Lastly it was acknowledged that there will be some unresolved issues that will need continued public discussion because they pose enforcement challenges, are totally hidden from view, or not enough is known about them yet.

Both a Proposal and a Discussion Document were posted for the April 2016 NOSB meeting. While comment was generally favorable to the approach taken, there clearly was the need for some refinement of the definitions and criteria. There was also confusion about which techniques were part of the proposal and which remained to be discussed further.

Goals of This Proposal/Document

The need for forward motion on this subject is more pressing every month. The fact that over 1000 pages of scientific references were submitted in public comment, with most of it being papers that came out since the NOSB GMO ad hoc Subcommittee was formed in 2012, indicates that the biotech community is rapidly outpacing any regulatory structure. The U.S. Department of Agriculture (USDA) has already ruled that certain plants produced with novel approaches to genetic manipulation will not be regulated as genetically modified organisms in the United States[3]. It is more imperative than ever that the organic community be very clear about where the line is drawn regarding genetic engineering.

Public Comment from the past two and a half years has indicated strong support for this effort on the whole, although there is not consensus on some details. Every organic stakeholder is clear that genetic engineering is an imminent threat to organic integrity. Every effort must be made to protect that integrity to the extent that the NOSB is able to contribute to that.

The Materials Subcommittee is ready to move forward to create a structure for reviewing new technologies, and disseminating the results of this review in a transparent manner. To this end, the proposal portion of this document includes supplements to the definition in the rule based on internationally accepted language, criteria to use in the reviews based on that definition, and a chart of those techniques that are clearly "excluded methods" based on the definition and criteria.

A separate discussion document contains the technologies, terms, and issues that we have not been able to agree on or do not yet have enough information on or that pose challenges that we have not yet taken up. These items are put out for discussion to collect further public comment. They will be reviewed at future NOSB meetings.

Definitions

In the previous Discussion Document we suggested a couple of possible definitions that would update the text in the rule to a more comprehensive one that would be flexible enough to accommodate future technologies and terms. We were inclined to favor the definitions in use by Codex Alimentarius that were also in the Cartagena Protocol.

During the course of public comment and subsequent discussion, it has become clear that more than one definition is important to the organic community, but that all the terms we suggest defining here would fall under the Excluded Methods definition in the rule and would not change, but would strengthen that definition. These definitions are to be used in Guidance to supplement and update the definition in the regulations, while leaving the rule itself intact. It is important to adopt some definitions that are widely

accepted internationally and thus provide common ground with other countries who are concerned about GMOs in organics.

Based on public comment from the spring 2016 proposal, we decided to add a definition for Classical/Traditional Plant Breeding. Traditional breeding is a term used in the Excluded Methods definition in the rule and is therefore important to clarify what it means. However because the other definitions and criteria are not unique to plants, we slightly changed the wording so that they are applicable to all organisms.

In October 2015 the International Federation of Organic Agriculture Movements (IFOAM) published a Discussion Paper on a proposed revision to their Position on Genetic Engineering.[4][5] Since other countries do not use the concept of "Excluded Methods", IFOAM proposed new definitions for three terms: Genetic Engineering (GE), Genetically Modified Organism (GMO), and Synthetic Biology. After examining their definitions, the Materials/GMO Subcommittee (MS) agrees that these three terms are important to define in the guidance we are proposing. However, we do not wish to take the old approach (that IFOAM is still using) of trying to capture all the methods and terms into one definition, because it will be out of date as soon as the next round of new technologies arrives.
Therefore we are proposing that the following definitions of terms and acronyms, with sources, be adopted by the NOSB as Excluded Methods[1]:

Genetic engineering (GE) – A set of techniques from modern biotechnology (such as altered and/or recombinant DNA and RNA) by which the genetic material of plants, animals, organisms, cells and other biological units are altered and recombined. (First sentence modified from IFOAM Position cited above)

Genetically Modified Organism (GMO) – A plant, animal, or organism that is from genetic engineering as defined here. This term will also apply to products and derivatives from genetically engineered sources. (Modified slightly from IFOAM Position cited above)

Modern Biotechnology – (i) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family, that overcomes natural, physiological reproductive or recombination barriers, and that are not techniques used in traditional breeding and selection. (From Codex Alimentarius[6])

Synthetic Biology[7] – A further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems. (Operational Definition developed by the Ad Hoc Technical Expert Group on Synthetic Biology of the UN Convention on Biological Diversity[8])

Non-GMO – The term that is used to describe or label a product that was produced without any of the excluded methods defined in the organic regulations and corresponding NOP policy. The term "non-GMO" is consistent with process-based standards of the NOP where preventive practices and procedures are in place to prevent GMO contamination while recognizing the possibility of inadvertent presence. (Modified based on public comment from Spring 2016 NOSB)

[1] Both definitions and criteria were worked on in between the Spring and Fall NOSB meetings by an ad hoc group with the following members: Julie Dawson, University of Wisconsin; David Gould, International Federation of Organic Agriculture Movements (IFOAM); Michael Hansen, Consumers Reports; Jaydee Hanson, Center for Food Safety; Kristina Hubbard, Organic Seed Alliance; Melody Meyer, United Natural Foods; James Myers, Oregon State University; Dana Perls, Friends of the Earth; Erica Renaud, Vitalis Organic Seeds; Dan Seitz, National Organic Standards Board (NOSB); Michael Sligh, Rural Advancement Fund International; Zea Sonnabend, Fruitilicious Farm and NOSB; Jim thomas, ETC Group; William Tracy, University of Wisconsin; Gwendolyn Wyard, Organic Trade Association.

Classical/Traditional plant breeding – Classical (also known as traditional) plant breeding relies on phenotypic selection, field based testing and statistical methods for developing varieties or identifying superior individuals from a population, rather than on techniques of modern biotechnology. The steps to conduct breeding include: generation of genetic variability in plant populations for traits of interest through controlled crossing (or starting with genetically diverse populations), phenotypic selection among genetically distinct individuals for traits of interest, and stabilization of selected individuals to form a unique and recognizable cultivar. Classical plant breeding does not exclude the use of genetic or genomic information to more accurately assess phenotypes, however the emphasis must be on whole plant selection.

This series of definitions provides a better framework than the existing definition, as it elaborates the various technologies that would be prohibited as well as those which would be allowed. We propose to combine these definitions, the principles and criteria discussed below, and the terminology chart presented into this Proposal for Guidance on Excluded Methods.

Principles and Criteria

The NOSB has its own set of Principles of Organic Production and Handling in the Policy and Procedures Manual[9]. The principles start with:

> 1.1 Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. These goals are met, where possible, through the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system.

Regarding Genetic Engineering:

> 1.11 Genetic engineering (recombinant and technology) is a synthetic process designed to control nature at the molecular level, with the potential for unforeseen consequences. As such, it is not compatible with the principles of organic agriculture (either production or handling). Genetically engineered/modified organisms (geo/gmos) and products produced by or through the use of genetic engineering are prohibited.

The following principals of Organic Agriculture are used by IFOAM[10] and summarize well the guidance for developing a position on GMO technology.

- Principle of Health: Organic Agriculture should sustain and enhance the health of soil, plant, animal, human and planet as one and indivisible.
- Principle of Ecology: Organic Agriculture should be based on living ecological systems and cycles, work with them, emulate them and help sustain them.
- Principle of Fairness: Organic Agriculture should build on relationships that ensure fairness with regard to the common environment and life opportunities.
- Principle of Care: Organic Agriculture should be managed in a precautionary and responsible manner to protect the health and well-being of current and future generations and the environment.

Using the principles above, biotechnology processes will be reviewed to the following criteria to determine if they are excluded methods:

1. The genome is respected as an indivisible entity and technical/physical insertion, deletions, or rearrangements in the genome is refrained from (e.g. through transmission of isolated DNA, RNA, or proteins). *In vitro* nucleic acid techniques are considered to be invasion into the plant genome.

2. The ability of a variety to reproduce in species-specific manner has to be maintained and genetic use restriction technologies are refrained from (e.g. Terminator technology).[11]
3. Novel proteins and other molecules produced from modern biotechnology must be prevented from being introduced into the agro-ecosystem and into the organic food supply.
4. The exchange of genetic resources is encouraged. In order to ensure farmers have a legal avenue to save seed and plant breeders have access to germplasm for research and developing new varieties, the application of restrictive intellectual property protection (e.g., utility patents and licensing agreements that restrict such uses to living organisms, their metabolites, gene sequences or breeding processes are refrained from.[12]

Most of the techniques that are considered to be genetic engineering are clearly not compatible with the principal of ecology because they do not work within living ecological systems or sustain them. They are also at odds with the Principal of Fairness because they are not available equally to all stakeholders and are often patented or used to create patented traits. There are significant questions around the Principle of care for the health and well-being of future generations and the environment. These concerns do not change just because a technique cannot be tested for or does not use DNA foreign to the target organism.

The secondary effects from the use of GMOs are starting to emerge clearly in parallel with the new technologies. Issues such as reduction in diversity on farms where GMOs are grown, the demise of beneficial species both above and below the soil, the decline in soil fertility and resilience from increased use of herbicides, the evolution of weeds resistant to those herbicides, the altered nutritional profiles of the GMO crop products, and the displacement of small farmers from their land are all violations of the principals of organic agriculture.[13]

Process and Product

Since the whole underpinning of the U.S. organic regulations is a process-based system, it makes sense that this concept carry over to defining excluded methods. This is indeed the basis of the current definition. However, this is not currently how U.S. government agencies regulate GMOs[14], or handle other issues such as pesticide residues or water quality standards.

Newer technologies, known as Targeted genetic modification (TagMo) or targeted genome editing, are emerging and being adopted quickly.[15] These are very clearly genetic engineering techniques but are not regulated by the current government structure because they do not involve DNA from a "pest" under the USDA APHIS regulatory structure. Many of these techniques involve precise changes in existing DNA without using foreign DNA from a different species. These new technologies make genetic modification much more accessible and less expensive. The resulting plants may not show up as genetically engineered in the commonly used testing methods because they contain no foreign DNA, just native DNA that has been changed at the allele level by humans.

Forward Movement towards Structure

FiBL Research Institute for Organic Agriculture from Switzerland submitted a comment in 2013 that included a chart that describes methods with a yes/no column for compatibility with organic standards for both plants and animals[16]. The NOSB posed adopting such a chart on the methods that receive consensus and can be incorporated into guidance. It is important to identify all of these terms so that it is clear that they fall under the definition of excluded methods, but these terms do not need to be added to the definition itself.

The first version of such a chart for the NOSB is presented here. Appendix A provides a brief description of each term with additional citations for those who want to find out more about the terms. There is so much terminology and so many techniques with similar or multiple names that we have added a column for additional names and types used for each general process. Along with lack of regulation of some of these processes, there is lack of standardization of the terms, so that new names and sometime proprietary ones are emerging all the time.

We would especially like to acknowledge the work done by the Center for Food Safety in their public comment for the April 2015 meeting. They have helped organize all the various terminology and provided substantial scientific papers that discuss all the terms.[17] The technologies are grouped by the tasks that the methods accomplish and the types of changes made to the engineered organism. In the context of this proposal we are not able to discuss most of the terms at length so please see the Appendix and the CFS cited comment for the full reference list.

For this version of the proposal, the ones that were marked "TBD" in the previous chart below are now moved to the accompanying Discussion Document. The ones presented here are those that we are voting on as either Excluded or Allowed. A column has been added for which criteria apply to the excluded techniques that have led to our conclusion to exclude them.

Terminology Chart				
Method and synonyms	Types	Excluded Methods	Criteria Applied	Notes
Targeted genetic modification (TagMo) syn. Synthetic gene technologies syn. Genome engineering syn. Gene editing syn. Gene targeting	Sequence-specific nucleases (SSNs) Meganucleases Zinc finger nuclease (ZFN) Mutagenesis via oligonucleotides CRISPR-Cas system* TALENs** Oligonucleotide directed mutagenesis (ODM) Rapid Trait Development System (RTDS) (Cibus)	YES	1, 3, 4	Most of these new techniques are not regulated by USDA and are hard to test for.
Gene Silencing	RNA-dependent DNA methylation (RdDM) Silencing via RNAi pathway RNAi pesticides	YES	1, 2, 4	
Accelerated plant breeding techniques	Reverse Breeding Genome Elimination FasTrack Fast flowering Dupont Seed Production Technology (SPT)	YES	1, 2, 4	These may pose an enforcement problem for organics because they are not detectable in tests.
Synthetic Biology	Creating new DNA sequences Synthetic chromosomes Engineered biological functions and systems.	YES	1, 3, 4	
Cloned animals and offspring	Somatic nuclear transfer	YES	1, 3	

Plastid Transformation		YES	1, 3, 4	
Marker Assisted Selection		NO		
Transduction		NO		

* CRISPR-Cas = Clustered regularly interspaced short palindromic repeats and associated protein genes.
** TALENs = Transcription activator-like effector nucleases.

Proposal

This proposal has three sections, to be used in NOP Guidance on Excluded Methods:
1. Approve the definitions of Genetic Engineering (GE), Genetically Modified Organism (GMO), Modern Biotechnology, Synthetic Biology, Non-GMO, and Classical/Traditional Plant Breeding as written above.
2. Approve the Principles and Criteria above that will be used in the evaluation of new technologies and terminologies.
3. Adopt the Terminology chart proposed above and the listings in it as presented, recognizing that this will be added to as further deliberations occur in the future.

Subcommittee Vote

Motion to accept the three sections of this proposal as stated above.
Motion by: Zea Sonnabend
Second: Emily Oakley
Yes: 4 No: 0 Absent: 1 Abstain: 1 Recuse: 0

Appendix A –
Brief Description and Additional Citations for Terms used in Excluded Methods Terminology Chart.

Only terms that are marked YES or NO as Excluded Methods are defined here. All those marked TBD are still being worked on in discussion. Those marked "syn." are defined in cited reference from Center for Food Safety Public Comment in April 2015[18]. Some other definitions are from the NOSB previous discussion document[19] and from the FiBL 2015 plant breeding dossier.[20]

Targeted genetic modification (TaqMo) (Kuzma and Kokotovich 2011, Kokotovich and Kuzma 2014) - a collective term for the zinc finger nuclease techniques that create DNA double-stranded breaks at specific genomic locations that can then be used to alter the target gene. The genetic modification would not necessarily involve transfer of nucleic acids from another species, nor would it be easy to detect in a final product.

- syn. Synthetic gene technologies (Then 2015)
- syn. Genome engineering (Voytas and Gao 2014)
- syn. Gene editing (Puchta and Fauser 2013)
- syn. Gene targeting (GT) (Puchta and Fauser 2013, Endo et al. 2015)
- syn. Sequence-specific nucleases (SSNs) (Voytas and Gao 2014):
- syn. Meganucleases (Gao et al. 2011, as cited in FSANZ 2013)
- syn. Site directed mutagenesis via oligonucleotides, zinc finger nuclease (ZFN) (Dow, APHIS 2012) - an introduction of recombinant DNA through transient molecules that are identified by zinc-finger nucleases, with or without a repair template. The techniques resemble transgenesis but the end products are similar to, and indistinguishable from, conventionally bred plants.
- syn. Clustered regularly interspaced short palindromic repeats and associated protein genes (CRISPR-Cas system) (NYTs 3/20/2015) – a protein called Cas9 enables breaks in DNA at specific spots so that additional pieces of DNA and RNA can be inserted.
- syn. Transcription activator-like effector nucleases (TALENs) (Sprink et al. 2014).
- syn. Oligonucleotide directed mutagenesis (ODM) (Lusser et al. 2011)
- syn. Cibus Rapid Trait Development System (RTDS) (Beetham et al. 2012 patent) - Similar to the oligonucleotide targeted DNA modification it does not leave behind transgenic material, only uses it to create a change in a precise area of a gene.

Gene silencing via RNAi and DNA methylation - Interfering with the regulation of gene expression through inserting methyl groups onto RNA and DNA that then suppress the expression of the gene. Can occur in nature, but is used as a recombinant technique in cancer research and plant breeding.

- syn. RNA-dependent DNA methylation (RdDM) (Lusser et al. 2011)
- syn. Gene silencing via RNAi pathway (Casacuberta et al. 2015, Baier et al. 2014, Lubasik and Zielenkiewicz 2014, Hirschi 2012, Heinemann et al. 2013, Lundgren and Duan 2013, Wagner et al. 2015) – A technique in which a small strand of RNA is inserted into a DNA sequence to regulate the expression of the gene. There is no change to the DNA sequence, but there is technical interference with the genome.
- RNAi-based pesticides (Palli 2014, Zhu 2013) – RNA interference (RNAi) is a technique in which gene silencing RNA strands are inserted into a target genome in order to regulate the expression of target genes. It was used to engineer rootworm resistant corn as well as to genetically engineer insects themselves.

Accelerated Plant Breeding Techniques

- Reverse Breeding (Dirks et al. 2009) – A process that uses several other techniques such as RNAi to suppress meiotic recombination, tissue culture, and then double haploidization to create parental lines that are homozygous to use in breeding F1 hybrids.
- Genome elimination (Comai 2014)

- FasTrack (Waltz 2012) – a breeding scheme that has so far been used in plums where an early-flowering gene from poplar is inserted into a plum tree. When the plum flowers in less than a year, it is crossed with non-transgenic varieties carrying desirable traits. Markers are used to identify the right traits and, at the end of the breeding program, only those are selected that do not have the transgene.
- Fast flowering (Flachowsky et al. 2011)
- DuPont's Seed Production Technology (SPT) (Waltz 2012)

Synthetic Biology (see definition in main document)

- Synthetic chromosomes (Shenoy and Sarma 2010, pp. 12-13; Gaeta et al. 2012)

Embryo Transfer in animals – a technique used in animal breeding. It involves inducing superovulation of donor with gonadotropins, artificial insemination, recovery of embryos, isolation and storage of embryos, transfer of embryos back into animals, and then pregnancy.

Plastid transformation (Maliga 2004, as cited in NOSB discussion 2014) – Plastids are semi-autonomous organelles within higher plants with a small, highly polyploid genome. Technology has been developed for genetic modification of this genome independent of nuclear DNA. Currently used commercially in tobacco, and widely researched.

Marker Assisted Selection – Molecular markers are used as diagnostic aids to determine differences in the DNA sequence. They can help in selecting desired traits. The markers do not change the DNA of living plants and are not considered to be genetic engineering.

[1] NOSB 2013. Excluded Methods Terminology Discussion Document. April 2013. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5102656

[2] National Organic Standards Board Materials/GMO Subcommittee. (2014). *Discussion Document on Excluded Methods Terminology*. August 22.

[3] Waltz, E. (2012). Tiptoeing around transgenics. *Nature Biotechnology*, *30*, 215-217. doi:10.1038/nbt.2143

[4] IFOAM – Organics International, 2015, 2015 Discussion Paper on a Proposed Revision to Position on Genetic Engineering and Genetically Modified Organisms in Organic Agriculture. https://gallery.mailchimp.com/75bdff144a46c1e451eecde10/files/Discussion_paper_on_GMO_position_2015.pdf

[5] IFOAM – Organics International, 2002, Postition on Genetic Engineering and Genetically Modified Organisms, P01, https://gallery.mailchimp.com/75bdff144a46c1e451eecde10/files/IFOAM_GMO_Position_Paper.pdf

[6] Codex Alimentarius Commission (2003). "Principles for the Risk Analysis of Foods Derived from Modern Biotechnology," *CAC/GL 44>2003*. Amended 2008, 2011, *available at:* http://www.fao.org/faoDwhoD codexalimentarius/shD proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BGL%2B44D2003%252FCXG_044e.pdf.

[7] Two other definitions were looked at when this one was chosen: **Synthetic Biology** – Designing and constructing biological devices, biological systems, biological machines and biological organisms using a range of methods derived from molecular biology and biotechnology, including in virtually all cases the techniques of genetic engineering or genetic modification. (From IFOAM Position cited above). **Synthetic biology** is a maturing scientific discipline that combines science and engineering in order to design and build novel biological functions and systems. This includes the design and construction of new biological parts, devices, and systems...as well as the re-design of existing, natural biological systems for useful purposes." (from SynBerc, the University of California/Department of Energy synthetic biology research consortium)

[8] Link to the European Commission's draft definition with discussion: http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihr_consultation_21_en.htm

[9] NOSB Policy and Procedures Manual: https://www.ams.usda.gov/sites/default/files/media/NOSB-PolicyManual.pdfhttps://www.ams.usda.gov/sites/default/files/media/NOSB-PolicyManual.pdf

[10] http://www.ifoam.bio/sites/default/files/poa_english_web.pdf

[11] FiBL Research Institute of Organic Agriculture 2013. Public Comment to NOSB. Docket AMS-NOP-12-0070

[12] FiBL Research Institute of Organic Agriculture 2015. Dossier No. 2 Plant Breeding Techniques: an assessment for organic farming.

[13] IFOAM – Organics International, 2015, 2015 Discussion Paper on a Proposed Revision to Position on Genetic Engineering and Genetically Modified Organisms in Organic Agriculture. https://gallery.mailchimp.com/75bdff144a46c1e451eecde10/files/Discussion_paper_on_GMO_position_2015.pdf

[14] Kuzma J, Kokotovich A (2011) Renegotiating GM crop regulation. EMBO reports 12: 883–888.

[15] Kokotovich A, Kuzma J (2014) Conflicting Futures: Environmental Regulation of Plant Targeted Genetic Modification. Bulletin of Science, Technology & Society 34: 108–120.

[16] FiBL Research Institute of Organic Agriculture 2013. Public Comment to NOSB. Docket AMS-NOP-12-0070

[17] CFS Comments to the NOSB, 2015, Docket #AMS_NOP_15-0002-0874

[18] CFS Comments to the NOSB, 2015. Reference List. http://www.regulations.gov/#!documentDetail;D=AMS-NOP-15-0002-0875

[19] National Organic Standards Board Materials/GMO Subcommittee. (2014). *Discussion Document on Excluded Methods Terminology*. August 22.

[20] FiBL Research Institute of Organic Agriculture 2015. Dossier No. 2 Plant Breeding Techniques: an assessment for organic farming.

National Organic Standards Board
Materials/GMO Subcommittee
Excluded Methods Terminology – Third Discussion Document
August 30, 2016

Note: The Materials Subcommittee is posting the same discussion document from February 2016 with one change. Embryo transfer in animals has been added to the terminology chart with a "TBD", after public comment from the Spring 2016 meeting indicated that it should be considered as allowed in organic livestock. This and all the issues within this document will warrant further discussion at future meetings once the proposal for definitions and criteria is in place. If you submitted comments to the Spring 2016 posting, you do not need to send them again.

Introduction and Background

In April 2013 the project was started to grapple with the definition of "excluded methods" in the USDA organic regulations. This is the definition that appears in the rule (7 CFR 205.2; Terms Defined):

> Excluded methods. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture. (Federal Register / Vol. 65, No. 246 / Thursday, December 21, 2000 / Rules and Regulations p. 80639)

The definition was based on the best efforts of the NOSB in 1995 and has provided adequate guidance to prohibit the use of the most obvious genetically engineered crops such as herbicide-resistant corn and soybeans and Bt cotton, as well as prohibit processing inputs such as genetically engineered yeasts and enzymes. However, this definition is in need of re-examination and updating due to rapid advances in recombinant DNA biotechnology since 1995 that have made for gray areas for the organic standards regarding interpretation and enforcement.

Please see the Excluded Methods Terminology Proposal from this same date for a full elaboration of the background and progress to this point.

This Discussion Document contains the technologies, terms, and issues that we have not been able to agree on or do not yet have enough information on or that pose challenges that we have not yet taken up. These items are put out for discussion to collect further public comment. They will be reviewed at future NOSB meetings.

Discussion
There are several areas for future discussion and work on this subject:

- Additional criteria for evaluating technologies that need to be considered.
- How to detect those technologies that are excluded but may not provide detectable genetically engineered DNA when tested.
- Enforcement of the excluded method provisions of the rule when they are not traceable and undetectable.
- Additional technologies and terms that may not be clearly prohibited as excluded methods.

- Whether the concepts adopted in the proposal should or could lead to Organic Plant Breeding standards and the regulation of the term "Organically Bred Variety (or Animal)"

Once the proposal section in the accompanying document is voted on the structure will be in place to continue looking at these issues. We are interested in input from the organic public on these issues and will continue to have a transparent process to keep excluded methods out of organic production.

A. Additional Criteria

In the 2015 publication on Plant Breeding from FiBL[i], the Research Institute for Organic Agriculture from Switzerland, there are several more criteria mentioned than we have adopted in our proposal. These include:

- The cell is respected as an indivisible functional entity and technical/physical invasion into an isolated cell on growth media is refrained from (e. g. digestion of the cell wall, destruction of the cell nucleus through cyto-plast fusions).
- A variety must be usable for further crop improvement and seed propagation. This means that the breeders' exemption and the farmers' right are legally granted and patenting is refrained from, and that the crossing ability is not restricted by technical means (e.g. by using male sterility without the possibility of restoration).
- The creation of genetic diversity takes place within the plant specific crossing barriers through fusion of egg cell and pollen. Forced hybridization of somatic cells (e.g. through cell fusions) is refrained from.

B. Detection and testing

Many in the organic community have proposed that there be some testing of at-risk seeds and crops for the presence of GMOs and a threshold beyond which the crop could not be sold as organic. Consumers throughout the world clearly want to know if their food has been genetically engineered. These tests are reliable indicators of DNA that has had foreign components introduced at the genome level.

However, in the newer gene splicing and gene editing technologies there is no foreign DNA introduced. The DNA in the genes has been moved around, or sequences introduced from within the same genome that change the expression of certain traits. Many if not most of these methods are not detectable with the existing tests for GMOs. While it is likely that such testing may be developed in the future, it becomes very challenging for the National Organic Program (NOP) and Accredited Certifying Agents (ACA) to determine if any new variety was produced with one of the newer excluded technologies.

Ideas for addressing this have included creating a website for plant varieties that are excluded, or some sort of affidavit system for ACAs to use for varieties known to be introduced from these methods. Any workable ideas for accomplishing a way to tell which varieties are excluded are welcome.

C. Enforcement

Hand in hand with the above detection issue is the question of how to enforce the exclusion of new technologies when they cannot be detected. Enforcement needs to be equal across all ACAs and there has to be adequate training for ACAs in how to recognize newer strains of GMOs and what to do about them. The same process that could be developed for detection could also tie into enforcement, but some creative approaches are needed for these issues since they are not being addressed by the USDA as a whole.

D. Additional technologies and terms

The chart presented in the Proposal document has a number of terms that are marked "TBD" in the Excluded Methods column. These are the ones that need further discussion to determine which of these should be added to the chart and which may not be appropriately deemed an excluded method. Some may be excluded for some uses but not others depending on exactly how the technique is carried out. They are repeated below, with a few notes:

Terminology Chart			
Method and synonyms	Types	Excluded Methods	Notes
Protoplast Fusion		*TBD*	There are many ways to achieve protoplast fusion and until the criteria about cell wall integrity is discussed, these technologies cannot yet be evaluated.
Cisgenesis		*TBD*	A very broad term that may need to be divided into some allowed and some excluded techniques.
Intragenesis		*TBD*	Similar to cisgenesis but gene sequences may be re-arranged.
Transposons		*TBD*	Used in animal vaccines. May be excluded in some situations but not others.
Cell Fusion within Plant Family		*TBD*	Subject of an NOP memo in 2013, the issue of detection of these varieties needs to be addressed before further policies can be adopted.
Embryo rescue in plants		*TBD*	Many sources including FiBL think this is not excluded but more study of the methods is needed.
TILLING	Eco-TILLING	*TBD*	Stands for Targeted Induced Local Lesions In Genomes. It is a type of mutagenesis combined with a new screening procedure.
Agro-infiltration		*TBD*	*In vitro* nucleic acids are introduced to plant leaves to be infiltrated into them. More study needed.
Doubled Haploid Technology		*TBD*	There are several ways to make double haploids and some do not involve genetic engineering but some do.
Induced Mutagenesis		*TBD*	This is a very broad term and needs to be divided and classified based on what induces the mutations, chemicals, radiation, or other stresses.
Embryo transfer in animals	Embryo rescue in animals	*TBD*	FiBL distinguishes embryo rescue in plants from animals.

E. Organic Plant Breeding

Some groups in Europe are moving ahead with developing a full set of organic plant breeding standards. If this become regulation there, then a label could be given for an "Organically Bred Variety". This is far from being able to be achieved in the U.S.A. with a very different approach to seed regulations as a whole. However, it is a potential next step and may be appropriate to tie into the discussion of some of the remaining terms above. For more information about this see the FiBL dossier cited above.

For instance a variety created with a cell fusion event for brassica male sterility might be allowed as seed in organic farming (as it is now) but prohibited from being used in a variety labeled as "Organically Bred Variety" with an organic breeding standard.

Discussion Questions

1. Are there any additional criteria for evaluating technologies that need to be considered?

2. Do you have any insights on how to detect those technologies that are excluded but may not provide detectable genetically engineered DNA?

3. Please offer any suggestions for enforcement of the excluded method provisions of the rule when they are not traceable or detectable.

4. Opinions are welcome on the terms in the chart above that may or may not be clearly prohibited as excluded methods.

Subcommittee Vote
Motion to adopt the third discussion document on excluded methods

Motion by: Zea Sonnabend
Seconded by: Emily Oakley
Yes: 5 No: 0 Absent: 1 Abstain: 0 Recuse: 0

[i] [i] FiBL Research Institute of Organic Agriculture 2015. Dossier No. 2 Plant Breeding Techniques: an assessment for organic farming.

March 30, 2017

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2642-So., Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-16-0100

RE: Handling Subcommittee – Bisphenol A (BPA) in Packaging (Discussion Document)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Handling Subcommittee's Discussion Document on Bisphenol A (BPA) in Packaging.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

The Handling Subcommittee is asking whether BPA should be prohibited in organic foods.
OTA is not in support of BPA usage in food contact applications, and we are glad to see that many organic brands have removed BPA from food contact materials in response to concerns and requests voiced by consumers. While OTA is not opposed to the prohibition of BPA under the organic regulations, we're challenged to see how BPA, when used in food packaging applications, could be explicitly prohibited without a significant rule change. We also have concerns about how this would implicate a review process for potentially thousands of other food contact substances that may or may not be outside of NOSB's scope of review.

The relevant section of the organic regulations referenced in the discussion document is **§ 205.272 - Commingling and contact with prohibited substance prevention practice standards**. As required in this section, handlers must implement measures necessary "to prevent the commingling of organic and non-organic products and protect organic products from contact with prohibited substances." Under the organic handling regulations, prohibited substances are ingredients, processing aids, sanitizers or other direct or secondary food additives used in or on processed products that are not on the National List.

Under § 205.272, the following are also expressly prohibited for use in the handling of any organically produced agricultural product or ingredient:

> (1) Packaging materials, and storage containers, or bins that contain a synthetic fungicide, preservative, or fumigant;

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www.OTA.com

(2) The use or reuse of any bag or container that has been in contact with any substance in such a manner as to compromise the organic integrity of any organically produced product or ingredient placed in those containers, unless such reusable bag or container has been thoroughly cleaned and poses no risk of contact of the organically produced product or ingredient with the substance used.

Our understanding is that the U.S. Food and Drug Administration (FDA) approval of food packaging (including the components of the packaging) is outside the scope of the USDA organic regulations unless they meet one or both of the conditions above, or if the packaging has been impregnated with a food packaging substance that is a "preservative" intended to become a component of and/or have a technical effect on the food. This kind of substance is regulated as either a direct or secondary food additive. An example would be packaging technology referred to as "active" or "intelligent" packaging that utilizes antioxidants in or on the packaging film to reduce lipid oxidation in the packaged food.

BPA is a component of packaging and is regulated as an indirect additive. It is also not a synthetic fungicide, preservative or fumigant. In order to prohibit BPA, OTA believes the regulations would need to be amended to expressly prohibit the substance for use in organic food packaging applications. Prohibiting BPA would set a precedent for extending NOSB's scope of review to other indirect additives used in food contact applications including (but not limited to) plastics; paper; adhesives; other substances used in food packaging such as colorants, antioxidants, antimicrobials, coatings; constituents of food additives such as the monomers of the polymeric material; components of conveyors that contact food; components of food grade equipment and contact surfaces; and many other food contact substances.

BPA has risen to the top of the pile of food contact materials because of the heightened interest in its safe use in food packaging, resulting in increased public awareness. OTA appreciates NOSB's call to organic stakeholders to gather information and discuss whether changes are needed in the regulations to ensure harmful substances do not come into contact with organic food. We recognize the task to be a huge undertaking and the implications are potentially significant. Nonetheless, we believe the topic warrants attention and further discussion.

Given the extremely short time to review the NOSB meeting materials and carry out OTA's member engagement process, we were not able to convene a task force or conduct further research on the other discussion document questions. We respectfully request that the discussion document be released again for the fall 2017 meeting when the Technical Review is available and stakeholders have more time to give this very complex topic the attention it deserves.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

Gwendolyn V. Wyard

Gwendolyn Wyard

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Vice President, Regulatory and Technical Affairs
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
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OMRI Materials REVIEW

News and Information for the Organic Community

Spring 2017

IN THIS ISSUE

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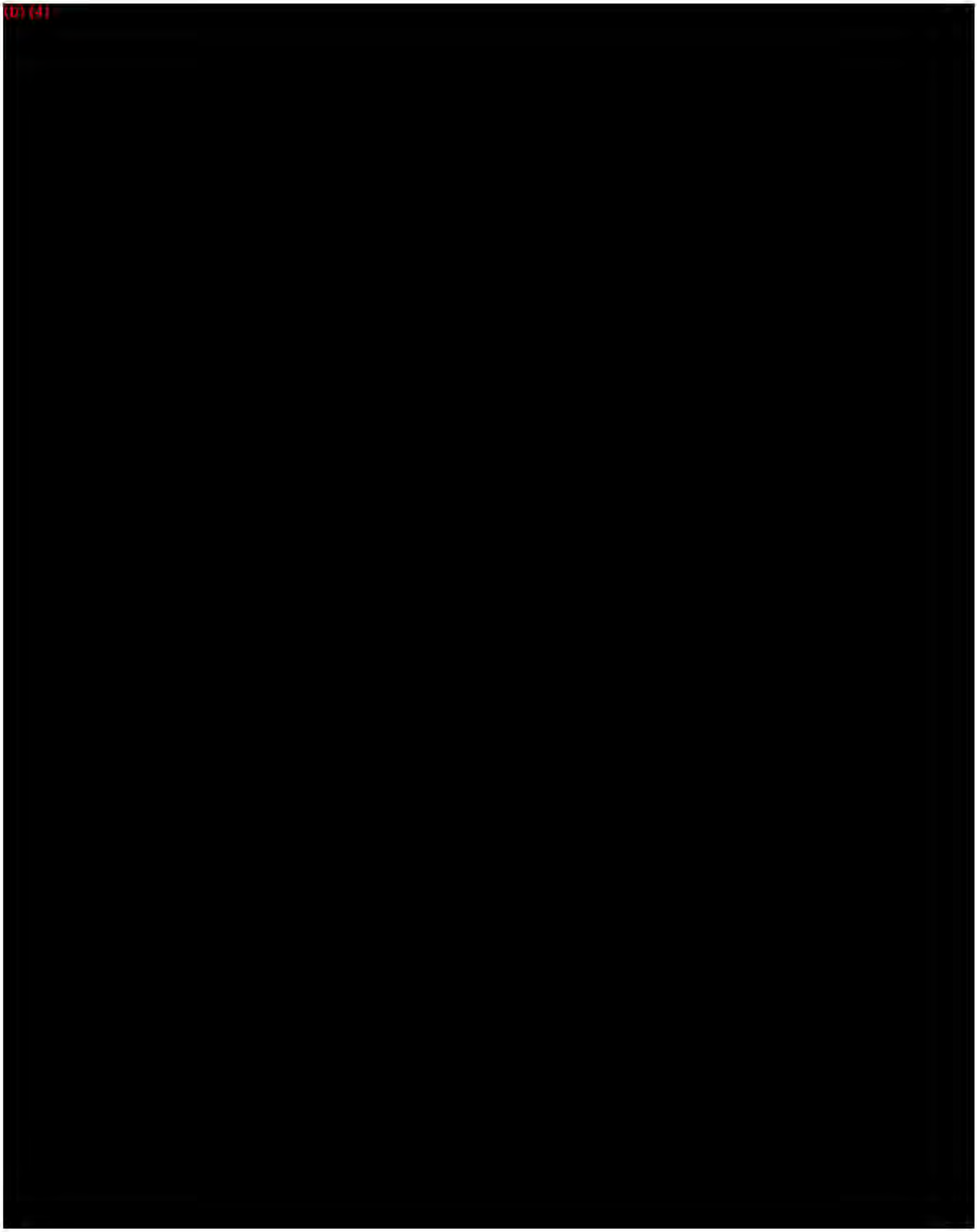

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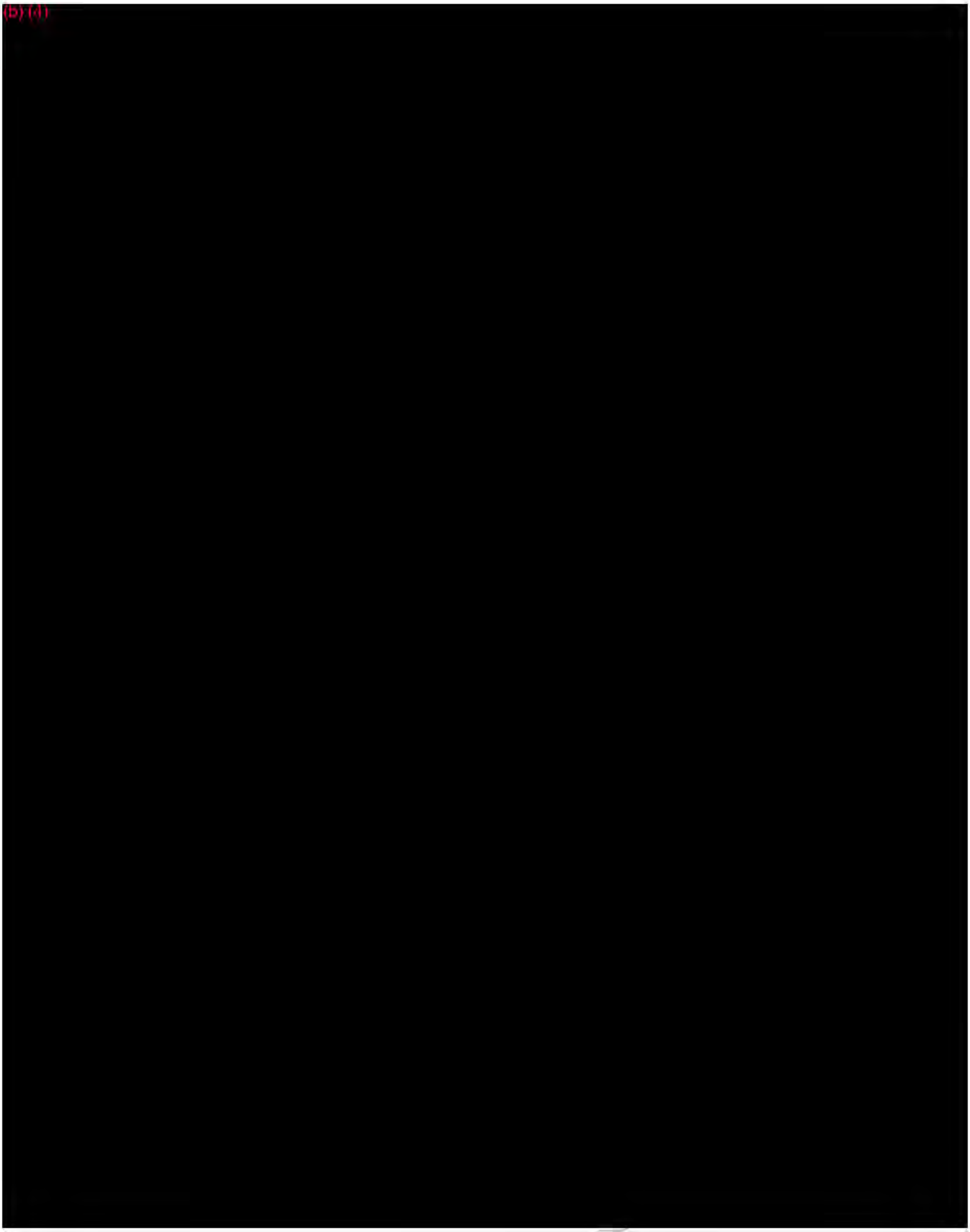

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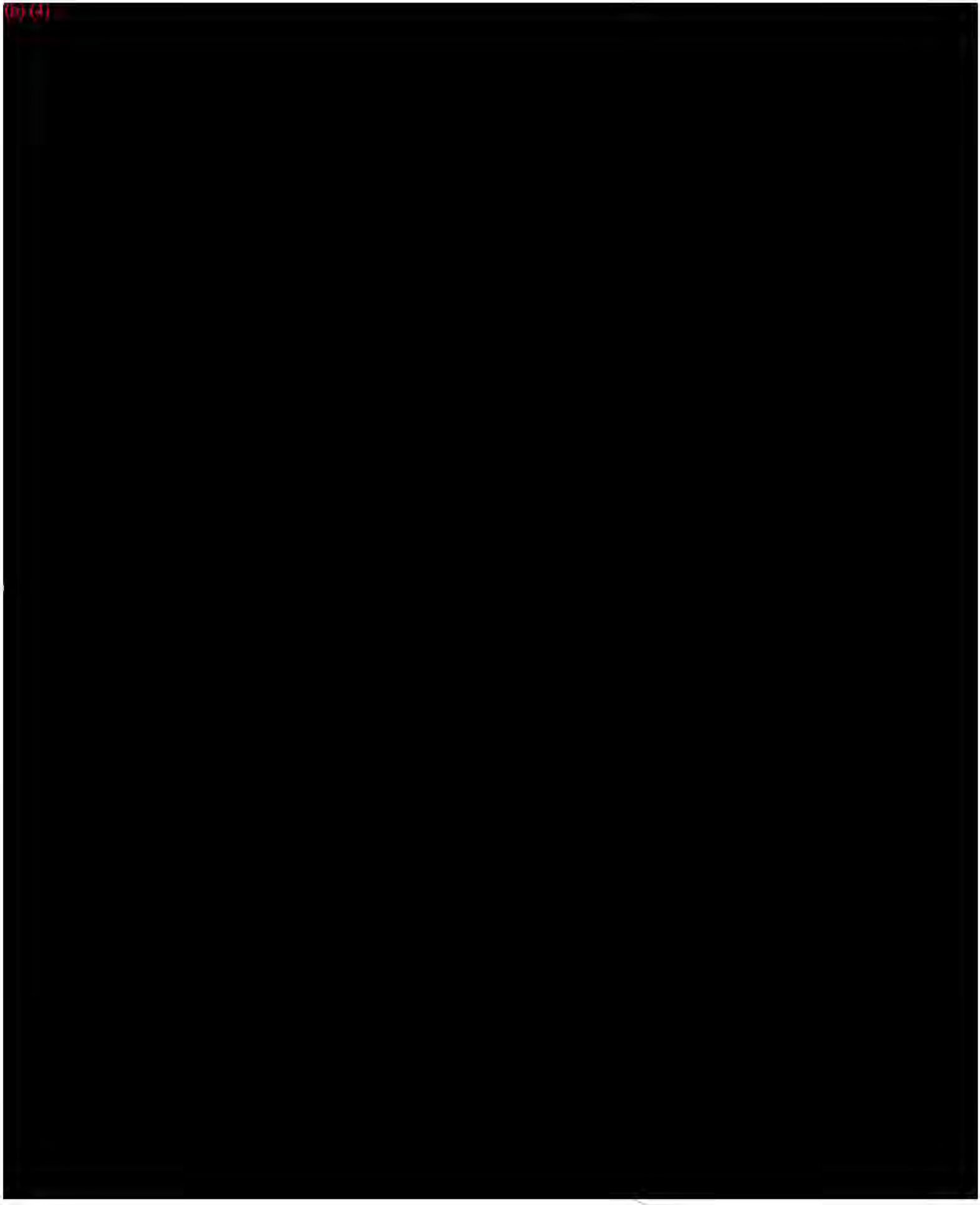

(b)(4)

Sunset 2019
Meeting 1 - Request for Public Comment
Livestock Substances §205.603
April 2017

Introduction
As part of the Sunset Process, the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2017. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the Petitioned Substances Database.

Request for Comments
While the NOSB will not complete its review and any recommendations on these substances until the Fall 2017 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2017 public meeting. Comments should be provided through Regulations.gov at www.regulations.gov by March 30, 2017 as explained in the meeting notice published in the Federal Register.

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review, which demonstrated that the substances were found to be: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should focus on providing new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance. Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

Guidance on Submitting Your Comments
Comments should clearly indicate your position on the allowance or prohibition of substances on the list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

For Comments That Support Substances Under Review:
If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

(1) not harmful to human health or the environment;
(2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and

(3) consistent with organic livestock production.

For Comments That Do Not Support Substances Under Review:
If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

(1) harmful to human health or the environment;
(2) unnecessary because of the availability of alternatives; and
(3) inconsistent with livestock production.

For Comments Addressing the Availability of Alternatives:
Comments may present information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

- Alternative management practices that would eliminate the need for the specific substance;
- Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
- Other organic or nonorganic agricultural substances.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review.

Written public comments will be accepted through March 30, 2017 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Sunset 2019
Meeting 1 - Request for Public Comment
Livestock Substances §205.603
April 2017

Note: The materials included in this list are undergoing early sunset review as part of November 18, 2016 NOSB recommendation on efficient workload re-organization.

Reference: 7 CFR 205.603 Synthetic substances allowed for use in organic livestock production

Chlorhexidine
Chlorine Materials: Calcium hypochlorite, chlorine dioxide, sodium hypochlorite
Glucose
Oxytocin
Tolazoline
Copper sulfate
Lidocaine
Procaine

Chlorhexidine

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (6) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.
Technical Report: 01/2010 TR; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1999 NOSB meeting minutes and vote; 11/2005 NOSB sunset recommendation; 11/2009 Annotation change/clarification; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17 (NOP renewal pending)

Background from Subcommittee:
Specific Uses of the Substance: Used as an antimicrobial during surgery for cleansing wounds, skin, and equipment. Also used as a pre- and post- teat dip to aid in controlling bacteria that causes mastitis. There are numerous synthetic disinfectants currently on the National List of Approved Synthetics for Organic Livestock production including iodine, ethanol, isopropanol, sodium hypochlorite, and hydrogen peroxide. Not all are useful both in a surgical environment and as a teat dip, as allowed under the chlorhexidine annotation.
Chlorhexidine reportedly kills mastitis-causing pathogens faster than iodine and is more persistent in its disinfection activity. Chlorhexidine is gentler on the skin than iodine, which is especially useful in

northern climates where an irritated udder and teats can be especially problematic for the animals in cold winter months.

Approved Legal Uses of the Substance: Used in agriculture for disinfection during livestock surgery, on teats pre and post milking and on milking equipment. Also used in food processing as a hard surface disinfectant and in human dentistry as a mouth wash and to disinfect equipment.

Discussion: In April 2015, the NOSB recommended adding one more teat dip: Acidified Sodium Chlorite- allowed for use on organic livestock as a pre and post teat dip treatment.

Additional information requested by NOSB

1. Does chlorhexidine provide an essential function that other natural materials or synthetics proposed or currently on the national list do not provide?
2. Is chlorhexidine used widely in organic livestock production?

Chlorine Materials

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

Technical Report: 2006 TR
Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 05/2006 NOSB sunset recommendation; 10/2010 NOSB recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17 (NOP renewal pending)

Background:
Specific Uses of the Substance: Sodium and calcium hypochlorite are chlorinated inorganic disinfectants used to control bacteria, fungi, and slime-forming algae that can cause diseases in people and animals (EPA, 1991, 1992). These disinfectants also are used in cleaning irrigation, drinking water, and other water and wastewater systems. Chlorine dioxide is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. It is used in cleaning water systems and disinfecting public drinking water supplies (ATSDR, 2004a). It also is used as a bleaching agent in paper and textile manufacturing, as a food disinfectant (e.g., for fruit, vegetables, meat, and poultry), for disinfecting food processing equipment, and treating medical wastes, among other uses (EPA, 2003a). Chlorine materials are currently used for disinfection of livestock facilities.

Approved Legal Uses of the Substance:
Regarding organic production, calcium hypochlorite, sodium hypochlorite, and chlorine dioxide are currently approved for disinfecting and sanitizing livestock facilities and equipment and as algicides, disinfectants, and sanitizers (including irrigation system cleaning) in organic crop production. Similarly, these chlorine materials are approved for disinfecting and sanitizing food contact surfaces in the production of processed products labeled as "organic" or "made with organic." Residual chlorine levels from these approved uses may not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (currently 4 mg/L).

Discussion: Previous public comments had asked for a comprehensive review of all sanitizers however, the Subcommittee feels that a review of that scope is beyond the sunset review process.

Additional information requested by NOSB

1. Are there less toxic disinfecting and sanitizing materials that could be substituted for chlorine materials?
2. Are all three chlorine materials needed for use in livestock production?

Glucose

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(11) Glucose
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 06/27/17 (NOP renewal pending)

Background:
Glucose has been on the National List since 1995, and has received minimal public comment, both pro and con at each sunset review. It is used most frequently in organic dairy operations, to manage ketosis or other situations where an infusion of glucose is needed to restore the blood sugar balance in an ill animal. On non-organic dairy operations, propylene glycol, glycerin or corticosteroids might also be used. Careful management of feed rations before and immediately after birthing is typically used to avoid the occurrence of ketosis. There may be some excipient ingredients in glucose used in livestock production.

Additional information requested by NOSB

1. Is this material essential in organic production and why?
2. Are there nonsynthetic materials or methods that can be used to treat the illnesses associated with glucose use?

Oxytocin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

(17) Oxytocin—use in post parturition therapeutic applications

Technical Report: 1995 TAP; 2005 TR

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 06/27/17 (NOP renewal pending)

Background:

Oxytocin is a hormone, naturally produced in the pituitary glands of humans, cattle and other mammals. In nonorganic production, it can be used regularly to help dairy cows relax and "let down their milk". There are some concerns with over use of oxytocin in nonorganic production systems, as well as the abuse of this hormone in the human population. In the NOP regulations, it is only allowed post birthing, in a therapeutic way to ease various dam issues that are associated with the birthing of the calf, including displaced abomasum and retained placenta. It has been on the National List of approved synthetics since 1995, with minimal public comment on this material, pro or con. Some organic milk marketers require their organic milk suppliers to not use this material. There was very little public comment on this material over the years, and it appears to be used rarely in organic production. However, it could be considered essential for animal health and welfare in emergency situations.

Additional information requested by NOSB

1. Is oxytocin an essential material for organic production and why?
2. Are there nonsynthetic alternatives, or other methods that can be used to accomplish the same results as oxytocin?

Tolazoline

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

(22) Tolazoline (CAS #-59-98-3)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian;

(ii) Use only to reverse the effects of sedation and analgesia caused by Xylazine; and

(iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

Technical Report: 2002 TAP

Petition(s): 2002 Petition

Past NOSB Actions: 09/2002 NOSB recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)

Sunset Date: 6/27/2017 (NOP renewal pending)

Background:
Tolazoline is used in conjunction with xylazine, which is used as a sedative, analgesic (pain killer) and muscle relaxant in veterinary medicine. Tolazoline is used to reverse the effects of xylazine.

During the 2015 comment period for the 2017 sunset, several comments were received indicating that xylazine/tolazoline are important tools for farmers and veterinarians and that they should stay on the list.

Additional information requested by NOSB

1. Is tolazoline still considered useful and/or necessary by the organic community for the purpose allowed?
2. Are there any alternative practices or substances available that might be preferable?

Copper Sulfate

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(1) Copper sulfate.
Technical Report: 1995 TAP; 2015 TR
Petition(s); N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017 (NOP renewal pending)

Background:
Copper Sulfate in livestock management is used specifically as a walk-through footbath to help control and prevent hoof- related diseases in dairy cattle and sheep. Some of the specific problems affect skin adjacent to the claw horn of dairy cattle and sheep, i.e., digital dermatitis (DD) (hairy heel warts), foot rot lesions (interdigital area and invading the subcutaneous tissue), and heel erosions. Depending on the severity of the infection the impact on managed cattle and or sheep ranges from minor discomfort to severe debilitating lameness, reproductive problems and in the dairy industry a reduction of milk production ranging from 20 to 50 percent (Brown, et al., 2000, Losinger, 2006). A five to ten percent copper sulfate solution is commonly used as the antimicrobial agent in the footbath and is considered effective for 150 to 300 animal passes.

According to the Technical Review commissioned by the Livestock Subcommittee, there are no natural (nonsynthetic) products available that can be used as a management strategy to treat hoof- related diseases and lameness in dairy cattle and sheep operations. However, there are various management tools available that could help reduce the cost of treatment and prevent hoof-related diseases. These include the use of additional dietary supplements (i.e., feeding of iodine, feeding of zinc methionine), free stall (cubicle) design, limiting contact with gravel or rocky surfaces, and hoof trimming practices (Maas 2009).

Zinc sulfate may be considered a viable alternative, and the NOSB voted at the Spring 2015 meeting to add this substance to the National List for foot and hoof treatment (rulemaking in process by NOP).

Additional information requested by NOSB

1. The livestock subcommittee requests public comment on the use of Copper Sulfate and its essentiality in organic processing.

2. Are there any alternative practices or substances available that might be preferable?

Lidocaine

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals
Technical Report: None
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation, 2016 annotation change recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017 (NOP renewal pending)

Background:
Lidocaine is a local anesthetic which has a rapid onset of action and is short term in duration. It numbs only the area to be worked on. For example, Lidocaine is used to humanely de-bud horns on calves, and for minor surgery on mature animals.

During the 2015 sunset review of lidocaine and procaine the Livestock Subcommittee was unable to find any record of the rationale for the much extended withdrawal period of 90 days for these materials when used on slaughter stock. Historical NOSB and NOP documents from 1995 to the present were reviewed. The December 2007 commentary (72 FR 70479) implies that perhaps the 90 days is a doubling of the FDA or FARAD (Food Animal Drug Residue Avoidance) withholding period, but no such 45 day withholding was found in FDA or FARAD or other sources.

In FARAD the recommended withdrawal interval for lidocaine in cattle is listed as 1 day for meat and 24 hours for milk after epidural use of lidocaine, and 4 days for meat and 72 hours for milk after subcutaneous use of lidocaine.

The NOSB in its initial request for public comment in April 2015, for Sunset 2107 Review had asked:

1. Since this material was last reviewed have alternative materials emerged?
2. What is the scientific rational for what appears to be an excessively long withdrawal period?
3. Is there research to indicate that a shorter withdrawal period would be appropriate?

In 2015 public comment did not provide any alternatives and did not provide any scientific rationale for the lengthy withholding period. Recommendations were received suggesting that a short withholding period would be scientifically acceptable. Lidocaine was unanimously approved for continued listing at the October 2015 NOSB meeting. A discussion document on changing the withholding period was presented at the October 2015 meeting, and a proposal to amend section 205.603 was unanimously approved by the NOSB at the April 2016 meeting as follows:

To amend Section 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals

In 2015 and 2016 public comment indicated broad public support from farmers, dairy organizations, industry groups and consumer groups to reduce the withholding period in order to ensure humane treatment of animals. The public finds that a 90-day withholding period is far in excess of the withholding period used in conventional livestock production. Public comment supports a recommendation for slaughter stock withholding period of 8 days, which is double the FARAD recommendation for subcutaneous use in conventional livestock. Public comment agreed with the rationale of using double the FARAD time for conventional production. The public supports a withholding period of 6 days, which is double the FARAD recommendation of 72 hours (3 days) for conventional milk production and 8 days for slaughter stock.

There was broad stakeholder support for continuing to list lidocaine and for the annotation for shorter withholding period.

Additional information requested by NOSB

No additional information requested.

Procaine

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(7) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals
Technical Report: N/A
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation, 2016 annotation change recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290)
Sunset Date: 6/27/2017 (NOP renewal pending)

Background:
Procaine is a local anesthetic which has a rapid onset of action and is of short term duration. It numbs only the area to be worked on and can be used to humanely de-bud horns on calves, and for minor surgery on mature animals.

During the 2015 Sunset Review of Lidocaine and Procaine the Livestock subcommittee was unable to find any record of the rationale for the much extended withdrawal period of 90 days for these materials when used on slaughter stock. Historical NOSB and NOP documents from 1995 to the present were reviewed. The December 2007 commentary (72 FR 70479) cited above implies that perhaps the 90 days is a doubling of the FDA or FARAD withholding period, but no such 45 day withholding was found in FDA or FARAD or other sources

FARAD provides information on procaine only as it relates to procaine with an antibiotic as part of delivery and thus it would not be used in organic production. Procaine on its own is apparently not readily available in the US and public comment from veterinarians only suggests a similarity with lidocaine. Procaine was recommended for continued listing because no public comment was provided to recommend its removal on any criteria. However procaine appears to be rarely used in organic livestock production.

The NOSB in its initial request for public comment in 2015 for Sunset 2017 Review, asked:

1. Since this material was last reviewed have alternative materials emerged?
2. What is the scientific rational for what appears to be an excessively long withdrawal period?
3. Is there research to indicate that a shorter withdrawal period would be appropriate?

In 2015 and 2016 Public comment did not provide any alternatives and did not provide any scientific rationale for the lengthy withholding period. Recommendations were received suggesting that a short withholding period would be scientifically acceptable. Procaine was unanimously approved for continued listing at the October 2015 NOSB meeting. A Discussion Document on changing the Withholding period was presented at the October 2015 meeting, and a Proposal to amend Section 205.603 was unanimously approved by the NOSB at the April 2016 meeting in DC. As follows:

To amend Section 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.

*(7) Procaine —as a local anesthetic. Use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals***.**

In 2015 and 2016 public comment indicated broad public support from farmers, dairy organizations, industry groups and consumer groups to reduce the withholding period in order to ensure humane treatment of animals. The public finds that a 90-day withholding period is far in excess of the withholding period used in conventional livestock production. Public comment supported a recommendation for slaughter stock withholding period of 8 days, which is double the FARAD recommendation for subcutaneous use in conventional livestock. Public comment agreed with the rationale of using double the FARAD time for conventional production**.** The public supports a withholding period of 6 days, which is double the FARAD recommendation of 72 hours (3 days) for conventional milk production and 8 days for slaughter stock.

There was broad stakeholder support for continuing to list procaine with the annotation for shorter withholding period. Public comment indicates procaine is not readily available in the United States and does not appear to be widely used. Procaine may not be essential and may not need to continue to be listed.

Additional information requested by NOSB

1. Is procaine used in organic livestock production?
2. Is procaine available in the US in its pure form or only in combination with antibiotics?

SAFETY DATA SHEET

1. Identification

Product identifier	**TELAZOL**
Other means of identification	
Synonyms	TELAZOL® * Tiletamine HCL and Zolazepam HCL
Recommended use	Veterinary anesthetic agent
Recommended restrictions	Not for human use

Manufacturer/Importer/Supplier/Distributor information

Company Name (US)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (EU)	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Reproductive toxicity (the unborn child)	Category 2
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
	Specific target organ toxicity, repeated exposure	Category 2 (central nervous system, kidney, pancreas)
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements

Signal word	Warning
Hazard statement	May cause drowsiness or dizziness. Suspected of damaging the unborn child. May cause damage to organs (central nervous system, kidney, pancreas) through prolonged or repeated exposure.

Precautionary statement

Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe mist or vapor. Use only outdoors or in a well-ventilated area. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If exposed or concerned: Get medical advice/attention. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Anesthetic drug: may cause central nervous system and cardiovascular system effects. May cause eye and skin irritation. May cause irritation of respiratory tract. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Mannitol		69-65-8	<6
Tiletamine hydrochloride		14176-50-2	50 mg/ml
Water for Injection		7732-18-5	
Zolazepam hydrochloride		33754-49-3	50 mg/ml

Composition comments In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. First-aid measures

Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If breathing is difficult, trained personnel should give oxygen. Get medical attention immediately.
Skin contact	Wash off with soap and plenty of water. Remove contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
Eye contact	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Call a physician or poison control center immediately.
Ingestion	Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.
Most important symptoms/effects, acute and delayed	May cause drowsiness and dizziness. Narcosis. Headache. Nausea, vomiting. Behavioral changes. Decrease in motor functions. Prolonged exposure may cause chronic effects. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Clinical use of this drug has caused respiratory depression, gastrointestinal disturbances, allergic skin rash. Anesthetic drug: may cause central nervous system and cardiovascular system effects
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed. Anesthetic drug: may cause central nervous system and cardiovascular system effects Monitor respiratory, cardiac and central nervous system.
General information	IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Ensure adequate ventilation. Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up	Ensure adequate ventilation. Avoid release to the environment. Prevent entry into waterways, sewer, basements or confined areas. Remove sources of ignition. Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Wear appropriate personal protective equipment. Provide adequate ventilation. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Avoid prolonged exposure. Wash thoroughly after handling. When using, do not eat, drink or smoke. Avoid release to the environment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store locked up. Store in a well-ventilated place. @ 15-30°C (59-86°F). Protect from sunlight. Use care in handling/storage. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

8. Exposure controls/personal protection

Occupational exposure limits	This mixture has no ingredients that have PEL, TLV, or other recommended exposure limit.
Biological limit values	No biological exposure limits noted for the ingredient(s).
Control banding approach	Tiletamine hydrochloride: Zoetis OEB 2 (control exposure to the range of 100ug/m3 to < 1000ug/m3) Zolazepam hydrochloride: Zoetis OEB 3 (control exposure to the range of 10ug/m3 to < 100ug/m3)
Appropriate engineering controls	Ensure adequate ventilation, especially in confined areas. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
Skin protection	
Hand protection	Wear protective gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Other	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection	No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. Chemical respirator with organic vapor cartridge, full facepiece, dust and mist filter.
Thermal hazards	Not applicable.
General hygiene considerations	Observe any medical surveillance requirements. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance	Liquid. (After reconstitution).
Physical state	Liquid.
Form	Liquid.
Color	Off-white.
Odor	Not available.
Odor threshold	Not available.
pH	3.5
Melting point/freezing point	Not available.

Initial boiling point and boiling range	212 °F (100 °C)
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Slightly Soluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.
Specific gravity	1.52 (Mannitol)

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. May include products of carbon, nitrogen. May include hydrogen chloride.

11. Toxicological information

Information on likely routes of exposure

Inhalation	May cause drowsiness and dizziness. Headache. Nausea, vomiting. May cause irritation to the respiratory system.
Skin contact	Prolonged skin contact may cause temporary irritation.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Symptoms related to the physical, chemical and toxicological characteristics	May cause drowsiness and dizziness. Narcosis. Headache. Nausea, vomiting. Behavioral changes. Decrease in motor functions. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Clinical use of this drug has caused respiratory depression, gastrointestinal disturbances, allergic skin rash. Anesthetic drug: may cause central nervous system and cardiovascular system effects

Information on toxicological effects

Acute toxicity	May be harmful if inhaled. May be harmful if swallowed.

Product	Species	Test Results
TELAZOL		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg (ATE)

Components	Species	Test Results
Mannitol (CAS 69-65-8)		
Acute		
Oral		
LD50	Mouse	22 g/kg
	Rat	13500 mg/kg
Zolazepam (CAS 31352-82-6)		
Acute		
Oral		
LD50	Rat	398 mg/kg
Subchronic		
LOAEL	Dog	10 mg/kg/day, 3 months [Target organ(s): Central Nervous System, Gastrointestinal system]
	Monkey	10 mg/kg/day, 3 months [Target organ(s): Central Nervous System]
NOAEL	Rat	10 mg/kg/day, 91 days [Target organ(s): Pancreas, Kidney]

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization Due to partial or complete lack of data the classification is not possible. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Suspected of damaging the unborn child. This compound can cross the placenta in pregnant women.

Specific target organ toxicity - single exposure May cause drowsiness and dizziness.

Specific target organ toxicity - repeated exposure May cause damage to organs (central nervous system, kidney, pancreas) through prolonged or repeated exposure.

Aspiration hazard Not an aspiration hazard.

Chronic effects May cause damage to organs through prolonged or repeated exposure.

Further information Anesthetic drug: may cause central nervous system and cardiovascular system effects. Accidental injection of this product may result in anesthetic and other central nervous system effects. Convulsions, lethargy, respiratory depression, and muscle relaxation may occur. Cardiovascular effects (increase heart rate, changes in blood pressure) may also occur. Pulmonary edema with resultant shortness of breath may be seen as well as nausea and vomiting.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code None known.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 08-13-2013

Revision date 04-28-2017

Version # 02

List of abbreviations ATE: Acute Toxicity Estimate according to REGULATION (EC) No 1272/2008 (CLP).

Disclaimer Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.

Revision information This document has undergone significant changes and should be reviewed in its entirety.

NOSB Fall 2017 Proposals and Discussion Documents						Vote threshold	Oakley	Baird	Buie	Swaffar	Rice	Behar	Chapman	Seltz	Mortensen	Ela	Bradman	De Lima	Romero-Brion	Yes (Y)	No (N)	Abstain (A)	Recuse (R)	Absent (T)	Pass/Fail
Subcommittee	**Substance/Motion**	**NL Section**	**Doc type**	**Motion by:**	**Seconded by:**																				
CACS	Motion to accept the proposal on Inspector Qualifications	NA	Proposal	Harriet Behar	Ashley Swaffar	2/3														0	0	0	0	0	**MISSING VOTE**
CACS	Motion to accept the proposal on Eliminating the incentive to convert native ecosystems to organic production	NA	Proposal	Harriet Behar	Emily Oakley	2/3														0	0	0	0	0	**MISSING VOTE**
LS	Motion to classify Glycolic acid - petitioned, as synthetic	205.603	Proposal	Ashley Swaffar	Harriet Behar	2/3														0	0	0	0	0	**MISSING VOTE**
LS	Motion to add Glycolic acid - petitioned at 205.603	205.603	Proposal	Ashley Swaffar	Jesse Buie	2/3														0	0	0	0	0	**MISSING VOTE**
LS	Motion to accept the proposal on Clarifying "emergency" for use of synthetic parasiticides in organic livestock production	NA	Proposal	Harriet Behar	Jesse Buie	2/3														0	0	0	0	0	**MISSING VOTE**
HS	Motion to classify Sodium dodecylbenzene sulfonate (SDBS) as non agricultural, synthetic	205.605(b)	Proposal	Scott Rice	A-dae Briones	2/3														0	0	0	0	0	**MISSING VOTE**
HS	Motion to add Sodium dodecylbenzene sulfonate (SDBS) at 205.605(b)	205.605(b)	Proposal	Joelle Mosso	Steve Ela	2/3														0	0	0	0	0	**MISSING VOTE**
HS	Motion to reclassify Magnesium chloride and move it's listing at 205.605(b) to 205.605(a)	205.605(b)	Proposal	Lisa de Lima	Steve Ela	2/3														0	0	0	0	0	**MISSING VOTE**
CS	Motion to classify Polyoxin D zinc salt - petitioned, as synthetic	205.601	Proposal	Jesse Buie	Emily Oakley	2/3														0	0	0	0	0	**MISSING VOTE**
CS	Motion to add Polyoxin D zinc salt - petitioned at 205.601(i)	205.601(i)	Proposal	Jesse Buie	Sue Baird	2/3														0	0	0	0	0	**MISSING VOTE**
CS	Motion to add Sulfur (as a molluscicide) - petitioned, at 205.601(h)	205.601	Proposal	Asa Bradman	Harriet Behar	2/3														0	0	0	0	0	**MISSING VOTE**
NON VOTING ITEMS																									

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Subcommittee	**Substance/Motion**	**NL Section**	**Doc type**	**Motion by:**	**Seconded by:**																				
CACS	Import Oversight	NA	DD	Tom Chapman	Ashley Swaffar																				
LS	Alcohols: ethanol, isopropanol	205.603(a)	2020 Sunset	NA	NA																				
LS	Aspirin	205.603(a)	2020 Sunset	NA	NA																				
LS	Biologics, vaccines	205.603(a)	2020 Sunset	NA	NA																				
LS	Electrolytes	205.603(a)	2020 Sunset	NA	NA																				
LS	Glycerine	205.603(a)	2020 Sunset	NA	NA																				
LS	Phosphoric acid	205.603(b)	2020 Sunset	NA	NA																				
LS	Lime, hydrated	205.603(b)	2020 Sunset	NA	NA																				
LS	Mineral oil	205.603(b)	2020 Sunset	NA	NA																				
LS	Sucrose octanoate esters	205.603	2020 Sunset	NA	NA																				
HS	Calcium carbonate	205.605(a)	2020 Sunset	NA	NA																				
HS	Flavors	205.605(a)	2020 Sunset	NA	NA																				
HS	Gellan gum	205.605(a)	2020 Sunset	NA	NA																				
HS	Oxygen	205.605(a)	2020 Sunset	NA	NA																				
HS	Potassium chloride	205.605(a)	2020 Sunset	NA	NA																				
HS	Alginates	205.605(b)	2020 Sunset	NA	NA																				
HS	Calcium hydroxide	205.605(b)	2020 Sunset	NA	NA																				
HS	Ethylene	205.605(b)	2020 Sunset	NA	NA																				
HS	Glycerides (mono and di)	205.605(b)	2020 Sunset	NA	NA																				
HS	Magnesium stearate	205.605(b)	2020 Sunset	NA	NA																				
HS	Phosphoric acid	205.605(b)	2020 Sunset	NA	NA																				
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Subcommittee	**Substance/Motion**	**NL Section**	**Doc type**	**Motion by:**	**Seconded by:**																				
HS	Sulfur dioxide	205.605(b)	2020 Sunset	NA	NA																				
HS	Xanthan gum	205.605(b)	2020 Sunset	NA	NA																				
HS	Fructooligosaccharides (FOS)	205.606	2020 Sunset	NA	NA																				
HS	Gums: Arabic, Carob bean, Guar, Locust bean	205.606	2020 Sunset	NA	NA																				
HS	Lecithin - de-oiled	205.606	2020 Sunset	NA	NA																				
HS	Tragacanth gum	205.606	2020 Sunset	NA	NA																				
CS	Alcohols: ethanol, isopropanol	205.601(a)	2020 Sunset	NA	NA																				
CS	Sodium carbonate peroxyhydrate	205.601(a)	2020 Sunset	NA	NA																				
CS	Newspaper or other recycled paper	205.601(b)	2020 Sunset	NA	NA																				
CS	Plastic mulch and covers	205.601(b)	2020 Sunset	NA	NA																				
CS	Aqueous potassium silicate	205.601(e)	2020 Sunset	NA	NA																				
CS	Elemental sulfur	205.601(e)	2020 Sunset	NA	NA																				
CS	Lime sulfur	205.601(i)	2020 Sunset	NA	NA																				
CS	Sucrose octanoate esters	205.601(i)	2020 Sunset	NA	NA																				
CS	Hydrated lime	205.601(j)	2020 Sunset	NA	NA																				
CS	Liquid fish products	205.601(j)	2020 Sunset	NA	NA																				
CS	Sulfurous acid	205.601(j)	2020 Sunset	NA	NA																				
CS	Ethylene	205.601(j)	2020 Sunset	NA	NA																				
CS	Microcrystalline cheesewax	205.601(j)	2020 Sunset	NA	NA																				
CS	Potassium chloride	205.602(d)	2020 Sunset	NA	NA																				
MS	Protecting the Genetic Integrity of Seed Grown on Organic Land	NA	DD	Dan Seitz	Dave Mortensen																				

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Subcommittee	**Substance/Motion**	**NL Section**	**Doc type**	**Motion by:**	**Seconded by:**																				
CACS	Motion to accept the proposal on Inspector Qualifications	NA	Proposal	Harriet Behar	Ashley Swaffar	2/3																			
CACS	Motion to accept the proposal on Eliminating the incentive to convert native ecosystems to organic production	NA	Proposal	Harriet Behar	Emily Oakley	2/3																			
LS	Motion to classify Glycolic acid - petitioned, as synthetic	205.603	Proposal	Ashley Swaffar	Harriet Behar	2/3																			
LS	Motion to add Glycolic acid - petitioned at 205.603	205.603	Proposal	Ashley Swaffar	Jesse Buie	2/3																			
LS	Motion to accept the proposal on Clarifying “emergency” for use of synthetic parasiticides in organic livestock production	NA	Proposal	Harriet Behar	Jesse Buie	2/3																			
HS	Motion to classify Sodium dodecylbenzene sulfonate (SDBS) as non agricultural, synthetic	205.605(b)	Proposal	Scott Rice	A-dae Briones	2/3																			
HS	Motion to add Sodium dodecylbenzene sulfonate (SDBS) at 205.605(b)	205.605(b)	Proposal	Joelle Mosso	Steve Ela	2/3																			
HS	Motion to reclassify Magnesium chloride and move it's listing at 205.605(b) to 205.605(a)	205.605(b)	Proposal	Lisa de Lima	Steve Ela	2/3																			
CS	Motion to classify Polyoxin D zinc salt - petitioned, as synthetic	205.601	Proposal	Jesse Buie	Emily Oakley	2/3																			
CS	Motion to add Polyoxin D zinc salt - petitioned at 205.601(i)	205.601(i)	Proposal	Jesse Buie	Sue Baird	2/3																			
CS	Motion to add Sulfur (as a molluscicide) - petitioned, at 205.601(h)	205.601	Proposal	Asa Bradman	Harriet Behar	2/3																			

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Subcommittee	**Substance/Motion**	**NL Section**	**Doc type**	**Motion by:**	**Seconded by:**																				
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LS	Electrolytes	205.603(a)	2020 Sunset	NA	NA																				
LS	Glycerine	205.603(a)	2020 Sunset	NA	NA																				
LS	Phosphoric acid	205.603(b)	2020 Sunset	NA	NA																				
LS	Lime, hydrated	205.603(b)	2020 Sunset	NA	NA																				
LS	Mineral oil	205.603(b)	2020 Sunset	NA	NA																				
LS	Sucrose octanoate esters	205.603	2020 Sunset	NA	NA																				
HS	Calcium carbonate	205.605(a)	2020 Sunset	NA	NA																				
HS	Flavors	205.605(a)	2020 Sunset	NA	NA																				
HS	Gellan gum	205.605(a)	2020 Sunset	NA	NA																				
HS	Oxygen	205.605(a)	2020 Sunset	NA	NA																				
HS	Potassium chloride	205.605(a)	2020 Sunset	NA	NA																				
HS	Alginates	205.605(b)	2020 Sunset	NA	NA																				
HS	Calcium hydroxide	205.605(b)	2020 Sunset	NA	NA																				
HS	Ethylene	205.605(b)	2020 Sunset	NA	NA																				
HS	Glycerides (mono and di)	205.605(b)	2020 Sunset	NA	NA																				
HS	Magnesium stearate	205.605(b)	2020 Sunset	NA	NA																				
HS	Phosphoric acid	205.605(b)	2020 Sunset	NA	NA																				
HS	Potassium carbonate	205.605(b)	2020 Sunset	NA	NA																				

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Subcommittee	**Substance/Motion**	**NL Section**	**Doc type**	**Motion by:**	**Seconded by:**																				
HS	Sulfur dioxide	205.605(b)	2020 Sunset	NA	NA																				
HS	Xanthan gum	205.605(b)	2020 Sunset	NA	NA																				
HS	Fructooligosaccharides (FOS)	205.606	2020 Sunset	NA	NA																				
HS	Gums: Arabic, Carob bean, Guar, Locust bean	205.606	2020 Sunset	NA	NA																				
HS	Lecithin - de-oiled	205.606	2020 Sunset	NA	NA																				
HS	Tragacanth gum	205.606	2020 Sunset	NA	NA																				
CS	Alcohols: ethanol, isopropanol	205.601(a)	2020 Sunset	NA	NA																				
CS	Sodium carbonate peroxyhydrate	205.601(a)	2020 Sunset	NA	NA																				
CS	Newspaper or other recycled paper	205.601(b)	2020 Sunset	NA	NA																				
CS	Plastic mulch and covers	205.601(b)	2020 Sunset	NA	NA																				
CS	Aqueous potassium silicate	205.601(e)	2020 Sunset	NA	NA																				
CS	Elemental sulfur	205.601(e)	2020 Sunset	NA	NA																				
CS	Lime sulfur	205.601(i)	2020 Sunset	NA	NA																				
CS	Sucrose octanoate esters	205.601(i)	2020 Sunset	NA	NA																				
CS	Hydrated lime	205.601(j)	2020 Sunset	NA	NA																				
CS	Liquid fish products	205.601(j)	2020 Sunset	NA	NA																				
CS	Sulfurous acid	205.601(j)	2020 Sunset	NA	NA																				
CS	Ethylene	205.601(j)	2020 Sunset	NA	NA																				
CS	Microcrystalline cheesewax	205.601(j)	2020 Sunset	NA	NA																				
CS	Potassium chloride	205.602(d)	2020 Sunset	NA	NA																				
MS	Protecting the Genetic Integrity of Seed Grown on Organic Land	NA	DD	Dan Seitz	Dave Mortensen																				

NOSB Fall 2017 Proposals and Discussion Documents						Vote threshold	Oakley	Baird	Buie	Swaffar	Rice	Behar	Chapman	Seitz	Mortensen	Ela	Bradman	De Lima	Romero Brion	Yes (Y)	No (N)	Abstain (A)	Recuse (R)	Absent (T)	Pass/Fail
Subcommitte	**Substance/Motion**	**NL Section**	**Doc type**	**Motion by:**	**Seconded by:**																				
CACS	Motion to amend language in the proposal to read "proposal" not discussion document.		Amendment	Scott Rice	Ashley Swaffar		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	T	Y	12	0	0	0	1	**PASS**
CACS	Motion to accept the proposal on Inspector Qualifications	NA	Proposal	Harriet Behar	Ashley Swaffar	2/3	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	T	Y	12	0	0	0	1	**PASS**
CACS	Motion to amend the language in the proposal as follows: remove from motion "and semi-natural" and "had been substantially altered over 50-100 years ago, but" and "since".		Amendment	Ashley Swaffar	Dan Seitz		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	T	A	11	0	1	0	1	**PASS**
CACS	Motion to accept the proposal on Eliminating the incentive to convert native ecosystems to organic production	NA	Proposal	Harriet Behar	Emily Oakley	2/3	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	T	N	11	1	0	0	1	**PASS**
	Motion to amend the the proposal to correct the section number listed in the motion to 205.603(a)			Ashley Swaffar	Emily Oakley	2/3	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	13	0	0	0	0	**PASS**
LS	Motion to classify Glycolic acid - petitioned, as synthetic	205.603	Proposal	Ashley Swaffar	Harriet Behar	2/3	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	13	0	0	0	0	**PASS**
LS	Motion to add Glycolic acid - petitioned at 205.603	205.603	Proposal	Ashley Swaffar	Jesse Buie	2/3	N	Y	Y	Y	Y	N	Y	N	N	N	N	Y	Y	7	6	0	0	0	**FAIL**
LS	Motion to accept the proposal on Clarifying “emergency” for use of synthetic parasiticides in organic livestock production	NA	Proposal	Harriet Behar	Jesse Buie	2/3	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	13	0	0	0	0	**PASS**
HS	Motion to classify sodium dodecylbenzene sulfonate (SDBS) as non agricultural, synthetic	205.605(b)	Proposal	Scott Rice	A-dae Briones	2/3	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	13	0	0	0	0	**PASS**
HS	Motion to add sodium dodecylbenzene sulfonate (SDBS) at 205.605(b)	205.605(b)	Proposal	Joelle Mosso	Steve Ela	2/3	N	N	N	N	N	N	N	N	N	N	N	N	N	0	13	0	0	0	**FAIL**
HS	Motion to reclassify magnesium chloride and move it's listing at 205.605(b) to 205.605(a)	205.605(b)	Proposal	Lisa de Lima	Steve Ela	2/3	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	13	0	0	0	0	**PASS**
CS	Motion to classify Polyoxin D zinc salt - petitioned, as synthetic	205.601	Proposal	Jesse Buie	Emily Oakley	2/3	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	13	0	0	0	0	**PASS**
CS	Motion to add Polyoxin D zinc salt - petitioned at 205.601(i)	205.601(i)	Proposal	Jesse Buie	Sue Baird	2/3	N	Y	Y	Y	Y	Y	Y	A	Y	Y	Y	Y	Y	11	1	1	0	0	**PASS**
CS	Motion to add Sulfur (as a molluscicide) - petitioned, at 205.601(h)	205.601	Proposal	Asa Bradman	Harriet Behar	2/3	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	13	0	0	0	0	**PASS**

NOSB Fall 2017 Proposals and Discussion Documents						Vote threshold	Oakley	Baird	Buie	Swaffar	Rice	Behar	Chapman	Seitz	Mortensen	Ela	Bradman	De Lima	Romero Brion	Yes (Y)	No (N)	Abstain (A)	Recuse (R)	Absent (T)	Pass/Fail
Subcommitte	**Substance/Motion**	**NL Section**	**Doc type**	**Motion by:**	**Seconded by:**																				
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LS	Phosphoric acid	205.603(b)	2020 Sunset	NA	NA																				
LS	Lime, hydrated	205.603(b)	2020 Sunset	NA	NA																				
LS	Mineral oil	205.603(b)	2020 Sunset	NA	NA																				
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LS	Phosphoric acid	205.603(b)	2020 Sunset	NA	NA																				
LS	Lime, hydrated	205.603(b)	2020 Sunset	NA	NA																				
LS	Mineral oil	205.603(b)	2020 Sunset	NA	NA																				
LS	Sucrose octanoate esters	205.603	2020 Sunset	NA	NA																				
HS	Calcium carbonate	205.605(a)	2020 Sunset	NA	NA																				
HS	Flavors	205.605(a)	2020 Sunset	NA	NA																				
HS	Gellan gum	205.605(a)	2020 Sunset	NA	NA																				
HS	Oxygen	205.605(a)	2020 Sunset	NA	NA																				
HS	Potassium chloride	205.605(a)	2020 Sunset	NA	NA																				
HS	Alginates	205.605(b)	2020 Sunset	NA	NA																				
HS	Calcium hydroxide	205.605(b)	2020 Sunset	NA	NA																				
HS	Ethylene	205.605(b)	2020 Sunset	NA	NA																				
HS	Glycerides (mono and di)	205.605(b)	2020 Sunset	NA	NA																				
HS	Magnesium stearate	205.605(b)	2020 Sunset	NA	NA																				
HS	Phosphoric acid	205.605(b)	2020 Sunset	NA	NA																				
HS	Potassium carbonate	205.605(b)	2020 Sunset	NA	NA																				

NOSB Fall 2017 Proposals and Discussion Documents						Vote threshold	Oakley	Baird	Buie	Swaffar	Rice	Behar	Chapman	Seitz	Mortensen	Ela	Bradman	De Lima	Romero-Brion	Yes (Y)	No (N)	Abstain (A)	Recuse (R)	Absent (T)	Pass/Fail
Subcommittee	**Substance/Motion**	**NL Section**	**Doc type**	**Motion by:**	**Seconded by:**																				
HS	Sulfur dioxide	205.605(b)	2020 Sunset	NA	NA																				
HS	Xanthan gum	205.605(b)	2020 Sunset	NA	NA																				
HS	Fructooligosaccharides (FOS)	205.606	2020 Sunset	NA	NA																				
HS	Gums: Arabic, Carob bean, Guar, Locust bean	205.606	2020 Sunset	NA	NA																				
HS	Lecithin - de-oiled	205.606	2020 Sunset	NA	NA																				
HS	Tragacanth gum	205.606	2020 Sunset	NA	NA																				
CS	Alcohols: ethanol, isopropanol	205.601(a)	2020 Sunset	NA	NA																				
CS	Sodium carbonate peroxyhydrate	205.601(a)	2020 Sunset	NA	NA																				
CS	Newspaper or other recycled paper	205.601(b)	2020 Sunset	NA	NA																				
CS	Plastic mulch and covers	205.601(b)	2020 Sunset	NA	NA																				
CS	Aqueous potassium silicate	205.601(e)	2020 Sunset	NA	NA																				
CS	Elemental sulfur	205.601(e)	2020 Sunset	NA	NA																				
CS	Lime sulfur	205.601(i)	2020 Sunset	NA	NA																				
CS	Sucrose octanoate esters	205.601(i)	2020 Sunset	NA	NA																				
CS	Hydrated lime	205.601(j)	2020 Sunset	NA	NA																				
CS	Liquid fish products	205.601(j)	2020 Sunset	NA	NA																				
CS	Sulfurous acid	205.601(j)	2020 Sunset	NA	NA																				
CS	Ethylene	205.601(j)	2020 Sunset	NA	NA																				
CS	Microcrystalline cheesewax	205.601(j)	2020 Sunset	NA	NA																				
CS	Potassium chloride	205.602(d)	2020 Sunset	NA	NA																				
MS	Protecting the Genetic Integrity of Seed Grown on Organic Land	NA	DD	Dan Seitz	Dave Mortensen																				

Work Agenda Suggestion from Materials Subcommittee
Sanitizer/Disinfectant/Cleanser Comprehensive Review
October 2017

Sanitizers and disinfectants are used in all areas of organic production, crops, livestock and food handling. These materials are present on the National List in each section of synthetics allowed in these three scopes. Petitions for new materials to be used in contact with food, livestock or crops/cropland are received regularly and existing NL sanitation materials are reviewed at sunset.

There has been discussion over the past couple of years, that the NOSB and the organic community could better assess these materials for essentiality and how they meet the criteria for inclusion on the NL, if there were a comprehensive review of sanitation materials. Providing background information on how to assess these materials by category, as well as seeking out least toxic materials with the same functionality, would be useful information for both the NOSB and organic producers. There is universal support among NOSB members that providing materials to organic producers to help them meet food safety guidelines is necessary and the goal of this work agenda item is not to limit these tools. In reality, having this review could help identify if there are materials needed to fill gaps in organic food safety.

The Materials Subcommittee would like to request the Executive Subcommittee to bring this forward to the National Organic Program as a new work agenda item. Since these materials are used across all scopes, the MS feels it is best suited to be reviewed in our subcommittee. The resulting framework developed by the MS would provide the NOSB crops, livestock and handling subcommittees with consistent and clear criteria when addressing the listing of sanitation materials.

Possible areas of discussion for this review:

- A Technical Review and/or other written document that would result in the MS developing a framework and questions for review of sanitation materials that are not removed before contact with crops/cropland, livestock or organic food. Providing information on which categories of sanitizers/disinfectants work best in hot or cold situations, are used in rotation with other materials to prevent bacterial resistance, are most readily available, and have the least negative environmental and human health impact are a few examples of what could be covered.
- Developing a methodology that can address how the material being reviewed compares to materials already on the NL, would be useful.
- A panel of experts might be convened at a future meeting, if the MS needs more information before the framework could be completed.
- Work with the NOP to review how other organic certification rules around the world address this unique area of materials review, and possibly recommend a change to our current method of review and approval listing, such as a separate section of the National List.
- Discussion if cleansers and detergents should also be reviewed and listed. Since they do not have direct contact with processed foods, they are typically not reviewed. They still may, for example, have environmental or human health impacts in their use.
- Information on which materials are required by law to be used in specific situations.

Sunset 2019
Meeting 2 - Review
Livestock Substances §205.603
November 2017

As part of the National List Sunset review process, the NOSB has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic livestock production.

Note: The materials included in this list underwent early sunset review as part of the November 18, 2016 NOSB recommendation on efficient workload re-organization.

Reference: 7 CFR 205.603 Synthetic substances allowed for use in organic livestock production

Chlorhexidine
Chlorine Materials: Calcium hypochlorite, chlorine dioxide, sodium hypochlorite
Glucose
Oxytocin
Tolazoline
Copper sulfate
Lidocaine
Procaine

Chlorhexidine

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (6) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

Technical Report: 01/2010 TR; 2015 TR

Petition(s): N/A

Past NOSB Actions: 10/1999 NOSB meeting minutes and vote; 11/2005 NOSB sunset recommendation; 11/2009 Annotation change/clarification; 04/2010 sunset recommendation; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice 2017 (82 FR 14420)

Sunset Date: 03/15/2022

Subcommittee Review

NOSB review:
There was strong public support for the continued listing of this material. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

NOSB vote:
Motion to remove chlorhexidine from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Harriet Behar
Seconded by: Ashley Swaffar
Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed

Chlorine Materials

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

Technical Report: 2006 TR

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 05/2006 NOSB sunset recommendation; 10/2010 NOSB recommendation; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice 2017 (82 FR 14420)

Sunset Date: 03/15/2022

Subcommittee Review

NOSB review:
There was strong public support for the continued listing of chlorine materials. The NOSB also recognizes the public's request for a comprehensive review of sanitizers, however, a review of that scope is beyond that of the sunset review process. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

NOSB vote:
Motion to remove chlorine materials from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Ashley Swaffar
Seconded by: Sue Baird
Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed

Glucose

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(11) Glucose
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review

NOSB review:
There was strong public support for the continued listing of this material. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

NOSB vote:
Motion to remove glucose from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Harriet Behar
Seconded by: Sue Baird
Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed

Oxytocin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

(17) Oxytocin—use in post parturition therapeutic applications

Technical Report: 1995 TAP; 2005 TR

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice 2017 (82 FR 14420)

Sunset Date: 03/15/2022

Subcommittee Review

NOSB review:

The NOSB has determined this material is not a necessary tool in organic dairy production. There are numerous alternative methods and materials for addressing the health issues where oxytocin would be used. Its removal addresses consumer expectation that organic dairy animals are not treated with synthetic hormones.

There was public support for the delisting of this material. Based on the Subcommittee review and public comment, the NOSB finds this material to be non-compliant with the OFPA criteria of essentiality, and recommends removal from the National List.

NOSB vote:

Motion to remove oxytocin from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) Section 2118 (7 U.S.C. 6517) National List (b) (1) (A) (ii) and (iii), Section 2119 (7 U. S. C. 6518 (m) (6) and (7) and/or 7 CFR 205.600(b) (1): essentiality

Motion by: Harriet Behar

Seconded by: Ashley Swaffar

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion passed

Tolazoline

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

(22) Tolazoline (CAS #-59-98-3)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian;

(ii) Use only to reverse the effects of sedation and analgesia caused by xylazine; and

(iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

Technical Report: 2002 TAP

Petition(s): 2002 Petition

Past NOSB Actions: 09/2002 NOSB recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review

NOSB review:
There was strong public support for the continued listing of this material. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

The Livestock Subcommittee noted, however, that were xylazine to be removed from the National List in the future, tolazoline, which is used in conjunction with xylazine, would probably no longer be needed for organic production. Thus if xylazine is removed, the NOSB should consider removing tolazoline as well.

NOSB vote:
Motion to remove tolazoline from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Daniel Seitz
Seconded by: Jesse Buie
Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed

Copper Sulfate

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(1) Copper sulfate.
Technical Report: 1995 TAP; 2015 TR
Petition(s); N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review

NOSB review:

There was strong public support for the continued listing of this material. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

NOSB vote:
Motion to remove copper sulfate from §205.603(b) as topical treatment, external parasiticide or local anesthetic based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Jessie Buie
Seconded by: Harriet Behar
Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed

Lidocaine

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals
Technical Report: None
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation, 2016 annotation change recommendation
Recent Regulatory Background: Sunset renewal notice 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review

NOSB review:
There was strong public support for the continued listing of this material. Based on the Subcommittee review and public comment, the NOSB finds this material compliant with OFPA criteria, and does not recommend removal from the National List.

NOSB vote:
Motion to remove lidocaine from §205.603(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Daniel Seitz
Seconded by: Francis Thicke
Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion failed

Procaine

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(7) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals
Technical Report: N/A
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010

sunset recommendation; 10/2015 sunset recommendation, 2016 annotation change recommendation
Recent Regulatory Background: Sunset renewal notice 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review

NOSB review:
Six written comments on procaine were submitted prior to the spring 2017 NOSB meeting, which made the following points: (i) procaine is rarely used, (ii) procaine is not as effective as lidocaine, which is used for the same purpose, (iii) procaine is only available in combination with the antibiotic penicillin, which is not allowed for use in organic livestock production, and (iv) since lidocaine is more effective than procaine, keeping procaine on the National List may create confusion. Several of these six comments suggested continued listing despite the points noted above.

Seven written comments on procaine were submitted prior to the fall 2017 NOSB meeting, several of which reiterated the concern that procaine is only available in combination with an antibiotic, and one of which stated that a number of products containing procaine have been voluntary withdrawn from list of FDA Approved Animal Drug Products and are not considered to be FDA approved. Only one comment recommended continued listing.

A majority of the Subcommittee members recommended that procaine be removed from the list due to the various concerns that had been raised, most notably that procaine is only available in combination with an antibiotic, and because it is widely considered to be less effective than lidocaine, which is used for the same purpose.

There was public support for delisting of this material based on the fact that this material is not available in a form without antibiotics. Based on the Subcommittee review and public comment, the NOSB finds this material to be non-compliant with OFPA criteria, and recommends removal from the National List.

NOSB vote:
Motion to remove procaine from §205.603(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: essentiality.
Motion by: Daniel Seitz
Seconded by: Sue Baird
Yes: 14 No: 1 Abstain: 0 Absent: 2 Recuse: 0

Outcome: Motion passed

Sunset 2019
Meeting 2 - Review
Livestock Substances §205.603
November 2017

Note: The materials included in this list are undergoing early sunset review as part of November 18, 2016 NOSB recommendation on efficient workload re-organization.

Reference: 7 CFR 205.603 Synthetic substances allowed for use in organic livestock production

Chlorhexidine
Chlorine Materials: Calcium hypochlorite, chlorine dioxide, sodium hypochlorite
Glucose
Oxytocin
Tolazoline
Copper sulfate
Lidocaine
Procaine

Chlorhexidine

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (6) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.
Technical Report: 01/2010 TR; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1999 NOSB meeting minutes and vote; 11/2005 NOSB sunset recommendation; 11/2009 Annotation change/clarification; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:
Specific Uses of the Substance:
Used as an antimicrobial during surgery for cleansing wounds, skin, and equipment. Also used as a pre and post teat dip to aid in controlling bacteria that cause mastitis.

There are numerous synthetic disinfectants currently on the National List for organic livestock production, including iodine, ethanol, isopropanol, sodium hypochlorite, and hydrogen peroxide. Not all are useful both in a surgical environment and as a teat dip, as allowed under the chlorhexidine annotation.

Chlorhexidine reportedly kills mastitis-causing pathogens faster than iodine and is more persistent in its disinfection activity. Chlorhexidine is gentler on the skin than iodine, which is especially useful in northern climates where an irritated udder and teats can be especially problematic for the animals in cold winter months.

Approved Legal Uses of the Substance: Used in agriculture for disinfection during livestock surgery, on teats pre and post milking and on milking equipment. Also used in food processing as a hard surface disinfectant and in human dentistry as a mouth wash and to disinfect equipment.

Discussion:
In April 2015 the NOSB recommended adding one more teat dip: acidified sodium chlorite—allowed for use on organic livestock as a pre and post teat dip treatment.

Questions for the public:

1. Does chlorhexidine provide an essential function that other natural materials or synthetics proposed or currently on the National List do not provide?

2. Is chlorhexidine used widely in organic livestock production?

Public comment:
Numerous certification agencies noted this to be an important material for organic livestock production. Chlorhexidine is useful as the active disinfectant in a teat dip in cold temperatures, as compared to iodine, which can be problematic in that type of situation. All commenters agreed chlorhexidine's use in

surgical procedures is essential. One public interest group noted that less toxic alternatives, such as vinegar, lavender essential oil, tea tree oil or hydrogen peroxide, might be better alternatives for the teat dip use, while another noted there are alternative teat dips to chlorhexidine.

The Subcommittee did not feel alternatives were present for this material, and were in favor of retaining it as an approved synthetic as annotated. This material fulfills specific functions and is a necessary livestock tool.

Subcommittee vote:
Motion to remove chlorhexidine from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Harriet Behar
Seconded by: Ashley Swaffar
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Chlorine Materials

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

Technical Report: 2006 TR
Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 05/2006 NOSB sunset recommendation; 10/2010 NOSB recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:
Background:
Specific Uses of the Substance: Sodium and calcium hypochlorite are chlorinated inorganic disinfectants used to control bacteria, fungi, and slime-forming algae that can cause diseases in people and animals (EPA, 1991, 1992). These disinfectants also are used in cleaning irrigation, drinking water, and other water and wastewater systems. Chlorine dioxide is an antimicrobial disinfectant and pesticide used to control harmful microorganisms, including bacteria, viruses, and fungi on inanimate objects and surfaces, primarily in indoor environments. It is used in cleaning water systems and disinfecting public drinking water supplies (ATSDR, 2004a). It also is used as a bleaching agent in paper and textile manufacturing, as a food disinfectant (e.g., for fruit, vegetables, meat, and poultry), for disinfecting food processing equipment, and treating medical wastes, among other uses (EPA, 2003a). Chlorine materials are currently used for disinfection of livestock facilities.

Approved Legal Uses of the Substance:
Regarding organic production, calcium hypochlorite, sodium hypochlorite, and chlorine dioxide are currently approved for disinfecting and sanitizing livestock facilities and equipment and as algicides,

disinfectants, and sanitizers (including irrigation system cleaning) in organic crop production. Similarly, these chlorine materials are approved for disinfecting and sanitizing food contact surfaces in the production of processed products labeled as "organic" or "made with organic." Residual chlorine levels from these approved uses may not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (currently 4 mg/L).

Additional information requested by NOSB

1. Are there less toxic disinfecting and sanitizing materials that could be substituted for chlorine materials?
2. Are all three chlorine materials needed for use in livestock production?

Discussion:
The Livestock Subcommittee has received several comments both supporting and opposing relisting.

Several commenters opposed to the relisting stated:

- There needs to be a comprehensive review of all sanitizers used.

Several commenters in support of relisting stated:

- Sodium hypochlorite is routinely used to sanitize many surfaces to kill pathogenic microorganisms. Chlorine dioxide is routinely used to kill pathogenic microorganisms in water lines because sodium hypochlorite is corrosive to the pipes. No alternatives currently allowed.
- Chlorine dioxide is very important in controlling the growth of microorganisms in our water lines. Sodium hypochlorite is not a suitable substitute in water lines because it is too corrosive.

Previous public comments asked for a comprehensive review of all sanitizers, but the Subcommittee feels that a review of that scope is beyond the sunset review process. While there are concerns about the relisting of this material, chlorine has been used for many years as a sanitizer and is necessary in the organic industry for proper sanitation.

This material satisfies the OFPA Evaluation criteria and the Livestock Subcommittee supports the relisting of chlorine materials.

Subcommittee vote:
Motion to remove chlorine materials from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Ashley Swaffar
Seconded by: Sue Baird
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Glucose

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(11) Glucose
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:
Background from Subcommittee: Glucose has been on the National List since 1995, with minimal public comment, both pro and con at each sunset review. It is used most frequently in organic dairy operations to manage ketosis or other situations where an infusion of glucose is needed to restore the blood sugar balance in an ill cow. On non-organic dairy operations, propylene glycol, glycerin or corticosteroids might also be used. Careful management of feed rations before and immediately after birthing is typically used to avoid the occurrence of ketosis. There may be some excipient ingredients in glucose used in livestock production.

Additional information requested by NOSB

1. Is this material essential in organic production and why?

2. Are there nonsynthetic materials or methods that can be used to treat the illnesses associated with glucose use?

Public comment:
Numerous certifiers stated this is a commonly used material on their certified organic dairy operations, other said it was not used a lot, but still supported relisting. Its use for managing ketosis was noted as essential by farmers, milk buyers, inspectors and the organic trade. Environmental and public interest groups stated there were no adverse effects and it is an important material to treat animals. No alternative materials or methods, other than feed ration management around birthing, were mentioned.

On an organic dairy farm, glucose is an essential animal health tool. It is used typically to treat ketosis, and there was universal approval for keeping this material on the National List. Since glucose is an ingredient in calcium gluconate used to treat milk fever, retaining glucose on the National List of approved synthetics also maintains this important tool for treatment of this ailment as well.

Subcommittee vote:
Motion to remove glucose from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Harriet Behar
Seconded by: Sue Baird
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Oxytocin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

(17) Oxytocin—use in post parturition therapeutic applications

Technical Report: 1995 TAP; 2005 TR

Petition(s): N/A

Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice 2017 (82 FR 14420)

Sunset Date: 03/15/2022

Subcommittee Review:

Background from Subcommittee: Oxytocin is a hormone, naturally produced in the pituitary glands of humans, cattle and other mammals. In nonorganic production, it can be used regularly to help nonorganic dairy cows relax and "let down their milk". There are some concerns with overuse of oxytocin in nonorganic production systems. In the USDA organic regulations, it is only allowed post-birthing, in a therapeutic way to ease various dam issues that are associated with the birthing of the calf, including retained placenta. It has been recommended for use with USDA organic livestock since the inception of the USDA organic regulations, with minimal public comment on this material, pro or con. Some organic milk marketers require their organic milk suppliers to not use this material. There was very little public comment on this material over the years, and it appears to be used rarely in organic production. However, it could be considered essential for animal health and welfare in emergency situations.

Additional information requested by NOSB for public comment

1. Is oxytocin an essential material for organic production and why?

2. Are there nonsynthetic alternatives, or other methods that can be used to accomplish the same results as oxytocin?

Public comment:

The two largest milk buyers in the U.S., CROPP Cooperative/Organic Valley and White Wave/Horizon did not support renewal of this material. Numerous comments stated the current annotation "use in post parturition therapeutic applications" is unclear, leading to uses on organic milk animals that do not meet the intention of this annotation. Commenters asked for clarity detailing what time frame is considered "post parturition", and which therapeutic applications are allowed. Some certifiers would not allow its use for "milk let down", others would not allow its use for displaced abomasum, while other certifiers would. Two different certifiers, Pennsylvania Certified Organic (PCO) and California Certified Organic Farmers (CCOF), noted a total of 47 operations had used it, others noted it was not commonly used. Those in favor of relisting stated this is an important material in the dairy health toolkit, to assist animals after giving birth. Those not in favor stated there were preventative measures, as well as other activities that could be performed post birthing, that make oxytocin unnecessary in organic livestock production.

Commenters also noted the annotation was not clear, and the specific health incidents leading to the allowed use of this synthetic hormone were not consistent between certifiers.

Subcommittee Discussion:
Oxytocin has been on the National List of approved synthetics since the USDA organic regulations were implemented. However, over time, methods and materials have been developed that make oxytocin less essential for maintaining animal health and welfare. The expectations and awareness of dairy production tools by consumers has changed over time. They now expect organic milk be produced without the use of synthetic hormones. The Livestock Subcommittee realizes that some producers may need to learn new methods to address post parturition issues, but we believe the knowledge and materials are present, so that there will be no interruption in commerce, economic hardship, or lessening of animal welfare if this material is removed from the National List of approved synthetics. Veterinarians who work with organic dairy farmers, as well as educational organizations that provide information to organic dairy producers can provide this information on the methods and materials used that make oxytocin no longer essential in an organic dairy system.

Subcommittee vote:
Motion to remove oxytocin from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) Section 2118 (7 U.S.C. 6517) National List (b) (1) (A) (ii) and (iii), Section 2119 (7 U. S. C. 6518 (m) (6) and (7) and/or 7 CFR 205.600(b) (1): essentiality
Motion by: Harriet Behar
Seconded by: Ashley Swaffar
Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Tolazoline

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

(22) Tolazoline (CAS #-59-98-3)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian;

(ii) Use only to reverse the effects of sedation and analgesia caused by Xylazine; and

(iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

Technical Report: 2002 TAP
Petition(s): 2002 Petition
Past NOSB Actions: 09/2002 NOSB recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:
Background:
Tolazoline is used in conjunction with xylazine, which is used as a sedative, analgesic (pain killer) and muscle relaxant in veterinary medicine. Tolazoline is used to reverse the effects of xylazine. Tolazoline was last reviewed in 2015 at which time the NOSB voted unanimously to renew it.

Discussion:
There were three written comments on tolazoline submitted prior to the Spring 2017 NOSB meeting:

- One brief comment indicated that the substance is rarely used.
- The second comment, also brief, stated that the substance should continue to be allowed, since its use lessens animal suffering; and
- The third comment, which was extensive, focused primarily on whether there is a reasonable basis for keeping xylazine—with which tolazoline works in conjunction—on the National List, since the scientific literature on xylazine indicates that there may be pharmacological side-effects and other problems associated with its use.

This material satisfies the OFPA evaluation criteria and the Livestock Subcommittee supports the relisting of tolazoline.

The subcommittee noted, however, that were xylazine to be removed from the National List in the future, tolazoline would probably no longer be needed for organic production. Thus if xylazine is removed, the NOSB should consider removing tolazoline as well.

Subcommittee vote:
Motion to remove tolazoline from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Daniel Seitz
Seconded by: Jesse Buie
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Copper Sulfate

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(1) Copper sulfate.
Technical Report: 1995 TAP; 2015 TR
Petition(s); N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:
Copper Sulfate is used in livestock management specifically as a walk-through footbath to help control and prevent hoof-related diseases in dairy cattle and sheep. Some of the specific problems that can affect skin adjacent to the claw horn of dairy cattle and sheep include digital dermatitis (DD) (hairy heel warts), foot rot lesions (interdigital area and invading the subcutaneous tissue), and heel erosions. Depending on the severity of the infection, the impact on managed cattle and/or sheep ranges from minor discomfort to severe debilitating lameness, reproductive problems, and, in the dairy industry, a reduction of milk production ranging from 20 to 50 percent (Brown, et al., 2000, Losinger, 2006). A five to ten percent copper sulfate solution is commonly used as the antimicrobial agent in the footbath and is considered effective for 150 to 300 animal passes.

According to the February 2015 technical evaluation report commissioned by the Livestock Subcommittee, there are no natural (non-synthetic) products available that can be used as a management strategy to treat hoof-related diseases and lameness in dairy cattle and sheep operations.

However, there are various management tools available that could help reduce the cost of treatment and prevent hoof-related diseases. These include the use of additional dietary supplements (i.e., feeding of iodine, feeding of zinc methionine), free stall (cubicle) design, limiting contact with gravel or rocky surfaces, and hoof trimming practices (Maas 2009). TR lines 575-580.

The Livestock subcommittee feels that copper sulfate, used after appropriate management practices and disposed of properly, provides a valuable tool to livestock producers and recommends this material stay on the National List.

Subcommittee vote:

Motion to remove copper sulfate from §205.603(b) as topical treatment, external parasiticide or local anesthetic based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Jessie Buie
Seconded by: Harriet Behar
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Lidocaine

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals
Technical Report: None
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation, 2016 annotation change recommendation
Recent Regulatory Background: Sunset renewal notice 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:
Background:
Lidocaine is a local anesthetic which has a rapid onset of action and is short term in duration. It numbs only the area to be worked on. For example, lidocaine is used to humanely de-bud horns on calves, and for minor surgery on mature animals.

Lidocaine was last reviewed in 2015 at which time the NOSB voted unanimously to renew it.
During the 2015 sunset review of lidocaine and procaine the Livestock Subcommittee was unable to find any record of the rationale for the much extended withdrawal period of 90 days for these materials when used on slaughter stock. Historical NOSB and NOP documents from 1995 to the present were reviewed. The December 2007 commentary (72 FR 70479) implies that perhaps the 90 days is a doubling of the FDA or FARAD (Food Animal Drug Residue Avoidance) withholding period, but no such 45 day withholding was found in FDA or FARAD or other sources.

A proposal—currently outstanding—to amend §205.603 was unanimously approved by the NOSB at the April 2016 meeting as follows:

To amend §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals

Discussion:
For the spring 2017 NOSB meeting, there were five comments submitted in support of the continued listing of lidocaine (three from organizations and two from individuals), and there were no comments submitted in opposition. Therefore, it appears that there is still broad stakeholder support for continuing to list lidocaine. Those commenters who mentioned the shorter withdrawal period in their comments stated that they supported it.

This material satisfies the OFPA Evaluation criteria and the Livestock Subcommittee supports the relisting of lidocaine.

Subcommittee vote:
Motion to remove lidocaine from §205.603(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none
Motion by: Daniel Seitz
Seconded by: Francis Thicke
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Procaine

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(7) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals
Technical Report: N/A
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation, 2016 annotation change recommendation
Recent Regulatory Background: Sunset renewal notice 2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:
Background:
Procaine is a local anesthetic which has a rapid onset of action and is of short term duration. It numbs only the area to be worked on and can be used to humanely de-bud horns on calves, and for minor surgery on mature animals.

Procaine was last reviewed in 2015, at which time the NOSB voted to renew it, with 3 "yes" votes to remove, 9 "no" votes, and 2 "abstentions."

During the 2015 Sunset Review of lidocaine and procaine the Livestock subcommittee was unable to find any record of the rationale for the much extended withdrawal period of 90 days for these materials when used on slaughter stock. Historical NOSB and NOP documents from 1995 to the present were reviewed. The December 2007 commentary (72 FR 70479) cited above implies that perhaps the 90 days is a doubling of the FDA or FARAD withholding period, but no such 45 day withholding was found in FDA or FARAD or other sources

A Proposal—currently outstanding—to amend §205.603 was unanimously approved by the NOSB at the April 2016 meeting in DC as follows:

> *To amend §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable. (7) Procaine —as a local anesthetic. Use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals***.**

Additional information requested by NOSB

1. If procaine were removed from the National List and only lidocaine were available for use as a local anesthetic in organic livestock production, would lidocaine fully meet all potential veterinary needs?
2. Is procaine currently only available for use in combination with an antibiotic?

Discussion:
There were six written comments on procaine submitted prior to the Spring 2017 NOSB meeting:

- One brief comment indicated that the substance is rarely used, but did not express an opinion on renewal.
- 4 brief comments supported renewal, one of which noted that procaine is not very widely used; and
- One comment, which was more extensive, recommended removal for the following reasons:
    - Procaine is used as a local anesthetic, but is not as effective as lidocaine.
    - Procaine is not widely available, except in combination with the antibiotic penicillin, which is not allowed for use in organic livestock production.
    - There is no benefit to using procaine vs. lidocaine, so having it on the National List likely only creates confusion.

Those commenters who mentioned the shorter withdrawal period in their comments stated that they supported it.

Given the comments received so far, the Subcommittee is unclear whether procaine is currently being used in organic livestock production, and whether it is only available in combination with an antibiotic.

Subcommittee vote:
Motion to remove procaine from §205.603(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: essentiality.
Motion by: Daniel Seitz
Seconded by: Sue Baird
Yes: 3 No: 2 Abstain: 0 Absent: 2 Recuse: 0

Natamycin

Crops

Identification of Petitioned Substance

Chemical Names:

$C_{33}H_{47}O_{13}N$

16-(3-Amino-3,6-didesoxy-beta-D-mannopyranosyloxy)-5,6-epoxy-8,12,14-trihydroxy-26-methyl-2,10-dioxo-1-oxacyclohexacosa-3,17,19,21,23-pentaen-13-carbonsaeure

22-((3-amino-3,6-dideoxy-beta-D-mannopyranosyl)oxy)-1,3,26-trihydroxy-12-methyl-10-oxo-6,11,28-trioxatricyclo(22.3.1.0(sup 5,7))octacosa-8,14,16,18,20-pentaene-25-carboxylic acid

(1R,3S,5R,7R,8E,12R,14E,16E,18E,20E,22R,24S,25R,26S)-22-[(3-amino-3,6-dideoxy-D-mannopyranosyl)oxy]-1,3,26-trihydroxy-12-methyl-10-oxo-6,11,28-trioxatricyclo[22.3.1.05,7]octacosa-8,14,16,18,20-pentaene-25-carboxylic acid

Other Name:

Natamicina; Natamycine; Natamycinum; Pimaricin; Pimaricine; Pimarizin; Tennecetin

Trade Names:

BioSpectra 100SC; BioShield 100SC; Natamycin L; Nature's Shield 100SC; Zivion M; Zivion P; Zivion S

CAS Numbers:

7681-93-8

Other Codes:

Antibiotic A-5283
EINECS 231-683-5
FDA UNII: 8O0C852CPO
E 235
INS 235
CL 12,625

Summary of Petitioned Use

Natamycin is used as a fungicide in mushroom production and as a post-harvest handling treatment of raw agricultural commodities to control fungal diseases. In 2016, a petition for classification of natamycin as an allowed nonsynthetic substance in organic production was submitted for review by the National Organic Standards Board (NOSB) (Technology Sciences Group, Inc. 2016). This technical report supports the NOSB's review of this petition and addresses specific focus areas requested by the NOSB Crops Subcommittee:

- Materials used in manufacture of natamycin that may include: soy protein isolate, ammonium sulfate, sodium nitrate, or beef extract (as nitrogen sources in the substrate); defoamers; pH adjuster (potassium hydroxide); yeast; bulking agents (xanthan gum); salt**.** *(See Evaluation Question #1)*
- Natamycin is usually applied with water or with a wax or oil in post-harvest handling. Provide information on how long it may remain on the food, or how quickly it breaks down (in darkness, UV or fluorescent light) *(See Evaluation Question #4)*
- Natamycin is "exempt" from any specific limitation on amount used in post-harvest handling, but has a 6 hour application to harvest time for mushrooms; need further information on why exempt and why a withdrawal time for mushrooms? Also, there is a limit to the amount used in cheese and meat products (acceptable Daily Intake allowed in cheese or processed meats (.3mg/kg) 20 ppm in the finished product). *(See Approved Legal Uses of the Substance)*
- Purity of natamycin is 98.17% or 98.27%, what is the remainder? What are the "other ingredients" in the two brand name products named in the petition, as well as any other brand name products containing natamycin for these petitioned uses? *(See Combinations of the Substance)*
- Does long term use lead to fungal resistance to natamycin? Are there horizontal gene transfer resistance issues with similar substances to natamycin? How widespread is its current use in

nonorganic mushroom production or post-harvest handling? How long has it been in use on nonorganic mushrooms and post-harvest handling? Fungal resistance and human health effects have been reviewed based on the use only on cheese and meat products, so knowing how long and how widespread the use is in mushrooms and post-harvest handling would be informative. *(See Historic Use and Evaluation Question #8)*

- Natamycin is used in human health to control fungal infections in the eye, and related very closely to an antibiotic used for vaginal candida. Need to also research effect on human intestinal flora. Also used in livestock to control ringworm. Are there other human or livestock health uses for natamycin, and any possible issues between this human health use and the petitioned use? *(See Evaluation Question #10)*

Note: Natamycin is referred to as both a fungicide and a fungistat in the literature. Under the strictest definition, a fungicide is a substance that kills fungi, whereas a fungistat is a substance that inhibits the growth of fungi (Mehrotra 2013). Under this definition, natamycin is a fungistat (*see Action of the Substance)*. The EPA more broadly defines a fungicide as a "chemical for the control of fungi" (EPA 2007a). Except when referred to specifically as such within literature, natamycin will be referred to under the broader definition (as a fungicide) within this report.

Characterization of Petitioned Substance

Composition of the Substance

Natamycin is composed of a macrocyclic lactone (large ring, Figure 1), and the amino-glycoside, mycosamine (small ring) (Brik 1976). Lactones are characterized by the presence of oxygen within the backbone of the ring, which originates from the reaction of a hydrocarbon chain with an alcohol (Bruice 2001). Furthermore, the lactone ring in natamycin contains a series of four alternating single and double bonds. The electrons from these bonds are distributed across the bond pairs equally, forming a region known as a "polyene,[1]" which is associated with unique physical and optical characteristics (Hamilton-Miller 1973). Molecules that follow this basic structural motif are termed polyene macrolides.

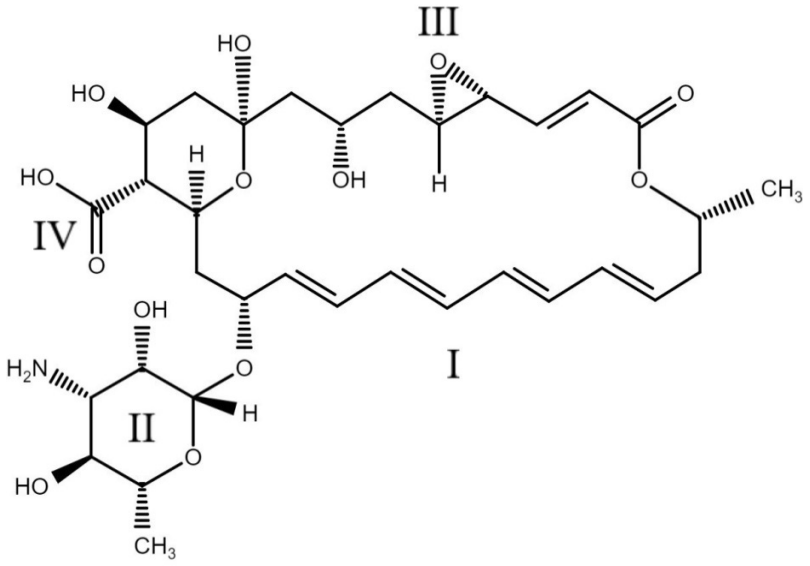

Figure 1: Chemical Structure of Natamycin, adapted from the National Library of Medicine (U.S. National Library of Medicine 2017a). Note the conjugated bonds forming the tetraene moiety, (I) which gives natamycin its optical properties; mycosamine, (II) which may contribute to natamycin antifungal activity; and the epoxide moiety (III) and carboxylic acid (IV) that are changed during acid degradation.

[1] Natamycin is more specifically a "tetraene" when one counts the specific number of bond pairs (four).

Source or Origin of the Substance

Natamycin is a naturally occurring compound produced by several soil bacteria including *Streptomyces natalensis* (Struyk, et al. 1957-1958), *S. chattanoogensis* (Martín and Aparicio 2009), *S. gilvosporeus* (Chen, Lu and Du 2008), and *S. lydicus* (Atta, et al. 2015). The European Food Safety Authority (EFSA) describes *Streptococcus lactis* producing natamycin (EFSA 2009); however, this source was not identified elsewhere in published literature. Commercial natamycin is produced from *S. natalensis*, and *S. gilvosporeus* primarily (VGP 2015). Natamycin is commercially produced using submerged aerobic fermentation with subsequent extraction and purification steps (*see Evaluation Questions #2 and #3).*

Properties of the Substance:

As a crystalline powder, natamycin is white to creamy in color (Brik 1994). The molecule has low solubility in water at a neutral pH, but dissolves at pH extremes (e.g., lower than pH 4.0, and above 10.0) (Brik 1981). It is soluble in organic solvents, such as alcohols, glycols, or formaldehyde (Struyk, et al. 1957-1958) (Burns 1959). Natamycin, like other polyene macrolides, is amphoteric (it can act as an acid or a base) but is neutral between pH 5.0 and 9.0 (Hamilton-Miller 1973). The carboxyl (Figure 1, IV) and the mycosamine groups (Figure 1, II) contribute to the amphoteric properties of the molecule (te Welscher, ten Napel, et al. 2008), with both becoming protonated at low pH, yielding a molecule with net positive charge (Koontz, et al. 2003). The low solubility of natamycin is considered advantageous in food surface applications because the substance will remain where it is applied, and not significantly migrate into the food (Stark and Tan 2003). For instance, after 28 days in Tilsiter cheese, natamycin migrated only 2.6mm (Kiermeier and Zierer 1975). The physical and chemical properties of natamycin are summarized in Table 1.

Table 1. Physicochemical Properties of Natamycin

Property	**Value**[a]
Physical state	Solid
Appearance	White to cream colored crystalline powder
Odor	None
Molecular weight	665.75 (g/mol)
Melting point	290°C
Water solubility	~30-100 ppm
pH	5-7.5
Density	303-588 g/L (loose vs. packed)

[a] **Sources: (Brik 1981), (Stark and Tan 2003), (Jones 2011)**

Natamycin can form three known crystal lattice structures: the commonly occurring alpha, and the less common and more heavily manipulated delta and gamma forms. These forms of natamycin are relatively stable in the absence of light. Alpha-natamycin crystals can be either hydrated, or dried further to form an anhydrous material. The commonly occurring trihydrate form (crystals containing three water molecules per natamycin) is more stable than the anhydrous form (Borden, Maher and Sklavounos 1999). Alpha-natamycin crystals are known to occur in two shapes: plates, and needles. Plate-shaped crystals are formed in standard manufacturing processes (described in responses to *Evaluation Question #2*). Needle-shaped crystals are formed by dissolving previously obtained natamycin crystals in water at either high or low pH (more than 10.0 or less than 4.0), followed by neutralization of the media over a period of 5-50 minutes and at temperatures between 5 and 35°C (De Haan and Van Rijn 2013).

Delta-natamycin is known to occur under specific manufacturing processes (van Rijn, et al. 1998). Delta-natamycin can be converted into another unique form, the trihydrate gamma-natamycin (not to be confused with the commonly occurring alpha-natamycin trihydrate, or simply natamycin). Delta-natamycin is anhydrous, and is more stable than anhydrous alpha-natamycin. Gamma-natamycin (a trihydrate) is also stable, and has enhanced bioactivity against some fungal species. Both delta and gamma crystals revert to alpha-natamycin after recrystallizing in water (van Rijn, et al. 1998).

Commercially available forms of natamycin are most likely in the (more stable) form of trihydrates (Stark and Tan 2003). Unless otherwise stated, the remainder of this report will address natamycin in the alpha crystalline trihydrate form.

Specific Uses of the Substance:

Natamycin is used for its antifungal properties, and is active over a wide pH range. Burns (1959) found that natamycin was active against *Saccharomyces carlsbergensis* from pH 4.0 to 10.0. It is effective against yeasts such as *Candida albicans, Cryptococcus neoformans* and *Saccaromyces cerevisiae*, and filamentous fungi such as *Aspergillus flavus, Penicillium chrysogenum, Trichoderma spp.*, and *Paecilomyces spp*. as well as many others (Struyk, et al. 1957-1958). Natamycin also demonstrates activity against parasitic protozoa, such as *Trypanosoma cruzi* (causal agent of Chagas disease) which, like many fungi, contain ergosterol in their cell membranes (Rolón, et al. 2006). While no longer considered within the fungi kingdom, oomycetes (such as the causal agent of Potato Late Blight, *Phytophthora infestans*) are notably insensitive to natamycin (Judelson and Blanco 2005) (WHO 2001).

Commercial applications of natamycin in crop, livestock, and food production can be grouped into three basic categories: 1) as an agricultural fungicide, either pre- or post-harvest, 2) as a livestock medication, and 3) as a preservative in processed foods.

Fungicide in agriculture

Natamycin is used to control fungal diseases in enclosed mushroom production facilities (EPA 2012a). EPA-approved labels include its use in the control of dry bubble disease, caused by *Lecanicilium fungicola* (also known as *Verticillium fungicola*), which affects commercially grown button mushrooms (*Agaricus bisporus*). The disease does not affect the vegetative portion of the fungus, but rather the edible mushroom, causing lesions and tissue disruption (such as stipe "blow-out" and other deformations). Natamycin may also be applied to mushrooms during production in an aqueous solution by hand or with an automatic watering system.

Natamycin is used as a post-harvest fungicide on fruit (including citrus, berries, pomes, stones, pineapples, melons, and bananas) to prevent spoilage caused by fungi such as *Penicillium spp.* and *Geotricum spp.* (Pace International 2016) (Huang, et al. 2016). Application methods vary depending on the label instructions and generally include first mixing with water or wax (see *Combinations of the Substance* for more information). Fruit application methods include dipping, drenching, spraying, and flooding (EPA 2017a).

Medical uses for livestock

Natamycin is used in animal health care applications as a veterinary drug. It has moderate activity against dermatophytes, yeasts and *Aspergillus*. It is used in some parts of the world to treat ringworm and candidosis in horses and cattle (Rochette, Engelen and Vanden Bossche 2003), and has also been used to treat nasal aspergillosis in horses. It is approved for use as an additive for feed and drinking water of broiler chickens (EPA 2012a).

Preservative in processed foods

Natamycin is commonly used in the U.S. to protect the surface of cheese and, in Europe and other countries, sausages against fungal development (Streekstra, Verkennis, et al. 2016). Natamycin is marketed for use in products such as cottage cheese, sour cream, yogurt, and packaged salad mixes (Siveele B.V. 2009). It is used in beverage products to prevent mold and yeast (Keefe 2015).

Approved Legal Uses of the Substance:

Approved uses in agriculture (pre and post-harvest)

Natamycin used as petitioned is regulated by the EPA. Antifungal products with natamycin as an active ingredient are subject to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and therefore must be registered with the EPA. Natamycin was approved by the EPA in 2012 for use as a fungistat on mushrooms grown in enclosed mushroom growing facilities (EPA 2012a). In 2016, the EPA further

approved its use in post-harvest facilities to control fungal disease on additional specified crops (EPA 2016b).

Natamycin is exempt at 40 CFR 180.1315 from the requirement of a tolerance for residues in or on mushrooms, pineapples, citrus, pome, stone fruit crop groups, avocado, kiwi, mango, and pomegranates when used in accordance with label directions and good agricultural practices. Natamycin's exemption from the requirement for a tolerance is based on the determination of EPA's Biopesticides and Pollution Prevention Division that data on the product chemistry and toxicity satisfy the current guideline requirements for tolerance exemption (EPA 2012a). For more information on toxicity, see *Evaluation Question #10*.

The EPA-approved label for Natamycin L includes use instructions for a 6-hour waiting period, or pre-harvest interval[2] (PHI), between application and harvest of mushrooms, whereas no PHI is indicated for other antifungal fruit wash uses because it is applied post-harvest. Originally, the label for Natamycin L approved by the EPA in 2012 included a 4-day (96-hour) PHI for mushrooms (EPA 2012c). In 2013, the EPA approved a shortening of the PHI to 6 hours as well as a shortening of the steaming required for spent mushroom media from 24 to 12 hours (EPA 2013). Information submitted to the EPA regarding the basis for the PHI or its shortening is not publicly available. In 2016, the label was amended to include post-harvest use on citrus, pome and stone fruit crops, avocado, kiwi, mango and pomegranate (EPA 2016b).

Approved uses in livestock production

Natamycin is listed in FDA regulations under 21 CFR 573.685 as an additive in broiler chicken feeds according to stated specifications, which detail use of the additive as part of a premix with calcium carbonate and lactose, used for retarding the growth of *Aspergillus parasiticus*. Levels for components in the premix are set and feed rates are specified to equal 11 ppm natamycin.

Natamycin is also approved by the FDA as an ophthalmic suspension under the New Drug Application number 050514 to suppress fungal eye infections such as blepharitis, conjunctivitis, and keratitis per FDA regulations at 21 CFR 449.40.

Approved uses in food processing

The FDA permits natamycin as a direct food additive at 21 CFR 172.155 for application on cheese as an antimycotic to inhibit the growth of yeast and mold. The listing includes specifications for purity (must be 95-99 percent pure, on an anhydrous basis) and limits heavy metal contaminants. It also limits natamycin content in finished cheese to 20 mg/kg.

Natamycin is also recognized by the FDA as Generally Recognized as Safe (GRAS) when used to prevent growth of food spoilage molds in yogurt at a minimum level not to exceed 5 mg/kg natamycin (FDA 2014), and also when used in ready-to-drink tea beverages, fruit flavored fruit-flavored energy drinks, sport and isotonic drinks, and fruit-flavored beverages at levels not to exceed 5 ppm (FDA 2015).

Action of the Substance:

Natamycin has two primary modes of action: inhibition of fungal growth and inhibition of mycotoxin production.

Inhibition of fungal growth

Natamycin's best known mode of action involves inhibition of fungal growth. Natamycin is effective against a wide array of fungi (Struyk, et al. 1957-1958), and disrupts normal cell membrane function by interfering with ergosterol (te Welscher, ten Napel, et al. 2008). Ergosterol is critical to fungi that contain it, as it is involved in a wide array of cellular processes, including growth (Parks and Casey 1995). When

[2] Pre-harvest interval is defined by the EPA as "the time between the last pesticide application and harvest of the treated crops" (EPA 2009).

ergosterol is blocked, fungal cells are unable to transport materials such as glucose and amino acids across cell membranes (te Welscher, van Leeuwen, et al. 2012).

Ergosterol is found in many (though not all) fungal cell membranes (Weete, Abril and Blackwell 2010) and the level of ergosterol in fungi fluctuates over time, across species, and at different developmental stages (Pasanen, et al. 1999). For example, during spore germination, the amount of ergosterol can increase more than four times in six hours (van Leeuwen, Smant, et al. 2008).

Much of the research on natamycin focuses on its effect on fungal spores, as opposed to mature vegetative tissue (hyphae). Natamycin's interference with the normal function of ergosterol inhibits the active uptake of vesicles (endocytosis, a fission process) (van Leeuwen, Golovina and Dijksterhuis 2009) and also affects the membrane fusion process of organelles (vacuoles), acting before cell membranes even contact each other (te Welscher, Jones, et al. 2010). Endocytosis and exocytosis are thought to be important elements in fungal germination and growth, and growth in fungi occurs in regions that are rich in sterols (such as ergosterol). Natamycin's interference with ergosterol is also associated with changes in the regulation of cell membrane proteins, such as sugar and amino acid transporters (te Welscher, van Leeuwen, et al. 2012). These changes block the uptake of nutrients by fungal spores, and in response, the fungi up-regulate the production of cell membrane proteins in order to attempt to overcome the nutrient shortage (te Welscher, van Leeuwen, et al. 2012). However, the researchers (te Welscher, van Leeuwen, et al. 2012)found that the effects of natamycin were reversible in *Aspergillus niger* and *Saccharomyces cerevisiae*, indicating that up-regulation of these proteins may not lead to lasting effects in these species.

Other polyene antimycotics such as amphotericin B, and nystatin (a tetrane), have been shown to form pores that increase the permeability (or "leakiness") of fungal cell membranes in addition to interfering with ergosterol (Aparicio, et al. 2016). This same mode of action was described in the 2006 Technical Report on Natamycin (ICF International 2006). Since 2006, understanding regarding natamycin's activity has progressed; unlike the other polyene antimycotics, it is now believed that natamycin does not form pore complexes that create leaks in cell membranes (te Welscher, ten Napel, et al. 2008).

The effect of natamycin on fungal membranes is substantial. The minimum inhibitory concentration (MIC), or the amount of natamycin needed to prevent growth against its targets is very low. For example, the MICs for isolates of *Penicillium, Mucor, Rhizopus, Paecilomyces, Fusarium*, and *Trichoderma* from commercial poultry feed ranged from 2.15 to 5.80 ppm (Brothers and Wyatt 2000). Some species, such as *Aspergillus spp.* tend to be more naturally tolerant of natamycin. The lower solubility estimate of natamycin in water at 30 ppm (Brik 1981), while low, exceeds the MIC for susceptible fungal targets. As levels of natamycin decrease due to diffusion, degradation, and absorption by fungi, natamycin is released from natamycin crystals into the surrounding substrate (Stark and Van Rijn 2010). This effectively balances the aforementioned losses and maintains concentrations that exceed the MIC for target species.

Inhibition of mycotoxin production

Fungi that contaminate food can produce mycotoxins. Minute levels of natamycin (1 ppm) can inhibit the production of aflatoxin B_1, ochratoxin, penicillic acid, and patulin (Ray and Bullerman 1982). Ray noted that natamycin's effect on mycotoxin inhibition is greater than its effect on fungal growth (see below). For example, a 10 ppm treatment of natamycin reduced growth of *Aspergillus ochraceous* by 46 percent, but reduced ochratoxin production by 100 percent. Research demonstrating the mechanism by which natamycin acts to reduce mycotoxin production was not found. It may be that the interference with membrane trafficking has a corresponding effect on mycotoxin production.

Assessment of whether natamycin acts as an antibiotic

The literature has established that natamycin is ineffective against bacteria (Struyk, et al. 1957-1958) (Burns 1959) (Brik 1981) (WHO 2002) due to the negligible presence of ergosterol in bacterial membranes (Aparicio, et al. 2016). With the exception of the EPA, most regulatory agencies would exclude natamycin from their respective definitions of "antibiotic" because natamycin has no effect on bacteria. Regulatory definitions from FDA and USDA would classify natamycin as an antimicrobial instead of an antibiotic.

The EPA's definition for antibiotics covers a broader variety of substances than most other regulatory agencies. The EPA defines antibiotics as: "*A metabolic product of one microorganism or a chemical that in low concentrations is detrimental to activities of specific other microorganisms. Examples include penicillin, tetracycline, and streptomycin. Not effective against viruses. A drug that kills microorganisms that cause mastitis or other infectious disease*" (EPA 2007b). The EPA's definition of the term "antibiotic" encompasses natamycin, as natamycin is a metabolic product of a microorganism (bacteria) that is detrimental to other microorganisms (fungi). When natamycin was specifically reviewed for use as a pesticide ingredient to control the germination of mold and yeast spores in mushroom substrates, the EPA stated that it was a fungistat, and a naturally occurring antimycotic compound. When describing its manufacture, they referred to it as an antibiotic (EPA 2012a).

While an explicit definition of "antibiotic" from the FDA could not be found, they state that "*Antibiotics are meant to be used against bacterial infections*" (FDA 2011). When natamycin is used as a drug, it is excluded from the FDA's implicit definition of an antibiotic as it has no activity against bacteria. Instead, it would fall under the term "antimicrobial": "*Antimicrobial drugs include all drugs that work against a variety of microorganisms, such as bacteria, viruses, fungi, and parasites. An antibiotic drug is effective against bacteria. All antibiotics are antimicrobials, but not all antimicrobials are antibiotics*" (FDA 2017).

Additionally, under the definition used by the USDA One Health Joint Working Group,[3] natamycin would be considered antimicrobial: "*…antimicrobial drugs are a broader category since they have activity against more than just bacteria and include synthetic medications such as sulfonamides*" (USDA 2014).

As with the FDA and USDA's use of the term, natamycin would be excluded from the definition of antibiotics by the World Health Organization (WHO) as it is not used to prevent or treat bacterial infection: "*Antibiotics are medicines used to prevent and treat bacterial infections*" (WHO 2016).

Combinations of the Substance:

With respect to the petitioned use, natamycin is not known to be a precursor to--or a component of--other synthetic substances on the National List at §205.601. Purified natamycin on its own is not currently sold for use as an agricultural fungicide, but is sold for further formulation. Commercially available natamycin products for agricultural use are formulated with other ingredients, as described below. Label instructions for some products require the applicator to first mix the natamycin product with water or wax. Further details on the type or identity of wax are not specified.

As of July 2017, there are eight EPA-registered natamycin products for use in enclosed mushroom production facilities or as a post-harvest fungicide. Since natamycin must be registered with the EPA, it is expected that these are the only commercially available products available for use in the U.S. for the petitioned uses. There are three EPA registration numbers associated with these eight products (see Table 2), each with natamycin as the reported active ingredient (EPA 2017a). All EPA registrations are held by DSM Food Specialties.

[3] The USDA One Health Joint Working Group includes the Animal and Plant Health Inspection Service (APHIS), Agricultural Research Service (ARS), Food Safety and Inspection Service (FSIS), Economic Research Service (ERS), National Agricultural Statistics Service (NASS), and the National Institute of Food and Agriculture (NIFA) (USDA 2014).

Table 2: Summary of EPA registered natamycin products as of July, 2017.

EPA Reg. No.	Number of registered products	Natamycin	Other ingredients	Product description
87485-1	1	91.02%	8.98%	Technical Grade of the Active Ingredient (TGAI) intended for formulating into fungicidal products
87485-2	6	10.34%	89.66%	For use on mushrooms; citrus; pome and stone fruit; avocado; kiwi; mango; pomegranate
87485-3	1	4%	96%	For use on pineapple

EPA Reg. No. 87485-1

This product has a purity of 91.02 percent natamycin. The composition of the other ingredients is not disclosed on the product label. In the petition, Technology Sciences Group, Inc. states that the product does not contain any ancillary substances, but that impurities may be present such as water of hydration, naturally occurring natamycin-related by-products co-extracted with the natamycin, residual solvent, and natamycin degradates (Technology Sciences Group, Inc. 2016). Therefore, the 8.98 percent other ingredients are expected to be composed of these substances, with the majority being composed of water of hydration, which makes up the natamycin trihydrate structure.

EPA Reg. Nos. 87485-2 and 87485-3

Natamycin is the only active ingredient in formulated products with EPA Reg. Nos. 87485-2 and 87845-3. Other ingredients used to formulate the products are not disclosed on labels or available Safety Data Sheets (SDS).

Formulation information for specific products within the scope of the petitioned use is not publicly available; however, formulants identified in natamycin patents are listed in Table 3. Many (but not all) of these substances are present on the 2004 EPA List 4, which indicates that they would be permitted as inerts under the NOP regulations in accordance with §205.601(m). They include pH adjustors and buffering agents (e.g., citric acid), thickening agents (e.g., xanthan gum), fillers (e.g., lactose), surfactants (e.g., sodium lignosulfonate), antifoaming agents (e.g. vegetable oils), and solvents (e.g., ethanol).

Table 3: Formulants noted in patents for agricultural uses of natamycin.

Patent holding company	U.S. Patent Number (and source)	Product form	Uses	Formulants
Gist-Brocades B.V.	5,552,151 (Noordam, et al. 1996)	Wettable powders for making suspensions	Non-specific agricultural products	*Thickening / bulking agents*: xanthan gum[iv], carrageenan[iv], methylcellulose[iv], gum Arabic[iv]. *Surfactants*: sodium dodecyl sulfate[iv] *Buffers:* citric acid[iv], mono[iv]-, di[iv]-, tri-sodium salts of citric acid[iv], mono[iv] and disodium salts of phosphoric acid[iv] *Fillers:* lactose[iv] or cellulose[iv]
Gist-Brocades B.V.	5,821,233 (van Rijn, et al. 1998)	Metallic salts and alternate crystal structures	Food preservation, agricultural products, pharmaceutical	*Carriers*: Fumed silica[iv], microcrystalline cellulose powder[iv].

Patent holding company	U.S. Patent Number (and source)	Product form	Uses	Formulants
DSM IP Assets, B.V.	7,816,332 (Stark and Van Rijn 2010)	Liquid solution	Vegetables, fruits, herbs, plants, and mushroom substrates	*Water*[iv]. *pH adjustors:* hydrogen chloride[iv], sulfuric acid[iv], citric acid[iv], lactic acid[iv], sodium hydroxide[iv], potassium hydroxide[iv], ammonium hydroxide[iv]. *Solvents:* food grade solvent such as ethanol[iv] if for agricultural or food use. Other uses include many other solvents.
Valent BioSciences Corporation	0271158* (Huang, et al. 2016)	Liquid suspension concentrate	Fruits, mushrooms, pre- and post-harvest	*Water*[iv]. *Anionic surfactants*: polyelectrolyte polymers (such as sodium lignosulfonate[iv]), modified styrene acrylic polymers[N], polyoxyethylene sorbitan trioleates[iv], polyoxyethylene sorbitol hexaoleates[iv], dioctyl sodium sulfosuccinate[iv], sodium salts of naphthalene sulfonates[iii]. *Diluents:* glycerol[iv], hexylene glycol[iii], dipropylene glycol[iii] , polyethylene glycol[iv]. *Preservatives:* benzoates[N] and potassium sorbate[iv]. *Antifoams:* silicone based antifoam agents[N], vegetable oils[N], acetylenic glycols[N], and high molecular weight adducts of propylene oxide[N]. *Antifreeze:* ethylene glycol[iii] , 1,2-propylene glycol[iv], 1,3-propylene glycol[N], 1,2-butanediol[N], 1,3-butanediol[iii], 1,4-butanediol[iii], 1,4-pentanediol[N], 3-methyl-1,5-pentanediol[N], 2,3-dimethyl-2,3-butanediol[N], trimethylolpropane[iii], mannitol[iii], sorbitol[iv], glycerol[iv], pentaerythritol[iii], 1,4-cyclohexanedimethanol[N], xylenol[N], bisphenol A[N]. *Miscellaneous:* the patent application describes applying the product with an additional coating wax.
DSM IP Assets, B.V.	8,420,609 (De Haan and Van Rijn 2013); 9.615,581 (De Haan and Van Rijn 2017)	Needle-shaped crystals in aqueous suspension	Fruits, vegetables, and seed	*Water*. *pH adjustors*: hydrogen chloride[iv], benzoic acid[iv], propionic acid[iv], sorbic acid[iv], acetic acid[iv], lactic acid[iv], or sodium hydroxide[iv]. *Carriers:* fumed silica[iv]. *Solvents:* C1-C4 alcohols[N], glacial acetic acid[iv]. *Surfactants:* sodium lauryl sulfate[iv], dioctyl sulfosuccinate[iv], calcium chloride[iv], non-ionic surfactants[N]. *Thickening / bulking agents:* hydroxypropylmethylcellulose [iv] (HPMC), carrageenan[iv], methylcellulose[iv], xanthan gum[iv], gellan gum[iv], gum Arabic[iv].

Patent holding company	U.S. Patent Number (and source)	Product form	Uses	Formulants
N/A, referenced by Stark	N/A (Stark and Tan 2003).	Emulsion	Fruits	*Emulsifier:* lecithin[iv].

Key: [*] = Patent application only, not granted; [iii] = Present on 2004 EPA List 3; [iv] = Present on 2004 EPA List 4; [N] = Not able to confirm 2004 EPA list status.

Formulants used with natamycin for other purposes, such as in beverages, baked goods, cheese coatings, and other dairy products are outside the scope of this report.

Status

Historic Use

The discovery of natamycin was first reported in 1958 (Struyk, et al. 1957-1958). At that time, it was named "pimaricin," based on the location from which the bacteria that produced it was found in Pietermaritzburg, South Africa. Natamycin was again discovered independently in 1959, this time named "tennecitin," based on the location of the soil isolate, which came from Chattanooga, Tennessee (Burns 1959). Later, it was named "natamycin" by the World Health Organization (Brik 1994).

Natamycin is unique, in that as of 2003, it was the only microbially derived antifungal compound used as a food preservative (Stark and Tan 2003). In addition to its well-established uses as a food additive for preserving cheese, sausage, and other food products, natamycin was studied as a potential fungicide for fruit diseases as early as 1958 (Eckert 1967).

In the United States, natamycin has been approved for use in mushroom production by the EPA since 2012, and since 2016 for post-harvest fruit production (EPA 2017a). No data was found regarding how many producers use it, how often, or in what total quantities for any of the petitioned uses. Published EPA reviews of natamycin did not include numerical estimates of the cumulative quantity of natamycin that was expected to be used (EPA 2016b, EPA 2012a). Pennsylvania State College of Agricultural Sciences, which maintains a dedicated mushroom research facility and provides extension support for mushroom growers, does not include natamycin as a chemical control in guides or fact sheets (Penn State College of Agricultural Sciences, n.d.) (Beyer n.d.).

Organic Foods Production Act, USDA Final Rule:

Natamycin is not listed in the Organic Foods Production Act (OFPA) nor in the NOP regulations.

For use as an input in crop production, the NOP regulations permit nonsynthetic substances that are not otherwise prohibited by §205.602 of the National List. The NOP Handbook contains guidance documents that describe the procedures used for classifying materials as synthetic or nonsynthetic. The Organic Materials Review Institute (OMRI) has classified natamycin as nonsynthetic and previously included natamycin products on the OMRI Products List©. Under NOP regulations, OMRI currently considers natamycin as an issue beyond resolution, as indicated on the OMRI website: "Although OMRI has determined that natamycin is a nonsynthetic material based on the Draft NOP Guidance on Classification of Materials (NOP 5033),[4] the NOP has stated that this substance is not allowed under the NOP regulations and has instructed OMRI not to list products containing natamycin" (OMRI 2017). The Washington State Department of Agriculture (WSDA) Organic Food Program also does not currently include any natamycin-based fungicides on its publicly available approved organic inputs lists (WSDA Organic Program 2017)

[4] Since publication of the issue on OMRI's website, the final version of the NOP Guidance Classification of Materials has been published (USDA NOP 2016b).

Natamycin is prohibited for use in organic processing and handling because it is a nonorganic substance which is not included on the National List sections 205.605 or 205.606. In December 2005, natamycin was petitioned as a nonsynthetic nonagricultural substance for use in organic processing and handling, specifically for use as post-baking surface treatment of baked goods to prevent or delay growth of mold (George Weston Bakeries, Inc. 2005). The NOSB Handling subcommittee considered the petition in 2007. The subcommittee's recommendation identified natamycin as synthetic, and the motion to add the substance to §205.605(b) failed (NOSB Handling Subcommittee 2007). The full NOSB considered the petition at the spring 2007 meeting. The minutes from that meeting indicate that the board members were persuaded that natamycin is not synthetic.[5] The full board voted on a motion to list natamycin on §205.605(a) as a nonsynthetic and the motion failed.[6] At the time, the Board did not separately vote on the classification of natamycin as synthetic or nonsynthetic.

International

Canadian General Standards Board Permitted Substances List (CAN/CGSB-32.311-2015)
http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/normes-standards/internet/bio-org/lsp-psl-eng.html
"Biological organisms" (living, dead, or non-viable) are permitted for use as crop production aids and materials on Table 4.3 of CAN/CGSB-32.311-2015. Examples given in the listing include microbial organisms (*Bacillus thuringiensis*) and microbial products (spinosad). Natamycin itself is not a biological organism; however, it could be considered a microbial product much like spinosad.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling, and Marketing of Organically Produced Foods (GL 32-1999)
http://www.codexalimentarius.org/standards/list-standards/en/?no_cache=1
http://www.codexalimentarius.org/download/standards/360/cxg_032e.pdf
The CODEX Alimentarius *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods*, Annex 2, Table 2 (Substances for Plant Pest and Disease Control), III lists "Microorganisms used for biological pest controls" with the condition that the need for use be recognized by the certification body or authority. Specific products of microbial fermentation such as spinosad and fermented product from *Aspergillus* appear on the same table under section 1: Plant and Animal. Natamycin is not specifically listed in this section.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:250:0001:0084:EN:PDF
While microorganisms used for biological pest and disease control are permitted in Annex II of EC No. 889/2008, natamycin is not listed as one of the permitted substances produced by microorganisms in Annex II. Annex II is a closed list, and spinosad is the only microbially produced substance listed as allowed for pest control.

Japan Agricultural Standard (JAS) for Organic Production
http://www.maff.go.jp/e/jas/specific/criteria_o.html
Natamycin is not specifically listed in JAS regulations. However, Notification No. 1605, Japanese Agricultural Standard for Organic Plants (JAS 2017), Article 5 lists substances for preparation and includes "Substances for preparation derived from microorganisms." Natamycin, while not itself a microorganism, is derived from microorganisms and therefore meets this definition.

[5] Excerpt from meeting transcript on March 28, 2007: "I think we've heard pretty compelling public comment yesterday and today and I think we are persuaded that natamycin is not in fact synthetic and so the prohibition for listing something for the purpose of being used as a preservative does not apply to a nonsynthetic."
[6] NOSB does not issue final recommendations for failed motions; there is no final recommendation to reference.

International Federation of Organic Agriculture Movements (IFOAM)
http://www.ifoam.bio/en/ifoam-norms
Bacterial preparations are listed as a permitted substance in Appendix 3: Crop Protectants and Growth Regulators. Natamycin is not specifically listed.

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

Evaluation Question #1: Indicate which category in OFPA that the substance falls under: (A) Does the substance contain an active ingredient in any of the following categories: copper and sulfur compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers? (B) Is the substance a synthetic inert ingredient that is not classified by the EPA as inerts of toxicological concern (i.e., EPA List 4 inerts) (7 U.S.C. § 6517(c)(1)(B)(ii))? Is the synthetic substance an inert ingredient which is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part 180?

Natamycin is a naturally occurring substance produced by bacteria, so an exemption from OFPA for a synthetic substance may not be applicable (see *Evaluation Question #3*, which suggests that natamycin may be classified as nonsynthetic based on NOP Guidance 5033-1). Natamycin inhibits spore germination and disrupts the normal function of membranes containing ergosterol. The EPA has not identified Natamycin as an inert (EPA 2017), but has approved its use as an active fungistat ingredient when used in enclosed mushroom growing facilities (EPA 2012a). Natamycin is exempted from the requirement of a tolerance for residues on fruits when used in post-harvest handling (EPA 2016a).

Evaluation Question #2: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Regardless of the application, natamycin production typically involves two primary steps: 1) biosynthesis of natamycin through submerged aerobic fermentation and 2) extraction and purification of natamycin from the post-fermentation broth through the use of solvents, pH/solubility adjustment, and/or physical means. Afterwards, natamycin may be formulated with other ingredients for end use. During these processes, the chemical structure of natamycin is not permanently changed. Depending on the solvents used, natamycin may form reversible intermediates that revert back to the original structure produced by bacteria, and it may gain or lose waters of hydration, depending on processing (such as when drying or producing solvates). Details of the chemical changes are described in *Evaluation Question #3*.

Biosynthesis of natamycin through fermentation
Natamycin occurs as a secondary metabolite in *Streptomyces spp.* and its production is positively affected by available oxygen (Beites, et al. 2011). As such, aerobic conditions are necessary for natamycin production. *Streptomyces spp.* are typically grown in submerged aerobic conditions in liquid growth media (Struyk, et al. 1957-1958) (Burns 1959) (Beites, et al. 2011) (Elsayed, Farid and Enshasy 2013). This process involves taking growth from a previous liquid culture, and using that to inoculate production volumes of liquid media. Growth media temperatures have been reported at 25°C for optimal production (Burns 1959), and 30°C (Elsayed, Farid and Enshasy 2013). Natamycin yield is reportedly optimal between pH 5.0 and 6.5 if maintained by pH control agents (Eisenschink and Olson 1993).

Eisenschink (1993) describes in detail a process for biosynthesizing natamycin. *Streptomyces sp.* spore suspensions are prepared and serially propagated until finally transferring to an 80,000 liter production fermentor. During fermentation, media is aerated through agitation or injection of sterile air in order to maintain a dissolved oxygen level of 20 to 80 percent. Components of the production (growth) media

include sources of nitrogen, carbon, vitamins, inorganic elements, and trace elements. Depletion of the carbon source negatively impacts natamycin yield, so it is added continually during production. The carbon source is discontinued prior to the completion of fermentation so that little to no carbon source is left at the termination of production. Antifoaming agents (such as silicone-based products) are added as needed. During fermentation, the pH of the production media decreases. Alkaline and other pH adjusting materials are added to increase and maintain the pH within the optimum range (such as sodium, potassium, or calcium hydroxides, along with sodium and potassium citrates). Growth proceeds through three phases: during the first phase, *Streptomyces sp.* increases, and natamycin increases exponentially. In the second phase, natamycin production continues, but linearly. In the final phase, natamycin concentration plateaus.

Improvements in natamycin growth media have led to decreases in the time to reach peak production. When Burns reported on natamycin in 1959, peak production occurred approximately 96 hours after inoculation (Burns 1959)(Table 3). In 2013, Elsayed et al. found that adding acetic and propionic acid to the growth medium in a 7:1 ratio yielded a 250 percent increase in natamycin production, with a decrease in production time from 96 to 84 hours (Elsayed, Farid and Enshasy 2013). Other nutrients may be used in growth media, such as ammonium sulfate or sodium nitrate, but these substances were not specifically mentioned in the literature.

The petition does not include specific details about the medium or technique used for biosynthesis. However, DSM has reported using a submerged aerobic fermentation method of production in the past (DSM Food Specialties Inc. 2015), and the European Food Safety Authority report included with the petition corroborates the use of this technique (Technology Sciences Group, Inc. 2016), and some information about DSM's growth media can be ascertained from their 2015 FDA GRAS notice (see Table 3).

Table 3: Natamycin growth media components

Source	Type	Components
(Struyk, et al. 1957-1958)	Experimental	Soybean meal, glucose, nutrient salts.
(Burns 1959)	Experimental	Peptone, phytone, beef extract, yeast extract, and glycerol. Inositol dextrin, and galactose were satisfactory replacements for glycerol as a carbohydrate source.
(Eisenschink and Olson 1993)	Patent	Difco "Bacto" peptone, Hormel peptone PSR 5, corn steep liquor, sodium chloride, glucose.
(Eisenschink, Millis and Olson 1997)	Patent	Carbon sources such as glucose, polysaccharides, and corn or potato starches. Non-yeast and yeast protein in a 3:1 to 9:1 ratio. Non-yeast protein sources include soy protein isolates, flours, or meals; or beef extract or protein hydrolysates. Yeast protein sources include extracts, autolysates, etc. Vitamins, inorganic elements and trace minerals: potassium, sodium calcium, boron, iron, copper zinc, etc. (undisclosed forms)
(Elsayed, Farid and Enshasy 2013)	Experimental	Glucose, beef extract, yeast extract, asparagine, and monopotassium phosphate, sodium acetate, and the sodium salt of propionic acid.
(DSM Food Specialties Inc. 2015)	Production	Undisclosed soy carbon source, inorganic salts, lye solution for pH control.

Extraction and purification

At the end of fermentation, the post-fermentation broth contains natamycin and various undesirable by-products of the fermentation process, such as biomass solids (bacterial mycelium), dissolved or suspended

nutrients, other fermentation products, and water (Raghoenath and Webbers 2000). Different strategies are used to extract and purify natamycin from the post-fermentation broth. Approaches for isolation of natamycin initially involved using organic solvents to isolate natamycin and adding low solubility liquids to create a precipitate (Struyk, et al. 1957-1958) (Burns 1959). More recent processes involve pH adjustments to recover natamycin, or using solubility enhancing salts and dilution (Eisenschink, Millis and Olson 1997) (Olson, Millis and Reimer 1997). Other current strategies omit the use of organic solvents, and instead rely on isolation through particle size and density sorting (Raghoenath and Webbers 2000). This section describes the evolution of natamycin processing, culminating in the petitioner's process.

Struyk and Burns relied on initially filtering, then moving natamycin into an alcohol solvent, and then forcing precipitation through the addition of a low solubility material (Struyk, et al. 1957-1958) (Burns 1959). Struyk used organic solvents such as formamide, and then water to precipitate natamycin, while Burns used n-butanol as the solvent, created a highly saturated solution through evaporation, and then added cold ether to precipitate natamycin. Struyk further purified natamycin by re-dissolving the crystals in hot methanol, followed by filtration and precipitation in water.

Cultor Food Science, Inc. patented a method whereby the broth culture pH level was adjusted with a base to 10 or 11 (Eisenschink, Millis and Olson 1997). Then, a water miscible solvent (preferably isopropanol) was added to further solubilize natamycin, followed by filtration to remove solids (mycelium). The solids were washed with additional solvent to extract additional residual natamycin. The pH of the solution was lowered with an acid (such as hydrochloric acid) to cause precipitation of natamycin, and then the crystals were subsequently isolated through filtration, washing with a water-isopropanol mixture, and evaporated or spray dried (Eisenschink, Millis and Olson 1997).

Biotechnical Resources L.P. patented a continuous flow process for the recovery of natamycin using methanol (Olson, Millis and Reimer 1997). Cool methanol was added to the broth, preferably at 15°C. The mixture was then pH adjusted to between 1 and 4.5 for 30 minutes to 30 hours. Alternatively, no pH adjustment was performed and instead, a solubility enhancing salt was added, such as calcium chloride. Solids were removed by filtration or centrifugation, and the pH of the solution was raised to between 6 and 9 with sodium hydroxide to precipitate natamycin crystals, unless a solubility enhancing salt had been added, in which case water was added to precipitate the crystals. The crystals were further washed and dried to increase the purity (Olson, Millis and Reimer 1997).

Gist-Brocades B.V. patented an isolation process in 2000 which omitted the use of organic solvents as the primary means of recovery (Raghoenath and Webbers 2000). Instead, biomass was first disintegrated using a variety of possible methods, preferably heat and pH treatment, and then natamycin crystals were isolated through gravity separation. Disintegration of the biomass took place for 1-8 hours preferably at 30-35°C, with sodium hydroxide, ammonium hydroxide, or potassium hydroxide being used to adjust the pH level to between 8 and 10, followed by neutralization with hydrochloric acid, phosphoric acid, sulfuric acid, or acetic acid. Neutralization preferably occurred after separation of natamycin from the broth. Other disintegration methods were covered by the patent, such as physical, enzymatic, and surface active chemical methods. Enzymatic treatments involved incubating cell wall and organic polymer decomposing enzymes such as lysozyme, xylanase, cellulose, protease, glucanase, lipase, and amylase. Disintegration with surface active agents included octylphenoxypolyethoxyethanol compounds, for example Triton X-100 for 1-24 hours. Separation of the larger natamycin crystals from the smaller disintegrates in the broth was accomplished using an upflow column or hydrocyclone, with additional water and sodium chloride added as necessary. The purity and yield were adjustable with this method, being able to produce an approximately 90 percent pure (anhydrous basis) natamycin product (Raghoenath and Webbers 2000).

Gist-Brocades also patented a process to make novel natamycin crystal forms claimed to have increased bioactivity (van Rijn, et al. 1998). Crystals of alpha-natamycin were dissolved in methanol, and then the solvent was evaporated under vacuum leaving a unique natamycin crystal form, called delta-natamycin. Delta-natamycin could also be hydrated in a 76 percent relative humidity environment to form the trihydrate gamma-natamycin with yet another crystal structure. Additionally, the patent described the preparation of natamycin salts (such as calcium and barium). These processes involved passing nitrogen

gas was passed through a saturated solution of calcium or barium hydroxide in water and adding natamycin. The resultant crystals were filtered and washed with water and acetone, then dried (van Rijn, et al. 1998).

The petitioner describes using heat to lyse the biomass, consistent with the initial process described in the 2000 Gist-Brocades patent[7] (but not necessarily subsequent steps). The mixture is then centrifuged to separate the biomass from the broth medium containing the natamycin crystals. DSM states that a solvent is added during this process to maintain microbiological stability. Based on a flow chart submitted to the EPA, the solvent may be n-propanol (DSM Food Specialties Inc. 2015). A pH adjusting process is used to precipitate the natamycin crystals from the broth, possibly using lye (sodium or potassium hydroxide) as one of the pH adjustors. The crystals are pressed in order to remove the solvent and excess water (Technology Sciences Group, Inc. 2016). In the aforementioned manufacturing process flow chart submitted to the EPA, the petitioner shows an additional resuspension of crystals in n-propanol and water, followed by washing, filtering, and drying.

DSM additionally patented a process whereby natamycin crystals are dissolved in an alkaline water solution with a pH level between 11.0 and 13.0 using sodium hydroxide (De Haan and Van Rijn 2013). The solution is then neutralized to a pH between 6.0 and 8.0 using hydrochloric acid, whereby natamycin crystals with a needle shape (as opposed to plate shape) form over a period of 10-30 minutes and at a temperature between 15-25°C. The crystals can then be dried or left in solution. According to the patent, the needle shaped crystals are advantageous when making natamycin suspensions (De Haan and Van Rijn 2013).

Evaluation Question #3: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).

Natamycin is commercially manufactured through biosynthesis, extraction, and purification as described in Evaluation Question #2. Biosynthesis of natamycin through fermentation is a naturally occurring biological process. NOP Guidance 5033, Classification of Materials, states at §4.7 that products of naturally occurring biological processes, such as fermentation are statutorily considered natural and nonsynthetic (USDA NOP 2016b). During the extraction and purification steps to recover natamycin from the post-fermentation broth, synthetic extractants may be used and temporary chemical changes may occur; however, the resulting natamycin substance is not chemically changed from the original substance that was produced by fermentation. NOP Guidance 5033 §4.6 states that nonorganic materials may be extracted with solvents, acid-base extraction, and physical methods such as filtration, crushing, centrifugation, and gravity separation (USDA NOP 2016b). Extraction techniques must meet three criteria in order for the extracted material to be considered nonsynthetic. Natamycin is evaluated against the decision tree in NOP Guidance 5033-1 below.

To further evaluate natamycin as described in Evaluation Question #2 against NOP Guidance 5033-1 (USDA NOP 2016a):

- *Is the substance manufactured, produced, or extracted from a natural source?(Box 1)*
  Natamycin is produced by a biological mediation of substrates via aerobic fermentation with *Streptomyces ssp.*).

- *At the end of the extraction process, does the substance meet all of the criteria described at §4.6 of NOP 5033?(Box 2b)*

    - *At the end of the extraction process, the material has not been transformed into a different substance via chemical change;*

[7] Gist-Brocades B.V. was purchased by DSM's parent company in 1998. The patent mentioned here was originally filed by Gist-Brocades in 1997.

The extraction methods used to isolate natamycin involve either physical processes, or processes that take advantage of natamycin's low solubility in solvents such as water, and relatively high solubility in other solvents such as methanol or at pH extremes. These processes do not permanently chemically alter natamycin. Some impurities may be formed incidentally, such as 13-hydroxy-2,4,6,8,10-tetradeca pentane-1-al (Brik 1976).

- *The material has not been altered into a form that does not occur in nature;*
  No information was found that elucidates under what circumstances natamycin is produced by *Streptomyces spp.* in nature, or if it is produced in sufficient quantity to form crystals. If natamycin were produced by *Streptomyces spp.* in the soil, there is no reason to believe it would differ from that produced in the methods described within this report.

- *Any synthetic materials used to separate, isolate, or extract the substance have been removed from the final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product.*
  Natamycin forms solid crystals which precipitate out of solution during the extraction process. Solvents and other materials used in processing are separated through physical means such as filtration, washing, and evaporation. A residual amount of solvents and other materials may remain, but are not considered to have a technical or functional effect in the final product.

- *Has the substance undergone a chemical change so that it is chemically or structurally different than how it naturally occurs in the source material?(Box 2)*
  Based on the information described above in 2b, natamycin does not undergo a chemical change so that it is chemically or structurally different. Other materials that have similar extraction and purification techniques have been classified as nonsynthetic, including citric acid and glucono delta-lactone, both classified as nonsynthetic on §205.605(a).

Evaluation Question #4: Describe the persistence or concentration of the petitioned substance and/or its by-products in the environment (7 U.S.C. § 6518 (m) (2)).

Application rates

As natamycin is effective at low concentrations, application rates are small. For the petitioned use in mushroom production, a maximum application rate of 0.65oz of natamycin (the technical grade of the active ingredient [TGAI]) per 1000 ft^2 is used (Technology Sciences Group, Inc. 2016). For post-harvest use in fruit production, labels for products with EPA Reg. No. 87485-2 give various application rates. For in-line aqueous applications, 28 to 114 fluid ounces of formulated end-product (10.34 percent natamycin TGAI) can cover 50,000 to 200,000 pounds of fruit, depending on target crop and disease. Application methods such as drenching and flooding use 57 to 114 fluid ounces per 100 gallons of water though it is not clear how many pounds of fruit this covers. Labels for products with EPA Reg. No. 87485-3 (for use on pineapples) show an application rate of 4 to 32 fluid ounces per gallon of water and aqueous dilution of wax, with 0.034 fluid ounces of this dilution applied to the peduncle (stem). Based on maximum label use rates for in-line flood applications (EPA Reg. No. 87485-2), natamycin is applied at 16mg/kg fruit.

Post-application residues on crops and in the environment

Residues remaining after application are low. In a crop field trial submitted for review to the EPA, maximum residues on unwashed mushrooms were 0.2370 mg/kg (Jones 2011). No crop study data was found regarding residues on fruits treated with natamycin post-harvest. As mentioned earlier in the *Approved Legal Use of Substance* section, natamycin is exempt from the requirement of a residue tolerance when used in accordance with label directions and good agricultural practices for post-harvest treatment on the following raw agricultural products: mushrooms, pineapples, citrus, pome, stone fruit crop groups, avocado, kiwi, mango, and pomegranates (EPA 2016a).

Water used to apply natamycin to fruit or that is leached from mushroom production may be one of the more likely sources for residues entering the environment, although information on this potential was not available in the literature. Other potential sources include residuals from natamycin-treated food products that enter the waste stream, and consumed food products that may pass through the digestive tract. The Joint FAO/WHO Expert Committee on Food Additives concluded that natamycin is minimally absorbed during digestion and is primarily excreted in the feces (WHO 2002). Therefore, if natamycin is still present on food products at the time of consumption, it may be possible that human sewage contributes to natamycin residues in the environment.

The manner in which enclosed mushroom production occurs limits the accumulation of natamycin and its breakdown products within mushroom substrates. As mushrooms are grown, they deplete their substrates, which must be entirely replaced (Munshi, et al. 2010). Spent mushroom substrates may go on to be used as soil amendments or compost feedstocks. Natamycin products registered for use on mushrooms are currently limited to EPA Reg. No. 87485-2, and contain label use instructions that direct users to steam spent substrate for at least 12 hours at 65°C or greater prior to disposal. Natamycin is stable above 100°C at neutral pH, and therefore would theoretically not break down by the steam treatment prescribed. In a field trial reviewed by the EPA, natamycin residues were not detected[8] in mushroom substrates after steam sterilization (Jones 2011). The fate of the natamycin (whether it was broken down by the treatment or otherwise removed) was not disclosed in the study.

After post-harvest processing, crops may be taken directly to market, refrigerated, or placed in controlled atmosphere storage. Natamycin, if protected from UV light, is stable in such conditions. The length of time that natamycin residues remain active likely depends on the presence of UV light, or whether formulants or packaging are used that protect natamycin. Due to its thermal stability, temperature is unlikely a factor in the length of time natamycin remains intact on fruit surfaces. Uneaten fruit that is disposed could theoretically create an avenue for minor amounts of natamycin to reach the environment.

Decomposition / degradation

Some information regarding the decomposition of natamycin is known, but a complete picture is far from evident. Much of the available information on its decomposition is based on applications of various wavelengths of light (Struyk, et al. 1957-1958) (Burns 1959) (Brik 1976) (Koontz, et al. 2003), solvents (Brik 1976), heat (Struyk, et al. 1957-1958) (Burns 1959), and pH extremes in a laboratory setting (Brik 1976) (Burns 1959) (Brik 1994). These studies do not necessarily reflect what happens to natamycin in the environment. Furthermore, studies have often focused on what inactivates natamycin (eliminating functionality), rather than its decomposition products. Studies that have investigated the decomposition of natamycin, such as performed by Brik (1976), do not identify how the decomposition products themselves would be further broken down, or whether they would be metabolized by native organisms in the environment.

Natamycin degrades in the presence of: ultraviolet (UV) light (Koontz, et al. 2003); oxidants such as peroxides, chlorine, and heavy metals (EFSA 2009); and pH extremes (Brik 1976). A 20 mg/L aqueous solution of natamycin without UV protectants was degraded within 24 hours when exposed to fluorescent lighting, such as that found in deli cases (Koontz, et al. 2003). Degradation does not involve complete molecular decomposition, but rather a loss of function or biological activity. When degraded with UV light, the primary change is that the polyene moiety loses a double bond, becoming a triene (Brik 1976). Oxidation also presents stability issues for natamycin. In one study, when applied to cucumber leaves, natamycin lost most of its activity within 3 hours in darkness due to autoxidation; however, it is not clear what form of natamycin was used (anhydrous or trihydrate) (Dekker 1963). Breakdown in the presence of acids creates free mycosamine and dimers (pairs) of natamycin and modified lactone rings much larger than natamycin itself (Brik 1976). Alkaline environments can hydrolyze the lactone ring, producing a non-cyclic aldehyde, while other parts of the ring can break down into acetone and acetaldehyde (Brik 1994). The EPA reports that natamycin is degraded by metals and metal ions, but the decomposition products are not mentioned (Jones 2011).

[8] With a limit of quantitation (LoQ) of 0.1mg/kg (ppm).

Natamycin can be UV- and/or oxidation stabilized by the addition of substances such as ascorbic acid (Burns 1959), plant juices (Dekker 1963), chlorophyll (Brik 1981), and sodium potassium chlorophyllin (Koontz, et al. 2003). Additionally, packaging or any other substance that absorbs light between 300 and 400nm will protect natamycin from photodegradation. Components of carnauba wax (used to coat fruit) have been shown to absorb UV light in the 250 to 350nm range (Freitas, et al. 2016). In black olives, application of 100mg/L of natamycin to brines suppressed fungal growth for the length of the trial (60 days) at room temperature. Quantification of natamycin present in the brine at the end of the trial was not evaluated, and it is not known what UV stabilizers may have been present (Hondrodimou, Kourkoutas and Panagou 2011).

Accumulation / biological fate

Information regarding the persistence, accumulation, or concentration of natamycin in the environment is not available in the literature. Natamycin has very low solubility in water, and therefore it is unlikely to build up in aquatic environments though may be incorporated into sediments if not broken down. In shallow or clear aquatic environments subject to sunlight, there is potential for natamycin to degrade due to its sensitivity to the UV spectrum, as discussed above.

While detailed information was limited with respect to natamycin, some biological fate data is present for nystatin, which shares physical and chemical similarities with natamycin. Nystatin lacks an epoxide ring which is present in natamycin (Figure 1, III), and its macrolide ring contains 38 members instead of natamycin's 26 (U.S. National Library of Medicine 2017b). Otherwise, nystatin is a tetraene macrolide antimycotic, containing mycosamine. Nystatin in the air has a half-life of 1.5 hours due to degradation by hydroxyl radicals; 2.6 hours due to ozone; and an unknown half-life due to photolysis by sunlight (U.S. National Library of Medicine 2006). A closed bottle test indicated that biodegradation (biological means) was slow for nystatin, and not an important environmental fate process. Bioconcentration in aquatic organisms was low, with a bioconcentration factor (BCF) value of 22; a material is not considered to pose a risk for bioconcentration until reaching a value of 1000 (Arnot and Gobas 2006).

Evaluation Question #5: Describe the toxicity and mode of action of the substance and of its breakdown products and any contaminants. Describe the persistence and areas of concentration in the environment of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)).

Natamycin inhibits spore germination and disrupts the normal function of membranes containing ergosterol, for which the EPA describes as a "non-toxic" mode of action (EPA 2016c). The EPA considers lethal, but non-toxic pesticides to include suffocating agents (oils), desiccants, and abrasives; in other words, materials that are not poisonous to the target organism (Leahy, et al. 2014).

Natamycin has low to moderate oral toxicity, depending on the animal (EFSA 2009). The European Food Safety Authority reported the oral LD50 in male rats was 2700 mg/kg, and 4700 mg/kg in females. The oral LD50 in mice was 1400 mg/kg, and 450 mg/kg for female guinea pigs. The No-Observed-Adverse-Effect Level (NOAEL) for rats in subchronic studies was 45 mg/kg of body weight per day.

A description of the toxicity mechanism was not found in published literature. Based on oral acute toxicity data, the EPA has classified it as category III (slightly toxic) (EPA 2012a). The EPA noted that no significant acute, subchronic, genotypic, developmental, or endocrinologic mammalian toxicity effects were observed, and toxicological endpoints were not identified (EPA 2016c). See *Evaluation Question #10* for more information on human toxicity.

Information regarding the breakdown products of natamycin under natural environmental conditions is not available in the published literature. However, in laboratory conditions under acidic or basic extremes, natamycin was found to decompose into mycosamine, acetone, aldehydes, acetaldehyde, ammonia, and various macrolide ring structures (e.g., aponatamycin) (Brik 1981). The median lethal dose (LD50) for mice

ranged from 150 to 600 mg/kg of body weight when treated via intraperitoneal injection[9] with decomposition products of natamycin (FDA 2015).

Although the decomposition products of natamycin under natural circumstances are not described in literature, the potential toxicity of the experimentally derived decomposition products is explored in the following paragraphs.

Mycosamine

Brik (1981) noted that the products of acid, alkaline, and UV-treated natamycin such as aponatamycin (one of the macrolides) and mycosamine are less toxic than the parent compound, but the animals tested or the method of application were not disclosed.

Acetone

Acetone is a naturally occurring ketone in the body, which can be metabolized for energy. Acetone has low toxicity with an oral LD50 values for adult rats of 5800-7138 mg/kg (U.S. National Library of Medicine 2015b). Values as high as this are extremely unlikely to occur through use of natamycin due to both the application rates involved, and through microbial oxidation of acetone by soil bacteria (Taylor, et al. 1980).

Aldehydes

Aldehydes are pervasive in the environment, and many have documented health risks (LoPachin and Gavin 2014). With the exception of acetaldehyde, no specific information is available for the forms of aldehydes created from the decomposition of natamycin. Acetaldehyde is very soluble in water, and also binds to soil or suspended particles. It is broken down by microorganisms and is not expected to build up in aquatic organisms. At concentrations of 0.1 percent, it can induce mutations in nematodes, and is expected to be a carcinogen, based on animal studies. It has an oral LD50 in rats of 1930 mg/kg (U.S. National Library of Medicine 2015a).

Ammonia

Ammonia is highly reactive, and can volatilize, adsorb to soil, be metabolized by microorganisms, or be taken in by plants. Ammonia is moderately toxic, with an oral LD50 in rats of 350 mg/kg. Concentrations of this amount due to the application of natamycin are extremely unlikely, based on application rates and reactivity (U.S. National Library of Medicine 2016).

Evaluation Question #6: Describe any environmental contamination that could result from the petitioned substance's manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)).

No literature from the EPA, FDA, National Institute of Environmental Health (NIEHS), the European Environment Agency (EEA), or from academic or independent papers was found that directly related to environmental contamination from the production, use, misuse, or disposal of natamycin. The EPA did not require Tier 1 studies to assess ecological hazards, environmental fate, groundwater data, or endangered species assessment prior to registration of natamycin (EPA 2012a). Furthermore, no published information could be found directly related to pollution created from the production of secondary metabolites by bacteria. An EEA report from 2010 noted that very little data on the environmental exposures, fate, and impact of pharmaceutical products in the environment exist (EEA 2010).

In the biosynthesis of natamycin, wastewater containing spent growth media, bacterial mycelium, pH adjusters, antifoaming agents, and other materials may be created. Wastewater treatment plants do not remove micro-pollutants completely (Martz 2012). Other metabolites or chemicals may be present in such wastewater, and if not treated properly, these materials may be emitted to the environment. Once released natamycin could migrate into sediments, but would be unlikely to bioconcentrate in aquatic organisms, based on similarities to nystatin as discussed in *Evaluation Question #4*.

[9] Intraperitoneal (IP) injection is the injection of a substance into the peritoneum (body cavity).

Misuse of the product, such as application at higher rates than approved by the EPA, would be unlikely to affect the surrounding environment due to the restricted locations that it is used (e.g., enclosed mushroom facilities, or in facilities post-harvest). Application to non-approved agricultural crops could negatively affect germination of other fungi, including beneficial fungi such as *Paecilomyces* and *Trichoderma sp.* (Brothers and Wyatt 2000).

Evaluation Question #7: Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling. Describe any environmental or human health effects from these chemical interactions (7 U.S.C. § 6518 (m) (1)).

Safety data sheets (SDS) indicate that natamycin products with EPA Reg. Nos. 87485-1, and -2 are chemically stable. An SDS for EPA Reg No. 87845-3 cannot be located using publically available resources. Specific chemical interactions are not known to occur beyond those described within manufacturing processes noted in *Evaluation Question* #2, with the exception that it is degraded by metal or metal ions (Jones 2011). Natamycin may be formulated with other inert ingredients (as described in *Combinations of the Substance),* but the specific identities of these materials are not publicly available. Natamycin may dissolve in some solvents, or break down in the presence of strong acids or bases. No information was found showing that natamycin is used as a precursor or a feedstock for production of other chemicals, whether used in organic crop production or otherwise.

Evaluation Question #8: Describe any effects of the petitioned substance on biological or chemical interactions in the agro-ecosystem, including physiological effects on soil organisms (including the salt index and solubility of the soil), crops, and livestock (7 U.S.C. § 6518 (m) (5)).

Natamycin used as petitioned is unlikely to significantly affect the agro-ecosystem due to its mode of action and because it is applied in post-harvest or enclosed mushroom facilities. As petitioned, natamycin would not be applied to soils directly (although it may be indirectly applied via spent mushroom media as a soil amendment). Furthermore, natamycin is not expected to have a direct effect on earthworms, mites, grubs, bacteria, nematodes, or algae, unless applied at very high dosages as ergosterol does not play a significant role in animal, plant, and bacterial membranes (Dupont, et al. 2012) (Sáenz, et al. 2012). It can affect protozoa and fungi; however, as petitioned it would not be applied to the soil, and could only affect them through mishandling or misapplication. It is not expected to affect soil temperature, water availability, pH, nutrient availability, salt concentration, solubility, or other soil physicochemical parameters. As petitioned, natamycin would be unlikely to affect plant-fungi dynamics in the soil, such as mycorrhizal relationships, because it is not applied to growing plants or the soil.

The EPA determined that based on its use in mushroom production, natamycin exposure to non-target organisms was not expected; however, they did not pursue environmental fate data, and assumed that it would solely be used indoors. The EPA did not identify any toxic endpoints, and natamycin presented little if any risk to nontarget organisms (EPA 2012a).

Potential for fungal resistance to natamycin

The specific petitioned uses have only been approved in the United States since 2012 (mushroom production) and 2016 (post-harvest); long term evaluations of resistance due to the use of natamycin as petitioned were not identified. Looking beyond the petitioned use, the European Food Safety Authority (EFSA) believed that there was a potential risk of the development of resistant fungi when natamycin was used as a food additive, but that the risk and level of resistance would be low (EFSA 2009). EFSA reported that studies conducted in cheese warehouses and dry sausage factories have not shown a change in the fungal flora during 10 years of natamycin application.

Numerous studies show that resistance to natamycin can be induced in the laboratory. Resistance to natamycin by fungi such as *Cryptococcus neoformans, Aspergillus fennelliae,* and *Candida albicans* has been induced *in vitro* since at least the 1970s (Kim and Kwon-Chung 1974) (S. Kim, J. Kwon-Chung, et al. 1975)

(DSM Food Specialties Inc. 2015) and earlier for other polyenes such as amphotericin B (Hebeka and Solotorovsky 1965). Resistance by fungi to natamycin has typically come at a fitness cost, with a loss or reduction of virulence, asexual reproduction, sexual reproduction, growth rate, and thermal tolerance. Increased resistance was associated with changes in biosynthesis of ergosterol or ergosterol-like sterols. More recently, 20 fungal isolates, most different species, were evaluated for resistance in a laboratory setting using incrementally increasing concentrations of natamycin. Resistance was induced in 13 of the 20 isolates, with *Aspergillus ochraceus* also showing a threefold increased resistance to amphotericin B and nystatin (Streekstra, Verkennis, et al. 2016). When natamycin was removed, most strains with increased tolerance showed reduced growth, but not all; *Aspergillus terreus, Colletotrichum musae,* and *Geotrichum candidum* showed changes in appearance, but not colony size. Other fitness parameters apart from colony growth rate were not evaluated. In another study, of 319 strains of yeast taken from inflamed cow udders, 40.8 percent were resistant to natamycin (Lassa and Malinowski 2007); however, this data was not compared to any previous analysis and so no conclusions regarding the acquisition of resistance can be made.

At the March 2017 meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the Russian Federation requested a safety re-assessment of natamycin for the Codex Committee of Food Additives to determine whether natamycin should remain on the General Standard for Food Additives (GSFA) list. The request referenced emerging data about the role of natamycin in promoting antimicrobial resistance and speeding up virulence and pathogenic potential of microorganisms that cause food-borne illness, as well as its effect on the misbalance of microflora in the gut, immunity status and other functions in the human body (CCFA 2017a). The referenced data was not included in the published meeting materials. The Egypt delegation questioned the proposed deletion of natamycin from the GSFA as being contrary to the CCFA procedures and opposed such a move due to the technological usage of natamycin under the approved safe limits (CCFA 2017b). However, the Committee agreed to obtain scientific advice and information is expected in December 2017 (CCFA 2017c).

The manner of application of natamycin as petitioned isolates both the antimycotic, and the population of fungi exposed to it. According to Anderson (2005), drug resistant phenotypes in fungi usually remain locally isolated and do not disseminate back into the larger population, unless there is a general advantage to the larger population (Anderson 2005). So far, natamycin resistant strains have been mostly (but not entirely) associated with reduced fitness (S. Kim, J. Kwon-Chung, et al. 1975) (Streekstra, Verkennis, et al. 2016), and therefore selection pressure would be low unless regularly exposed to natamycin. As natamycin is used more widely, selection pressures may increase, but to what extent is not clear.

Potential for horizontal gene transfer resistance

Horizontal gene transfer (HGT) is the exchange of genetic material between strains or species, as opposed to vertical exchange between parent and offspring within species. HGT primarily occurs in prokaryotes (such as bacteria). Recently, HGT has been identified in eukaryotes, though more barriers to its occurrence exist and the rate of transfer is low, based on current analyses (Ku, et al. 2015) (McInerney 2017). Identifiable HGT events themselves are typically not recent, having occurred in distant evolutionary history. It is thought that when HGT does occur in eukaryotes such as fungi, the other partner is more often a bacterium, though not always (Fitzpatrick 2012). Due to natamycin's mode of action, acquisition of direct resistance through HGT is difficult. While bacteria can carry resistance genes to the antibiotics that they produce (Jiang, et al. 2017), actinomycetes (such as *Streptomyces*) do not carry antimycotic resistance genes as the bacteria do not have the target molecule (such as ergosterol) in the first place (Seipke, et al. 2012). Therefore, HGT of resistance between bacteria and fungi is unlikely.

Examples of fungal-fungal HGT events do exist, including gene clusters encoding toxins such as fumonisin, to transfer of multiple complete chromosomes (Fitzpatrick 2012). Dalhoff and Levy state that fungal-fungal HGT has led *Candida spp.* and *Aspergillus fumigatus* to produce biofilms and gain resistance to polyene antimycotics (Dalhoff and Levy 2015). Biofilms and polyene resistance are known to occur in both *Candida* (Nett, et al. 2010) and *Aspergillus spp.* (Krappmann and Ramage 2013), and biofilms are associated with polyene resistance, but the acquisition by these species of those traits through HGT as Dahloff and

Levy suggest could not be confirmed in other publications. No documented direct resistance due to HGT could be found for the polyene antimycotics natamycin, amphotericin B, nystatin, or rimocidin.

Evaluation Question #9: Discuss and summarize findings on whether the use of the petitioned substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

When used as petitioned, natamycin is unlikely to be harmful to the environment. If label instructions are followed, it is not applied to crops growing directly in soil. It has low toxicity to humans and other animals, and is not used at concentrations that would create a risk of acute exposure. Native fungi and protozoa in the agro-ecosystem are unlikely to be exposed to natamycin, except potentially through disposal of waste water. As natamycin activity is degraded by UV light and oxidants, the bioactivity of natamycin, once released, is likely to be low (unless the natamycin product has been formulated with stabilizers and is insufficiently diluted). While the environmental fate and breakdown products are not well documented, the known substances are unlikely to be harmful at the recommended application rates. Based on available data, fungal resistance to natamycin has yet to occur in a significant way, as discussed in *Evaluation Question #8*.

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

Natamycin's exemption from the requirement for a tolerance of pesticide residue on food is based on the EPA's determination that there is a reasonable certainty that no harm will result from aggregate exposure to natamycin residues when used according to product labeling. The EPA evaluates pesticides by looking at toxicity of the substance as well as expected exposure through food and drinking water. Under these considerations, the EPA categorized natamycin as a Toxicity Category IV[10] active ingredient (EPA 2012b). Natamycin was found to have an acute oral toxicity of LD_{50}[11] > 3,000 mg/kg (Toxicity Category III), acute dermal toxicity of LD_{50} > 5,050 mg/kg (Toxicity Category IV), acute inhalation toxicity of LC_{50} > 2.39 mg/L (Toxicology Category IV), and primary eye irritation was severely irritating but with no positive effects after 24 hours (Toxicity Category III); Primary Dermal Irritation was slightly irritating (Toxicity Category IV). Natamycin is not a contact dermal sensitizer, is not a mutagen and is not cytotoxic (EPA 2016b) (EPA 2012a).

The JECFA established an allowed daily intake (ADI) for natamycin of 0-0.3 mg/kg of body weight in 1976. Human studies had shown no toxicological effects at a level of 3 mg/kg body weight per day, and an uncertainty factor of 10 was further included to calculate the ADI. The European Food Safety Authority (EFSA) estimated that the highest levels of human exposure to natamycin via food additive applications on cheese and sausage would be below the ADI, at 0.1 mg/kg body weight per day for children and below 0.05 mg/kg body weight per day for adults (EFSA 2009). At the time the ADI was established the JECFA also concluded that natamycin is poorly absorbed in the gut, and is primarily excreted in feces (JECFA 1976). The Committee considered additional studies in 2002 and reconfirmed the ADI.

In 2009 the EFSA published a review of natamycin's safety as a food additive. The report cited numerous animal tests which identified No-Observed-Adverse-Effect Levels (NOAELs) for natamycin in rats and dogs. These levels, all above the ADI, ranged from 45 to 6.25 mg/kg body weight per day for adverse effects such as decreased food intake, diarrhea, decreased body weight, and in one study, obesity. The EFSA reported no concerns for genotoxicity of natamycin, and rat tests evaluating reproductive toxicity resulted in a NOAEL of 50 mg/kg body weight per day (EFSA 2009).

[10] Toxicity Categories are defined at 40 CFR 156.62. Toxicity Category I indicates the highest level of toxicity. Category III indicates low toxicity and Category IV, the lowest toxicity.

[11] Lethal Dose $(LD)_{50}$ is the amount of a material, given all at once, which causes the death of 50 percent of a group of test animals.

The JECFA report from the 2002 meeting acknowledged that use of natamycin as an antifungal agent in food would result in exposure of intestinal microflora to its residues. However, the Committee speculated that because fungi are much less abundant in the human gastrointestinal tract than bacteria, and bacteria are not affected by polyenes, the consequences of indigenous microflora exposure to natamycin in the gut would be minimal (WHO 2002). One concern regarding microbial exposure to natamycin is the potential for development of resistance. Studies supporting the JECFA conclusion included surveys of cheese and sausage factories where natamycin has been used as a preservative. No change in composition or sensitivity of contaminating fungi to natamycin was found with the exception of one yeast strain in one of the studies. The authors reportedly found no yeasts or molds that were resistant to natamycin after several years of natamycin use (De Boer and Stolk-Horsthuis 1977). The authors also attempted to develop fungal strains resistant to natamycin under laboratory conditions by exposure to increased concentrations over 25-30 transfers. After 25 passes, *Candida albicans* was minimally less sensitive to natamycin, with 12-50µg/ml needed to induce sensitivity rather than the initial concentration of 2.5-12µg/ml. The resistant strains were reported to have reduced metabolic and growth rates and reverted to normal growth, metabolism and sensitivity to natamycin after polyene exposure had stopped (De Boer and Stolk-Horsthuis 1977) (WHO 2002). Reasons cited for the lack of development of fungal resistance to natamycin when used as a food additive include its environmental instability and its lethal antifungal activity (Delves-Broughton, et al. 2005).

Not all of the literature agrees on the absence of risk for the development of fungal resistance to natamycin and, by extension, to other antifungal polyenes, particularly those with importance as medical treatments. Dalhoff and Levy (2015) describe how applications of natamycin in yogurt and beverages (which are not surface applications but are mixed in) expose intestinal microflora to increased concentrations of natamycin in the gut. According to the authors, this could increase the potential risk for development of polyene resistance in resident *Candida albicans* and *Saccharomyces cerevisiae* within the gut. The level of potential natamycin exposure from beverages presented in the report (500 ppm) far exceeds what is allowed according to the GRAS determination for use in beverages (5 ppm). However, the authors maintain that even at levels currently permitted by regulation which are well below the ADI, the fecal concentration of natamycin may exceed its minimum inhibitory concentration (MIC) (Dalfhoff 2015). The MIC is the lowest concentration of a substance (e.g., natamycin) that inhibits the growth of a target species, such as *Candida sp.* Increased exposure of a target organism to a substance can lead to an increased MIC, which indicates that the target organism's susceptibility to the substance has been diminished. Dalhoff and Levy (2015) based their claim regarding the potential development of natamycin resistance in part on a study which reported on the effects of natamycin administered orally in combination with butylscopolamine for the treatment of intestinal candidosis at a daily dose of 400 mg for 10 days in 356 individuals. Dahloff and Levy claim that the results showed that the susceptibility of *Candida spp.* to natamycin was significantly reduced during the exposure period and that it returned to normal levels when checked 3 months post-exposure. However, as Streekstra, Keuter and Wilms (2015) point out in their response to Dalhoff and Levy (2015), the original authors of the study concluded that there had been no marked changes to the MIC of natamycin as a consequence of the natamycin treatment (Streekstra, Keuter and Wilms 2015) (Gehring, et al. 1990).

In general there is a lack of evidence in the literature to show that applications of natamycin in food at regulatory-approved levels lead to fungal resistance as has been seen in certain medical applications (Kaushik, et al. 2001) and other laboratory studies.

The use of natamycin as an antifungal agent in food may have some benefits to human health, namely, the suppression of mycotoxins that contaminate food. Mycotoxins are secondary metabolites of certain fungi which can be carcinogenic, teratogenic, hemorrhagic, or dermatitic. Several studies have shown natamycin to inhibit the production of mycotoxins and molds that produce them (Delves-Broughton, et al. 2005). For example, Medina et al. (2007) found natamycin to be very effective in controlling the production of ochratoxin A over a range of available water and temperature conditions on grape-based media (Medina, et al. 2007).

Natamycin is one of numerous polyene antifungal agents used in medical applications. It is used topically to treat fungal infections of the eye. Specifically, it acts against fungal keratosis, as well as a broad spectrum of other fungi, yeasts, and some protozoa and algae. It was previously used topically in humans against fungal infections of the skin and mucous membranes applied in the form of a cream, ointment, suspensions or tablets; however, current medical use is confined to topical treatment of fungal infections of the cornea and to prevent such infections in contact lens wearers (WHO 2002).

Natacyn® is the FDA-approved antifungal drug for topical ophthalmic administration with natamycin as the active ingredient. Its label describes the active ingredient as a tetraene polyene antibiotic which has *in vitro* activity against a variety of yeast and filamentous fungi, including *Candida*, *Aspergillus*, *Cephalosporium*, *Fusarium* and *Penicillium*. It describes the mode of action similar to that described by the petitioner for control of fungal diseases in agricultural commodities – through binding of the molecule to the sterol moiety of the fungal cell membrane. The label also states that natamycin is not effective *in vitro* against gram-positive or gram-negative bacteria. Further, systemic absorption is not expected with topical use of the product on the eye and gastrointestinal absorption is very poor (Alcon Laboratories, Inc. 2008). Potential side effects from use of the drug are listed as: allergic reaction, change in vision, chest pain, corneal opacity, dyspnea, eye discomfort, eye edema, eye hyperemia, eye irritation, eye pain, foreign body sensation, paresthesia, and tearing (Alcon Laboratories, Inc. 2008). However, these potential risks are not associated with natamycin in the literature, but may be due to inactive ingredients in Natacyn®. One is a preservative, benzalkonium chloride (BAK), which is a quaternary ammonium that has been shown to have allergenic and toxic effects in various studies (Baudouin, et al. 2010).

The label associated with the petitioned use of natamycin as an agricultural fungicide includes the health warnings: "Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, and chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse." However, similar to the ophthalmic drug label, these risks are not clearly linked to natamycin in the literature and may be due to the presence of other undisclosed ingredients.

Evaluation Question #11: Describe all natural (nonsynthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

Controlling fungal diseases affecting mushrooms is theoretically challenging as both host and pathogen are from the same taxonomic kingdom and potentially susceptible to the same materials. Additionally, the potential for consumers to ingest pesticides on mushrooms and post-harvest handled fruit requires that fungicides must have low toxicity to mammals (Gandy and Spencer 1981). NOP regulatory allowances differ for materials used as fungicides in mushroom production and post-harvest handling so these uses are discussed separately below.

Nonsynthetic alternatives for mushroom production

Nonsynthetic substances may be used for disease control, unless prohibited or limited at §205.602. Natamycin may be considered a nonsynthetic substance, based in the information provided in *Evaluation Question #3*. Additional nonsynthetic controls such as thyme oil have demonstrated the ability to reduce the incidence of *Verticillium fungicola* (causal agent of dry bubble disease) both *in vitro* (Tanović, et al. 2009), and in mushroom houses (Beyer 2015). As an active ingredient, thyme oil is exempt from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and may not need to be registered for legal use (EPA 2017c).

Aerated spent mushroom substrate (SMS) tea inhibited 100 percent of *V. fungicola* mycelial growth, compared with prochloraz, which inhibited 91 percent mycelial growth. Cropping studies of SMS formulated with peat showed 34 to 73 percent disease reduction, while prochloraz reduced disease by 4 to 7 percent (Gea, et al. 2014). Furthermore, no negative effect on mushroom growth occurred through the use

of the SMS tea. Gea speculated that production of strong iron-chelating compounds (siderophores) produced by specific bacteria (pseudomonads) may have been involved in suppression of *V. fungicola*.

Mushroom alcohol (1-octen-3-ol) shows encouraging results in reduction dry bubble disease. It is registered with the EPA for use as an insect attractant, but not currently for enclosed mushroom production. The substance is responsible for the odor of mushrooms and produced by *Agaricus bisporus* (button mushrooms) through the enzymatic cleavage of linoleic acid. Berendsen demonstrated that when concentrated, the volatile compound was able to inhibit spore germination of *V. fungicola*. Application of a 1.25 percent solution of 1-octen-3-ol in small and commercial scale studies was as effective as prochloraz-manganese in reducing dry bubble disease. 1-octen-3-ol affected is not selective though, and mushroom yield was also reduced somewhat (Berendsen 2011).

Synthetic alternatives for mushroom production

Synthetic fungicides allowed for use in organic crop production include materials at §205.601(i): aqueous potassium silicate (derived from naturally occurring sand), fixed coppers, copper sulfate, hydrated lime, hydrogen peroxide, lime sulfur or elemental sulfur, horticultural and narrow range oils, and potassium bicarbonate. Many of these are not well suited for use in enclosed mushroom production, due to toxicity or insufficient selectivity. Cropping studies conducted by Pennsylvania State University found that paraffin oil (which may be allowed under the NOP definition of narrow range oil) was similarly effective as natamycin in controlling *Verticillium fungicola*; they both showed some control over *V. fungicola*, but control was reduced during the second flush of mushroom growth (Beyer 2015).

Nonsynthetic alternatives for post-harvest handling

Nonsynthetic substances may be used on raw agricultural commodities post-harvest, unless prohibited or limited at §205.602. Examples of materials that could theoretically be used to prevent spoilage include: nitrogen gas, nonsynthetic microbial preparations, glucosinolates (from plants in the family Brassicaceae) and vaporized acetic acid. Vaporized acetic acid acts as a disinfectant and is applied directly (Sholberg and Gaunce 1995). When tested on a wide variety of fruits, Sholberg found that low concentrations (≤5.4mg/L) of vaporized acetic acid significantly reduced post-harvest decay caused by *Penicillium expansum* and *Botrytis cinerea,* and the treatment itself did not cause additional fruit damage. No information on commercial products utilizing the technology was found.

Microbial preparations such as Bio-Save® 10LP Biological Fungicide (JET Harvest Solutions; Apopka, FL) based on *Pseudomonas syringae*, act as antagonists to decay causing fungi. Mechanisms of action include competition for nutrients and space, production of anti-fungal metabolites, parasitism, and reducing pathogen enzyme activity (Mari, Bertolini and Pratella 2003). Apples wounded and inoculated with blue mold (*Penicillium expansum*) were left untreated or treated with *Pseudomonas syringae* (Bio-Save 10LP), cyprodinil, thiabendazole, or a combination. At a concentration of 2.8 X 10^8 CFU/ml, the *P. syringae* treatment reduced blue mold 100 percent (Errampalli and Brubacher 2006). Field trials using another *P. syringae* product (Bio-Save 100) showed a significant reduction in disease incidence of wounded apples after two weeks of storage at 13°C as compared with a water control (Chen, et al. 1997).

Coatings such as waxes and shellacs, listed at §205.605(a) and §205.606, respectively, are processing materials that can decrease plant tissue senescence (ripening), and thus help delay the point at which spoilage due to fungi occurs (Lin and Zhao 2007).

At least one organism that produces natamycin, *Streptomyces lydicus* is registered with the EPA as an active ingredient for use in pesticide products and is used in 21 registered products (EPA 2017b). There are 6 products on the OMRI List as of July 2017[12] that declare *S. lydicus* on the label (OMRI 2017b).

[12] Two of these six OMRI Listed products are not EPA Registered because they are not intended for sale in the United States, and therefore are not subject to EPA regulation.

Synthetic alternatives for post-harvest handling

NOP Guidance 5023: Substances Used in Post-Harvest Handling of Organic Products clarifies that synthetic crop input materials listed at §205.601 are not permitted for post-harvest use, unless specifically annotated as such; there are no substances on §205.601 permitted for the petitioned post-harvest uses. Therefore, synthetic alternatives for post-harvest fungicidal applications are limited to those found at §205.605(b). Decay causing fungi are spread to fruit and harvest bins in the field, and subsequently spores are transferred in processing waters (Mari, Bertolini and Pratella 2003). Materials that could be used to prevent or slow decay include acidified sodium chlorite, hydrogen peroxide, ozone, peracetic acid, and chlorine materials, in accordance with any annotations or restrictions. Many products exist that contain these materials which disinfect the surface of produce as well as processing water (OMRI 2017b).

Carbon dioxide and nitrogen can be used in controlled atmosphere storage which slows ripening, delaying fruit softening and subsequent spoilage, and is a commonly used technology (Bapat, et al. 2010) (Thompson 2016).

Evaluation Question #12: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

Mushroom production alternative practices

Pathogenic fungi such as *Trichoderma* and *Verticillium* species can exist in mushroom growth substrates (e.g., compost, casing). *Verticillium fungicola*, the causal agent for dry bubble disease is abundant in materials that are used for casing, and is spread on infected equipment, hands, clothing, water, dust, and by vectors such as mites and insects (Sharma, Kumar and Sharma 2007) (Gea, et al. 2014). Beyer reported that a single infected mushroom could produce 30 million spores in an hour (Beyer n.d.), and spores can survive in moist soil for one year (Sharma, Kumar and Sharma 2007). Vegetative mycelium of *Agaricus bisporus* (button mushroom) is resistant to infection, but sporocarp (mushroom) related tissue is highly susceptible (Berendsen 2011). Sporocarp tissue develops in the mushroom casing, and so hygiene for this part of the growth substrate is especially important. Fully resistant cultivars are not known, though some strains have shown partial resistance (Berendsen 2011). Symptoms include deformed sporocarp tissue, splits in the stem, and necrotic spots or blotches (Beyer n.d.).

Disease prevention strategies largely revolve around hygiene. Farms, equipment, and personnel must be kept clean. Casings can be heat or steam treated, which has been demonstrated to prevent spore germination (Sharma, Kumar and Sharma 2007). The condition of the underlying compost is less critical to disease development, with only very high spore concentrations able to induce disease (Beyer n.d.). Controlling dust and limiting water movement within the house is necessary to prevent moving an infection from one area to another. Water splashed while cleaning floors can cause disease epidemics, so low-pressure, or waterless floor cleaning methods are preferable. Controlling vectors such as flies and mites before they can spread spores is necessary (Gea, et al. 2014). In vitro studies indicate that reduced susceptibility can also be achieved through the use of strains that form fruiting bodies earlier (Berendsen 2011). Infected mushrooms should not be disturbed or removed, but can be covered in salt or alcohol (Beyer n.d.).

Post-harvest disease management

Post-harvest disease management strategies are crop-specific and well described in literature. Generally speaking, hygiene is important to the prevention of disease (Suslow 2000). Diseased or wounded fruit should not be intermingled with fruit in good condition. Fruit should be cooled as quickly as possible. Storage life for fruits (and prevention of decay) varies depending on cultivar, climate, harvest timing, and nutritional conditions. Common fungi that cause decay in post-harvest fruits include *Botrytis cinerea* (gray mold), *Colletotrichum acutatum* (anthracnose), *Mucor piriformis* (mucor rot), *Penicillium spp.* (green mold, blue mold), and many others (Smilanick 2011) (Mari, Bertolini and Pratella 2003) (Almenar, et al. 2007). As fruit ages it undergoes physiological changes during ripening and senescence such as increased respiration rate, ethylene production, conversion of starches into sugars, and softening due to changes in cell walls (Thompson 2016). These processes can increase susceptibility of produce to fungi. After disinfection (if

possible), refrigeration and controlled atmosphere storage can be used to control these physiological processes and prevent or delay the fruit's susceptibility, or slow infections.

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National Organic Standards Board
Handling Subcommittee Proposal
Reclassification of Magnesium Chloride
December 19, 2017

Summary of Proposed Action:
The Handling Subcommittee proposes to change the classification of magnesium chloride from a nonagricultural synthetic substance to a nonagricultural non-synthetic substance and move the substance from §205.605(b) to §205.605(a) of the National List.

Subcommittee Review:
During the 2015 sunset review, magnesium chloride was recommended for continued listing on the National List but issues related to classification were raised. The Handling Subcommittee requested public comment on whether or not this material should be reclassified as non-synthetic since it is simply derived from sea water by brine drying, with no ancillary substances. Public comment at the time supported the reclassification of~~at~~ magnesium chloride ~~should be reclassified~~ as non-synthetic and that it be moved from ~~its listing at~~ §~~-~~205.605(b) to §~~-~~205.605(a). However, information provided in the 2016 TR indicates that magnesium chloride can be produced both synthetically and non-synthetically, and the annotation "derived from seawater" can apply to both.

Magnesium chloride produced by reacting a magnesium compound or mineral with hydrochloric acid is considered synthetic. This is because the substance undergoes a chemical change so that it is chemically or structurally different from how it naturally occurs in the source material. (TR 2016, 352- 354)

Natural sources of magnesium chloride can be extracted by various means which may affect the classification of the final substance as synthetic or non-synthetic. Evaporation and crystallization are physical processes which do not result in chemical change. Magnesium chloride extracted from brine by the two-step process involving calcium hydroxide and carbon dioxide is not chemically or structurally different from how it naturally occurs in the source material. (TR 2016, 352-361)

During the 2017 sunset review of magnesium chloride, information from the 2016 TR was incorporated into the review. A series of questions was posed to the public requesting feedback on the impact of reclassification in regards to feasibility of ~~switching~~moving its listing, sufficiency of supply, and functionality. Most public comment was focused on retaining magnesium chloride on the National List due to its essentiality in tofu production, as well as in infant formula and dietary supplements. Public comment ~~which~~ that addressed the reclassification included: Two certifiers who commented that reclassification would result in a small impact on users; one manufacturer who uses the material was supportive of reclassification with the current annotation; one organization supported reclassification if the material was found to be non-synthetic and suggested an annotation restricting its use to making tofu, and one organization who requested clarification on which forms would become prohibited as a result of reclassification.

Evaluation q~~Q~~uestions #1 and #2 in the 2016 TR go into detail ~~on~~ about where and how magnesium chloride can be produced non-synthetically from a variety of natural commercial sources including seawater, terminal lake brines, subsurface brine deposits, and mined mineral deposits. The Handling Subcommittee compared these processes to the Decision Tree for Classification of Materials as

Synthetic or Nonsynthetic (NOP 5033-1) and determined that magnesium chloride produced via these sources ~~them to be non-synthetic as they do~~ does not go through any chemical changes, and therefore is non-synthetic.

The Handling Subcommittee proposes that magnesium chloride remain on the National List. However, the ~~Handling~~ Subcommittee is bringing forward this proposal to change the listing from §205.605(b) to §205.605(a) due to the determination that magnesium chloride is available in a non-synthetic form. Additionally, the Handling Subcommittee proposes the annotation "derived from seawater" is removed since there are multiple sources from which non-synthetic magnesium chloride can be derived.

Vote in Subcommittee:
Motion to remove the annotation that reads "derived from seawater", and to reclassify magnesium chloride as non-synthetic and move it's listing from §205.605(b) to §205.605(a) ~~and change its listing and annotation to "Magnesium Chloride" from §205.605(b) to §205.605(a)~~

Motion by: Lisa de Lima
Seconded by: Steve Ela
Yes: 4 _No: 0 _Abstain: 0 _Absent: 3 _Recuse: 0

2018 NOSB SUBCOMMITTEE ASSIGNMENTS & CALL SCHEDULE

Phone number: (b) (6) Passcode: (b) (6)

ADMIN TEAM Mon prior to ES call, 2 - 3 ET/11 - 12 PT
Tom Chapman, NOSB Chair
Harriet Behar, NOSB Vice Chair
Scott Rice, Secretary
NOP staff: Michelle Arsenault

EXECUTIVE SUBCTTE 2nd Fri, 1 - 2:30 ET/10 - 11:30 PT
NOSB Officers
NOSB Subcommittee Chairs
NOP staff: Jenny Tucker, Paul Lewis, Devon Pattillo, Michelle Arsenault

CACS 2nd Tue, 3 - 4 ET/12 - 1 PT
Scott Rice, Chair
Emily Oakley, Vice Chair
Harriet Behar
Tom Chapman
Lisa de Lima
A-dae Romero-Briones
Ashley Swaffar
NOP staff: Devon Pattillo

CROPS 1st and 3rd Tue, 2 - 3 ET/11 - 12 PT
Steve Ela, Chair
Emily Oakley, Vice Chair
Sue Baird
Harriet Behar
Asa Bradman
Jesse Buie
Joelle Mosso
Dave Mortensen
Francis Thicke (outgoing)
NOP staff: Devon Pattillo

HANDLING 1st & 3rd Tue, 1 - 2 ET/10 - 11 PT
Lisa de Lima, Chair
Scott Rice, Vice Chair
Joelle Mosso
Asa Bradman
Tom Chapman
Steve Ela
A-dae Romero-Briones
NOP staff: Devon Pattillo

LIVESTOCK/AQUA 1st & 3rd Tue, 3 - 4 ET/12 - 1 PT
Ashley Swaffar, Chair
Sue Baird, Vice Chair
Harriet Behar
Jesse Buie
A-dae Romero-Briones
Dan Seitz
Francis Thicke (outgoing)
NOP staff: Devon Pattillo

MATERIALS/GMO ad hoc 2nd Tue, 2 - 3 ET/11 - 12 PT
Harriet Behar, Chair
Dan Seitz, Vice Chair (Livestock Rep)
Tom Chapman
Lisa de Lima (Handling Rep)
Emily Oakley (Crops Rep)
Dave Mortensen
NOP staff: Lisa Brines

POLICY DEV 2nd Tue, 1 - 2 ET/10 - 11 PT
Dan Seitz, Chair
Lisa de Lima, Vice Chair
Jesse Buie
Tom Chapman
Harriet Behar
NOP staff: Devon Pattillo

INERTS WORKING GROUP
TBD
NOP staff Lisa Brines

1st & 3rd Tue
1:00 ET/12 CT/11 MT/10 PT: Handling
2:00 ET/1 CT/12 MT/11 PT: Crops
3:00 ET/2 CT/1 MT/12 PT: Livestock/Aqua

2nd Tue
1:00 ET/12 CT/11 MT/10 PT: PDS
2:00 ET/1 CT/12 MT/11 PT: MS/GMO ad hoc
3:00 ET/2 CT/1 MT/12 PT: CACS

Mon prior to ES call
2:00 ET/1 CT/12 MT/11 PT: Admin Team

2nd Fri
1:00 ET/12 CT/11 MT/10 PT: Executive Committee

Sodium Citrate

Crops

Identification of Petitioned Substance

Chemical Names:

Monosodium citrate, disodium citrate, trisodium citrate, sodium citrate

Other Name:

Sodium dihydrogen citrate, disodium hydrogen citrate, Trisodium 2-hydroxypropane-1,2,3-tricarboxylate

Trade Names:

Citrosodina, Natrocitral, Citnatin, Orange Eno

CAS Numbers:

18996-35-5;
144-33-2;
68-04-2;
6132-04-3; 6858-44-2

Other Codes:

Pubchem ID: 6224; InChI Key: HRXKRNGNAMMEHJ-UHFFFAOYSA-K
InChI: InChI=1S/C6H8O7.3Na/c7-3(8)1-6(13,5(11)12)2-4(9)10;;;/h13H,1-2H2,(H,7,8)(H,9,10)(H,11,12);;;/q;3*+1/p-3
Canonical SMILES: C(C(=O)[O-])C(CC(=O)[O-])(C(=O)[O-])O.[Na+].[Na+].[Na+]
EC Number: 200-675-3, 218-618-2
FEMA Number: 3026
ICSC Number: 1218
RTECS Number: GE8300000
UNII: RS7A450LGA

Summary of Petitioned Use

Sodium citrate is used as an anticoagulant in the collection of slaughterhouse blood. Slaughterhouse blood is used to make the soil amendment, blood meal. Slaughterhouse blood can be processed in different ways to make blood meal. The petition requests the addition of sodium citrate to the National List (§ 205.601), allowed for use in crop production to prevent animal blood coagulation after collection and during processing of blood for production of blood meal.

Characterization of Petitioned Substance

Composition of the Substance:

Sodium citrate is a soluble white powder. It has many uses. One of which is as an anticoagulant in the collection and processing of animal blood. Sodium citrate treated blood may be used for production of the soil amendment, blood meal. Animal blood meal is allowed in organic crop production as a soil amendment.

Source or Origin of the Substance:

Sodium citrate is a salt derivative of citric acid. Citric acid is naturally occurring. Sodium citrate is chemically produced by the same process as citric acid (NOP, 2015). Commercially, citric acid is produced microbiologically mostly from the sugar refinery byproduct, molasses. The mycelial fungus *Aspergillus niger* or *Candida* spp. yeasts are frequently used for these fermentation processes. Citric acid from fermentation is neutralized with sodium hydroxide and crystalized in the production of sodium citrate. Sodium citrate can be produced microbiologically, directly from cultures of the yeast *Yarrowia lipolytica*, since this organism can tolerate a higher pH (Kamzolova et al., 2015).

Sodium citrate is routinely added to blood as it is removed from animal carcasses during processing. The addition of sodium citrate keeps blood flowing and minimizes extensive cleaning of clotted blood from extraction and collection equipment. Anticoagulants have been considered incidental to blood meal production and part of the standard identity for blood, since a substantial portion of added sodium citrate is removed during manufacturing. Furthermore, it may not be reliably possible for manufacturers to

determine if anticoagulants have been added to blood for blood meal production (Bungum, 2017). Animals can be bled, and their blood collected without the addition of sodium citrate. This practice is not common for large animal processing plants (Food Safety Authority of Ireland, 2013; NCPS Board of Consultants and Engineers, 2016).

Properties of the Substance:

Sodium citrate, the sodium salt derivative of citric acid, is a crystalline white powder with a melting point of >300°C. Its molecular formulae are: anhydrous: $C_6H_5O_7Na_3$; hydrated: $C_6H_5O_7Na_3 \cdot nH_2O$ (n = 2 or 5) or $C_6H_5Na_3O_7$ or $C_6H_5O_7$. 3Na. It has a molecular weight of 258.08 grams/mole. A two-dimensional structure of sodium citrate is provided in Figure 1. Previous technical reviews for citric acid and sodium citrate are available on the NOP website (NOP, 2015).

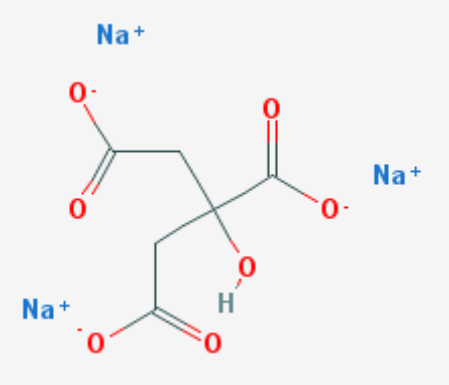

Figure 1 2D Sodium Citrate Structure

(PubChem, 2017)

Specific Uses of the Substance:

Sodium citrate is routinely used as an anticoagulant for blood collection during slaughtering and processing of ~~conventionally farmed~~ livestock~~for blood in the~~. It may be applied to the sticking knife, to improve blood flow during bleeding or added to collection or storage tanks to improve stability. Blood products are separated, cooked and dried into powder at the meat processing plant or further processing plants. Storage and transfer of blood requires refrigeration. (b) (5) [redacted] hese differ in clotting or no clotting, drying steps and the separation of red blood cells. Some examples are batch dried, ring dried and spray dried rendering. Batch dry rendering is simple cooking of whole blood with indirect high-pressure steam to remove moisture. Ring dried rendering requires coagulation and separation of the coagulated blood from fluids. The coagulum is separately dried. In spray drying, which requires the use of sodium citrate, flowing blood treated with anticoagulant is sprayed into a warm chamber where it instantly becomes a fine powder. Drying method affects the characteristics and quality of the final product. With meat inspection, blood meal can also be used for conventional human and animal nutrition. In addition to simply drying clotted whole blood, blood may be fractionated during processing to separate red blood cells from plasma or remove specific higher valued products before dried meal is produced.

Approved Legal Uses of the Substance:

Sodium citrate has been verified to be of low concern based on experimental and modeled data for use as a chelating agent (anticoagulant), a preservative, an antioxidant, a processing aid and an additive (EPA Safer chemical ingredients list). Sodium citrate is included in the FDA list of substances generally regarded as safe. It is the sodium salt of citric acid prepared by fermentation and neutralization of citric acid with sodium hydroxide or sodium carbonate. The product occurs as colorless crystals or a white crystalline powder. It may be prepared in an anhydrous state or may contain two moles of water per mole of sodium citrate (21 CFR 184.1751). Sodium citrate is listed in the National List as an allowed synthetic for use in organic handling (§205.605b). The sodium salts of citric acid – monosodium citrate, disodium citrate and tri

sodium citrate – are collectively listed as "sodium citrate." These substances are used similarly as pH control/buffering agents and stabilizers in food products. The original technical review found sodium citrate to be consistent with the OFPA 2119(m) criteria (NOSB, 2010). Sodium citrate is not allowed for use in organic crop production.

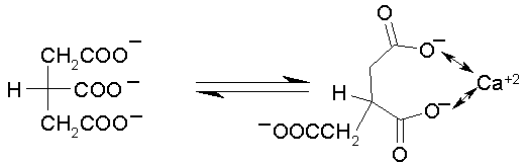

Figure 2 Chelation of Ca^{++} by Sodium Citrate

Action of the Substance:

Blood is an important meat animal processing byproduct. Blood meal, a non-synthetic product of animal byproduct processing, is allowed for use as a soil amendment in organic crop production (205.203(c)). Approximately 4-5% of live animal weight is collectable blood which contains approximately 10% of animal protein. When fresh blood is extracted from an animal, fibrinogen in the blood is converted to fibrin. The presence of fibrin catalyzes the formation of a fibrous network that enmeshes blood cells and other blood components into a clot. Clotting can be inhibited by vigorous agitation, chilling or by the addition of anticoagulants. Sodium citrate is an anticoagulant commonly used for collecting blood in slaughterhouses (Fernando, 1992). Ionic calcium is essential for the conversion of fibrinogen to fibrin. Sodium citrate acts to chelate or remove available calcium required for the fibrinogen to fibrin conversion preventing blood coagulation (clotting). In chelation, calcium binds to the dentate carboxyl moieties of citrate (Fig. 2).

Blood can become recalcified through cell breakdown and bacterial degradation. When calcium is available for fibrinogen to fibrin conversion, clotting resumes. After bleeding warm blood is only stable for approximately eight hours. Without refrigeration, fresh whole blood must be processed and dried shortly after bleeding. Even with the addition of sodium citrate, animal byproduct producers reduce whole blood degradation, bacterial contamination and further clotting by chilling stored blood with stirring prior to inspection and further downstream processing. This is important, if blood must be transported to another facility. Chilled whole blood held at 2-3°C is stable for approximately 120 hours which facilitates off site processing (Labudde Group, 2017; Sjoberg, 2017).

Combinations of the Substance:

Sodium citrate is added directly to blood as it is collected during meat animal processing. It may be dissolved in water and added as a solution to speed its action. Other substances are not generally used in combination for byproduct meat animal blood processing.

Status

Historic Use:

Sodium citrate was first used as an experimental anticoagulant in blood transfusion for dogs in the 1890s (Mollison, 2000; Hedley-Whyte and Miamed, 2010). By 1915, the minimum amount of sodium citrate necessary for anticoagulation of blood without side effects had been determined for human use (Lewisohn, 1915). By 1918, the military development of an acceptable procedure for human blood transfusion and blood storage became a necessity. Sodium citrate at 0.2% was not only safe for humans use, but could be used for routine transfusion practice and storage of whole blood for up to two weeks (Arthus, 1905; Lewisohn, 1918). Sodium citrate has been used as an anticoagulant for the collection of slaughterhouse blood since the late 1800s (Wismer-Pedersen, 1988).

Organic Foods Production Act, USDA Final Rule:

Sodium citrate is listed on 205.605(b), synthetics allowed for processed products labeled as organic.

International

Canada - Canadian General Standards Board Permitted Substances List. Sodium citrate is listed in CAN/CGSB-32.311-2015 — Organic production systems - Permitted substances lists sodium citrate as a food additive, as a food grade cleaner, disinfectant and sanitizer (without removal), and as a cleaner, disinfectant and sanitizer (removal is mandatory).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) -

According to Codex Alimentarius GL 32-1999, sodium citrate is not permitted for use in organic production of food of plant origin, but is permitted for use in organic production in processed food of animal origin as follows: butter milk (plain) (stabilizer only); dairy-based drinks, flavored and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks); fermented milks (plain), heat-treated after fermentation (stabilizer only); renneted milk (stabilizer only); condensed milk and analogues (plain) (stabilizer only); cream (plain) and the like (stabilizer only); milk powder and cream powder (plain) (stabilizer only); unripened cheese (stabilizer only); processed cheese (emulsifier only); dried whey and whey products, excluding whey cheeses; processed comminuted meat, poultry, and game products, restricted to sausages; to be used in pasteurization of egg whites only in the following: egg products.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

Commission Regulation (EC) No 889/2008 lays down rules for the use of sodium citrate. It is permitted in the production of processed organic food for preparation of foodstuffs of animal origin, but not permitted in foodstuffs of plant origin.

Japan Agricultural Standard (JAS) for Organic Production—

The Japanese Agricultural Standard for Organic Processed Foods allows the use of sodium citrate limited to dairy products or albumen and sausage as low temperature pasteurization. The Japanese Agricultural Standard for organic livestock does not allow the use of sodium citrate. The Japanese Agricultural Standard for organic plants does not allow the use of sodium citrate. The Japanese Agricultural Standard for organic feeds does not allow the use of sodium citrate.

International Federation of Organic Agriculture Movements (IFOAM) –

The IFOAM norms allow the use of sodium citrates for production of processed foods as an additive and as a processing aid.

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

Evaluation Question #1: Indicate which category in OFPA that the substance falls under: (A) Does the substance contain an active ingredient in any of the following categories: copper and sulfur compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers? (B) Is the substance a synthetic inert ingredient that is not classified by the EPA as inerts of toxicological concern (i.e., EPA List 4 inerts) (7 U.S.C. § 6517(c)(1)(B)(ii))? Is the synthetic substance an inert ingredient which is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part 180?

As an anticoagulant used in processing blood for blood meal, sodium citrate may be considered a production aid (7 USC 6517(c)(1)(B)(i)). Sodium citrate is the sodium salt of citric acid prepared from citric acid by neutralizing citric acid with sodium hydroxide or sodium carbonate followed by a crystallization step. Commonly available forms are anhydrous or dehydrate.

Evaluation Question #2: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Sodium citrate is produced by addition of sodium carbonate monohydrate to a hot aqueous solution of citric acid. The resulting solution is then evaporated until crystallization has taken place. Another synthetic method used for producing sodium citrate is decomposing calcium citrate with an alkali metal salt (sodium). Citric acid production is described in a 2015 NOP technical report. Some microorganisms can produce sodium citrate directly during fermentation. Sodium citrate is directly recovered from citric acid fermentation broth by removing impurities at pH 9-13 and concentrating the resulting fluid at pH 10-13. The organisms for this type of fermentation are yeasts, such as *Candida, Bretanomyces, Debaryomyces, Hanseula, Koeckera, Torulopsis, Pichia, Triospora, Saccharomyces* and bacteria such as *Corynebacterium* and *Arthrobacter* (Tsuda et al., 1975). In another process, *Yarrowia lipolytica* ferments glycerol-containing biodiesel waste and produces sodium citrate, which is filtered from the culture after pH adjustment to 7-8 with NaOH (Kamzolova et al., 2015).

Evaluation Question #3: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).

Sodium citrate is synthetic. It is currently classified as synthetic in 205.605(b). The use of sodium citrate as an anticoagulant depends on the application and process approach. When a farm animal is slaughtered blood is released in an amount equivalent to 6-7% of the lean meat of the carcass based on total protein. Many cultures consider meat animal blood a food (Wismer-Pedersen, 1988). In addition to uses in food, animal blood has many uses in feed, laboratory, medical, industrial and fertilizer applications (Ockerman and Hansen, 2000).

Blood is composed of two primary fractions separable by centrifugation: the plasma and the red blood cells. Red blood cells contain the protein hemoglobin (Fernando, 1992). A relatively small quantity of white blood cells and platelets are also present. Plasma contains the proteins albumin, globulin and fibrinogen. Fibrinogen is involved in clotting. Greater than 80% of raw blood is water (Fernando, 1992).

The efficiency of blood collection depends on the animal, the length of time permitted for bleeding and the method for collection (Fernando, 1992). Blood from slaughterhouse animals is usually collected in one of two ways depending upon the application. It can be collected hygienically for use in foods and products, such as hemoglobin and plasma proteins. A closed draining system can be used where blood from the slaughterhouse animal is not exposed to air and is drained directly from the body of the animal; for example, using a hollow knife connected to vacuum piping (Fig 3). Blood for food or therapeutic applications must come with a guarantee that it is sourced from veterinary-approved disease-free animals and is free from contamination. In alive and healthy animals, blood is "sterile", in the sense that it can be consumed. However, collecting blood hygienically requires additional equipment, adds cost and slows down any slaughtering line speed (Bah et al., 2013). Transport of harvested blood to a processing facility may also require the use of a refrigerated tanker truck (Fernando, 1992). Another method for collecting animal blood is open draining into buckets, trays or onto the floor. This method is particularly susceptible to contamination and not likely to be suitable for food or therapeutic applications. Rather blood collected this way is used industrially or for fertilizer production. In any case it is prudent to consider collecting blood as a byproduct rather than discarding it. Blood has a high chemical oxygen demand (COD) (500,000 milligrams O_2/liter). As a result, disposal of large quantities of slaughterhouse blood can cause environmental problems (Kostic et al., 2013).

After bleeding clotting takes place in three to ten minutes depending on the environmental temperature. Clotting is caused by the conversion of soluble fibrinogen in the blood to insoluble fibrin by the enzyme thrombin. Clotting does not occur in circulating blood because there are natural anticoagulants present in intact blood vessels. Clotting may or may not be desirable for processing depending on the use of collected blood (Fig 4). Some of the commercial processes used for ~~the~~ production of blood meal, which is used as a soil amendment in organic crop production require blood to clot ~~in order~~ to separate the solids from water. However, blood is a complex product and some value-~~-~~added production streams may require the use anticoagulants to permit collection and separation of erythrocytes and protein products in addition to the production of blood meal. Clotting can be efficiently inhibited with the addition of 0.2 % sodium citrate during blood collection (Lewisohn, 1915). ~~However, blood is a complex product and some value added production streams may require the use anticoagulants to permit collection and separation of erythrocytes and protein products in addition to the production of blood meal. Clotting can be efficiently inhibited with the addition of 0.2 % sodium citrate during blood collection (Lewisohn, 1915).~~ Regulations for the use of

sodium citrate in the food and pharmaceutical industry vary from country to country (Ockerman and Hansen, 2000). Sodium citrate removes ionic calcium from solution. Ionic calcium is necessary for clotting to occur (Kingston et al., 2001).

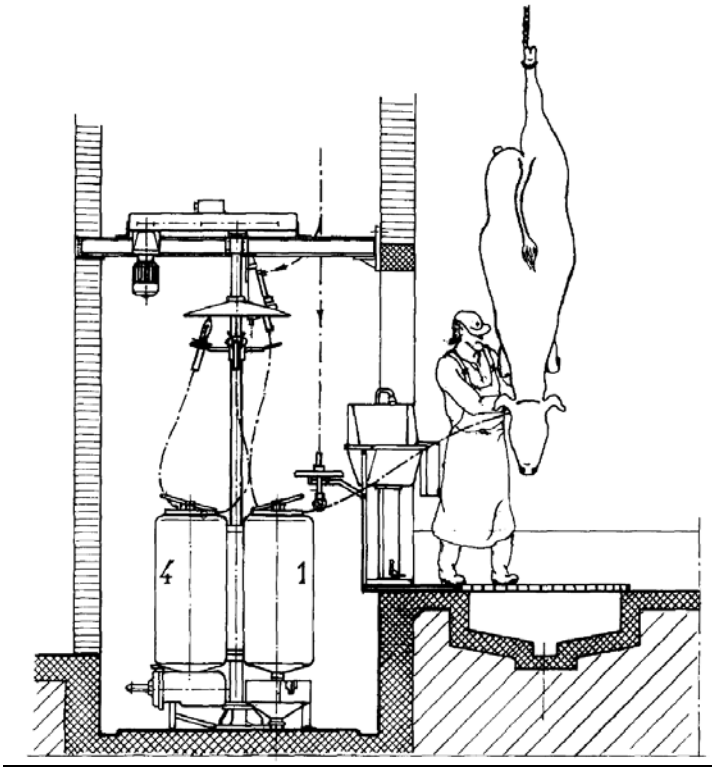

Fig. 3 Example of equipment to hygienically collect blood in an abattoir (*from* Wismer-Pedersen, 1988).

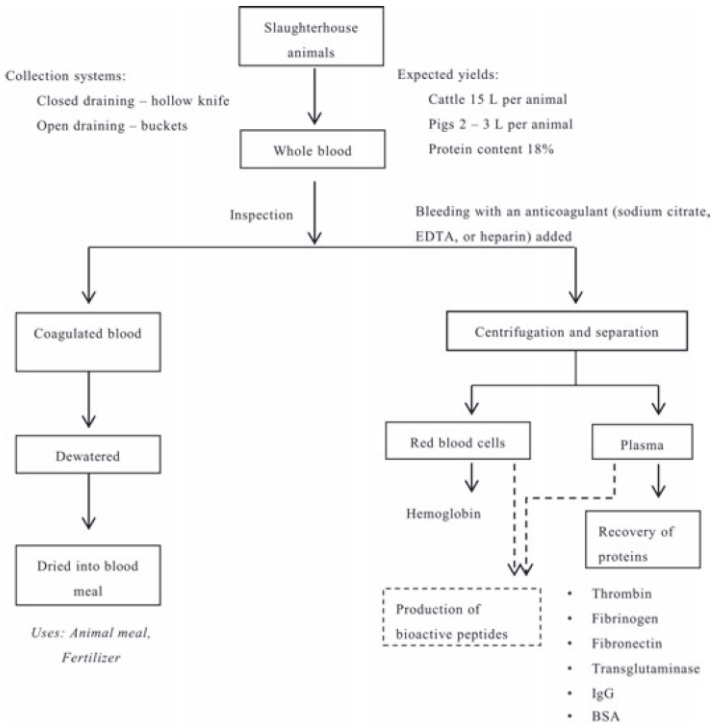

Fig. 4 Treatment of slaughterhouse blood for specific uses (*from* Fernando, 1992)

Sodium citrate is an allowed synthetic substance for use as an ingredient in organic processing (205.605(b)). Sodium citrate is not on the National List for use in organic crop production.

<u>Evaluation Question #4:</u> Describe the persistence or concentration of the petitioned substance and/or its by-products in the environment (7 U.S.C. § 6518 (m) (2)).

Sodium citrate is the sodium salt of citric acid. It is highly mobile in the environment and partitions to the aquatic compartment. Sodium citrate is rapidly degraded microbiologically in sewage works, in surface waters and in soil. Generally, citric acid and its salts have not been judged by the EPA or Organization for Economic Cooperation to be substances that present a hazard to the environment (EPA, 1992; OECD, 2001).

<u>Evaluation Question #5:</u> Describe the toxicity and mode of action of the substance and of its breakdown products and any contaminants. Describe the persistence and areas of concentration in the environment of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)).

Sodium citrate is of low acute toxicity to freshwater fish, daphnia, algae and marine species. Similarly, sodium citrate has no obvious toxic potential against protozoans and many species or strains of bacteria including activated sludge micro-organisms (EPA, 1992; OECD, 2001).

<u>Evaluation Question #6:</u> Describe any environmental contamination that could result from toxicity due to the petitioned substance's manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)).

Sodium citrate is produced biologically by the same submerged fermentation process with starch/sucrose-based media as citric acid, but is neutralized in the presence of appropriate alkaline solutions (e.g., sodium hydroxide or sodium carbonate) and crystallized. Several agricultural waste residues and by-products are used as production substrates for sodium citrate production including molasses, fruit pomace waste, wheat bran, coffee husk, and cassava bagasse. Most of the substrates would otherwise be composted, but represent a value-added component in sodium citrate production (Dhillon et al., 2011). Fermentation waste can be composted. However, the production of 1 ton of citric acid produces 40 tons of acidic wastewater with a high chemical oxygen demand. Production wastewater can be treated by biohydrogen production, electrochemical oxidation, membrane filtration and anaerobic and aerobic bacterial digestion. Studies are underway to repurpose this wastewater stream for methane production (Zhang et al., 2014).

Evaluation Question #7: Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling. Describe any environmental or human health effects from these chemical interactions (7 U.S.C. § 6518 (m) (1)).

Sodium citrate is very soluble in water and microbiologically degradable. As an anticoagulant for slaughterhouse blood, sodium citrate is used at a concentration of 0.2-0.4% and may become a component of the meat processing effluent. As a low concentration component (≤0.08%) of blood meal used as a soil amendment it is expected for sodium citrate to become a metabolite of soil bacteria.

Evaluation Question #8: Describe any effects of the petitioned substance on biological or chemical interactions in the agro-ecosystem, including physiological effects on soil organisms (including the salt index and solubility of the soil), crops, and livestock (7 U.S.C. § 6518 (m) (5)).

Sodium nitrate is used at a concentration of 0.2-0.4% in whole fresh blood. Blood is mostly composed of water (≥80%). Thus, dried blood meal is expected to contain no more than ~0.1% sodium citrate. Potential organic fertilizer nitrogen sources vary in nitrogen cost and nitrogen mineralization rate. Blood meal has a nitrogen content of about 12% and 75% of organic carbon and nitrogen is mineralized after 8 weeks at 25°C. The rest can be found in humus components (Ciavatta et al., 1997). Blood meal is comparable to liquid fertilizers, e.g. liquid fish (Gaskell and Smith, 2007). It can be prepared by spray drying hemolyzed red blood cells from sodium citrate treated slaughterhouse blood and is a good soil amendment for the prevention of iron chlorosis in plants (Gruppo Farpro, 2017; Kalbasi and Shariatmadari, 1993). Mossbauer and electron paramagnetic spectra revealed that iron from the blood meal amendment is associated with the porphyrin heme group of hemoglobin. There is an advantage to application of iron in blood meal since it is bound to an organic moiety easing plant uptake of iron. However, when high $CaCO_3$ is present in the soil, the iron bound porphyrin is likely to aggregate and cause the iron to be retained in the soil. Sodium citrate does not appear to negatively affect soil fertility (Yunta et al., 2013). As a fertilizer, blood meal produced using sodium citrate treated blood, provides sources of nitrogen, phosphorus, and calcium; improves soil structure; promotes beneficial soil microorganisms; encourages earthworms; increases plant growth and yield; provides a balanced supply of nitrogen, phosphorus, and potassium, and organic matter including amino acids, albumin, globulin, cholesterol, and calcium; increases the growth promoters tricontanol and gibberellic acid; reduces waterlogging plant stress and reduces plant stress recovery time (Quilty and Cattle, 2011). Application of blood meal as soil amendment causes soil electrical conductivity, organic matter and pH to increase (Citak and Sonmez, 2011).

Evaluation Question #9: Discuss and summarize findings on whether the use of the petitioned substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

Sodium citrate is the sodium salt of citric acid. Citric acid has been produced for many years in high volumes and added to processed food and beverages, used in pharmaceutical preparations and in household cleaners as well as in special technical applications (OECD, 2000). Citric acid is a well-known component of carbohydrate metabolism in living organisms, and is found naturally in soil and water. It degrades readily when in contact with a variety of microorganisms that are found in soil, natural waters and sewage treatment systems (EPA, 1992). Citric acid is of low acute toxicity to freshwater fish, daphnia and algae and a few marine species, e.g. crabs, green algae, diatoms. Similarly, citric acid has no obvious toxic potential against protozoans and many species or strains of bacteria including activated sludge micro-organisms. Monitoring data has shown that while raw sewage contains up to 10 milligrams citrate/liter, background concentrations in river water range between < 0.04 and maximally 0.2 mg/l, and between 0.025 and 0.145 mg/l in Atlantic coast surface seawater. However, these water concentrations for citrate do not only arise from manmade citric acid. Citric acid is extremely widespread in plant and animal tissues and fluids and every single eukaryotic organism produces citric acid and excretes part of it to the environment. Based on a large volume of available data collected by the Organization for Economic Development citric acid was not judged to be a substance that presents a hazard to the environment (OECD, 2000).

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

Industrial releases of citric acid can occur from the production site and its use in industrial processes. Consumers are directly exposed to citric acid or its salts in diluted concentrations in many products from soft drinks and processed food to common household cleaners, detergents and washing powders. There is no acceptable daily intake level. Occupational exposure may occur during manufacturing and processing of sodium citrate. There is no recommended occupational exposure level. Citric acid has a low acute toxicity by oral application in both rat (LD50 = 3,000– 12,000 mg/kg, 3 different values) and mouse (LD50 = 5,400 mg/kg). General effects consisted of physiological disturbances (acidosis and calcium deficiency), while "high" doses caused nervous system effects as well as severe damage to the stomach mucosa. By subcutaneous application, LD50 values of 5,500 mg/kg in rats and 2,700 mg/kg in mice have been reported. Injection of citric acid by various routes in rats, mice and rabbits (no doses stated) caused nervous system, lung, spleen and liver effects that were in part attributed to acidosis and calcium deficiency. Ingestion of a single dose of 25 g of citric acid by a woman (corresponding to approx. 417 mg/kg) caused vomiting and near dying in one reported case. Volunteers given oral doses of potassium or magnesium citrate corresponding to approx. 4.7 g of citric acid did not suffer any overt gastrointestinal effects. Injection of large volumes of citrated blood during transfusion may lead to hypocalcaemia and changes in blood composition with concomitant nausea, muscle weakness, breathing difficulties and even cardiac arrest. Sodium citrate is a strong irritant to the eyes and a moderate skin irritant (OECD, 2000).

Evaluation Question #11: Describe all natural (non-synthetic) substances or products which may be used in place of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

There are not many non-synthetic substances or products that may be used as anticoagulants for slaughterhouse blood processing. Such substances would need to prevent the proenzyme, thrombinogen from converting to thrombin, prevent the proenzyme fibrinogen from converting to fibrin and/or prevent the web-like matrix formation of fibrin in the blood, e.g. chelating calcium ions. Naturally, the glycoprotein heparin serves as an anticoagulant in blood vessels and in the intestines. Because heparin is chemically extracted from animal byproducts and crystallized as a salt, it is not considered non-synthetic. Heparin is prohibited for use in livestock care (205.105(a)). Although, phosphates are considered non-synthetic, they are not included in section 205.601 of the National List and not allowed for use in organic crop production. However, a mixture of phosphates containing 22% Na_2HPO_4, 22%$Na_4P_2O_7$, 16% $Na_2H_2P_2O_7$ and 40% NaCl at a rate of 10 grams/liter is an effective anticoagulant. Sodium oxalate may also be used as an anticoagulant, but it is considered poisonous and may not be appropriate for application to soil as a soil amendment (Ockerman and Hansen, 2000).

Plant, bacterial and fungal proteolytic enzymes such as papain, bromelin, trypsin, fibrinolysin, bacterial protease N, bacterial protease P, bacterial protease S and others have been used in place of anticoagulants industrially to extract proteins from blood. These enzymes act proteolytically on fibrin to prevent clotting and support a process to provide good quality protein (Quaglia and Massacci, 1982).

Evaluation Question #12: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

In practice, blood flows from an animal after it is stuck with a knife (Fig 3). The blood can be collected in troughs or tanks beneath the animal. If a hollow knife is used with an anticoagulant injected at knifepoint whole blood can be pumped aseptically to tanks for further processing. Further processing can include conventional use in foods and feed if the animal carcass from which it came is approved by a meat inspector. An anticoagulant can also be added to the open troughs or tanks to facilitate additional separations, e.g. whole blood may be separated into red blood cells and plasma and the fractions are dried or processed separately. Separated red blood cells can be dried or spray dried for use in blood meal for fertilizer.

Without added anticoagulant, clotted blood is collected and processed by separating clotted blood from the water component, drying and grinding. (Stevenson and Lloyd, 1979). Blood that is collected in this way can be directly batch dried. In this drying process, water may be added to the blood as it is charged into a batch cooker that simply dries the blood to 2-10% moisture. In batch coagulation followed by batch drying raw blood is first coagulated with steam. The coagulum is then separated by draining off liquid before it is moved to a drier for drying. Continuous coagulation before drying is the most commonly used process. In each of these processes, an anticoagulant is optional (Fernando, 1992). Rapid chilling of blood to 1-2° C (34-

36°F) will prevent coagulation without an anticoagulant, but blood will coagulate when the temperature increases. Agitation and refrigeration are routinely used where blood must be stored or transported prior to processing to prevent microbial growth. ~~For processing blood to blood meal, this approach would requires continuous refrigerationchilling and stirring.~~ Vigorous stirring of blood ~~will~~ causes fibrin to adhere to the stirring rod and prevent coagulation, however this process damages red blood cells (Ockerman and Hansen, 2000). This process called defibrination removes the potential of blood to clot. Defibrinated blood is available commercially.

Blood is an edible byproduct of meat processing. Edible blood is regulated in the same way as other meat products and must be inspected prior to consumption by the supervising agency. Edible by-products are perishable and must be chilled quickly after slaughter and processed or moved into retail trade (Ricke et al., 2012). O~~At least o~~ne certified organic ~~certified organic~~ slaughterhouse in the US provides blood for human consumption (Kaufman, 2015; Organic Integrity Database (Operation Profile (7360000108) updated on 12/14/2017)). Sodium citrate ~~is normally not~~may be added to fresh whole blood collected for human consumption~~. However,~~ ~~an anticoagulant (e.g. sodium citrate) may still be used in blood collection for D~~~~large scale production of d~~ried blood as a food grade ingredient may contain less than 0.1% of sodium citrate by weight. Producers must usually follow hazard analysis critical control point (HAACP) principles, clean equipment after each use and document the origin of each batch of blood. Regardless of w~~Without~~hether or not an anticoagulant is used, storage of fresh blood is maintained with stirring and chilling in closed containers (Food Safety Authority of Ireland, 2013). Chilling in this case in this case also inhibits the growth of bacterial contaminants.

Labels for blood meal advertised for use as fertilizer do not normally indicate the animal origin of the product, the condition of the animals, whether an anticoagulant (e.g. sodium citrate) was used or the process that was used for production. Thus, unless specifically stated on the label, it may not be possible to determine if sodium citrate was used as an anticoagulant during the collection of blood to be used for blood meal. There are no organic production operations listed in the organic integrity database for 2017 that are certified to provide organically produced blood for food or fertilizer.

Slaughterhouse blood processing end products' technical and sanitary requirements determine their costs and production efficiencies. Lots that are rejected for a higher priced product may be acceptable for another less expensive product. Specifically, reliable sourcing of blood meal prepared from slaughterhouse blood that was not treated with sodium citrate may require traceabilty and segregation of the non-treated material after it was withdrawn from animals independently of how the blood meal was prepared. Such information could be provided on the product label or obtained from a process verification audit.

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NOSB Materials Report: Petition & Technical Report Status

Updated: 1/5/2018

Spring 2018 proposals due 2/21/2018

Aquaculture

Overdue items in red

Changes since last report in yellow

Petitioned Inerts - on hold

NL Section	Substance	Type	Technical Report	Next Step	Due Date	NOSB Meeting	Notes
Crops	Natamycin (PDF)	Petition to classify as nonsynthetic	New report in clearance for posting	Subcommittee proposal		TBD	Petition sent to CS on 9/9/2016. TR requested on 11/17/16. TR sent to CS on 11/13/2017; TR approved on 12/5/2017
Crops	Calcium acetate (PDF)	Add to 205.601	TBD	Petition sufficiency review, including TR request, if applicable	1/17/18	TBD	Sent to CS on 11/20/17
Crops	Sodium Citrate	Petition, Add to 205.601		Revised TR under review	2/18/18	TBD	Petition sent to CS on 7/28/16; Full TR requested 10/04/16; TR sent to CS on 8/7/2017; TR determined insufficient on 9/9/17; add'l Q sent to contractor on 12/12/2017; revised TR sent to CS on 12/20/2017
Crops	Sulfur	Petition, Add to 205.601, molluscicide	Livestock report available	Subcommittee proposal	2/21/18	Spring 2018	Petition sent to CS on 6/08/2017; Petition determined sufficient 9/19/17; no TR requested
Crops	Allyl Isothiocyanate (AITC)	Crops, Add to 205.601	Ltd TR Request	TR in development - expected Feb/Mar 2018		TBD	Sent to CS on 7/6/2016; Ltd TR request 10/04/16; TR assigned 11/18/16

NOSB Materials Report: Petition & Technical Report Status

Updated: 1/5/2018
Spring 2018 proposals due 2/21/2018

Aquaculture
Overdue items in red
Changes since last report in yellow
Petitioned Inerts - on hold

NL Section	Substance	Type	Technical Report	Next Step	Due Date	NOSB Meeting	Notes
Crops	Polyoxin D Zinc Salt (PDF)	Add to 205.601	2012 (PDF)	TR sufficiency review	2/20/17	Spring 2018	Sent to CS on 6/16/2016; Ltd TR request 10/04/16; TR assigned 11/18/16; 2nd addendum sent to CS on 10/27/2017; TR sent to CS on 12/19/2017
Crops	Ammonium Citrate (PDF)	Add to 205.601	TBD	Petition sufficiency review, including TR request, if applicable	12/26/17	TBD	TR request in development
Crops	Ammonium Glycinate (PDF)	Add to 205.601	TBD	Petition sufficiency review, including TR request, if applicable	12/26/17	TBD	TR request in development
Handling	Ethiopian pepper	Petition, add to 205.606	Not requested	Petition sufficiency review, including TR request, if applicable		Spring 2018	Sent to HS on 2/9/2017; Pet determined sufficient on 4/4/2017; no TR needed; additional Qs sent to petitioner on 7/24/17; additional Qs sent to petitioner on 11/8/17
Handling	Japones pepper	Petition, add to 205.606	Not requested	Petition sufficiency review, including TR request, if applicable		Spring 2018	Sent to HS on 2/9/2017; Pet determined sufficient on 4/4/2017; no TR needed; additional Qs sent to petitioner on 7/24/17; additional Qs sent to petitioner on 11/8/17

NOSB Materials Report: Petition & Technical Report Status

Updated: 1/5/2018
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Aquaculture	Overdue items in red
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	Petitioned Inerts - on hold

NL Section	Substance	Type	Technical Report	Next Step	Due Date	NOSB Meeting	Notes
Handling	Bisphenol A (BPA)	See Notes	Technical Report (PDF)	Subcommittee Proposal or Discussion Document	2/21/18	Spring 2018	NOP memo on Packaging, Nov 2014; initial TR inadequate - sent for external contracting; new TR sent to HS on 7/10/2017; TR found sufficient on 8/1/2017
Handling	Sodium dodecylbenzene sulfonate (SDBS)	Add to 205.605(b)	Technical Report (PDF)	Subcommittee Proposal	2/21/18	Spring 2016; Spring 2018 (est)	Petition sent to HS on 11/2/15; petition determined sufficient on 12/1/2015; no TR needed; referred back to SC at April 2016 NOSB Mtg; TR requested on 5/17/16; TR sent to HS on 5/30/2017; Addendum posted and sent to HS on 7/12/17; TR found sufficient on 8/1/2017
Handling	Silver Dihydrogen Citrate			TR under revision		Spring 2018	Petition determined sufficient on 3/7/17; TR requested; add'l Q for contractor received on 12/5/2017

NOSB Materials Report: Petition & Technical Report Status

Updated: 1/5/2018
Spring 2018 proposals due 2/21/2018

Aquaculture
Overdue items in red
Changes since last report in yellow
Petitioned Inerts - on hold

NL Section	Substance	Type	Technical Report	Next Step	Due Date	NOSB Meeting	Notes
Handling	Tamarind seed gum	Petition, add to 205.606	TBD	TR in development - expected March 2018		Spring 2018	Sent to HS on 2/15/2017; Additional questions for the petitioner provided on 4/5/2017; Petition addendum sent to HS on 8/10/2017; TR Requested on 10/3/2017
Handling	Sodium Chlorite for production of chlorine dioxide gas	Add to 205.605		TR in development - expected February 2018		Fall 2016; TBD	Petition sent to HS on 12/02/2015; Pet determined incomplete on 4/13/2016; add'l info sent to HS on 5/5/2016; Petition determined sufficient on 6/7/16; Proposal vote 8/16/16; taken back to subcommittee for further work; TR requested on 6/6/2017
Livestock	Oxalic acid (PDF)	Add to 205.603	TBD	TR Development		TBD	Sent to LS on 10/27/17; TR Requested on 12/8/2017
Livestock	Glycolic acid (PDF)	Add to 205.603		TR Review	1/8/18	TBD	Sent to LS on 6/6/2016; TR requested 7/19/2016; TR assigned 11/18/16; Draft TR sent to LS 11/7/17

NOSB Materials Report: Petition & Technical Report Status

Updated: 1/5/2018

Spring 2018 proposals due 2/21/2018

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	Petitioned Inerts - on hold

NL Section	Substance	Type	Technical Report	Next Step	Due Date	NOSB Meeting	Notes
Livestock	Thymol	Petition, Add to 205.603		Petitioner notified of insufficiency; resubmission expected		TBD	Sent to LS on 2/1/17; LS determined insufficient 4/4/17; Additional Q for petitioner sent on 4/26/2017; Addendum sent to LS on 5/26/2017; Additional Q for petitioner sent on 8/15/2017; 2nd Addendum posted; More info requested on 12/8/2017

NOSB Materials Report: Petition & Technical Report Status

Updated: 1/12/2018

Spring 2018 proposals due 2/21/2018

Aquaculture

Overdue items in red

Changes since last report in yellow

Petitioned Inerts - on hold

NL Section	Substance	Type	Technical Report	Next Step	Due Date	NOSB Meeting	Notes
Crops	Natamycin (PDF)	Petition to classify as nonsynthetic	Technical Report (2017)	Subcommittee proposal		TBD	Petition sent to CS on 9/9/2016. TR requested on 11/17/16. TR sent to CS on 11/13/2017; TR approved on 12/5/2017 (posted 1/25)
Crops	Calcium acetate (PDF)	Add to 205.601	TBD	TR Development		TBD	Sent to CS on 11/20/17. Petition determined sufficient 2/7/18. TR requested w/additional questions; TR request in development
Crops	Sodium Citrate	Petition, Add to 205.601	Posting to web in progress	Subcommittee proposal		TBD	Petition sent to CS on 7/28/16; Full TR requested 10/04/16; TR sent to CS on 8/7/2017; TR determined insufficient on 9/9/17; add'l Q sent to contractor on 12/12/2017; revised TR sent to CS on 12/20/2017; TR approved on 2/7/18
Crops	Sulfur	Petition, Add to 205.601, molluscicide	Livestock report available	Subcommittee proposal	2/21/18	Spring 2018	Petition sent to CS on 6/08/2017; Petition determined sufficient 9/19/17; no TR requested
Crops	Allyl Isothiocyanate (AITC)	Crops, Add to 205.601	Ltd TR Request	TR in development - expected Feb/Mar 2018		TBD	Sent to CS on 7/6/2016; Ltd TR request 10/04/16; TR assigned 11/18/16

NOSB Materials Report: Petition & Technical Report Status

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Spring 2018 proposals due 2/21/2018

Aquaculture	
	Overdue items in red
	Changes since last report in yellow
	Petitioned Inerts - on hold

NL Section	Substance	Type	Technical Report	Next Step	Due Date	NOSB Meeting	Notes
Crops	Polyoxin D Zinc Salt (PDF).	Add to 205.601	2012 (PDF)	TR sufficiency review	2/20/17	Spring 2018	Sent to CS on 6/16/2016; Ltd TR request 10/04/16; TR assigned 11/18/16; 2nd addendum sent to CS on 10/27/2017; TR sent to CS on 12/19/2017. Petition addendum sent to CS 02/07/18
Crops	Ammonium Citrate (PDF)	Add to 205.601	TBD	Petition sufficiency review, including TR request, if applicable	12/26/17	TBD	TR request in development
Crops	Ammonium Glycinate (PDF)	Add to 205.601	TBD	Petition sufficiency review, including TR request, if applicable	12/26/17	TBD	TR request in development
Handling	Ethiopian pepper	Petition, add to 205.606	Not requested	Petition sufficiency review, including TR request, if applicable		Spring 2018	Sent to HS on 2/9/2017; Pet determined sufficient on 4/4/2017; no TR needed; additional Qs sent to petitioner on 7/24/17; additional Qs sent to petitioner on 11/8/17
Handling	Japones pepper	Petition, add to 205.606	Not requested	Petition sufficiency review, including TR request, if applicable		Spring 2018	Sent to HS on 2/9/2017; Pet determined sufficient on 4/4/2017; no TR needed; additional Qs sent to petitioner on 7/24/17; additional Qs sent to petitioner on 11/8/17

NOSB Materials Report: Petition & Technical Report Status

Updated: 1/12/2018
Spring 2018 proposals due 2/21/2018

Aquaculture
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Changes since last report in yellow
Petitioned Inerts - on hold

NL Section	Substance	Type	Technical Report	Next Step	Due Date	NOSB Meeting	Notes
Handling	Bisphenol A (BPA)	See Notes	Technical Report (PDF)	Subcommittee Proposal or Discussion Document	2/21/18	Spring 2018	NOP memo on Packaging, Nov 2014; initial TR inadequate - sent for external contracting; new TR sent to HS on 7/10/2017; TR found sufficient on 8/1/2017
Handling	Sodium dodecylbenzene sulfonate (SDBS)	Add to 205.605(b)	Technical Report (PDF)	Subcommittee Proposal	2/21/18	Spring 2016; Spring 2018 (est)	Petition sent to HS on 11/2/15; petition determined sufficient on 12/1/2015; no TR needed; referred back to SC at April 2016 NOSB Mtg; TR requested on 5/17/16; TR sent to HS on 5/30/2017; Addendum posted and sent to HS on 7/12/17; TR found sufficient on 8/1/2017
Handling	Silver Dihydrogen Citrate			TR under revision		Spring 2018	Petition determined sufficient on 3/7/17; TR requested; add'l Q for contractor received on 12/5/2017
Handling	Tamarind seed gum	Petition, add to 205.606	TBD	TR in development - expected March 2018		Fall 2018	Sent to HS on 2/15/2017; Additional questions for the petitioner provided on 4/5/2017; Petition addendum sent to HS on 8/10/2017; TR Requested on 10/3/2017 (expected by 2/21/18)

NOSB Materials Report: Petition & Technical Report Status

Updated: 1/12/2018

Spring 2018 proposals due 2/21/2018

Aquaculture	
	Overdue items in red
	Changes since last report in yellow
	Petitioned Inerts - on hold

NL Section	Substance	Type	Technical Report	Next Step	Due Date	NOSB Meeting	Notes
Handling	Sodium Chlorite for production of chlorine dioxide gas	Add to 205.605		TR Review	3/15/18	Fall 2016; TBD	Petition sent to HS on 12/02/2015; Pet determined incomplete on 4/13/2016; add'l info sent to HS on 5/5/2016; Petition determined sufficient on 6/7/16; Proposal vote 8/16/16; taken back to subcommittee for further work; TR requested on 6/6/2017; TR sent to HS on 1/9/2018
Livestock	Oxalic acid (PDF)	Add to 205.603	TBD	TR Development		TBD	Sent to LS on 10/27/17; TR Requested on 12/8/2017; TR request in development
Livestock	Glycolic acid (PDF)	Add to 205.603	Technical Report (2017)	NOSB Subcommittee Proposal		Spring 2018	Sent to LS on 6/6/2016; TR requested 7/19/2016; TR assigned 11/18/16; Draft TR sent to LS 11/7/17; TR determined sufficient on 1/12/2018; TR posted to web 1/23/2018

NOSB Materials Report: Petition & Technical Report Status

Updated: 1/11/2018

Overdue items in red

Changes since last report in yellow

NL Section	Substance	Type	Technical Report	Next Step	Due Date	NOSB Mtg 1	NOSB Mtg 2	Sunset Date	Notes
205.605(b)	Alginates	Sunset 2020	2015 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(e)	Aqueous potassium silicate	Sunset 2020	2014 TR	NOSB Meeting #1		Spring 2018	Fall 2018	6/22/2020	
205.601(i)	Aqueous potassium silicate	Sunset 2020	2014 TR	NOSB Meeting #1		Spring 2018	Fall 2018	6/22/2020	
205.606	Arabic gum	Sunset 2020	1995 TAP	TR Review	4/2/2018	Spring 2018	Fall 2018	3/15/2022	single report for all gums. TR sent to HS on 1/30/2018
205.603(a)	Aspirin	Sunset 2020	1995 TAP	TR Review	2/19/2018	Spring 2018	Fall 2018	3/15/2022	TR sent to LS on 12/20/2017
205.605(a)	Calcium carbonate	Sunset 2020	1995 TAP	TR Review	3/30/2018	Spring 2018	Fall 2018	3/15/2022	TR sent to LS on 01/29/2018
205.605(b)	Calcium hydroxide	Sunset 2020	1995 TAP	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.606	Carob bean gum	Sunset 2020	1995 TAP	TR Review	4/2/2018	Spring 2018	Fall 2018	3/15/2022	single report for all gums. TR sent to HS on 1/30/2018
205.605(b)	Diglycerides	Sunset 2020	2015 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.603(a)	Electrolytes	Sunset 2020	2015 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(e)	Elemental sulfur	Sunset 2020	1995 TAP	TR Review	3/12/2018	Spring 2018	Fall 2018	44635	new TR for livestock use available
205.601(i)	Elemental sulfur	Sunset 2020	1995 TAP	TR Review	3/12/2018	Spring 2018	Fall 2018	44635	new TR for livestock use available
205.601(j)	Elemental sulfur	Sunset 2020	1995 TAP	TR Review	3/12/2018	Spring 2018	Fall 2018	44635	new TR for livestock use available
205.601(a)	Ethanol	Sunset 2020	2014 TR - Ethanol	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.603(a)	Ethanol	Sunset 2020	2014 TR Ethanol	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(k)	Ethylene	Sunset 2020	2011 Supplemental TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.605(b)	Ethylene	Sunset 2020	1999 TAP - Processing	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	TR Requested - Low Priority
205.605(a)	Flavors	Sunset 2020	2005 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.606	Fructooligosaccharides	Sunset 2020	2015 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.605(a)	Gellan gum	Sunset 2020	2006 TAP	TR Review	4/2/2018	Spring 2018	Fall 2018	3/15/2022	single report for all gums. TR sent to HS on 1/30/2018
205.603(a)	Glycerine	Sunset 2020	2010 TAP (Livestock)	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	TR Requested - Low Priority
205.606	Guar gum	Sunset 2020	1995 TAP	TR Review	4/2/2018	Spring 2018	Fall 2018	3/15/2022	single report for all gums. TR sent to HS on 1/30/2018
205.601(i)	Hydrated lime	Sunset 2020	2001 TAP	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.603(b)	Hydrated lime	Sunset 2020	2015 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(a)	Isopropanol	Sunset 2020	2014 TR - Isopropanol	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.603(a)	Isopropanol	Sunset 2020	2014 TR Isopropanol	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.606	Lecithin—de-oiled	Sunset 2020	2009 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(e)	Lime sulfur	Sunset 2020	2014 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(i)	Lime sulfur	Sunset 2020	2014 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(j)	Liquid fish products	Sunset 2020	2006 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.606	Locust bean gum	Sunset 2020	1995 TAP	TR Review	4/2/2018	Spring 2018	Fall 2018	3/15/2022	single report for all gums. TR sent to HS on 1/30/2018
205.605(b)	Magnesium stearate	Sunset 2020	1995 TAP	TR Review	3/30/2018	Spring 2018	Fall 2018	3/15/2022	TR sent to HS on 1/29/2018
205.601(o)	Microcrystalline cheesewax	Sunset 2020	none	TR Review	3/13/2018	Spring 2018	Fall 2018	3/15/2022	TR sent to CS on 1/11/2018
205.603(b)	Mineral oil	Sunset 2020	2015 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.605(b)	Monoglycerides	Sunset 2020	2015 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(b)	Newspaper or other recycled paper	Sunset 2020	2017 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	

NOSB Materials Report: Petition & Technical Report Status

Updated: 1/11/2018

Overdue items in red

Changes since last report in yellow

NL Section	Substance	Type	Technical Report	Next Step	Due Date	NOSB Mtg 1	NOSB Mtg 2	Sunset Date	Notes
205.601(c)	Newspaper or other recycled paper	Sunset 2020	2017 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.605(a)	Oxygen	Sunset 2020	1995 TAP	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	TR Requested - Low Priority
205.603(a)	Phosphoric acid	Sunset 2020	2003 TAP (Handling)	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	TR Requested - Low Priority
205.605(b)	Phosphoric acid	Sunset 2020	2003 TAP	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	TR Requested - Low Priority
205.601(b)	Plastic mulch and covers (petroleum-based other than polyvinylchloride (PVC))	Sunset 2020	1995 TAP	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	TR Requested - Low Priority
205.605(b)	Potassium carbonate	Sunset 2020	1995 TAP	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	TR Requested - Low Priority
205.602(e)	Potassium chloride	Sunset 2020	1995 TAP	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	TR Requested - Low Priority; no TR
205.605(a)	Potassium chloride	Sunset 2020	1995 TAP	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(a)	Sodium carbonate peroxyhydrate	Sunset 2020	2014 TR	NOSB Meeting #1		Spring 2018	Fall 2018	6/22/2020	
205.601(e)	Sucrose octanoate esters	Sunset 2020	2005 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.603(b)	Sucrose octanoate esters	Sunset 2020	2005 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.605(b)	Sulfur dioxide	Sunset 2020	2011 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(j)	Sulfurous acid	Sunset 2020	2014 TR	NOSB Meeting #1		Spring 2018	Fall 2018	6/22/2020	
205.606	Tragacanth gum	Sunset 2020	none	TR Review	4/2/2018	Spring 2018	Fall 2018	3/15/2022	single report for all gums. TR sent to HS on 1/30/2018
205.603(a)	Vaccines	Sunset 2020	2011 TR (Vaccines from Ex	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.605(b)	Xanthan gum	Sunset 2020	2016 TR	TR Review	4/2/2018	Spring 2018	Fall 2018	3/15/2022	single report for all gums. TR sent to HS on 1/30/2018

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Sunset 2022	48
Sunset 2020	4

NOSB	National Organic Standards Board
NOP	National Organic Program
TR	Technical Report
ES	Executive Subcommittee
CS	Crops Subcommittee
LS	Livestock Subcommittee
HS	Handling Subcommittee
SD	Standards Division
NL	National List

205.601 § 205.601 Synthetic substances allowed for use in organic crop production.
205.602 § 205.602 Nonsynthetic substances prohibited for use in organic crop production.
205.603 § 205.603 Synthetic substances allowed for use in organic livestock production.
205.604 § 205.604 Nonsynthetic substances prohibited for use in organic livestock production.
205.605 § 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”
205.606 § 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

Sodium Chlorite, for Generation of Chlorine Dioxide Gas

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
Sodium chlorite
Chlorine dioxide

Other Name:
Chlorite (sodium salt)
Chlorous acid, sodium salt
Chlorite sodium
Chlorine dioxide, monohydrate
Chlorine oxide
Chlorine (IV) oxide
Chlorine peroxide
Chloroperoxyl

Trade Names:
Textone (sodium chlorite)
Textile (sodium chlorite)
Alcide LD (sodium chlorite)
Neo Silox D (sodium chlorite)
Caswell No. 755 (sodium chlorite)
Scentrex™ (sodium chlorite)
Alcide (chlorine dioxide)
Aseptrol (chlorine dioxide)
DioxiClear (chlorine dioxide)
MicroClear (chlorine dioxide)
RenNew-D (chlorine dioxide)
Tristel (chlorine dioxide)

CAS Numbers:
7758-19-2 (sodium chlorite)
10049-04-4 (chlorine dioxide)

Other Codes:
EINECS: 231-836-6 (sodium chlorite)
EINECS: 233-162-8 (chlorine dioxide)
RTECS: VZ 4800000 (sodium chlorite)
RTECS: FO 3000000 (chlorine dioxide)
UN: 1496 (sodium chlorite)
UN: 9191 (chlorine dioxide)
UNII: G538EBV4VF: (sodium chlorite)
UNII: 8061YMS4RM (chlorine dioxide)
ICSC: 1045 (sodium chlorite)
ICSC: 0127 (chlorine dioxide)

Summary of Petitioned Use

Chlorine dioxide (CDO) is currently allowed under the National Organic Program (NOP) regulations at 7 CFR §205.605(b) as a nonagricultural synthetic substance that may be used as an ingredient in or on processed products labeled "organic" or "made with organic (specified ingredients or food group(s) for disinfecting and sanitizing food contact surfaces." Sodium chlorite is not currently listed under NOP regulations; however, acidified sodium chlorite is permitted at 7 CFR §205.605(b) for "secondary direct antimicrobial food treatment and indirect food contact surface sanitizing." The primary use of CDO in organic food processing is as a disinfecting and sanitizing agent, with applications ranging from treatment of food contact surfaces and "facilities and equipment" for organic livestock production, to use as an algicide for preharvest treatment of organic crops. The petition before the NOP is to extend the allowed use of chlorine dioxide gas for use as an antimicrobial agent, sanitizer, and/or disinfectant for the direct treatment of fruits and vegetables. The Federal Food and Drug Administration (FDA) currently permits the application of aqueous chlorine dioxide solutions for antimicrobial disinfection of fruits and vegetables.

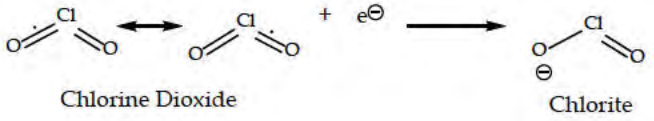
Characterization of Petitioned Substance

Composition of the Substance:

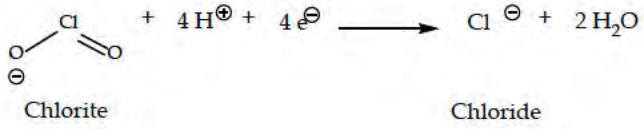
Sodium chlorite is an inorganic salt that exists as a white crystalline solid. It is commercially available as technical grade (80% purity), as well as a premade chlorine dioxide release mixture, where the chlorite salt is impregnated on calcined clay. Sodium chlorite as a solid is slightly hygroscopic (absorbs water).

Chlorine dioxide can be synthetically generated in several ways, most of which use a sodium chlorite precursor, which is activated through oxidation to the neutral radical species.

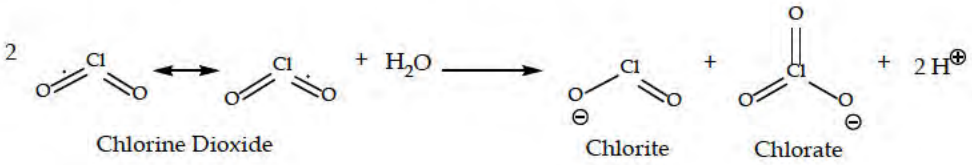
Chlorine dioxide gas is highly reactive, and can be explosive in concentrations greater than 10% (v/v) (ICPS, 2002; WHO, 1998). Chlorine dioxide gas undergoes decomposition by reduction to form chlorite ions (Equation 1). The resulting chlorite remains reactive, and can undergo further reduction to chloride, which is the predominant end-product of chlorine dioxide decomposition (Equation 2). In the absence of a reducing agent (i.e., when CDO is unable to act as an oxidant), it forms decomposition products of chlorite and chlorate ions (Equation 3). With these decomposition reactions in mind, chlorite, chlorate, and chloride are all potential by-products for the use of chlorine dioxide gas (JECFA, 2008).



Equation 1



Equation 2



Equation 3

Source or Origin of the Substance:

Several industrial synthetic procedures are used in the production of sodium chlorite, which include the following: the treatment of chlorine dioxide with sodium hydroxide and a reducing agent (e.g., sodium sulfite), the treatment of chlorine dioxide with sodium peroxide (Na_2O_2), or an alkaline solution of hydrogen peroxide (H_2O_2).

Due to the reactivity of chlorine dioxide (CDO) gas, and its explosive nature when concentrated, CDO is generated on-site prior to required usage. There are several methods for the generation of CDO gas from sodium chlorite, all of which involve the oxidation of the chlorite ion to the neutral radical species. This oxidation process can be completed by treatment with H^+ from an acid, or electrochemically by the electrolysis of a sodium chlorite solution, and by treatment with chlorine gas (Cl_2).

Properties of the Substance:

The properties of calcium carbonate are summarized in Table 1.

Table 1. Properties of Sodium Chlorite and Chlorine Dioxide

Property	Sodium Chlorite	Chlorine Dioxide
CAS registry number	7758-19-2	10049-04-4
Molecular formula	$NaClO_2$	ClO_2
Molecular weight	90.45 g/mol	67.46 g/mol
Color	White crystalline solid (80% technical grade, slightly hygroscopic)	Greenish yellow to orange gas
Density/Specific gravity	Crystal: 2.468 g/cm³	1.765 g/cm³ at -56 °C

	1.642 at 0 °C	1.62 g/cm^3 at -11 °C
Melting point	180 – 200 °C, decomposes at melting point	-59 °C
Boiling point	No data	11 °C
Water solubility	39 g/L at 30 °C	3.0 g/L at 25 °C and 34 mmHg

Sources: Budavari, 1989; FSANZ, 2003; PubChem 24870; PubChem 23668197
Specific Gravity = Ratio of the density of a substance compared to the density of a reference substance (e.g., water).

Specific Uses of the Substance:

Chlorine dioxide (CDO) is well known for its antimicrobial effects through oxidative inactivation (Stubblefield et al., 2014; Lee et al., 2015; Park et al., 2017). When used as a fumigation agent, there are no residual traces of the CDO disinfectant, or disinfection by-products (DBP) of chlorite and chlorate, as identified in equations 1 and 3 (JECFA, 2008). The efficacy of CDO gas against a wide range of microorganisms has been demonstrated in several studies across a variety of fruits and vegetables (Gomez-Lopez et al., 2009; Goodburn et al., 2013; Park et al. 2015; Lee et al., 2015). These studies also relate the increased efficacy of CDO in gas form, compared to its use in aqueous solution, which is primarily due to the increased penetration of the gas treatments, as well as the ability to effectively treat irregular surfaces (Subblefield et al., 2014; Lee et al. 2015; Park et al., 2017).

The current allowed usage for chlorine dioxide in organic food processing is as a disinfection and sanitizing agent for food contact surfaces, facilities, and equipment for crop and livestock production, as well as for the processing of "organic" or "made with organic" ingredients and food groups (7 CFR §205.601(a), 205.603(a), and 205.605(b)). However, CDO is an active disinfectant produced by the acidification of sodium chlorite, which is permitted at 7 CFR §205.605(b) as "secondary direct antimicrobial food treatment and indirect food contact surface," with the exception that acidification must be completed with citric acid. This petition is to extend the use of CDO in gaseous form for the antimicrobial treatment of products labeled "organic" or "made with organic (specified ingredients or food group(s))."

CDO is permitted by the FDA as an antimicrobial treatment for a range of food products, including fruits and vegetables and poultry processing (21 CFR §173.300). CDO is also used as bleaching agent in both flour and whole wheat flour (21 CFR §137.105(a) and 137.200(a)). CDO is also widely used in the sanitation and treatment of water systems, and is allowed by the FDA as a disinfectant in bottled water (21 CFR §165.110(b)).

Beyond treatment of food and agricultural products, CDO is also widely used in the paper industry for the bleaching of cellulose and paper pulp (EPA, 2000; Gomez-Lopez et al., 2009), and for the treatment of medical and hazardous waste (40 CFR §268.42(a)).

Approved Legal Uses of the Substance:

The FDA has approved the usage of sodium chlorite at 21 CFR §186.1750(b) as "a slimicide in the manufacture of paper and paperboard that contact food," at levels of 125 – 250 ppm. Sodium chlorite is also approved for use as an adhesive with no limitations (21 CFR §175.105(c)), the bleaching of "food starch-modified," with levels "not to exceed 0.5 percent." (21 CFR 172.892(b)).

Sodium chlorite is a major component of acidified sodium chlorite (ASC). ASC is permitted by the FDA at 21 CFR §178.1010(b) for antimicrobial "use on food processing equipment and utensils," and "dairy processing equipment." ASC is also permitted by the FDA for antimicrobial use with generally recognized as safe (GRAS) acids for the antimicrobial treatment of poultry, and as a component of ASC, which is used to treat fruits and vegetables, poultry, red meat, seafood, and raw agricultural products (21 CFR §173.325).

The FDA has also permitted chlorite as an allowed residual disinfectant in bottled water, with a maximum concentration of 1.0 mg/L (21 CFR §165.110(b)).

The USDA NOP has approved the usage of ASC at 7 CFR §205.605(b) as a synthetic for "secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only," for "processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

Chlorine dioxide is permitted for the safe use in food "as an antimicrobial agent in water used in poultry processing," and to "wash fruits and vegetables that are not raw agricultural commodities in an amount not to exceed 3 ppm residual chlorine dioxide," with the exception that "treatment of fruits and vegetables with chlorine dioxide shall be followed by a potable water rinse or by blanching, cooking, or canning" (21 CFR 173.300(b)). CDO is permitted by the FDA for the "bleaching and artificial aging" of flour and whole wheat flour, "in a quantity not more than sufficient" (21 CFR §137.105(a) and 137.200(a)). CDO has also been approved at 21 CFR §178.1010(b) for use as a component of aqueous solutions, with a minimum concentration of 100 ppm, and a maximum concentration of 200 ppm, for use "on food-processing equipment and utensils, and on other food-contact articles." The FDA has also permitted CDO as an allowed residual disinfectant in bottled water, with a maximum concentration of 0.8 mg/L (21 CFR §165.110(b)).

The current allowed usage for chlorine dioxide in organic food processing is as a disinfection and sanitizing agent for food contact surfaces, facilities, and equipment for crop and livestock production, and for the processing of "organic" or "made with organic" ingredients and food groups (7 CFR §205.601(a), 205.603(a), and 205.605(b)).

The EPA permits the use of CDO at 40 CFR §180.940(b) and (c) as an ingredient in "an antimicrobial pesticide formulation [that] may be applied to: Dairy processing equipment, and food-processing equipment and utensils," when the "end-use concentration is not to exceed 200 ppm."

The EPA also permits the use of CDO as a disinfecting and sanitizing agent for water systems. The EPA includes CDO as a component of "total chlorine," which is required for public water systems that do not use filtration (40 CFR §141.72(a)). Under these EPA regulations there is a maximum disinfectant level goal of 0.8 mg/L of chlorine dioxide (40 CFR §141.54 and 141.65). The EPA allows the use of CDO as an agent for the "chemical or electrolytic oxidation" of medical and hazardous wastes (40 CFR §268.42(a)).

The EPA allows the use of CDO as a bleaching agent in the paper pulping process (40 CFR §430.01).

Action of the Substance:

Chlorine dioxide gas, as generated from sodium chlorite, acts as an antimicrobial agent whose mode of action is not entirely understood. The most accepted explanations of the activity of CDO are in relation to the disruption of protein synthesis, and the loss of permeability controls of cellular walls and membranes (EFSA, 2008; Gomesz-Lopez et al., 2009; Park et al., 2015; Meireles at al., 2016). These disruptions to cellular processes are due to the oxidation strength of CDO, which upon reaction is primarily reduced to chlorite (Equation 1). The resulting disinfection by-product chlorite remains reactive, and when in contact with electron-rich species (i.e., organic matter), is further reduced to chloride ions (Equation 2). CDO is effective for the inactivation of bacteria, viruses, and protozoa over a wide pH range (Neal et al., 2012; Yang et al., 2013; Stubblefield et al., 2014; Park et al., 2015).

Several studies have indicated that gaseous CDO treatments are as, or more, effective than aqueous treatments. The increase in efficacy of gaseous CDO has been attributed to increased penetration ability, which is especially important for the treatment of biofilms, and improved contact with irregular surfaces (Stubblefield et al., 2014; Park et al., 2015; Park et al., 2017). CDO has also been documented as having a synergistic effect with high relative humidity, which is likely due to the stability and high solubility of the gas in aqueous solution (Park et al., 2015; Park et al., 2017; Visvalingam et al., 2017).

Combinations of the Substance:

Sodium chlorite, for use in the generation of chlorine dioxide gas, is available in several combinations. Sodium chlorite is available as a white crystalline solid (80%, technical grade). Technical grade sodium chlorite may be used in combination with citric acid to form acidified sodium chlorite, which is identified on the National List. Treatment of solid sodium chlorite with an acid also results in the generation of the petitioned substance, chlorine dioxide gas. Alternatively, solid sodium chlorite may be oxidized with chlorine (Cl_2) gas, resulting in the generation of chlorine dioxide gas.

Sodium chlorite is also marketed in the form of sachets, in which the sodium salt is impregnated in a zeolite, such as calcined clay. Sodium chlorite impregnated zeolites can then be treated with solid or liquid acids to generate CDO gas. If a liquid acid is used, an unspecified buffer is also present to control the formation and release of the chlorine dioxide gas (NOSB, 2016).

Status

Historic Use:

Aqueous chlorine dioxide has historically been used in organic agricultural production as a disinfectant and sanitizer for facilities, equipment, and utensils due to its antimicrobial properties. Within organic agricultural production, chlorine dioxide has also been a component of the antimicrobial solutions derived from acidified sodium chlorite (ASC). ASC has been used as an antimicrobial treatment of fruits and vegetables when acidified with citric acid, and followed by treatment of the product to remove residual disinfectant and by-products. (7 CFR §205.605(b)).

Within non-organic agricultural production, CDO is also used for the antimicrobial treatment of poultry, and as a component of ASC, is used for treatment of fruits and vegetables, poultry, red meat, seafood, and raw agricultural products (21 CFR §173.325).

Organic Foods Production Act, USDA Final Rule:

Neither sodium chlorite nor chlorine dioxide are listed in the Organic Foods Production Act of 1990.

Sodium chlorite is listed in the USDA organic regulations at 7 CFR §205.605(b) as an allowed synthetic under "Acidified sodium chlorite," and is approved as a "secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only."

Chlorine dioxide is listed in the USDA organic regulations at 7 CFR §205.601(a) as an allowed synthetic substance for organic crop production, with the exception that "residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act." CDO also appears in 7 CFR §205.603(a) as an allowed substance for the "disinfecting and sanitizing facilities and equipment," used in organic livestock production. CDO is also listed in USDA organic regulations at 7 CFR §205.605(b) as an allowed synthetic material for "disinfecting and sanitizing food contact surfaces."

International

Canadian General Standards Board Permitted Substances List

Sodium chlorite is not listed in CAN/CGSB-32.311-2015.

Chlorine dioxide is listed in CAN/CGSB-32.311-2015, Table 7.3 "Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event," with the exception that CDO levels do not exceed maximum levels for safe drinking water, Table 7.4. "Cleaners, disinfectants, and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory," with permission for use "up to maximum label rates."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) -

Neither sodium chlorite nor chlorine dioxide are listed in the GL 32-1999 CODEX.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

Neither sodium chlorite nor chlorine dioxide are listed in EC No. 834/2007 and 889/2008.

Japan Agricultural Standard (JAS) for Organic Production

Neither sodium chlorite nor chlorine dioxide are listed in the JAS for Organic Production.

International Federation of Organic Agriculture Movements (IFOAM)

Sodium chlorite is not listed in the IFOAM Norms.

Chlorine dioxide is listed in the IFOAM Norms in Appendix 4, Table 2, "Indicative List of Equipment Cleansers and Equipment Disinfectants," with a limitation of "an intervening event or action must occur to eliminate risks of contamination."

Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Sodium chlorite is manufactured from the chemical or electrochemical reduction of sodium chlorate—in the presence of hydrochloric acid (HCl)—resulting in the formation of chlorine dioxide. The synthesized chloride dioxide is then reacted with hydrogen peroxide (H_2O_2) and aqueous sodium hydroxide (NaOH) (21 CFR §186.1750(a)), producing an aqueous solution of 30 – 50% sodium chlorite. The solution can then be dried to yield solid sodium chlorite, or further diluted to obtain aqueous solutions of a desired concentration (JECFA, 2007).

Chlorine dioxide can be manufactured in a variety of ways, most of which are derived from the treatment of a sodium chlorite precursor with an activator (i.e., oxidant). As stated in the above description of the manufacture of sodium chlorite, chlorine dioxide may also be formed by the chemical or electrochemical reduction of chlorate ions (ClO_3^-) in the presence of hydrochloric acid (HCl) (JECFA, 2007).

Due to the reactive nature of CDO, and its propensity for explosion when concentrated, it is generated on-site at the point-of-use, and is typically generated by the activation of sodium chlorite (Gomez-Lopez et al., 2009; Lee et al., 2015). CDO may be generated by the treatment of sodium chlorite with chlorine gas (Cl_2), which is the most common industrial means for the formation the petitioned substance (JECFA, 2008; EFSA, 2008; Lee et al., 2015; Clordisys, 2016; Meireles et al., 2016). CDO may also be generated by the treatment of sodium chlorite with H^+. This acid may by hydrochloric, or any other acid, and may be introduced in both solid and solution forms (Lee et al., 2015; Meireles et al., 2016; EFSA, 2016, NOSB, 2016; Visvalingam, 2017). Furthermore, the H^+ may be produced electrochemically by the electrolysis of an aqueous sodium chlorite solution (Yu et al., 2014; EFSA, 2016).

Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.

Sodium chlorite and the subsequently generated chlorine dioxide gas are synthetic materials made by chemical processes, and are not created by naturally occurring biological processes. Neither sodium chlorite nor chlorine dioxide are derived from agricultural sources. The manufacture of both sodium chlorite and chlorine dioxide are described above in **Evaluation Question #1**.

The ability to produce the desired CDO gas from sodium chlorite with any acid allows for the selection of one of several GRAS acid sources (e.g., citric acid).

Evaluation Question #3: If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

There is no published literature that indicates the presence of a natural or non-synthetic source of the petitioned substance. Due to the instability of the generated CDO species, it is not long-lived. Likewise, its precursor and major initial decomposition product (chlorite) is also reactive, and is further reduced to chloride (Cl^-), as seen in Equation 2.

Evaluation Question #4: Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.

Sodium chlorite has been designated by the FDA as generally recognized as safe (GRAS) at 21 CFR §184.1750(b), and is allowed as an "ingredient used at levels from 125 to 250 parts per million as a slimicide in the manufacture of paper and paperboard that contact food."

Chlorine dioxide is not listed in the FDA as GRAS. However, the generation of CDO from sodium chlorite in calcined or sulfated kaolin clay, or from the combination of particles of sodium polyphosphate, magnesium sulfate, sodium silicate, and sodium chlorite incorporated into low density polyethylene, do appear in the FRA GRAS inventory (GRN 000161; GRN 000062).

Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b)(4)).

The primary request for the petitioned substance is for the allowed use of chlorine dioxide gas in organic food processing as a disinfecting/sanitizing antimicrobial agent for direct food contact with agricultural products such as fruits and vegetables.

While this request does not indicate the primary use of CDO as a preservative, there have been literature reports that indicate treatment of fruits and vegetables with CDO gives preservative qualities by increasing the shelf-life of products. This action is likely due to the inactivation of microorganisms that facilitate food spoilage (Gomez-Lopez et al., 2009; NOSB, 2016; EFSA, 2016).

Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).

There is no published literature that indicates that the use of either sodium chlorite or chlorine dioxide treatments act to recreate or improve flavors colors, texture, or nutritive values in products. However, chlorine dioxide is allowed by the FDA as a "bleaching and artificial aging" agent for both flour and whole wheat flour at 21 CFR §137.105(a) and 137.200(a).

Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).

There are no direct reports in the literature that link CDO applications to degradation of the nutritional quality of the treated products. While the reactivity of CDO with phenolic species has the potential to impact the content of phytochemicals in treated products, there have been no studies that document phytochemical degradation (Gomez-Lopez et al., 2009). A study has shown CDO to be unreactive towards amino acids (EFSA, 2005), and in general, the literature supports that CDO is unreactive toward the nutritional content of treated products (Gomez-Lopez et al., 2009; EFSA, 2005; NOSB, 2016).

Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600 (b)(5)).

Since the source of sodium chlorite for CDO generation can vary, there is the potential for heavy metal contamination within the sodium chlorite precursor. The solid is manufactured to an 80% purity as 'technical grade,' and in general, no purification steps are documented. While the remaining 20% is likely to be other sodium salts (i.e., sodium chloride, sodium carbonate, etc.), the lack of purification steps does not rule out the presence of heavy metal contaminants (e.g., lead), although lead would be limited by manufacture specifications to 5 mg/kg (JECFA, 2007a). However, there have been no reports of the presence of heavy metals or other contaminants in the petitioned substance.

Despite the potential for trace heavy metal contaminants, the generation and application of chlorine dioxide as a gas results in trace impurities remaining in the sachet, or gas generator—meaning that they will not contact the food surface. This is in direct comparison with the use of aqueous solutions of CDO, such as ASC, which may result in a transfer of trace impurities to food surfaces (Clordisys, 2016).

Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

When used as petitioned, neither sodium chlorite nor chlorine dioxide are expected to have a negative impact on the environment or biodiversity. Due to the reactive nature of gaseous CDO, it is not expected to persist or bioaccumulate in the environment (NOSB, 2016). As seen in Equations 1 and 3, CDO rapidly decomposes to chlorite (ClO_2^-) and chlorate (ClO_3^-), with the final endpoint being chloride (Cl^-) (GRN 000161; JECFA, 2007a; Lee et al., 2015; Clordisys, 2016; Park et al., 2017). Chloride is prevalent in nature and physiology, and therefore, will not provide an adverse impact at anticipated concentrations (WHO, 2000).

Due to the high reactivity of both CDO gas and its chlorite by-product, residual CDO, chlorite, and chlorate concentrations are below those observed for approved aqueous treatments using CDO or ASC in solution, and residual concentrations are often below the analytical limit of detection (LOD) (GRN 000161; Gomez-Lopez et al., 2009; Stubblefield et al., 2014). Due to the lack of appreciable residues of chlorine dioxide, chlorate, or chlorite post CDO gas treatment, there is no need for the potable water rinse that is currently requited for aqueous treatments, such as with ASC. The ability to eliminate the requirement for the post-treatment rinse allows for a reduction in waste water effluent, further protecting environmental concerns (NOSB, 2016; Clordisys, 2016).

Years of CDO use for water treatment have had no reported adverse environmental effects, and the proposed methods in this petition would use lower concentrations than present in water treatment applications (Gomez-Lopez et al., 2009). CDO has also been documented as facilitating oxidation, rather than chlorination processes. Importantly, this results in the absence of trihalomethanes (THMs), which are documented environmental hazards and carcinogens.

Despite the anticipation of low levels of persisting CDO and subsequently formed chlorite, both substances have been documented as being dangerous to aquatic environments (FDA, 2006). However, environmental studies show that the LC_{50}s for a range of aquatic species are higher than the anticipated concentrations for the petitioned substances, which, combined with the reported facile degradation of CDO and sodium

chlorite, indicate that concentrations of the substances in the environment will be insignificant compared to background environmental concentrations.

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

Chlorine dioxide is a known respiratory irritant, and irritant of the eyes and mucus membranes; however, due to lack of study, required concentrations for irritation are not well defined (WHO, 2000; IPCS, 2002; NOSB, 2016). The Occupational Safety and Health Administration (OSHA) has designated CDO as an air contaminant, and has established a short-term exposure limit of 0.3 ppm during any 15-minute period of a 10-hour workday, or a permissible exposure limit of 0.1 ppm for a time-weighted average over an 8-hour workday (29 CFR §1910.1000). However, as stated above in **Evaluation Question #9**, CDO is highly reactive, and is expected to rapidly decompose, making CDO exposure possible only for isolated on-site incidents.

Due to the rapid decomposition of CDO, it is unlikely to result in the formation of any human health effects. As seen in Equations 1 and 3, CDO rapidly decomposes to chlorite (ClO_2^-) and chlorate (ClO_3^-), with the final endpoint being chloride (Cl^-) (GRN 000161; JECFA, 2007a; Lee et al., 2015; EFSA, 2016; Clordisys, 2016; Park et al., 2017). Chloride is prevalent in nature and physiology, and therefore, will not provide an adverse impact at anticipated concentrations.

Both chlorite and chlorate are readily absorbed in the body; however, due to the physiological prevalence of chloride in the body, there are no reliable analytical methods to track their metabolism (EPA, 2000; WHO, 2000). Current studies suggest that following ingestion both oxychloro anions are reduced to chloride, which is excreted in urine (EPA, 2000). Furthermore, the estimated intake values anticipated of chlorite and chlorate are well below the no-observed-adverse-effect-level (NOAEL) of 30 mg/kg as identified by the WHO (WHO, 2000).

Neither chlorate, chlorite, nor CDO have been characterized as carcinogens (EPA, 2000; IPCS, 2002; Gomez-Lopez et al., 2009). CDO has also been documented as facilitating oxidation, rather than chlorination processes. Importantly, this results in the absence of trihalomethanes (THMs), which are documented environmental hazards and carcinogens.

The European Food Safety Authority (EFSA) has recently reviewed the possible effect of antimicrobial treatments for the emergence of antimicrobial resistance, and have reported that there are no documented cases of antimicrobial resistance from CDO treatments (EFSA, 2008).

Due to the low persistence of CDO, chlorite, and chlorate residues following product treatments with gaseous CDO, risks to human health due to implementation of antimicrobial CDO treatments are minimal (GRN 000161; Gomez-Lopez et al., 2009; Stubblefield et al., 2014; Park et al., 2017).

Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

Non-chemical treatments for inactivation of microorganisms are prevalent in the literature. These methods include irradiation with UV or pulsed light, as well as ionizing radiation, which has been regarded as among the most effective inactivation treatments (Ramos et al., 2013; Meireles et al., 2016).

Given the importance of fruits and vegetables to a balanced nutritional diet, the safeguarding of these products for consumption is paramount. With the possibility of contamination at several points along the supply chain—from growth/production, to processing and distribution—effective disinfection techniques are important to maintain the safety of agricultural products from foodborne pathogens, which is even more important given that these products may be consumed raw. Based on this information, in concert with studies that show water washes alone do no significantly reduce the prevalence of foodborne

pathogens, alternatives to microorganism safeguards are not recommended (Neal et al., 2012; Goodburn et al., 2013; Ramos et al., 2013; Park et al., 2015; Meireles et al., 2016).

Evaluation Question #12: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

Acids (Alginic, Citric, and Lactic)

Weak organic acids (e.g., alginic, citric, and lactic acids) are permitted under USDA NOP regulations at 7 CFR §205.605(a). Many organic acids also have widespread consumer approvals and GRAS status with the FDA and European Commission (EC) (Meireles et al., 2016). They have documented antimicrobial ability due to environmental pH reduction, which result in disturbances to membrane permeability, anion accumulation, and reduction of intracellular pH resulting interference to nutrient transport and macromolecular synthesis (Parish et al., 2003; WHO, 1998; Inatsu et al., 2005; and Miller et al., 2009).

However, the use of acids as disinfecting and sanitizing agents may result in changes to the organoleptic properties of the products, including flavor and other sensations (Meireles et al., 2016). The use of organic acids also may provoke corrosion in processing equipment, and has a high associated cost of use. The application of organic acids, such as citric acid, also requires a dramatic increase in concentration of the disinfectant ($5 \times 10^3 - 1 \times 10^4$ ppm for citric acid compared to < 200 ppm for CDO) (Meireles et al., 2016).

Enzymes

Enzyme's mode of action is the direct attack on the developmental processes of biofilms, and in the process catalyze the formation of antimicrobial agents, making them an effective means of biofilm inactivation and removal (Simones et al., 2010, Thallinger et al., 2013; Meireles et al., 2016).

However, the heterogeneous nature of enzyme treatments, coupled with the long treatment times required, limit their effectiveness as a standalone treatment option (Augustin et al., 2004; Lequette et al., 2010; Meireles et al., 2016).

Microorganisms

Microorganisms can be used as a means of eliminating foodborne pathogens, primarily by introduction of beneficial microorganisms, which compete for resources with pathogenic microorganisms (Ramos et al., 2013). Among the most prevalent microorganisms used for the prevention of pathogenic organisms is lactic acid bacteria (LAB). LAB not only competes for resources, but also produces antibacterial chemicals, such as organic acids and bacteriocins—most predominantly nisin (Rogers, 2008). While the application of microorganisms offers a promising alternative to chemical treatments, their uses are organism specific, and further research is required before their applications as disinfecting and sanitizing treatments are industrially viable (Ramos et al., 2013; Ling et al., 2015; Meireles et al., 2016).

Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b) (1)).

There are no direct reports in the literature that offer the use of an organic agricultural product (7 CFR §205.600(b)) as a viable alternative to the disinfection and sanitizing qualities of CDO gas generated from activation of sodium chlorite.

Report Authorship

The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:

- Philip Shivokevich, Assistant Professor of Chemistry, Lander University
- Audrey Nicoleau, Technical Writer, Savan Group

All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

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Sulfur TR:

Technical Review Sufficiency Determination

• Is consistent in format, level of detail and tone
The TR is consistent and provides clear explanation and sufficient detail.

• Is technically objective and free from opinions or conjecture
The research is presented objectively and without opinions or presumptions.

• Is written in a style appropriate for non-technical readers (e.g. free of technical jargon)
While there is technical jargon and chemical references, it is explained throughout the TR, and can be understood. The document is written in a manner to minimize additional research on the reader's part.

• Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance
The information gathering, information synthesis, document preparation and quality assurance is sufficient in this current TR.

• Is based on the best available information that can be obtained within the designated time frame
Reviews history of sulfur use appropriately.

• Is thoroughly supported using literature citations
Additional information on human epidemiological studies investigating sulfur exposure are needed.

• Addresses all evaluation questions in the TR template
All evaluation questions are addressed. Additional information on safety/use and potential community exposures would be valuable.

Overall the sulfur TR is sufficient. However, some additional information should be included:

1. Under Question #10: **Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).**

The report should review a recent study evaluating sulfur use and respiratory function in children livening near agricultural applications. See: https://ehp.niehs.nih.gov/ehp528/

Rachel Raanan, Robert B. Gunier, John R. Balmes, Alyssa J. Beltran, Kim G. Harley, Asa Bradman, and Brenda Eskenazi. Elemental Sulfur Use and Associations with Pediatric Lung Function and Respiratory Symptoms in an Agricultural Community (California, USA) Environ Health Perspect; DOI:10.1289/EHP528

2. Additional information on recent worker exposures and health impacts may be available through the California Department of Pesticide Regulation illness database: http://www.cdpr.ca.gov/docs/whs/2014pisp.htm

For example, up to 10 illness incidents were reported in 2014.

3. More information on the formulations would be useful. For example, there is a trend in California grape growing regions to promote wettable formulations versus dust for pesticide applications. More discussion on trends in the use of these formulations the potential for worker and community exposures would be valuable.

Petition sent to CS 01/09/18
Petition sufficiency /TR request due XXXXX
Additonal questions requested:
Petition found sufficient XXXX

Note: Subcommittee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

National Organic Standards Board (NOSB)
Materials/GMO ad hoc Subcommittee Meeting Notes
Tuesday, January 9, 2018 2:00 pm ET

Attending: Harriet Behar (HB), Chair; Dan Seitz (DS), Vice Chair; Lisa de Lima (LD); Dave Mortensen (DM)
Absent: Tom Chapman (TC); Emily Oakley (EO)
Staff: Michelle Arsenault (MA); Lisa Brines (LB); Paul Lewis (PL)

Work agenda

Materials Projects	Contact	Notes	Discussed, Voted	Meeting
Research Priorities Proposal May 2012 Framework Proposal	EO	Subcommittee reps to MS DS - LS EO - CS LD - HS RPs from Subcomm due to MS in July	NA	Fall 2018
Petition and TR tracking	HB/LB	Ongoing	NA	NA
GMO Projects	**Contact**	**Notes**	**Vote**	**Meeting**
Non-GMO organic seed integrity proposal (formerly Seed Purity from GMOs)	DS, DM, HB	Part of Seed purity doc will be incorporated into "Prevention Strategies for Excluded Methods in Crops and Handling" doc. MS submitted a request to the ES in August to convene a seed purity task force. Pending NOP approval, for future work agenda.	Jan 23	Spr 2018
Excluded Methods Terminology	HB	Proposal	Jan 9	Spr 2018

Other Projects

Project Idea	Contact	Notes*	Vote	Meeting
Contamination of Farm Inputs Discussion Document	HB	Moved to Materials from Crops for continued work.	Jan 23	Spr 2018
Sanitizers	HB, EO, JM, AB	Pending NOP approval	Jan 9	Spr 2018

Agenda

- Approval of December 12, 2017 notes
- Materials and TR update (LB)
- Sanitizers review update (HB and NOP)
- Genetic integrity of seed used on organic land (DS, DM, HB)
- Excluded methods terminology (HB)
- Contamination of farm inputs (HB)
- Other items
- Adjourn

Discussion

- **The notes of** December 12 were approved with no changes.
- **Materials and TR update (LB).** The NOP sent the January materials report last week, and asked for feedback or edits. LB updated the group on pending TRs, petitions (one for Livestock), and a petition addenda in progress for Polyoxin D zinc salt. LB also noted her impending departure from NOP on January 19; the NOP will provide an update on the January 12 Executive call about the transition.
- **Sanitizers review update (HB and NOP).** The MS is revising a work agenda request for sanitizers, and is seeking additional feedback from NOP about its request to refine the project, given the broad scope. The goal is to conduct a comprehensive review of sanitizers to develop a framework, which the NOSB could use to review future petitions. Currently there are a number of sanitizers in various sections on the National List, and it is difficult to determine the need for new ones based on what is currently available. The group discussed various resources in order to move this forward, including a technical report that focuses on alternatives and/or advice from academia. A member suggested adding specific questions to the TR request, and perhaps for future petitioners. The NOP reminded the group that the requested information must align with OFPA criteria.
- **Genetic integrity of seed used on organic land (DS, DM, HB).** The group discussed a preliminary draft proposal on genetic integrity of seed, including tolerance levels, testing, and who would bear the cost. A member offered that as a consumer, the regulations can be very complex, and any progress the NOSB could make in this area would be beneficial to protect consumers without necessarily requiring rulemaking. The will of the group is to develop a document for the Spring meeting to elicit public feedback. The co-leads will discuss this further and reach out to other NOSB members. The Subcommittee will discuss this again on the next call.
- **Excluded methods terminology (HB).** On the last MS call the NOP noted that the NOSB should not recommend definitions for excluded method technologies that are different than those used by others parts of USDA. The NOP suggested that the NOSB defer to APHIS, since they are the regulatory agency responsible for defining those terms. A member noted that the MS is seeking to define approximately eight (8) terms or technologies, which are not controversial, and which are already accepted by the biotechnology community. The MS could develop a draft document, then seek feedback from APHIS, on these terms. A member expressed concern about the pace of the project if the NOSB has to wait for another government agency to produce a list of technologies, when the industry is moving at a much quicker pace.
- **Contamination of farm inputs (HB).** Deferred to next call.
- **Other items.** The MS added an additional call on January 23, 2018, and may add one more.
- **The meeting was adjourned**

Previous MS Notes

Future Call Schedule (2nd Tuesday 2:00 ET)

December 12, 2017
January 9, 2018
January 23, 2018 - additional call
Contamination of farm inputs (HB).
Genetic integrity of seed used on organic land (DS, DM, HB).
February 13, 2018
March 13, 2018
April 10, 2018
May 8, 2018
June 12, 2018
July 10, 2018
August 14, 2018
September 11, 2018
October 9, 2018
November 13, 2018
December 11, 2018

Spring 2018 Milestones	Target dates (tentative)
New NOSB member orientation	TBD
NOSB - Spring 2018 proposals due to NOP	Feb 21, 2018
NOP - Complete Spring 2018 NOSB meeting tentative agenda	Mar 6, 2018
NOP - Post proposals, "Open" public comment	Mar 6, 2018
Discuss work agendas on ES call	Mar 9, 2018
Public comment closes	Apr 4, 2018
NOP - Send compiled public comments to NOSB	Apr 9, 2018
Work agendas finalized on ES call (last call before fall meeting)	Apr 13, 2018
Public comment webinar(s)	Apr 17 & 19, 2018
Spring 2018 NOSB meeting – Tucson, AZ	Apr 25-27, 2018

Protecting the Genetic Integrity of Organic Seed ---Harriet Behar draft January 9, 2018

The USDA National Organic Program regulations do not allow the use of "excluded methods" in certified organic production. Excluded methods is the term used when referring to Genetic Engineering (GE). The USA has many GE crops, 94% of the soybeans, 92% of the corn, 94% of the cotton (cottonseed oil is a foodstuff derived from cotton), 75% of the Hawaiian papaya crop, 90% of the sugar beets and 90% of the canola is Genetically Engineered. Planting stock is not immune to Genetic Engineering, with the non-browning apple poised to be in the marketplace in a few years, as well as fish, pigs, and a wide variety of vegetables and fruits. Various traits are engineered into these crops, with herbicide resistance the main trait and the presence of insecticides in every speck of DNA within those plants the second most popular trait inserted into the genetic material of these patented and unique "life forms".

There is no testing required by the USDA organic regulations, either of seed nor of crops, for the presence of unwanted genetically engineered materials. For many years farmers, who purchase and plant nonorganic seed due to the lack of organic seed commercial availability, have needed to obtain nonGE affidavits if their seed is a type that has a Genetically Engineered equivalent in the marketplace. These affidavits have been accepted as proof by their organic certifiers, that the seed is nonGE. Even if a seed or crop has been found to be "contaminated" with unwanted genetic material, technically it does not lose its organic certification status. Depending on the requirements of the ultimate buyer, and the integrity of the seller, some of these known contaminated seeds and crops are expected to make it into the organic production stream and ultimately the organic market.

In the raw crop marketplace, there is a "wild-west" attitude where some buyers are performing extensive and expensive testing and others perform more inexpensive tests, only periodically, or none at all. Some buyers do testing of grower supplied samples, semis when they are unloaded at the facility and of cleaned product before it is shipped out to the next customer. Others do not. This inconsistency in the marketplace, both for seed and for the final crop, leaves organic growers vulnerable to the whim of buyers as well as to genetic contamination that occurred from no fault of their own in the field, during transport or at the cleaning facility. The European Union, as well as other international and domestic buyers, have a tolerance limit, allowing some GE contamination (.9%), while still accepting the product as organic. There are no prescribed or consistent GE tolerance levels for U.S. domestic organic production.

Most organic seed producers take protection of genetic integrity quite seriously. They monitor their custom growers, or their own facilities, when planning location, planting dates, pollination times for their crops in comparison to GE crops in the neighborhood, transportation and more. Even with this careful oversight, some corn seed breeders report almost 20% contamination of their organic corn seed with unwanted GE germplasm. These seed breeders then destroy these lots of seed. As a result, they raise the prices of the remaining organic corn seed to cover this loss, resulting in higher prices to organic farmers.

Since there is an allowance for the use of nonorganic seed when organic seed cannot be found of an equivalent variety in the quality and quantity desired, this offers another risk to GE contamination of organic crops. If you start out with GE contaminated seed, you multiply the amount you have once you have grown the crop. Nonorganic seed producers do not perform the same due diligence in testing and oversight to protect against GE contamination as organic seed breeders. Some may state in their nonGE affidavits that their assessment of nonGE presence is "to the best of their ability", since they are not actually testing to prove this statement as true.

The issue of maintaining the genetic integrity of organic and nonorganic seed and planting stock grown on organic land and sold in the organic marketplace is complex with no easy answers. Organic seed and planting stock growers and the farmers who buy their products can be at odds, even though they are both seeking the same outcome of avoidance of GE whenever possible. Non-GE labeling such as the nonGMO project is not a guaranteed 100% GE free, with a .9% tolerance level allowed in foods for human consumption and a 5% allowance of GE contamination in livestock feeds whose final product would then be labeled as nonGMO or nonGE. Organic producers, who are expected to have a 0% tolerance, lose market share to nonGMO labeled products who allow this tolerance level yet consumers believe the two are identical when it comes to GE contamination.

The challenges of protecting the genetic integrity of seeds used in organic production are not small ones, but the organic community of seed breeders, farmers, processors and consumers need clear direction from the National Organic Program for consistency and organic integrity.

The NOSB proposes the following be placed into NOP guidance.

a. All lots of organic seed that have a GE equivalent or are at risk of cross pollination by similar species, should be tested for presence of GE contamination, with .9% the maximum allowed presence.
b. All lots of nonorganic seed that have a GE equivalent or are at risk of cross pollination by similar species, should be tested for presence of GE contamination, with .9% the maximum allowed presence.
c. Further research needs to be done to determine if different crops should have the same percentage of GE tolerance, but for now all levels are .9%.
d. Based upon the pervasiveness of GE contamination and the higher risk of movement of various crops' genetic material in the wind and other means, should there be different GE contamination tolerance percentages by crop?
e. Seeds that have been bred with traits which prevent cross pollination, do not need to have each lot tested, but there should be documentation with spot checks that no GE traits have been found in the seed. The protocols are listed below for this type of spot checking…..
f. Personnel taking the samples have read and follow the attached protocol for the sampling methods.
g. The following sampling methods are acceptable….
h. The following testing methods are acceptable….
i. The following testing laboratories are approved….

Note: Subcommittee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

National Organic Standards Board (NOSB)
Livestock/Aquaculture Subcommittee (LS) Meeting Notes
Tuesday, January 16, 2018 3:00 pm ET

Attending: Ashley Swaffar, (AS), Chair; Sue Baird (SB), Vice Chair; A-dae Romero-Briones (ARB); Harriet Behar (HB); Dan Seitz (DS);
Absent: Jesse Buie (JB); Francis Thicke (FT)
Staff: Devon Pattillo (DP); Michelle Arsenault (MA)

Work Agenda

Petitioned Materials						
Substance	**Nat'l List §**	**Contact**	**TR requested**	**Notes**	**Scheduled, Discussed, Voted**	**Meeting**
Thymol Petition Addendum	205.603	HB		Petition sent to LS 02 01 17. Response/request for TR due 03 03 17. LS requested additional info from petitioner. Petition addendum sent to LS 05 26 17. Response due 07 25 17. LS sent additional questions to petitioner 08 15 17. Response sent to LS 10 06 17. LS requested additional info 12 08 17. Petitioner notified of insufficiency; Resubmission expected.	Mar 7, Apr 4, Aug 1, Oct 17	Spr 2018
Glycolic Acid, 2016	205.603	AS	Y	Petition sent to LS 06 06 15. Response/request for TR due 08 08 16. TR requested 07 19 16. TR sent to LS 11 07 17. Response/request for TR due 01 08 18. TR found sufficient 12 19 17.	Jul 19, 2016, Dec 19	Spr 2018
Oxalic Acid	205.603	HB	Y	Petition sent to LS 10 27 17. Response/request for TR due 12 26 17. Petition found suff 12 5 17. TR Requested 12 5 17	Dec 5	TBD
Aquaculture Substances (See table below)				On hold until aquaculture rule is published.	TBD	TBD

2020 Sunsets TR Requests: July 2017, Summary: Spr 2018, Review: Fall 2018						
Name	**National List §**	**Con tact**	**TAP/TR**	**Notes**	**Scheduled, Discussed**	**Review Meeting**

Alcohols: Ethanol, Isopropanol	205.603	JB	N	1995 TAP; 2014 TR Ethanol; 2014 TR Isopropanol	Dec 5	Summary: Spr 2018 Review: Fall 2018
Aspirin	205.603	AS	Y	1995 TAP. TR requested 07 28 17. TR in contracting. TR sent to LS 12 20 17. Response due 02 19 18	Dec 19	"
Biologics, Vaccines	205.603	HB	N	2011 TR (Vaccines from Excluded Methods); 2014 TR (Aquaculture)	Dec 19	"
Electrolytes	205.603	HB	N	1995 TAP; 2015 TR	Dec 19	"
Glycerine	205.603	SB	N	2010 TAP (Livestock)	Feb 6	"
Phosphoric acid	205.603	DS	N	2003 TAP (Handling). Low priority	Jan 16	"
Lime, hydrated	205.603	ARB	N	1995 TAP; 2015 TR	Feb 6	"
Mineral oil	205.603	ARB	N	2002 TAP; 2015 TR	Feb 6	"
Sucrose octanoate esters	205.603	SB	N	2005 TR	Feb 6	"

Other projects

Project	Contact	TR Reqst ?	Notes	Discussed, Voted	Meeting
Defining emergency treatment for parasiticides	HB	N	Approved for addition to work agenda 07 15 16. Discussion doc. Postponed until Fall 2017	Dec 5, Dec 19, Jan 16, Feb 6, Feb 20	Proposal Spr 2018
Research Priorities (RP)	HB/AS/SB	NA	RPs due to MS Aug 2017		Fall 2018
Organic poultry task force	ARB/AS/HB		Discuss formation of Task Force - on hold pending resolution of OLPP final rule.	NA	NA

* Yellow highlight indicates committee action needed *Highlight indicates review completion/vote taken

Agenda

- Approve notes from December 19, 2017
- 2020 sunset: Glycerine (SB) - discuss
- 2020 sunset: Sucrose octanoate esters (SB) - discuss
- 2020 sunset: Phosphoric acid (DS) - discuss

- 2020 sunset: Lime, hydrated (ARB) - discuss
- 2020 sunset: Mineral oil (ARB) - discuss
- 2020 sunset: Biologics, Vaccines (HB) - discuss
- Defining emergency treatment for parasiticides (HB)
- Other items
- Adjourn

Discussion

- **Notes from the** December 19 were approved with no changes
- **2020 sunset: Phosphoric acid (DS).** Phosphoric acid was recently reviewed and the Board voted unanimously to have it remain on the list. The lead will forward the current review to the Chair for submission to the NOP.
- **2020 sunset: Biologics, vaccines (HB).** The lead noted that vaccines are preventative and the NOSB supports continued listing**.** The group discussed adding a single listing for all GMO vaccines, rather than listing them individually. A member added that there are sometimes issues with implementation and certification, as some operations are referencing the National List and some are using the regulation. The LS would like to add this to the work agenda, acknowledging that currently they are not being encouraged to work on any projects outside of sunset or petitions. The group discussed framing the request in terms of enforcement, or perhaps submitting a petition. Members edited some of the questions in the draft review, and the lead will edit the draft document for further discussion on the next call.
- **Defining emergency treatment for parasiticides (HB).** The lead posed some questions to the group regarding guidance. The Subcommittee expressed an interest in working on hierarchy and methods for use of parasiticides, before inputs are considered. The goal would be to put some tools in place, without necessarily mandating them. The LS Chair suggested a definition for "emergency" rather than a rule or guidance, as there was no public support for developing a hierarchy. Members are supportive of enhancing the definition. The NOP noted that there are already some requirements for use of parasiticides included, although they could be clarified or expanded upon.
- **2020 sunset: Glycerine (SB). Deferred to next call.**
- **2020 sunset: Sucrose octanoate esters (SB). Deferred to next call.**
- **2020 sunset: Lime, hydrated (ARB). Deferred to next call.**
- **2020 sunset: Mineral oil (ARB). Deferred to next call.**
- **Other items**
- **The meeting was adjourned.**

Previous LS Notes

Future Call Schedule (1st and 3rd Tuesdays 3:00 ET)

December 19, 2017
- Glycolic Acid (AS) - TR suff due
- 2020 sunset: Aspirin (AS) - discuss
- 2020 sunset: Biologics, Vaccines (HB) - discuss
- 2020 sunset: Electrolytes (HB) - discuss
- Defining emergency treatment for parasiticides (HB)

January 2, 2018 - cancelled

January 16, 2018
- 2020 sunset: Glycerine (SB) - discuss

2020 sunset: Sucrose octanoate esters (SB) - discuss
2020 sunset: Phosphoric acid (DS) - discuss
2020 sunset: Lime, hydrated (ARB) - discuss
2020 sunset: Mineral oil (ARB) – discuss
2020 sunset: Biologics, Vaccines (HB) - discuss
Defining emergency treatment for parasiticides (HB)

February 6, 2018

2020 sunset: Glycerine (SB). Deferred to next call.
2020 sunset: Sucrose octanoate esters (SB). Deferred to next call.
2020 sunset: Lime, hydrated (ARB). Deferred to next call.
2020 sunset: Mineral oil (ARB). Deferred to next call.
2020 sunset: Biologics, vaccines (HB).
Defining emergency treatment for parasiticides (HB)

February 20, 2018

Defining emergency treatment for parasiticides (HB)

March 6, 2018
March 20, 2018
April 3, 2018
April 17, 2018
May 1, 2018
May 15, 2018
June 5, 2018
June 19, 2018
July 3, 2018
July 17, 2018
August 7, 2018
August 21, 2018
September 4, 2018
September 18, 2018
October 2, 2018
October 16, 2018
November 6, 2018
November 20, 2018
December 4, 2018
December 18, 2018

Spring 2018 Milestones	Target dates (tentative)
New NOSB member orientation	TBD
NOSB - Spring 2018 proposals due to NOP	Feb 21, 2018
NOP - Complete Spring 2018 NOSB meeting tentative agenda	Mar 6, 2018
NOP - Post proposals, Open public comment	Mar 6, 2018
Discuss work agendas on ES call	Mar 9, 2018
Public comment closes	Apr 4, 2018

NOP - Send compiled public comments to NOSB	Apr 9, 2018
Work agendas finalized on ES call (last call before fall meeting)	Apr 13, 2018
Public comment webinar(s)	Apr 17 & 19, 2018
Spring 2018 NOSB meeting – Tucson, AZ	Apr 25-27, 2018

Aquaculture petitions						
Substance	**Nat'l List §**	**Contact**	**TR requested**	**Notes**	**Scheduled, Discussed, Voted**	**Meeting**
Aquaculture-CO_2, (for aquatic plants)	205.609	TF/CBo	N	Petition sent to CS 5 30 12. Will rqst modification from petitioner (for use pattern). Updated petition was deemed sufficient. TR deemed unnecessary.	NA	Proposal TBD
Aquaculture-Chlorine (for aquatic plants)	205.609	FT	2011 Crops TR 2006 TR 1995 TAP	Petition sent to CS on 5 30 12. Determine petition sufficiency. CS requested clarification from petitioner 11 20 12. 2011 TR deemed suff for this review 11 20 12. Additional aquaculture TR deemed unnecessary. Sent follow up questions to petitioner. Response deemed sufficient.	NA	Proposal TBD
Aquaculture-Micronutrients (for aquatic plants)	205.609	FT	2010 TR (Nickel) 6/2013 Minerals TR	Petition sent to CS on 06 08 12. Petition sufficiency response due 08 08 12? CS sent request to NL Mgr. 12 04 12 for additional info. Questions clarified by petitioner. Petition found sufficient 06 18 13 and 07 02 13. TR deemed unnecessary.	NA	Proposal TBD

Aquaculture-Lignin sulfonate (chelating agent for aquatic plants) CAS #s 9009-75-0, 8062-15-5, 8061-51-6	205.609	JR	2/2011 Crops TR 7/2013 TR Aquatic Animals TR	Petition sent to CS on 07 03 12. Petition Sufficiency Response due 09 04 12. CS sent request to NL Mgr 12 04 12 for additional info and TR. Questions clarified by petitioner. Petition found sufficient 6 18 13 and 07 02 13.	NA	Proposal TBD
Aquaculture-Vitamins (B1, B12, H) for aquatic plants	205.609	CW	4/2013 Aquatic Animals TR	Petition sent to CS 08 10 12. Petition Sufficiency response due 10 10 12. Petition found sufficient 06 18 13.	NA	Proposal TBD
Aquaculture - Biologics: Vaccines for Aquatic Animals	205.611	JR	2011 TR (Vaccines made from GMOs)	Petition sent to LS 06 14 12. Petition found sufficient and TR requested on 05 21 13. (NOP note: TR sent to LS 01 24 14. TR deemed sufficient 02 03 14	NA	Proposal TBD
Aquaculture - Chlorine (for aquatic animals)	205.611	FT	N Crops 2011 Crops 2006 Crops 1995 Livestock 2006 Handling 2006	Petition sent to LS on 05 30 12. Petition found sufficient 07 03 12. No TR requested	NA	Proposal TBD
Aquaculture – Tocopherols (for aquatic animals)	205.611	TF/CBo	2013 TR 1995 TAP rvw	Petition sent to LS on 05 30 12. Petition found sufficient 08 06 12. TR requested 08 06 12. Draft TR sent to LS on 04 16 13. TR found sufficient 06 04 13	NA	Proposal TBD
Aquaculture – Vitamins (for aquatic animals)	205.611	CW/FT	Yes 2013 TR	Petition sent to LS 05 30 12. Response due ~07 30 12. Petition found suff 08 06 12. Requested joint TR with minerals 08 06 12. TR sent to LS 04 29 13. TR found suff 06 18 13.	NA	Proposal TBD
Aquaculture - Trace Minerals (for aquatic animals)	205.611	CW/FT	2013 TR	Petition sent to LS on 06 08 12. Response due ~08 08 12. Petition found sufficient 08 06 12? Requested joint TR with Vitamins 08 06 12. TR sent to LS 06 25 13. Suff due 08 27 13. TR found sufficient 07 16 13. Fall 2013 meeting cancelled.	NA	Proposal TBD

NOSB Crops Subcommittee
Polyoxin D Zinc Salt
TR Sufficiency Review

January 16, 2018

Introduction

Polyoxin D Zinc Salt (EPA Reg. No. 68173-1) is a fungicide derived from *Streptomyces cacaoi* var *asoensis,* a soil borne microorganism, through an aerobic fermentation process. The active portion of Polyoxin D Zinc Salt is Polyoxin D which is produced by a microorganism that is naturally occurring in the soil. Polyoxin D inhibits the growth of phytopathogenic fungal cell wall chitin by competitively inhibiting chitin synthease. Without chitin, susceptible fungi are unable to continue growing and infecting plant cells.

Background

Polyoxin D Zinc Salt was petitioned in 2012 as a synthetic substance to be allowed for use in Organic Crop Production (CFR 205.601). The NOSB noted in its Petitioned Material Proposal that the manufacturer of Polyoxin D Zinc Salt could not confirm the source of the zinc salt, as to whether it was "virgin" zinc from a mine or from a recycled zinc source. Furthermore, the manufacturer chose to withhold disclosure of its manufacturing process, citing it as proprietary and confidential business information. The listing motion in the subcommittee was rejected by a vote of 3 yes, 4 no and 1 abstention.

On April 11, 2013, the formal recommendation of the NOSB to add Polyoxin D Zinc Salt to 205.601 in the National List failed by a vote of 6 yes and 9 no. The rationale being that the material was deemed non-essential.

In Kaken Pharmaceutical Co., Ltd response to NOP TR dated September 23, 2012, zinc is a mined material and zinc is also recycled. Both links provided for documentation purposes were not functional. Their response goes on to state that Kaken is not the producer of the zinc source used in the production of Polyoxin D Zinc Salt and does not know if the zinc is "virgin" zinc from a mine or recycled zinc.

Finally, a review of the status of Polyoxin D Zinc Salt among international organizations was reviewed in the December 12, 2017 TR. The Japanese Agricultural Standard for Organic Production does not include Polyoxin D Zinc Salt on Table 2. (JMAFF, 2012). Evaluation Question#5 line 226 states that Polyoxin D Zinc Salt has been in use as an antifungal agent for over 40 years in Japan on rice and approved in the USA and Mexico on food crops for over 5 and 3 years respectfully and for non-food crops in the USA for over 16 years. The product is derived naturally in Japan from *Steptomyces cacaoi* var *asoensis* and has a unique mode of activity by inhibiting fungal cell wall synthesis.

Below are questions and answers posed by the Subcommittee during the previous review process. These responses are from the firm Conn & Smith, Inc., Professionals in Pesticide Regulatory Services in a letter dated October 26, 2017. These questions and answers are significant as we move forward in the current review process.

Q1 a: Could Polyoxin D function without the zinc salt added to it to improve surface retention?

A1a: Polyoxin D without the zinc salt is not an EPA registered pesticide. It would be prohibitively costly to pursue EPA registration of polyoxin D (without the zinc) as a new active ingredient. New efficacy studies would be required. Commercially viable efficacy is not anticipated. If commercially viable efficacy could be demonstrated, well over 1 million dollars in new EPA registration studies would be required.

Surface tension is not the issue. Water solubility is the issue. Polyoxin D is very water soluble and would wash off the plant surface. Contact with the plant surface is needed for efficacy.

Q1 b: Would there be a possible replacement that would be non-synthetic?

A1 b: This will depend upon the published efficacy data for each crop/ disease combination of any candidate non-synthetic replacement. This question also misses an important point. Polyoxin D zinc salt provides a new mode of action for organic growers who already have a short list of available modes of action. A new mode of action provides a tool for resistance management. Pathogen resistance to some fungicide active ingredients has been observed. More information of fungicide resistance is available from the Fungicide Resistance Action Committee at http://www.frac.info/home.

Q1 c: What is the action and use of Polyoxin D complex by itself compared to with zinc added?

A1 c: "Polyoxin D complex" does not exist. • Polyoxin D zinc salt is an EPA registered pesticide. • Polyoxin complex is not an EPA registered pesticide. Polyoxin complex is produced by Kaken and registered by Kaken for use in Asia. Polyoxin complex is chemically quite different than polyoxin D and polyoxin D zinc salt. • Polyoxin D zinc salt and polyoxin complex have very different efficacy. World-wide, there is: • No commercial production of polyoxin D without the conversion to the zinc salt; and • No commercial use of polyoxin D without the conversion to the zinc salt. The pending petition is limited to polyoxin D zinc salt and its SSC (S% suspension concentrate) formulation.

Q2: There are numerous studies referenced by the petitioner that the Subcommittee would like verification on to help with the validity of the claims of the petitioner. Some specific examples are studies referenced for: soil studies, beneficial insect impact studies, impact on beneficial soil fungi, mode of action, etc.

A2: Kaken welcomes the comments of the technical reviewer. Kaken notes: • The studies on soil, beneficial insects, and beneficial soil fungi are applied biology studies, whereas the mode of action studies is physical chemistry (kinetics) studies. • To provide the requested technical evaluation, the technical reviewer will need technical expertise in both biology and physical chemistry (kinetics).

Q3a: Update on global organic use or recognition?

A3 a: The polyoxin D zinc salt SSC formulation is specifically designed for the US organic market. At this time, organic use has been requested for the US only. No applications have been approved or are pending in other parts of the world. Correction of the error-filled September 23, 2012 NOP technical report is effectively a necessary first step before Kaken can realistically consider requesting organic approval in any other part of the world.

Q3 b: Any changes?

A3 b: Yes, there have been many changes in the United States and internationally. An NOP petition supplement is planned.

Technical Review Sufficiency Determination

• **Is consistent in format, level of detail and tone**
The TR is consistent and provides clear explanation and sufficient detail.

• **Is technically objective and free from opinions or conjecture**
The research is presented objectively and without opinions or presumptions.

• **Is written in a style appropriate for non-technical readers (e.g. free of technical jargon)**
While there is technical jargon and chemical references, it is explained throughout the TR, and can be understood. The nature of the topic requires advanced technical knowledge, but the document is written in a manner to minimize additional research on the reader's part.

• **Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance**

The information gathering, information synthesis, document preparation and quality assurance is sufficient in this current TR.

• **Is based on the best available information that can be obtained within the designated time frame**
The TR contains information that is important to the Crops Subcommittee in determining the validity of the petitioner's use of this product.

• **Is thoroughly supported using literature citations**
The TR is well-referenced and includes approximately 33 citations spanning both recent and earlier research on the subject.

• **Addresses all evaluation questions in the TR template**
All evaluation questions are adequately addressed. Additionally, subsequent questions posed by the Crops Subcommittee were addressed in the Limited Scope Technical Review completed by Conn and Smith in a letter dated October 26, 2017.

Petition sent to CS 06.16.16
Petition sufficiency /TR request due 08 16 16
Petition found sufficient 08.16.16
CS requested Limited Scope TR 10. 04. 16
Limited Scope TR received 10.26.17
Updated Draft TR Report 12.12.17

Calcium Carbonate

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
Calcium carbonate
Marble
Limestone
Vaterite
Calcite
Carbonic acid, calcium salt
Chalk

Other Name:
E 170
Aragonite
Dolomite
Calcium milk

Trade Names:
Caltrate
Maalox
Tums
Oyster Shell Calcium
Alcalak

CAS Numbers:
471-34-1 (calcium carbonate)
308068-21-5 (marble)
1317-65-3 (limestone)
13701-58-1 (vaterite)
13397-26-7 (calcite)
72608-12-9 (carbonic acid, calcium salt)
13397-25-6 (chalk)

Other Codes:
CI: 77220 (calcium carbonate)
INS: 170(i) (calcium carbonate)
ICSC: 1193 (calcium carbonate)
UNII: H0G9379FGK (calcium carbonate)
EC: 207-439-9 (calcium carbonate)
EC: 215-279-6 (limestone)
EC: 603-785-3 (calcite)
EC: 615-782-4 (carbonic acid, calcium salt)
EC: 603-784-8 (chalk)

Summary of Petitioned Use

Calcium carbonate is currently allowed under the National Organic Program (NOP) regulations at 7 CFR 205.605(a) as a nonagricultural nonsynthetic substance that may be used as an ingredient in or on processed products labeled "organic" or "made with organic (specified ingredients or food group(s))." Within food production, calcium carbonate has many applications including use as a coloring agent, acidity regulator (pH), food stabilizer, anticaking agent, and for nutritional fortification (EFSA, 2011c).

Characterization of Petitioned Substance

Composition of the Substance:
Calcium carbonate is an inorganic salt of natural (nonsynthetic) origin found in mineral deposits such as limestone and chalk. Calcium carbonate is among the most abundant matter in the earth's crust, with a composition of approximately 10% of sediments (Al Omari et al., 2016). Calcium carbonate is commercially available as a white microcrystalline powder of varying particle sizes, with a purity ≥98% (EFSA, 2011c).

Source or Origin of the Substance:
Calcium carbonate is isolated from natural mineral formations, primarily limestone and chalk, and from oyster shells. Calcium carbonate is isolated from raw minerals by calcination, a process of "heating to high temperatures in air or oxygen," during which the calcium carbonate ($CaCO_3$) is converted to calcium oxide (CaO), with carbon dioxide (CO_2) gas being released during the process (Al Omari et al., 2016; IUPAC, 2014). Calcination is followed by slaking, a process in which the calcium oxide (CaO) is hydrated through the addition of water (H_2O) to form the more stable form of lime, calcium hydroxide ($Ca(OH)_2$) (Hassibi, 1999). Finally, calcium carbonate is reformed in a purified state through the process of carbonation, in which carbon dioxide (CO_2) gas is bubbled through an aqueous slurry of calcium hydroxide ($Ca(OH)_2$),

resulting in the formation and precipitation of calcium carbonate ($CaCO_3$) (Domingo et al., 2004; EFSA, 2011c). Calcium carbonate may also be produced by crystallization of $CaCO_3$ formed via a salt metathesis reaction (Weiss et al., 2014).

Properties of the Substance:

The properties of calcium carbonate are summarized in Table 1.

Table 1. Properties of Calcium Carbonate

CAS Registry Number	471-34-1
Molecular Formula	$CaCO_3$
Molecular Weight	100.09 g/mol
Appearance	A white or nearly white powder or microcrystalline powder
Bulk Density	ca. 400 – 1,400 kg/m^3
Melting Point	825 °C (decomposition)
Water Solubility	0.14 g/L (20 °C)

Sources: PubChem 10112; Al Omari et al., 2016; Millipore-Sigma, 2015; EFSA, 2011c.

Specific Uses of the Substance:

Calcium carbonate is used for a wide range of applications in the food and agriculture industries. These applications include use as a coloring agent, food stabilizer, anticaking agent, gelling agent, glazing and release agent, thickener, bulking agent, acidity regulator, dough conditioner, and nutritional fortification additive (Al Omari et al., 2016; EFSA, 2011c; NOSB, 1995; NOSB, 2015). In addition to being a nutritional additive to food, calcium carbonate is also used as a dietary supplement, and in antacids (EFSA, 2011c; NOSB, 2015; PubChem 10112).

Calcium carbonate is also used in agricultural practices for the treatment and conditioning of soils, primarily as a means of adjusting soil pH. These treatment and conditioning practices may use calcium carbonate in a variety of forms, ranging from the precipitated salt to ground limestone (USGS, 2008). Moreover, calcium carbonate has been used in formulations to protect trees and their fruits (in orchards) from browsing game damage, when applied as a liquid solution that hardens to form a protective coating (EFSA, 2011a, b).

Approved Legal Uses of the Substance:

The United States Department of Agriculture (USDA) NOP has approved the usage of calcium carbonate at 7 CFR 205.605(a) as a nonagricultural, nonsynthetic substance that may be used as an ingredient in or on processed products labeled "organic" or "made with organic (specified ingredients or food group(s))."

The United States Environmental Protection Agency (EPA) allows the use of calcium carbonate as an "inert ingredient permitted in minimum risk pesticide products," at 40 CFR 152.25. The EPA also allows calcium carbonate as an "inert ingredient applied to animals," at §180.930.

The United States Food and Drug Administration (FDA) allows the use of calcium carbonate as a "color additive mixture for coloring drugs" at 21 CFR 73.1070, and as a "color additive mixture for coloring foods" at §73.70. The FDA allows the use of calcium carbonate in "lakes (Ext. D&C)" for "eternally applied drugs and cosmetics," at §82.2051. Calcium carbonate is also approved for use as a "colorant for polymers" at §178.3297. The FDA allows the use of calcium carbonate as a "component of the food-contact surface of paper and paperboard" at §176.170.

The FDA allows the use of calcium carbonate as an "active ingredient" in "antacid products for over the counter (OTC) human use" at §331.11. The FDA allows the use of calcium carbonate as a food stabilizer at §181.29 and §169.115. The FDA allows the use of calcium carbonate as a binding agent in meat and poultry pieces at §424.21.

The FDA has allowed the usage of calcium carbonate for the production of calcium citrate by the neutralization of citric acid at §184.1195, the production of calcium gluconate by the neutralization of gluconic acid at §184.1199, the production of calcium glycerophosphate by the neutralization of glycerophospjoric acid at §184.1201, the production of calcium lactate by the neutralization of lactic acid at §184.1207, and for the production of calcium oxide (CaO) by "calcination at temperatures of 1,700-2,450 °F" at §184.1210.

The Alcohol and Tobacco Tax and Trade Bureau (TTB) of the United States Department of the Treasury allows the use of calcium carbonate for the "treatment of wine and juice" at 29 CFR 24.246(2b).

Action of the Substance:

Calcium carbonate has several uses, with the primary applications being for regulation of acidity and for nutritional fortification of foods. In terms of regulation of acidity, there are several venues for this application, including the regulation of the gastrointestinal pH of humans, the acid contents in food and beverages (e.g., wine), and the pH of soils. In these applications, the carbonate anion acts as a base, which is able to neutralize both strong and weak acids, resulting in the formation of a new calcium salt and carbon dioxide (CO_2) gas (Al Omari et al., 2016; EFSA, 2011c; Holman and Stone, 2001; Oates, 1998). Although calcium carbonate has very low water solubility, the ionic compound is broken up by acids, greatly increasing the solubility of the calcium cation, and providing access to the basic properties of the carbonate anion (EFSA, 2011c; Oates, 1998).

Calcium carbonate is also used for nutritional fortification of food, as well as a dietary supplement. When used in this capacity, the water insoluble calcium carbonate is broken into its corresponding ions by stomach acid, as described above in acid regulation. Once the calcium ion has been liberated from the carbonate anion, it can be absorbed by the body via both active transport and passive diffusion, with the remainder of the ion being excreted in feces (Heaney, 2002). Once absorbed by the body, the majority of calcium is stored in the skeleton (EFSA, 2011c).

Combinations of the Substance:

Calcium carbonate is commercially available as a white or nearly white powder or microcrystalline powder without additional substances (e.g., inert ingredients, stabilizers, preservatives, carriers, anticaking agents, or other materials), with a purity ≥98%. When sold as ground limestone, the majority of the product is comprised of calcium carbonate (≥94%), although it has been noted that due to the natural formation of limestone, other minerals, including aluminum and magnesium, may be present in variable amounts (Al Omari et al., 2016; EFSA, 2011c; USGS, 2008).

Calcium carbonate is also a precursor to the substance calcium citrate, which is identified on the National List. As described above in **Approved Legal Uses of the Substance**, calcium citrate is formed by the neutralization of citric acid by the base calcium carbonate, as outlined at 21 CFR 184.1195.

Status

Historic Use:

Calcium carbonate has been used in organic agricultural production with a range of applications. These include its use as an acidity regulator (both in food and in soil), as a stabilizer, and for general use in the processing and preparation of foods.

Organic Foods Production Act, USDA Final Rule:

Calcium carbonate is not listed in the Organic Foods Production Act of 1990.

Calcium carbonate is listed at 7 CFR 205.605(a) as a nonagricultural nonsynthetic substance that may be used as an ingredient in or on processed products labeled "organic" or "made with organic (specified ingredients or food group(s)," and is also allowed for use in organic crop and livestock production at §205.105.

International

Canada - Canadian General Standards Board Permitted Substances List.

Calcium carbonate is listed in the Canadian General Standards Board Permitted Substances List (CAN/CGSB-32.311-2015) in Table 4.2 as allowed for "soil amendments and crop nutrition," with the exception that the calcium carbonate must be "mined," and from a "non-synthetic source." Calcium carbonate is also described as being allowed to "protect plants from harsh environmental conditions, such as frost and sunburn, infection, the buildup of dirt on leaf surfaces, or injury by a pest."

The Canadian General Standards Board Permitted Substances List (CAN/CGSB-32.311-2015) also identifies calcium carbonate in Table 6.3 as a "food additive," with the exception "prohibited for use as a colouring agent," and in Table 6.5 as a "processing aid." Calcium carbonate is also described as being in the form of lime as a "cleaner, disinfectant and sanitizer permitted on organic product contact surfaces for which a removal event is mandatory."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) -
Calcium carbonate appears under CODEX GL 32-1999 guidelines as an allowed substance in "Table 1: Substances for use in Soil Fertilizing and Conditioning," without additional conditions, in "Table 3.1 Food additives, including carriers," without additional conditions, for use in "livestock and bee products," with specific conditions of "Milk products. Not as a colouring agent," and also for use in plant products, without additional conditions.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Calcium carbonate is allowed under EC No. 889/2008 as a "fertilizer and soil conditioner," with the condition that it be "only of natural origin," as a "feed material of mineral origin," and as a "processing aid" for the "preparation of foodstuffs of plant origin," without specific conditions.

Japan Agricultural Standard (JAS) for Organic Production
Calcium carbonate is listed in the Japanese Agricultural Standard for Organic Plants (notification no. 1605) in Table 1 as a "fertilizer and soil improvement substance," with the exception that it must be "derived from natural sources, or natural sources without the use of chemical treatment." Calcium carbonate as a "wettable powder" is listed in Table 2 as a "substance for pant pest and disease control," which is "limited to the use for preventing harmful effects of copper wettable powder."

Calcium carbonate is listed in the Japanese Agricultural Standard for Organic Processed Foods (notification no. 1606) as a "food additive" in Table 1, with the exception that the substance is "limited to be used for dairy products (except for coloring) and for cheese as a coagulating agent."

Calcium carbonate is listed in the Japanese Agricultural Standard for Organic Feeds (notification no. 1607) in Article 4 in the form of limestone as a "production method for organic feeds."

International Federation of Organic Agriculture Movements (IFOAM) –
Calcium carbonate is listed in the IFOAM Norms in Appendix 4, Table 1, as an allowed "additive and processing/post-harvest handling aid" with a limitation of "not for coloring."

Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Calcium carbonate is a naturally occurring mineral which is prevalent in the earth's crust (approximately 10%) and is found in all regions of the globe (Al Omari et al., 2016). Calcium carbonate is the major component of limestone and can be isolated and used as ground limestone. However, limestone is naturally occurring and may also contain other minerals (e.g., aluminum, magnesium, etc.) in varying amounts (Al Omari et al., 2016; EFSA, 2011c; USGS, 2008).

In the production of synthetic calcium carbonate, the ground limestone then undergoes a calcination process, during which the calcium carbonate limestone ($CaCO_3$) is converted to calcium oxide quicklime (CaO), with the loss of carbon dioxide (CO_2) gas (Domingo et al., 2004). The quicklime is then slaked, through the controlled addition of water (H_2O), resulting in the formation of calcium hydroxide slaked lime ($Ca(OH)_2$), which undergoes carbonation for the formation and precipitation of calcium carbonate ($CaCO_3$) (Domingo et al., 2004).

According to the FDA at 21 CFR 184.1191, calcium carbonate can be prepared "(1) as a byproduct in the 'Lime soda process;' (2) by precipitation of calcium carbonate from calcium hydroxide in the 'Carbonation process;' or (3) by precipitation of calcium carbonate from calcium chloride in the 'Calcium chloride process'."

In the "Lime soda process," a water softening procedure, slaked lime (calcium hydroxide ($Ca(OH)_2$)) is reacted with soda ash (sodium carbonate (Na_2CO_3)) in a salt metathesis, from which calcium carbonate is precipitated (Britannica, 2018).

In the carbonation of calcium hydroxide, slaked lime ($Ca(OH)_2$)) is added to a solution of carbonic acid (H_2CO_3), which has been prepared by the high-pressure injection of carbon dioxide (CO_2) gas into water (H_2O). Upon mixing, the solutions undergo a salt metathesis reaction, from which calcium carbonate is precipitated (Al Omari et al., 2016; Domingo et al., 2004; Brecevic and Kralj , 2007).

In the "calcium chloride process," calcium chloride ($CaCl_2$) and magnesium chloride ($MgCl_2$) solutions are adjusted to reach a pH of 7, at which point a solution of sodium carbonate (Na_2CO_3) is mixed in, resulting in the formation and precipitation of calcium carbonate (Al Omari et al., 2016; Montes-Hernandez et al., 2007).

Calcium carbonate may also be formed synthetically via a salt metathesis reaction, such as the combination of solutions of ammonium carbonate ($(NH_4)_2CO_3$) and calcium acetate ($Ca(CH_3COO)_2$) under an atmosphere of carbon dioxide (CO_2) gas (Al Omari et al., 2016; Weiss et al., 2014).

Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a chemical process or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.

The majority of isolated calcium carbonate is derived from marine life, as calcium carbonate is a major component of the shells of marine organisms, pearls, and egg shells (Beruto and Giordan, 1993). The mineral deposits of calcium carbonate are then composed of the "skeletal remains and other biological constituents that include fecal pellets, lime mud (skeletal), and microbially mediated cements and lime muds." (Al Omari et al., 2016).

Calcium carbonate is also naturally formed by biomineralization processes of photosynthetic microalgae. The biomineralization process is achieved by enzymatic fixation of carbon dioxide (CO_2) gas, to form bicarbonate ions (HCO_3^-), which are then converted to calcium carbonate ($CaCO_3$) in the presence of calcium sources (Al Omari et al., 2016).

Calcium carbonate is isolated from the natural mineral deposits described above, and then is processed according to one of the methods described above in **Evaluation Question #1**, for the precipitation of purified calcium carbonate for commercial uses.

Evaluation Question #3: If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

Calcium carbonate is a natural, nonsynthetic substance, although it may also be manufactured via salt metathesis reactions, such as the combination of solutions of ammonium carbonate ($(NH_4)_2CO_3$) and calcium acetate ($Ca(CH_3COO)_2$) to produce calcium carbonate as a precipitate, as described in **Evaluation Question #1** (Al Omari et al., 2016; Weiss et al, 2014).

Evaluation Question #4: Specify whether the petitioned substance is categorized as Generally Recognized as Safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.

Calcium carbonate has been listed as GRAS by the FDA at 21 CFR 184.1191 "with no limitation other than good manufacturing practice." Calcium carbonate has also been listed as GRAS as a "food additive," by the FDA at §582.1191, and as a "nutrient and/or dietary supplement" at §582.5191. Furthermore, ground limestone has been given GRAS status by the FDA at §184.1409 as long as it is composed of "not less than 94 percent" calcium carbonate.

Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b)(4)).

Calcium carbonate does not function as a preservative.

Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).

Calcium carbonate has been used as a coloring or whitening agent, with applications including paints, soaps, paper, cement, cosmetic products (e.g., mouth washes, creams, lotions), and medical and food products (DDW, 2014; Oregon DHS, 1998). However, in historic organic food processing, both within the United States and internationally, calcium carbonate is not allowed for coloration purposes (see **Status** section).

One of the major applications of calcium carbonate is for nutritional fortification, and it is also used directly as a dietary supplement for nutritional purposes. In this mode of action, the insoluble slat is broken down by stomach acid into its ions. Once in ionic form, the calcium cation (Ca^{2+}) may be absorbed into the body via active transport and/or passive diffusion, where it is then stored primarily in the skeleton (Heaney, 2002; EFSA, 2011c).

Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).

The incorporation of calcium carbonate into food or feed will result in an enhancement of calcium ions (Ca^{2+}), which is absorbed and stored in the skeleton, as described above in **Evaluation Question #6**.

Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600 (b)(5)).

No residues of heavy metals or other contaminants have been reported in the commercially available precipitated calcium carbonate. However, it has been noted that ground limestone (which is essentially calcium carbonate) may contain varying amounts of aluminum and magnesium (EFSA, 2011c; USGS, 2008).

Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

The processing of calcium carbonate has the potential to provide negative environmental outcomes. These are largely centered on the resulting impacts to water systems, both above and below ground. Many mineral deposits containing calcium carbonate can serve as aquifers, which yield water to wells (USGS, 2008). Their possible contamination may be the result of natural contaminants, or from spills or other contaminants produced in the mining process (USGS, 2001). The disruption to ground water may also result in the decline of the local water table, which can have far-reaching effects. If the quarry site is in contact with the water table, flooding of the operation may result, causing the water to be pumped out and rerouted (USGA, 2001).

Mining may also have negative effects on biodiversity. As described above, mineral extraction efforts may result in the decline or reorganization of the water table and pumping of the sites may also change the state of surface water. These changes will result in a range of impacts to the surrounding ecosystems, depending on the scope and the identity of the ecosystem. There are also potential impacts to the disruption of subterranean environments (e.g., caves), which house species that may not be able to cope with habitat loss (USGS, 2001).

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

There are limited studies on the impact of calcium carbonate on humans. In the reported studies, increased intake of calcium can result in hypercalcemia and the formation of kidney stones when total daily calcium intake reaches levels at or above 2000 mg (Al Omari et al., 2016; EFSA, 2011c). The potential for hypercalcemia and alkalosis has been noted when subjects ingested calcium carbonate 2.0 to 16.5 g/day in the form of dietary supplements in concert with "large amounts" of milk or cream for the treatment of peptic ulcers (Martindale, 2002). Robson and Heading reported acute hypercalcemia and recurrent nephrolithiasis in three subjects that regularly ingested large quantities (7 to 15 g/day) of a calcium carbonate/sodium bicarbonate powder for 10 years (EFSA, 2011c; Robson and Heading, 1978). Bolland et al. report the increased risk of myocardial infraction in subjects whose intake calcium was above 805 mg/day, although it was noted that there was no effect below this threshold (Bolland et al., 2010).

Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

Due to the many applications of calcium carbonate, both in food and other industries, there are no alternative practices that reduce the value of calcium carbonate, which has become an integral part of agricultural production, processing, as well as human nutrition and health.

Evaluation Question #12: Describe all natural (nonsynthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

Sodium bicarbonate ($NaHCO_3$) and sodium carbonate (Na_2CO_3) are both natural substances that, like calcium carbonate, can be used for acid regulation (increasing pH). Sodium carbonate is a naturally-formed substance, which is found in the naturally occurring mineral trona, a mixture of hydrated sodium carbonate (Na_2CO_3) and sodium bicarbonate ($NaHCO_3$) (Solvay, 2014). Trona is a feedstock for the production of soda ash (sodium carbonate (Na_2CO_3)), and following extraction, the mineral is ground and calcined to produce sodium carbonate monohydrate ($Na_2CO_3 \bullet H_2O$), which can undergo further calcination to remove the hydrate (water molecule) (Kirk-Othmer, 2012). Sodium bicarbonate can be formed from the isolated sodium carbonate by treatment with water (H_2O) and a carbon dioxide (CO_2) source (PubChem 516892). Like calcium carbonate, both sodium carbonate and sodium bicarbonate are

effective acid regulators and are sometimes found in the same products and procedures for acid regulation (PubChem 10340).

Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b) (1)).

Calcium hydroxide ($Ca(OH)_2$) (listed as hydrated lime), sodium carbonate (Na_2CO_3), and potassium bicarbonate ($KHCO_3$) are all listed as allowed nonsynthetic substances at 7 CFR 205.601. Calcium hydroxide provides the best alternative for calcium carbonate, as it provides both major functions of acid regulation (increasing pH), as well as a nutritional additive. (NOSB, 2002). However, calcium hydroxide has increased water solubility, and increased basicity compared to calcium carbonate, making it less desirable for some food processing applications (PubChem 6093208). Calcium hydroxide acts as a firming agent in addition to acid regulation (JECFA, 1965).

Sodium carbonate (Na_2CO_3) and potassium bicarbonate ($KHCO_3$) can also be used for acid regulation (increasing pH). However, like calcium hydroxide, these bases have much higher water solubility than calcium carbonate, and therefore do not require the presence of an acid to become soluble and 'active,' making them less desirable for some applications (PubChem 10340; PubChem 516893; PubChem 6093208; PubChem 10112).

Report Authorship

The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:

- Philip Shivokevich, Assistant Professor of Chemistry, Lander University
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- Anna Arnold, Technical Writer, Savan Group

All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

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Magnesium Stearate

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
Magnesium stearate
Octadecanoic acid magnesium salt
Magnesium octadecanoate

Other Name:
Stearic acid magnesium salt
Magnesium distearate

Trade Names:
N/A

CAS Numbers:
557-04-0

Other Codes:
EC-No. 209-150-3
INS No. 470(iii)

Summary of Petitioned Use

Magnesium stearate is used as a lubricant or anticaking agent in food processing and handling. Magnesium stearate is currently listed on the National List of Allowed and Prohibited Substances as a synthetic nonagricultural (nonorganic) substance allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" (7 Code of Federal Regulation (CFR) 205.605(b)). Magnesium stearate is permitted for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))" but is prohibited in agricultural products labeled "organic."

Characterization of Petitioned Substance

Composition of the Substance:

Magnesium stearate is a fatty acid, salt-type anionic surfactant with its appearance being white powder with a creamy feeling. It is a compound of magnesium with a mixture of solid organic acids obtained from edible sources and consists chiefly of variable proportions of magnesium stearate and magnesium palmitate (Pharmacopeia 2010).

The Food Chemicals Codex (FCC) requires that the material assays with an acceptance criteria of not less than (NLT) 6.8% and not more than (NMT) 8.3% magnesium oxide (MgO) (Pharmacopeia 2010). The structure of magnesium stearate is shown in Figure 1.

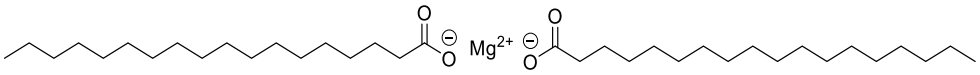

Figure 1. Structure of magnesium stearate.

Source or Origin of the Substance:

Magnesium stearate is produced by the reaction of sodium stearate with magnesium salts or by treating magnesium oxide with stearic acid (Nora 2005).

Properties of the Substance:

Physical and chemical properties of the substance are summarized in Table 1.

Table 1: Physical and Chemical Properties of Magnesium Stearate (Nora 2005).

Property	Value
Chemical formula	$C_{36}H_{70}O_4Mg$
Molar mass	591.24 g/mol
Appearance	White fine powder

Solubility, water	Insoluble
Melting point	200° C
Density	1.028 g/cm^3

Specific Uses of the Substance:

The most common use of magnesium stearate in food handling and processing is as an anticaking agent in common salt; spices; vegetable, beverage, and fruit powders; powdered soups; powdered sauces; leavening agents; and confectionery such as hard candy (Luck 2005).

Magnesium stearate is often used as an antiadherent in manufacturing medical tablets, capsules and powders (Swarbrick 2001, Ritter 2008). In fact, magnesium stearate is the most commonly used lubricant for tablets, preventing ingredients from sticking to manufacturing equipment during the compression of chemical powders into solid tablets (Weiner 1999).

Approved Legal Uses of the Substance:

Magnesium stearate is currently listed on the National List of Allowed and Prohibited Substances as a synthetic nonagricultural (nonorganic) substance allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" (7 CFR 205.605(b)). Magnesium stearate is permitted for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))" but is prohibited in agricultural products labeled "organic."

Magnesium stearate is listed as Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration (21 CFR 184.1440). It is considered GRAS if it is produced as a white precipitate by adding an aqueous solution of magnesium chloride to an aqueous solution of sodium stearate which meets two key criteria: that it is derived from stearic acid obtained from edible sources and that it conforms to the requirements of 21 CFR 172. 860(b)(2). Magnesium stearate must also meet the specifications outlined in the Food Chemicals Codex, and it can be used in food with no limitation other than current good manufacturing practice (21 CFR 184. 1440(b)).

Magnesium stearate is approved by FDA for the following applications:

- As a lubricant and release agent as defined in 21 CFR 170.3(o)(18); as a nutrient supplement as defined in 21 CFR 170.3(o)(20); and as a processing aid as defined in 21 CFR 170.3(o)(24)
- As a stabilizer for use as a prior-sanctioned food ingredient employed in manufacturing food-packaging materials (21 CFR 181.29)
- As a defoaming agent used in processing beet sugar and yeast (21 CFR 173.340 (a)(3))
- As a food additive permitted for direct addition to food for human consumption used or intended for use as a binder, emulsifier, and anticaking agent in food in accord with good manufacturing practice (21 CFR 172.863(b))

Action of the Substance:

Magnesium stearate performs several roles depending on its application. As an anticaking agent, it serves as a natural lubricant, repelling water due to its hydrophobic nature and preventing water from entering packaging to prevent clumping of the food products, supplements, or pharmaceutical ingredients. In the manufacturing process, the addition of magnesium stearate helps ensure that the composition of product mixtures is consistent.

As an anti-foaming agent, adding magnesium stearate retards negative changes and foaming height of a material when it is heated.

Combinations of the Substance:

Magnesium stearate is a common excipient (an inactive ingredient) added to active ingredients such as pharmaceuticals, supplements, and food products. As magnesium stearate is permitted for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))" but is

prohibited in agricultural products labeled "organic," it is not typically used in combination with any substances on the National List for organic agricultural production.

Status

Historic Use:

Per 7 CFR 205.605(b), magnesium stearate is not typically used in producing organic agricultural goods. In conventional agricultural production, it is routinely added during food handling/processing as an anticaking agent in common salt; spices; vegetable, beverage, and fruit powders; powdered soups; powdered sauces; leavening agents; and confectionery such as hard candy (Luck 2005).

Organic Foods Production Act, USDA Final Rule:

Magnesium stearate is currently listed on the National List of Allowed and Prohibited Substances as a synthetic nonagricultural (nonorganic) substance allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" (7 CFR 205.605(b)). Magnesium stearate is permitted for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))" but is prohibited in agricultural products labeled "organic."

International

The Canadian General Standards Board (CGSB) includes nonsynthetic sources (and synthetic sources provided that nonsynthetic sources are not commercially available) of magnesium stearate as a permitted substance for organic production systems under CAN/CGSB-32.311-2015 for use as an anticaking or releasing agent in products whose contents are ≥70% and <95% organic ingredients.

The Codex Alimentarius Commission's "Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods" lists magnesium stearate (INS No. 470(iii)) as a food additive that may be used in foods as an anticaking agent, emulsifier, or thickener under the conditions of good manufacturing practices (GL 32-1999).

Magnesium stearate was not found to be listed under any other international standard for organic handling and processing.

Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Magnesium stearate can be produced through the following procedure (Luck 2005):

First, sodium stearate is produced from the saponification of stearic acid and sodium hydroxide. The sodium stearate undergoes a double decomposition reaction with magnesium sulfate to yield the finished product. For example, in a prototypical reaction, stearic acid and water are added to the reactor and heated to 85° C, stirred until they dissolve, and then slowly added to a sodium hydroxide solution which is preheated to 75° C.

After the saponification reaction is completed, the reaction mixture is maintained at 72° C and slowly added to a preheated (55° C) magnesium sulfate solution. After this metathesis reaction, the water is removed through centrifugation. The filtered cake is then washed with water until sulfate ion requirements are met, and then the filtered cake is dried. In some instances, magnesium stearate is directly synthesized from the reaction of magnesium oxide and food-grade stearic acid.

Stearic acid is derived from natural animal and vegetable sources. Fats and oils rich in stearic acid are more abundant in animal fat (up to 30%) than in vegetable fat (typically <5%) (Beare-Rogers 2001). The

important exceptions are cocoa butter and shea butter, where the stearic acid content (as a triglyceride) is 28–45%. Stearic acid is obtained from fats and oils by the saponification of the triglycerides using hot water (Anneken 2006). The resulting mixture is then distilled, and the resulting commercial stearic acid is often a mixture of stearic and palmitic acids, although purified stearic acid is available. Stearic acid is listed as GRAS by the U.S. Food and Drug Administration (21 CFR 184.1090) if it is produced commercially from hydrolyzed tallow derived from either edible sources or from hydrolyzed, completely hydrogenated vegetable oil derived from edible sources.

Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a chemical process or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.

Magnesium stearate is formulated through a chemical process: either the reaction of sodium stearate with magnesium sulfate or the direct reaction of magnesium oxide with stearic acid. Stearic acid is readily derived from natural sources such as fats and oils derived from animal or vegetable fat, and is recognized as GRAS (21 CFR 184.1090). In addition, magnesium sulfate is usually obtained from natural sources as a hydrate salt (Seeger 2005) and is also recognized as GRAS (21 CRF 184.1443 and 582.5443). Magnesium oxide is produced through the calcination of magnesium carbonate ($MgCO_3$) or magnesium hydroxide (MgOH) at > 1400 °C (Seeger 2005), and it is recognized as GRAS (21 CFR 184.1321; 582.1431; 582.5431).

Evaluation Question #3: If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

Magnesium stearate is a synthetic material solely manufactured by a chemical process, and is not extracted from naturally occurring plant, animal, or mineral sources. Magnesium stearate is produced by a chemical process from either the reaction of sodium stearate with magnesium sulfate or the direct reaction of magnesium oxide with stearic acid (Luck 2005).

Evaluation Question #4: Specify whether the petitioned substance is categorized as Generally Recognized as Safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.

Magnesium stearate is listed as Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration (21 CFR 184.1440). It is considered GRAS if it is produced as a white precipitate by adding an aqueous solution of magnesium chloride to an aqueous solution of sodium stearate which meets two key criteria: that it is derived from stearic acid obtained from edible sources and that it conforms to the requirements of 21 CFR 172. 860(b)(2). Magnesium stearate must also meet the specifications outlined in the Food Chemicals Codex (21 CFR 184. 1440(b)) and can be used in food with no limitation other than current good manufacturing practice.

Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b)(4)).

The primary technical function or purpose of magnesium stearate is for use as a processing aid in organic handling. Its intended uses are as an anticaking agent in common salt; spices; vegetable, beverage, and fruit powders; powdered soups; powdered sauces; leavening agents; and confectionery such as hard candy (Luck 2005). No published literature was located to suggest that the petitioned substance is being used primarily as a preservative.

Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).

There was no information found to suggest that magnesium stearate is used to recreate or improve flavors, colors, textures, or nutritive values lost in the processing of agricultural products. While magnesium stearate can provide a small amount of magnesium, an essential mineral, manufacturers primarily use magnesium stearate as an anticaking agent in the production of agricultural products, pharmaceuticals, and dietary supplements.

Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).

Magnesium stearate is listed as Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration (21 CFR 184.1440) and is expected to have no effect or potential effect on the nutritional quality of food when used according to good manufacturing practices.

Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600 (b)(5)).

In the process for the manufacturing of the petitioned substance, no heavy metals or other contaminants in excess of FDA tolerances have been reported. The Food Chemicals Codex recognizes lead as a potential inorganic impurity for magnesium stearate, and the lead concentration must assay with an acceptance criteria of not more than 5 milligrams/kilogram (mg/kg) (Pharmacopeia 2010).

Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

The most common manufacturing process for magnesium stearate uses three ingredients: stearic acid, sodium hydroxide, and magnesium sulfate. Due to the properties of these compounds, there is limited potential for harmful effects to the environment or biodiversity.

To the best of the investigator's knowledge, there is limited toxicity research on stearic acid, focusing mostly on toxicity effects in food and cosmetic ingredients (ACT 1990). Based on its low acute toxicity, it would likely present a low risk to the environment if spilled.

Magnesium sulfate is a naturally occurring mineral, readily found in the environment as kieserite (magnesium sulfate monohydrate) or epsomite (magnesium sulfate heptahydrate) is highly soluble in water and is not expected to volatize or to undergo hydrolysis. In freshwater and saltwater, the magnesium sulfate complex acts as the primary source of total magnesium. An important removal process for magnesium sulfate in water is the ion exchange that occurs with calcium present in sediments. The uptake of magnesium by water is significant and results in sulfate reduction, meaning that aquatic contamination is unlikely (Bodek 1988). However, one study found that magnesium sulfate, and the magnesium ion in particular, can be toxic at concentrations in the low mg/L range to species that inhabit very low ionic strength surface waters (van Dam 2010). In seawater, high temperature areas act as sinks for magnesium(Pettine 1994). Magnesium sulfate is not expected to be persistent in aquatic systems or bioconcentrate in the food chain and is not likely to be harmful to the aquatic environment because it is highly mobile.

In soil, weathering removes magnesium sulfate by increasing its mobility through the soil. Weathering increases the solubility of magnesium sulfate. In acidic soils, high solubility prevents the persistence of magnesium minerals. In moist soils, volatilization of magnesium sulfate is not of concern because the compound is considered ionic and will not volatilize (Bodek 1988).

The hazard of sodium hydroxide for the environment is caused by the hydroxide ion, as it can have a strong pH effect (EPA 1988). A high concentration in water will result in toxic effects for aquatic organisms

(e.g., fish). However, a low concentration in water will not result in effects on aquatic organisms because the sodium hydroxide will be neutralized by other substances present in water (for example dissolved carbon dioxide, organic acids) and thus the pH will not increase. Because sodium hydroxide is neutralized in the environment, the substance is not persistent and will not accumulate in organisms or in the food chain. Bioaccumulation also will not occur.

Magnesium stearate (i.e., octadecanoic acid, magnesium salt) is classified by the U.S. Environmental Protection Agency (EPA) on their List of Inert Pesticide Ingredients (List 4A) as a minimal risk inert ingredient and is expected to have a negligible impact on the environment or biodiversity.

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

Magnesium stearate is composed mainly of magnesium salts of stearic and palmitic acids, obtained from edible fats and oils. Magnesium stearate is currently classified as not being a hazardous substance and possesses no known hazards not otherwise classified (HNOC) or not covered by Globally Harmonized System (GHS) labels (Sigma-Aldrich 2016).

The Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) recently performed a safety evaluation of magnesium stearate, incorporating a range of published studies with genotoxicity testing (JECFA 2015). Under the acidic conditions of the stomach, magnesium stearate is converted into its constituent magnesium ion (cation) and stearic/palmitic acids (anions) upon digestion. The palmitic and stearic acids and their salts are constituents and products of the metabolism of edible oils and fats, for which the metabolic fate is well understood. Thus, these fatty acids were of no toxicological concern.

Acute and short-term toxicity studies in rats were determined to be not relevant, as extraordinarily large doses were required to observe a negative biological response. For example, the oral median lethal dose (LD_{50}) in rats was found to be greater than 10 grams/kilogram (g/kg) of body weight (bw), indicating that magnesium stearate is practically nontoxic. Similar studies were unable to suggest any genotoxicity potential or reproductive toxicity of magnesium stearate.

The Committee estimated the theoretical dietary exposure to magnesium stearate based on proposed maximum use levels, which results in a potential total dietary exposure to magnesium stearate of 44 mg/kg bw per day for children and 83 mg/kg bw per day for adults, corresponding to 2 and 4 mg/kg bw per day of magnesium respectively. This would contribute up to an additional 240 mg/day to the background exposure to magnesium from food of 180–480 mg/day. The Committee noted that the consumption of the food additive may lead to an additional dietary exposure to stearic and palmitic acids in the order of 5 g/day.

As an acceptable daily intake (ADI) of "not specified" has been established for a number of magnesium salts used as food additives, the Committee concluded that there are no differences in the evaluation of the toxicity of magnesium stearate compared with other magnesium salts and confirmed the ADI of "not specified" for magnesium stearate. However, the Committee did express concern that the use of magnesium salts in many food additives may result in combined exposure that may lead to a laxative effect.

Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

The undesirable caking and deliquescence (i.e., absorption of moisture from the air to dissolve or become liquid) of bulk powders is a common problem in a number of industries, including the food industry (Zafar 2017). Bulk powder caking is a very challenging topic, as it is difficult to predict how a powder will behave.

According to Zafar (2017), there are number of approaches available that may reduce the caking propensity of a material without the addition of anticaking agents:

1. Decreasing the fines content of the powder
2. Minimizing moisture content
3. Identifying the major caking component and identifying if an alternative is available
4. Reducing temperature and humidity cycling where appropriate
5. Reducing consolidation load where appropriate.

Evaluation Question #12: Describe all natural (nonsynthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

Naturally occurring carbonates of calcium, cellulose, and rice hull powder could be used as an all-natural (nonsynthetic) substitute for the petitioned substance. Calcium carbonate is currently listed on the National List. However, only synthetic forms of cellulose are listed on the National List (7 CFR 205.605).

There are several other, mainly synthetic, alternative products that could be substituted for the petitioned substance. With respect to the applications as a defoamer, silicon dioxide is listed as a synthetic allowed substance on the National List (7 CFR 205.605(b)). Cellulose can serve as an alternative anticaking agent to magnesium stearate and is included on the National List as a synthetic allowed substance for use in regenerative casings, as an anticaking agent (non-chlorine bleached), and as a filtering aid (7 CFR 205.605(b)). Calcium carbonate (nonsynthetic) and calcium phosphates (synthetic) are also possible anticaking alternatives included on the National List (7 CFR 205.605).

Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b) (1)).

There are several organic agricultural products that could be used as alternatives for the petitioned substance. Cellulose powder extracted from organic agricultural products, such as organically produced oat and soybean hulls, corn stalks, or sugar beets (Aubrey 2014). However, establishing supply chain systems to accumulate the plant materials is often cost-prohibitive. Rice hull powder from organically grown rice could also be used as an anticaking agent. Moreover, natural silica, or silicon dioxide, can be used as an anticaking agent and extracted from the plant cells of rice husk (Zakharov 1993). Powdered rice has also been demonstrated to be an effective anticaking agent in table salt and a concentration of 1% rice powder could take the place of other anticaking food additives in salt and spice production (Akay 2009).

Report Authorship

The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:

- Bradley Aaron McKeown, Ph.D. Research Scientist, University of Virginia
- Anna Arnold, Technical Writer, Savan Group

All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

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Note: Subcommittee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

National Organic Standards Board (NOSB)
Materials/GMO ad hoc Subcommittee Meeting Notes
Tuesday, January 30, 2018 2:00 pm ET draft

Attending: Harriet Behar (HB), Chair; Emily Oakley (EO), Vice Chair; Dave Mortensen (DM); Tom Chapman (TC)
Absent: Dan Seitz (DS); Lisa de Lima (LD)
Staff: Michelle Arsenault (MA); Paul Lewis (PL)

Work agenda

Materials Projects	Contact	Notes	Discussed, Voted	Meeting
Research Priorities Proposal May 2012 Framework Proposal	EO	Subcommittee reps to MS DS - LS EO - CS LD - HS RPs from Subcomm due to MS in July	NA	Fall 2018
Petition and TR tracking	HB/LB	Ongoing	NA	NA
GMO Projects	**Contact**	**Notes**	**Vote**	**Meeting**
Non-GMO organic seed integrity proposal (formerly Seed Purity from GMOs)	DS, DM, HB	Part of Seed purity doc will be incorporated into "Prevention Strategies for Excluded Methods in Crops and Handling" doc. MS submitted a request to the ES in August 2017 to convene a seed purity task force. Pending NOP approval, for future work agenda.	Jan 30	TBD
Excluded Methods Terminology	HB	Proposal	Jan 9	TBD

Commented [AM-A1]: As per NOP

Commented [AM-A2]: As per NOP

Other Projects

Project Idea	Contact	Notes*	Vote	Meeting
Contamination of Farm Inputs Discussion Document	HB	Moved to Materials from Crops for continued work.	Jan 30	TBD
Sanitizers	HB, EO, JM, AB	Pending NOP approva	Jan 9	Spr 2018

Commented [AM-A3]: As per NOP

Commented [AM-A4]: Pending

Agenda

- Approval of January 9, 2018 notes
- Materials and TR update
- Genetic integrity of seed used on organic land (DS, DM, HB)
- Other items
- Adjourn

Discussion

- **The notes of** January 9 were approved with no changes.
- **Update from program on changes to NOP operations.** The NOP has asked the Board to focus on petitions, sunset reviews, and organic integrity, which aligns with the current administration's priorities. Members offered their feedback about this change, and asked that the NOP reconsider items that are currently completed or nearly completed, and are ready for the Spring meeting, such as the discussion document on marine materials. Members discussed various options for moving forward with projects in light of this change. The Board plans to discuss this further on the February 9 Executive call.
- **Materials and TR update (MA).** The NOP forwarded two TR's to the Handling Subcommittee – on for magnesium stearate and one for calcium carbonate.
- **Genetic integrity of seed used on organic land (DS, DM, HB).** Two members discussed the draft document, including thresholds and testing.
- **Other items.** None
- **The meeting was adjourned**

Previous MS Notes

Future Call Schedule (2nd Tuesday 2:00 ET)

January 23, 2018 - cancelled
January 30, 2018 - additional call
Contamination of farm inputs (HB).
Genetic integrity of seed used on organic land (DS, DM, HB).
February 13, 2018
March 13, 2018
April 10, 2018
May 8, 2018
June 12, 2018
July 10, 2018
August 14, 2018
September 11, 2018
October 9, 2018
November 13, 2018
December 11, 2018

Spring 2018 Milestones	Target dates (tentative)
New NOSB member orientation	TBD
NOSB - Spring 2018 proposals due to NOP	Feb 21, 2018
NOP - Complete Spring 2018 NOSB meeting tentative agenda	Mar 6, 2018
NOP - Post proposals, "Open" public comment	Mar 6, 2018
Discuss work agendas on ES call	Mar 9, 2018
Public comment closes	Apr 4, 2018
NOP - Send compiled public comments to NOSB	Apr 9, 2018
Work agendas finalized on ES call (last call before fall meeting)	Apr 13, 2018
Public comment webinar(s)	Apr 17 & 19, 2018
Spring 2018 NOSB meeting – Tucson, AZ	Apr 25-27, 2018

NOP Petitioned Substance Checklist for OFPA Exemptions and 7 C.F.R. § 205.600(b)

Petitioned Substance: Pullulan
Date Petitioned: 1/31/2018
Petition Area: ☐ Crop Production ☐ Livestock Production ☒ Handling

Citation	Criteria	
OFPA § 6508(b)(1)	Is the substance a fertilizer containing synthetic ingredients or any materials prohibited under this chapter or under the applicable State organic certification program; or	☐ Yes ☒ No ☐ TBD ☐ N/A
OFPA § 6508(b)(2)	Is the substance used as a source of nitrogen, phosphorous, lime, potash, or any materials that are inconsistent with the applicable organic certification program?	☐ Yes ☒ No ☐ TBD ☐ N/A
OFPA § 6517(c)(1)(A)	Based on consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency (EPA), is the use of the substance:	
(i)	Harmful to human health or the environment;[1] Verification, as applicable: ☐ FDA GRAS ☐ EPA Tolerance or Tolerance Exemption ☒ FDA GRAS Notice ☐ Other or N/A: Click here to enter text.	☐ Yes ☒ No ☐ TBD ☐ N/A
(ii)	Necessary to the production or handling of the agricultural product because of unavailability of wholly natural substitute products;	TBD[2]
(iii)	Consistent with organic farming and handling;	TBD[2]
OFPA § 6517(c)(1)(B)(i)	Is the substance used in production?	☐ Yes ☒ No
	Does the substance contain an active synthetic ingredient in the following categories: copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers;	☐ Yes ☐ No ☐ TBD ☒ N/A

[1] If the Department of Health and Human Services (DHHS) or EPA has authorized the use of the petitioned substance under the scope of its authority, or the petitioned substance does not fall under the regulatory authority of DHHS or EPA (e.g., soil amendments), then the petition moves forward for additional assessment.
[2] This item is determined by the National Organic Standards Board during its review.

OFPA § 6517(c)(1)(B)(ii)	Is the substance used in production and contains synthetic inert ingredients that are not classified by the Administrator of the EPA as inerts of toxicological concern?[3]	☐ Yes ☐ No ☒ N/A
OFPA § 6510(a)(4)	Is the substance used in handling and is an ingredient that is not organically produced?	☒ Yes ☐ No ☐ TBD ☐ N/A
7 C.F.R. § 205.600(b)	Is the substance a synthetic substance to be used as a processing aid or adjuvant?	☐ Yes ☒ No ☐ TBD
NOP Staff Reviewer: Devon Pattillo		
Date: 2/21/2018		
Notes: Click here to enter text.		

7 C.F.R. § 205.2 Terms defined.

Fertilizer. A single or blended substance containing one or more recognized plant nutrient(s) which is used primarily for its plant nutrient content and which is designed for use or claimed to have value in promoting plant growth.

Inert ingredient. Any substance (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) other than an active ingredient which is intentionally included in any pesticide product (40 C.F.R. 152.3(m)).

Nonsynthetic (natural). A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in § 6502(21) of the Act (7 U.S.C. § 6502(21)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term is used in the Act.

Processing aid. (1) Substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its finished form;

(2) A substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and

(3) A substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at insignificant levels and does not have any technical or functional effect in that food.

Synthetic. A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

[3] Formulated pesticide products must comply with 7 C.F.R. §§ 205.601(m) or 205.603(e), as applicable. See also NOP 5008 – Reassessed Inert Ingredients.

NOP Petition Guidelines Checklist

Petitioned Substance: Pullulan
Date Petitioned: 1/31/2018
Petition Area: ☐ Crop Production ☐ Livestock Production ☒ Handling

ITEM A	
	Item A.1 – Section of the National List
☒ Yes ☐ No	Does the petition indicate the category for which the substance is being petitioned for inclusion on or removal from the National List?
	For what use category is the substance petitioned? ☐ Synthetic substances allowed for use in organic crop production, § 205.601; ☐ Non-synthetic substances prohibited for use in organic crop production, § 205.602; ☐ Synthetic substances allowed for use in organic livestock production, § 205.603; ☐ Non-synthetic substances prohibited in organic livestock production, § 205.604; ☒ Synthetic or non-synthetic nonagricultural (non-organic) substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients);" § 205.605(a) or (b); NOTE: Petition further requests listing at 205.605 be restricted to "made with organic" ☐ Non-organically produced agricultural products allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." § 205.606; ☐ Removal of a substance included on the National List in § 205.60X; or ☐ Amendment of current listing on the National List in § 205.60X. ☐ Other:
	Item A.2 – OFPA Category (Crop and Livestock Materials)
☐ Yes ☐ No ☒ N/A	Does the petition indicate whether the petitioned substance contain an active synthetic ingredient in one of the following OFPA categories (7 U.S.C. § 6517(c)(1)(B)(i)): ☐ Copper and sulfur compounds ☐ Toxins derived from bacteria ☐ Pheromones ☐ Soaps ☐ Horticultural oils ☐ Fish emulsions

	☐ Treated seed ☐ Vitamins and minerals ☐ Livestock parasiticides and medicines ☐ Production aids ☒ N/A (Handling Materials) **Notes:** Click here to enter text.
	Item A.3 – Inert Ingredients
	If the substance is a synthetic inert ingredient intended for use in a pesticide product, please see NOP Notice 11-6 for more information. **Notes:** Click here to enter text.
	ITEM B
	Does the petition provide:
☒ Yes ☐ No	**1.** The substance's common name? **Notes:** Click here to enter text.
☒ Yes ☐ No	**2.** The manufacturer's or producer's name, address and telephone number? **Notes:** Click here to enter text.
☒ Yes ☐ No	**3.** The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer or disinfectant? If the substance is an agricultural product, the petition must provide a list of the types of product(s) (e.g., cereals, salad dressings) for which the substance will be used and a description of the substance's function in the product(s) (e.g., ingredient, flavoring agent, emulsifier, processing aid). **Notes:** Click here to enter text.
☒ Yes ☐ No	**4.** A list of the crop, livestock or handling activities for which the substance will be used? If used for crops or livestock, the substance's rate and method of application must be described. If used for handling (including processing), the substance's mode of action must be described. **Notes:** Click here to enter text.
☒ Yes ☐ No	**5.** The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product? **Notes:** Click here to enter text.
☒ Yes ☐ No ☐ N/A	**6.** For handling substances, information about the ancillary substances (including, but not limited to, carriers, emulsifiers or stabilizers) that may be included with the petitioned substance, including function, type of substance, and source, if known? **Notes:** Click here to enter text.
☒ Yes ☐ No ☐ N/A	**7.** A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance? **Notes:** Click here to enter text.
☒ Yes ☐ No ☐ N/A	**8.** Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers? **Notes:** Click here to enter text.
☒ Yes ☐ No ☐ N/A	**9.** The Chemical Abstracts Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance? **Notes:** Click here to enter text.

☒ Yes ☐ No ☐ N/A	**10.** The substance's physical properties and chemical mode of action including: (a) chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use or manufacture; (d) effects on human health; and (e) effects on soil organisms, crops, or livestock? **Notes:** Click here to enter text.
☒ Yes ☐ No ☐ N/A	**11.** Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies? **Notes:** Click here to enter text.
☒ Yes ☐ No ☐ N/A	**12.** Research information about the substance, which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies that present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List? With respect to petitions for § 205.606, this criteria should be responded to with research concerning the availability of organic alternatives. **Notes:** Click here to enter text.
	13. A "Petition Justification Statement" that provides justification for one of the following actions requested in the petition:
☐ Yes ☐ No ☒ N/A	***A. Inclusion of a synthetic on the National List, §§ 205.601, 205.603, 205.605(b)*** • Does the petition provide why the synthetic substance is necessary for the production or handling of an organic product? • Does the petition describe the non-synthetic substances or alternative cultural methods that could be used in place of the petitioned synthetic substance? • Does the petition summarize the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support the use of it instead of the use of a non-synthetic substance or alternative cultural methods?
☐ Yes ☐ No ☒ N/A	***B. Removal of a synthetic from the National List, §§ 205.601, 205.603, 205.605(b)*** • Does the petition provide why the synthetic substance is no longer necessary or appropriate for the production or handling of an organic product? • Does the petition describe non-synthetic substances or alternative cultural methods that could be used in place of the petitioned synthetic substance?
☐ Yes ☐ No ☒ N/A	***C. Inclusion of a prohibition of a non-synthetic, §§ 205.602 and 205.604*** • Does the petition provide why the non-synthetic substance should not be permitted in the production of an organic product? • Does the petition describe other non-synthetic substances or alternative cultural methods that could be used in place of the petitioned substance?
☐ Yes ☐ No ☒ N/A	***D. Removal of a prohibited non-synthetic from National List, §§ 205.602 and 205.604*** • Does the petition provide why the non-synthetic substance should be permitted in the production of an organic product? • Does the petition summarize the beneficial effects to the environment, human health, or farm ecosystem from use of the non-synthetic substance that supports its use instead of the use of other non-synthetic substances or alternative cultural methods?
☒ Yes ☐ No ☐ N/A	***E. Inclusion of a non-synthetic or non-agricultural product on the National List, § 205.605(a)*** • Does the petition describe how the substance is necessary for use in organic handling?

	• Does the petition describe non-synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned non-synthetic substance? • Does the petition summarize potential effects of the substance on the environment, or human health that support its use instead of the use of non-synthetic substances on the National List or alternative cultural methods?
☐ Yes ☐ No ☒ N/A	***F. Removal of a non-synthetic, non-agricultural substance from the National List, § 205.605(a)***. • Does the petition describe how the substance is no longer necessary for use in organic handling? • Does the petition describe non-synthetic substances or alternative cultural methods that could be used in place of the petitioned substance?
☐ Yes ☐ No ☒ N/A	***G. Inclusion of a non-organically produced agricultural product on the National List, § 205.606.*** *Important Note: The petition must state why the material should be permitted in the production or handling of an organic product. Specifically, the petition must include current industry information regarding availability of and history of unavailability of an organic form of the material.* • Does the petition provide a comparative description as to why the non-organic form of the ingredient/substance is necessary for use in organic handling? o Does the petition provide current and historical industry information/research/evidence that explains how or why the ingredient/substance cannot be obtained organically in the **appropriate form** to fulfill an essential function in a system of organic handling? o Does the petition provide current and historical industry information/research/evidence that explains how or why the ingredient/substance cannot be obtained organically in the **appropriate quality** to fulfill an essential function in a system of organic handling? o Does the petition provide current and historical industry information/research/evidence that explains how or why the ingredient/substance cannot be obtained organically in the **appropriate quantity** to fulfill an essential function in a system of organic handling? • Does the petition provide industry information on ingredient /substance non-availability of organic sources including but not limited to the following guidance on commercial availability evaluation criteria: o Region of production (climate, number of other regions of production); o Number of suppliers and amount produced; o Current and historical supplies related to weather events (weather-related disasters such as hurricanes, floods, droughts that temporarily halt production or destroy crops or supplies); o Trade-related issues (e.g., evidence of hoarding, war, trade barriers, civil unrest) that may temporarily restrict supplies; and o Any other issues that may present a challenge to a consistent supply.
☐ Yes ☐ No ☒ N/A	***H. Removal of a non-organically produced agricultural product from the National List, §205.606***. *Important Note: The petition must state why the material should be prohibited from use in a non-organic form. Any information acquired since the original petition to add the material to the National List should be provided.*

	• Does the petition provide a comparative description as to why the non-organic form of the ingredient/substance is not necessary for use in organic handling? o Does the petition provide research/evidence that explains how or why the ingredient/substance can be obtained organically in the **appropriate form** to fulfill an essential function in a system of organic handling? o Does the petition provide research/evidence that explains how or why the ingredient/substance can be obtained organically in the **appropriate quality** to fulfill an essential function in a system of organic handling? o Does the petition provide research/evidence that explains how or why the ingredient/substance can be obtained organically in the **appropriate quantity** to fulfill an essential function in a system of organic handling? • Does the petition provide industry information on ingredient /substance availability of organic sources including but not limited to the following guidance on commercial availability evaluation criteria: o Region of production (climate, number of other regions of production); o Number of suppliers and amount produced; o Current and historical supplies related to weather events (weather-related disasters, hurricanes, floods, droughts that temporarily halt production or destroy crops or supplies); o Trade-related issues (e.g., evidence of hoarding, war, trade barriers, civil unrest) that may temporarily restrict supplies; and o Any other issues that may present a challenge to a consistent supply.
☐ Yes ☐ No ☒ N/A	***I. Adding, amending, or removing an annotation for a listed substance (all sections)*** • Does the petition provide: o Evidence that the current annotation is flawed, unnecessary, or outdated. o Information on why a new annotation is needed, with reference to the review criteria.
NOP Staff Reviewer: Devon Pattillo	
Date: 2/21/2018	
Notes: Click here to enter text.	

Petition to Amend 7 CFR §205.601 to Add Polyoxin D Zinc Salt as a Synthetic Substance Allowed for Use In Organic Crop Production (May 31, 2016): February 2, 2018 Addendum

NON-CONFIDENTIAL

Submitted on Behalf of:
Kaken Pharmaceutical Co., Ltd.
Agrochemicals and Animal Health Products
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US Agent for Kaken Pharmaceutical Co., Ltd.

February 2, 2018

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EXECUTIVE SUMMARY

Proposed Amendment
Kaken Pharmaceutical Co., Ltd. (Kaken) proposes to *amend 7 CFR §205.601(i) to add polyoxin D zinc salt* as a synthetic substance allowed for use in organic crop production as plant disease control.

Petitioned Substance
The petitioned substance is *limited* to polyoxin D zinc salt which is a 1:1 complex of polyoxin D and zinc. The CAS number for polyoxin D zinc salt is 146659-78-1. The U.S. Environmental Protection Agency registration number of Polyoxin D Zinc Salt Technical is EPA Reg. No. 68173-1. The associated formulation proposed for use in organic agriculture is limited to the polyoxin D zinc salt 5SC formulation [Veggieturbo 5SC Suspension Concentrate Fungicide (EPA Reg. No. 67173-4) and Oso 5%SC Fungicide (EPA Reg. No. 67173-4-70051)].

Polyoxin D is *naturally occurring*. It is a fermentation product of a naturally occurring microorganism that is *not* genetically modified.

Polyoxin D is highly water soluble. To reduce its water solubility and thereby increase resident time on plant surfaces, polyoxin D is converted to polyoxin D zinc salt via a simple chemical reaction. This simple chemical reaction is the rationale for the National Organic Standards Board's April 2013 recommended classification of polyoxin D zinc salt as a synthetic substance. Kaken purchases the starting material containing zinc and does *not* control the origin of the zinc (mined vs recycled).

Based upon detailed chemical analyses submitted to and reviewed and accepted by the US EPA, Polyoxin D Zinc Salt Technical (EPA Reg. No. 68173-1) does *not* contain any toxicologically significant heavy metal impurities at or above the level of detection.

Petition Scope
Fourteen polyoxins have been identified and have been designated polyoxin A through polyoxin N. Polyoxin A through polyoxin N each have a *different* chemical structure. The properties of polyoxins vary with the chemical structures.

The petitioned substance does *not* include all polyoxins. Specifically, the petitioned substance does *not* include:

- Polyoxin A through C;
- Polyoxin E though N;
- Polyoxin A through C in combination with zinc; and/or
- Polyoxin E though N in combination with zinc.

Polyoxin Complex is *outside* the scope of this petition. Polyoxin Complex is a produced by Kaken and is marketed in Asia. Polyoxin Complex contains multiple polyoxins and has significantly different efficacy compared to polyoxin D zinc salt.

Not an Antibiotic
Worldwide, Polyoxin D Zinc Salt Technical is produced and registered *exclusively* by Kaken Pharmaceutical Co., Ltd. (Kaken). This does *not* make Polyoxin D zinc salt an antibiotic. Polyoxin D and polyoxin D zinc salt are *not* antibiotics. Worldwide, polyoxin D and polyoxin D zinc salt have *never* been marketed for use as pharmaceuticals for use in human medicine or in veterinary medicine. Based upon screening data, polyoxin D has *no commercially viable efficacy* against tested common human or veterinary pathogens (bacteria, fungi, and yeast).

Reduced Risk Pesticide

Polyoxin D zinc salt is a *reduced risk biopesticide* for the control of listed fungal pathogens on crops.

- Polyoxin D is *naturally occurring*. It is a fermentation product of a naturally occurring microorganism (non-GMO).
- Polyoxin D zinc salt has a *non-toxic mode of action*. It is a competitive enzyme inhibitor and stops the growth and pathogenicity of sensitive crop pathogenic fungi. Polyoxin D zinc salt *does not kill the target fungi*.

Polyoxin D zinc salt is regulated by the US Environmental Protection Agency's Biopesticide and Pollution Prevention Division, *i.e.*, the *same* US EPA Division that regulates the NOP *non-synthetic* active ingredients. The currently permitted NOP synthetic active ingredients:

- Are *not* considered by the US EPA to be reduced risk pesticides; and
- Are regulated as conventional pesticides by the US EPA Registration Division.

Polyoxin D zinc salt has been classified by NOP as a synthetic substance due to the chemical reaction used to convert polyoxin D to polyoxin D zinc salt. Nonetheless, as a reduced risk biopesticide, polyoxin D zinc salt *is in many ways like an NOP non-synthetic pesticide product*. During the spring 2013 public hearing, Dr. Davis, a former chair of the NOSB Crops Subcommittee, described polyoxin D zinc salt as a "naturally derived fermentation product with a twist."

Especially Low Risk to Humans from Short-Term and Long-Term Exposure

The US Environmental Protection Agency has determined that the polyoxin D zinc salt 5% suspension concentrate formulation (a.k.a. Veggieturbo and Oso) is practically non-toxic via oral, dermal, and inhalation exposure. Also, it is not irritating. The polyoxin D zinc salt 5% SC formulation does not cause eye irritation or skin irritation. The risk from short term exposure is so low that *EPA does not require a first aid statement* for the polyoxin D zinc salt 5% SC formulation.

The US Environmental Protection Agency has determined that the polyoxin D zinc salt has no toxicological end-point to use in a human risk assessment. Polyoxin D zinc salt:

- Does *not* cause genetic damage (is *not* mutagenic);
- Does *not* cause birth defects (is *not* teratogenic);
- Does *not* cause infertility (is *not* a reproductive toxin);
- Does *not* cause cancer (is *not* carcinogenic);
- Does *not* cause adverse effects on the nervous system (is *not* neurotoxic);
- Does *not* cause adverse effects on the immune system (is *not* immunotoxic); and
- Does *not* cause adverse effects in any organ system (is *not* chronically toxic).

Low Environmental Exposure

The polyoxin D zinc salt 5SC formulation is effective at low application rates. The maximum application rate is 13 fl oz formulation/acre (equivalent to *0.045 lb AI/acre*). By comparison:

- Nu Cop 50 WP (EPA Reg. No. 45002-7) containing 77% (w/w) copper hydroxide is applied to grapes at a maximum of 2 lb/acre (equivalent to *1.54 lb AI/acre*; and
- Micro Sulf (EPA Reg. No. 55146-7) containing 80% sulfur is applied to grapes at a maximum rate of 10 lb formulation/acre (equivalent to *8.0 lb AI/acre*).

Therefore, the polyoxin D zinc salt application rate is *significantly lower* (34 times lower and 178 times lower in these examples) than some example OMRI-listed alternative products on an active ingredient basis.

Rapid Environmental Degradation

The US Environmental Protection Agency has determined that the polyoxin D zinc salt degrades rapidly in water and soil under normal environmental conditions. Therefore, polyoxin D zinc salt will not accumulate in the environment. Polyoxin D degrades to a small organic molecule first identified in dog urine. This degradate is absorbed by roots and serves as a crop nutrient.

Low Environmental Risk

The zinc in polyoxin D zinc salt is applied at a micronutrient level that is beneficial to plants.

The US Environmental Protection Agency has determined that polyoxin D zinc salt:

- Is practically non-toxic to birds, algae, honey bees;
- Is moderately toxic to fish and aquatic invertebrates; and
- Does *not* pose a risk to surface water or groundwater when used as directed.

Risk is the product of Hazard and Exposure.

Risk = Hazard x Exposure.

Given the low application rate and rapid degradation rate of polyoxin D zinc salt, *i.e.*, *low environmental exposure*, the US EPA has determined that the polyoxin D zinc salt has *low environmental risk, including for fish and aquatic invertebrates*.

Separately, Kaken has conducted additional studies summarized in the May 31, 2016 petition that have determined that polyoxin D zinc salt, when used as directed, *does not adversely effect*:

- Earthworms;
- Growth or development of ladybird beetles; and
- Beneficial soil fungi.

Its low environmental risk enables polyoxin D zinc salt to play an important role in *integrated pest management (IPM)* programs.

Unique, Non-Toxic Mode of Action and Resistance Management

Polyoxin D zinc salt has a unique, non-toxic mode of action. No other active ingredient registered for use in North America has the same mode of action (FRAC Code 19). This unique, non-toxic mode of action enables polyoxin D zinc salt to play an important role in *resistance management* programs. In 45 years of commercial use, there have been *no reports of pest resistance to polyoxin D zinc salt*.

Grower Need

Based upon *disease economic significance and efficacy data alone*, there is organic grower need for the polyoxin D zinc salt 5SC formulation for treatment of:

- Blueberries for control of:
  - Alternaria blight (*Alternaria* spp.); and
  - Botrytis blight (*Botrytis cinerea*);
- Caneberries for control of:
  - Botrytis fruit rot (*Botrytis cinerea*); and
  - Powdery mildew (*Podosphaera aphanais*);
- Cranberries for control of:
  - Cottonball (Monilinia oxycocci); and
  - Fruit rot complex (*Coleophoma empetri*, *Colletotrichum acutatum*, *Colletotrichum gloeosporioides*, *Phyllosticta vaccinii*, and *Physalospora vaccinii*, etc.);
- Grapes for control of:
  - Phomopsis fruit rot (*Phomopsis viticola*);
- Strawberries for control of:
  - Anthracnose fruit rot (*Colletotrichum acutatum*);
  - Gray mold (*Botrytis cinerea*);
  - Leather rot (*Phytophthora cactorum*); and
  - Phomopsis fruit rot (soft rot) (*Phomopsis obscurans*); and
- Basil for control of:
  - Downy mildew (*Peronospora belbahrii*).

OMRI-listed alternatives initially identified as having comparable or superior efficacy and therefore identified for more detailed comparisons were:

- Blueberries/mummyberry (*Monilinia vaccinii-corymbosi*): Optiva;
- Grapes black rot (*Guignardia bodwellii*): Badge X2 and Nu-Cop 50 WP;
- Grapes/bunch rot (*Botrytis cinerea*): Double Nickel 55 and Double Nickel LC;
- Grapes/downy mildew (*Plasmopara viticola*): Badge X2, Cueva, and Oxidate;
- Grapes/powdery mildew (*Erysiphe necator*): Micro Sulf, Lifegard WG and Stargus; and
- Strawberries/Phomopsis leaf spot (*Phomopsis obscurans*): Cueva.

Based upon more detailed analysis for other crop/disease combinations for berries and small fruits, there is organic grower need for:

- Blueberry/mummyberry control. Compared to Optiva, the polyoxin D zinc salt 5SC formulation offers organic blueberry growers:
  - Competitive efficacy for control of mummyberry;
  - A treatment option *after* mummyberry is first observed;
  - Competitive worker and environmental safety;
  - A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and
  - Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.

- Grape/black rot control. Compared to Badge X2 and Nu-Cop 50 WP, the polyoxin D zinc salt 5SC formulation offers organic grape growers:
  - Competitive efficacy for control of black rot;
  - Greater crop, worker, and environmental safety;
  - An opportunity to reduce the amount of copper applied to their vineyards and thereby reduce the negative effects of copper on soil;
  - Reduced (EPA's minimum) personal protective equipment requirement;
  - Greater flexibility in growing the crop (0-day PHI instead of 1-day; 4-hour worker re-entry interval instead of 48-hours or 24-hours);
  - A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and
  - Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.

- Grape/bunch rot control. Compared to Double Nickel 55 and Double Nickel LC, the polyoxin D zinc salt 5SC formulation offers organic grape growers:
  - Competitive or superior efficacy for control of bunch rot;
  - A treatment option *after* bunch rot is first observed;
  - Competitive worker and environmental safety;
  - A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and
  - Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.

- Grape/downy mildew control. Compared to Badge X2, Cueva, and Oxidate, the polyoxin D zinc salt 5SC formulation offers organic grape growers:
  - Competitive or superior efficacy for control of downy mildew;
  - An opportunity to reduce the amount of copper applied to their vineyards and thereby reduce the negative effects of copper on soil;
  - Greater to significantly greater crop, worker, and environmental safety;
  - Reduced (EPA's minimum) personal protective equipment requirement;
  - Greater flexibility in growing the crop [0-day PHI instead of 1-day PHI; 4-hour worker re-entry interval instead of 48 hours (Badge X2)];
  - A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and
  - Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.

- Grape/powdery mildew control. Compared to Micro Sulf, Lifegard WG and Stargus, the polyoxin D zinc salt 5SC formulation offers organic grape growers:
  - Competitive or superior efficacy for control of powdery mildew;
  - A treatment option *after* powdery mildew is first observed;
  - An opportunity to reduce the amount of copper applied to their vineyards and thereby reduce the negative effects of copper on soil;
  - Competitive or superior crop, worker, and environmental safety;
  - Greater flexibility in growing the crop [0-day PHI instead of 1-day PHI; 4-hour worker re-entry interval instead of 48 hours (Badge X2)];
  - Increased applicator comfort (no respirator is required as is required for Lifegard WG and Stargus);
  - A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and
  - Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.

- Strawberry/Phomopsis leaf spot (blight). Compared to Cueva, the polyoxin D zinc salt 5SC formulation offers organic strawberry growers:
  - Competitive efficacy for control of Phomopsis leaf spot;
  - A treatment option *after* Phomopsis leaf spot is first observed;
  - Competitive or superior crop, worker, and environmental safety;
  - A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM);
  - Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.

Please note:

- For scheduling reasons, the grower needs analysis is limited to berries and small fruits and basil. Similar results are anticipated if other crop/disease combinations were analyzed.
- There is no EPA registered, OMRI-listed alternative for treatment of cranberries for control of cottonball (*Monilinia oxycocci*).

Compatibility with OMRI-Listed Alternative Products

The polyoxin D zinc salt 5SC formulation, when added to a treatment program, provides *superior control* of blueberry mummyberry fruit infections (fruit strikes) than when the following products are used alone:

- Actinovate (containing *Streptomyces lydicus* WYEC 108; no FRAC Code; biological);
- Double Nickle LC (containing *Bacillus amyloliquefaciens* strain 747; FRAC Code 44);
- Regalia (containing *Reynoutria sachalinensis* extract; FRAC Code P5), and
- NovaSource's Lime-Sulfur (containing calcium polysulfide; FRAC Code M2).

Kaken does *not* recommend the use of polyoxin D zinc salt as a tank-mix partner or as part of a treatment program with products containing *Trichoderma* fungi (Bio-Tam and RootShield).

No Non-Synthetic Alternative

For a pesticide product to be used in the United States, it must be registered by the U.S. Environmental Protection Agency (US EPA). The registration includes detailed descriptions of the starting materials, production process, and final product specifications plus a large volume of human and environmental safety data. These details are fixed for polyoxin D zinc salt.

Polyoxin D (without the zinc) is *not* a non-synthetic alternative to polyoxin D zinc salt. Polyoxin D (without the zinc) is *not* a US EPA registered pesticide. The time and expense of pursuing such a registration would be prohibitive. Even if this were not the case, commercially significant efficacy would first need to be demonstrated.

Crop Residue and Export Considerations

The US EPA has established a tolerance exemption for residues of polyoxin D zinc salt for all crops (pre-harvest and post-harvest) treated according to good agricultural practice (40 CFR §180.1285).

Crops grown in the United States using the polyoxin D zinc salt 5SC formulation according to the US EPA registered label may be exported to:

- Canada;
- Mexico;
- New Zealand;
- South Korea; and
- Taiwan.

These countries have made similar low risk determinations for polyoxin D zinc salt and have enacted regulations that are similar to EPA's tolerance exemption. Numerical maximum residue limits (MRLs) have not been established.

Kaken is pursuing additional imported crop authorizations for polyoxin D zinc salt that are similar to the US EPA's tolerance exemption. Applications to permit importation of crop commodities treated with polyoxin D zinc salt are pending or in preparation. The list of pending applications include the European Union.

Cultural Practices

Kaken proposes that the inclusion of the allowed synthetic active ingredients listed in 7 CFR §205.601(i), by itself, is evidence that cultural practices alone are *not* sufficient to address organic grower needs.

Use of Polyoxin D Zinc Salt as Part of Resistance Management Programs and Integrated Pest Management (IPM) Programs

In the efficacy trials, the polyoxin D zinc salt 5SC formulation was applied application after application. This is an *artificial* design to demonstrate efficacy for each crop/disease combination. Kaken intends that the polyoxin D zinc salt 5SC formulation, when used commercially, will be:

- Rotated and/or tank-mixed with other products with different modes of action; and
- Part of thoughtfully designed resistance management programs and integrated pest management (IPM) programs.

Level Playing Field

Kaken proposes that the National Organic Standards Board and the National Organic Program should have a level playing field when considering proposed additions to the list of synthetic substances allowed for use in organic crop production. The criteria used in the evaluation of polyoxin D zinc salt should be no more restrictive than those applied to the synthetic substances currently listed in 7 CFR §205.601(i) as permitted in organic agriculture for use on crops as plant disease control.

INTRODUCTION

On May 31, 2016, Kaken Pharmaceutical Co., Ltd. to the National Organic Program (NOP) a Petition to Amend 7 CFR §205.601 to Add Polyoxin D Zinc Salt as a Synthetic Substance Allowed for Use In Organic Crop Production (May 31, 2016).

The purpose of this addendum is to update the May 31, 2016 petition to:

- Propose new uses for organic growers consistent with the January 3, 2018 EPA stamped accepted label; and
- Provide:
  - The most recent stamped accepted label for VEGGIETURBO 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4; January 3, 2018);
  - Summaries of new efficacy data for the polyoxin D zinc salt 5SC formulation;
  - Summaries of published efficacy data for US EPA registered OMRI-listed alternative products;
  - An update regarding international regulatory approvals for imported crop commodities; and
  - An updated rationale for approval of the petition.

US EPA STAMPED ACCEPTED LABEL

The current label for Veggieturbo 5SC Suspension Concentrate Fungicide was stamped Accepted by the US EPA on January 3, 2018 and includes many new uses. Please see Appendix 1 for a copy of the EPA stamped accepted label.

NEWLY PETITIONED USES

The proposed new uses of the polyoxin D zinc salt 5SC formulation for use in organic production are use on:

- Grapes for treatment of:
  - Black rot (*Guignardia bodwellii*);
  - Downy mildew (*Plasmopara viticola*); and
  - Phomopsis fruit rot (*Phomopsis viticola*);
- Strawberries for treatment of:
  - Anthracnose fruit rot (*Colletotrichum acutatum*);
  - Leather rot (*Phytophthora cactorum*);
  - Phomopsis leaf spot (blight) (*Phomopsis obscurans*); and
  - Phomopsis fruit rot (*Phomopsis obscurans*); and
- Basil for treatment of:
  - Downy mildew (*Peronospora belbahrii*).

CROP GROUP 13: BERRIES AND SMALL FRUITS: GRAPES: Black rot (*Guignardia bidwellii*)

Economic Importance
(Source: 2015 Organic Production and IPM Guide for Grapes. Cornell University Cooperative Extension.)

Black rot is one of the most serious diseases of grapes in the eastern United States and has the potential to be the "Achilles heel" for organic producers. Fruit rot is the most damaging phase of the disease, but all green tissues of the vine are susceptible to infection. This disease can be especially damaging in organic production because organic-approved fungicides are largely ineffective. Therefore, strict implementation of sanitation practices and other available horticultural techniques is essential, especially on moderately to highly susceptible varieties. Black rot can cause complete crop loss in warm, wet years if it is not properly managed.

Biology
(Source: 2015 Organic Production and IPM Guide for Grapes. Cornell University Cooperative Extension.)

Infected leaves develop relatively small, brown circular lesions surrounded by distinct dark margins; black, pimplelike fruiting bodies ("pycnidia") are scattered within these spot-like lesions. Black, elongated lesions on petioles (leaf stems) may cause affected leaves to wilt and drop. Large, black, elliptical lesions on infected shoots may contribute to breakage by wind. The disease is most common and damaging on berries which appear chocolate brown when first infected, but soon become dark brown with numerous black, pimple-like pycnidia on the surface. Berries eventually shrivel into hard, black raisin-like mummies, most of which remain firmly attached to the berry stem. The black rot fungus overwinters primarily in these mummified fruit, either on the vineyard floor or in clusters retained within the vine. It can also overwinter within cane lesions when these develop.

Rain triggers the release of infective spores from all sources, and infection occurs if susceptible tissues remain wet for a sufficient length of time, which depends on temperature.

Hours of Leaf Wetness Required for a Black Rot Infection Period At Various Temperatures Following a Rain (Source: R. A. Spotts. 1977. The Ohio State University.)	
Temperature (°F)	Hours of Continual Wetness from Rain
50	24
55	12
60	9
65	8
70	7
75	7
80	6
85	9
90	12

Spores within cane lesions are available for infection starting at bud break. However, the majority of overwintering spores in most vineyards (those within mummified fruit on the ground) first become available about 2–3 weeks after bud break, reach peak levels about 1–2 weeks before bloom, and are usually depleted within one to several weeks after the start of bloom, depending on the season. However, in years with dry spring weather when only a few rains occur, the fungus does not discharge all of its spores as early as usual, and significant spore discharge may extend several weeks beyond bloom if this is when rains finally develop.

Pycnidia develop within lesions caused by current season infections and release a new crop of spores during the late spring and summer, beginning about 2–3 weeks after infection first occurs. These secondary rounds of spore release and infection are responsible for disease spread and are the cause of most economic loss when it occurs. Fruit are highly susceptible to infection for the first 2–3 weeks after bloom. They become progressively less susceptible as they continue to develop, finally becoming highly resistant about 5–8 weeks after bloom, depending on the variety and year. In general, "Concord" fruit appear to become resistant about 1–2 weeks earlier than those of Vinifera varieties. Thus, the most critical time to control berry infections is during the first few weeks after the start of bloom.

Cultural Control
(Source: 2015 Organic Production and IPM Guide for Grapes. Cornell University Cooperative Extension.)

Removal of mummified clusters from the canopy during pruning significantly reduces disease pressure for the coming season; burying mummies on the ground before or soon after budbreak, by cultivation or covering them with mulch, also can contribute to a reduction of inoculum if disease was severe the previous season. **CAUTION:** When mummified fruit are not dropped to the ground during dormant pruning operations, large numbers of spores will be produced within the canopy throughout the period of berry development. Research has shown that this prolonged period of high spore production, combined with the closeness of the spores to newly-developing berries, significantly increases the pressure for berry rot. *Therefore, complete removal of mummies from the canopy is an absolutely critical component of a black rot management program for organic growers.* (Emphasis added.)

All fungicides currently approved for organic production are weak against black rot, although copper has moderate efficacy if applied very regularly. Therefore, growers of organic grapes should pay strict attention to the above sanitation procedures, because they are the most important defenses against this disease, which can be the "Achilles heel" of organic grape production in eastern viticulture. Cultural practices that open the canopy also are beneficial because they promote drying and improve spray coverage.

Management Options

Management Options (Source: 2015 Organic Production and IPM Guide for Grapes. Cornell University Cooperative Extension.)	
Scouting/thresholds	Severe loss is usually the result of disease spread within and among clusters after it first gets established on a few berries in the early stages of fruit development. Scout for symptoms of black rot regularly beginning 10 days to 2 weeks after cap fall. Remove diseased clusters and/or consider regular copper applications during wet weather periods on varieties where this material can be used, especially if more than a trace level of disease is found.
Slightly susceptible varieties	Cascade, Cayuga White, Chancellor, Chelois, Corot noir, DeChaunac, Elvira, GR7, Ives, Marquette, Noiret, Traminette, Vidal blanc, and Vignoles.
Cultural management	*Sanitation*. Remove all mummies from the canopy and drop to the ground during dormant pruning operations. Around bud break, cultivate beneath the vines to bury mummies or cover them with mulch. *Canopy management*. Prune and train the vines to promote air circulation and speed drying of the leaves and fruit. Establish new plantings away from wooded areas, where wild grapes can serve as a source of black rot spores.
Chemical treatment	Copper products on varieties not sensitive to this material.

2016 IR-4 Grower Priority

The most recent IR-4 Workshop for prioritization of research to address grower needs for disease control was held September 21, 2016 in Orlando, FL. Black rot control on grapes was identified as a grower need for prioritization (organic category *and* fruit category).

CROP GROUP 13: GRAPES: Downy mildew (*Plasmopara viticola*)

Economic Importance
(Source: Ash, G. Downy Mildew of Grape. 2000. *The Plant Health Instructor*. DOI: 10.1094/PHI-I-2000-1112-01. Updated 2005.)

Downy mildew is a highly destructive disease of grapevines in all grape-growing areas of the world where there is spring and summer rainfall at temperatures above 10º C (50º F). Crop losses in individual years can be 100% if the disease is not controlled during favorable weather. Early infection of young bunches can lead to significant crop loss, whereas, severe leaf infection affects the source-sink relationship in the vine and may lead to defoliation and possible sunburn or lack of fruit ripening. This destruction of leaf tissue may affect sugar accumulation and growth in the subsequent season. Currently, there are no suitable sources of resistance in commercially acceptable varieties, so fungicides are the primary means of disease control.

Biology
(Source: 2015 Organic Production and IPM Guide for Grapes. Cornell University Cooperative Extension.)

Downy mildew is caused by a fungus-like organism that can infect berries, leaves, and young shoots. Leaf lesions appear as yellow or reddish-brown areas on the upper surface, with corresponding white, downy, or cottony fungal growth directly opposite on the lower surface. (Note that downy mildew growth appears only on the lower surface of a leaf lesion and looks cottony, whereas powdery mildew can occur on both sides of the lesion and looks more like baby powder). Leaf lesions become brown and dead with age, and severely infected leaves fall prematurely. Young, infected shoots and cluster stems may curl and are characteristically covered with the white, "downy" growth of the fungus on mornings following rain or dew the night before. Berries on infected cluster stems may fail to set or can turn brown and eventually shrivel, depending on the time of infection. Berries that are directly infected while very young may become entirely covered with a fuzzy white fungal growth when wet from evening rain or early morning dew. Cluster infections that occur later in the season cause berries to remain hard, with a mottled light green to brown or red appearance.

Frequent rainfall and high humidity are the most important environmental factors promoting downy mildew epidemics. The downy mildew organism overwinters as dormant spores within infected leaves on the vineyard floor or (more commonly) within the upper soil layer, and first becomes active in the spring about 2–3 weeks before bloom. Infective spores are then produced during rainy periods if temperatures are above 52°F, and are splashed from the soil onto susceptible tissues to cause the season's first (primary) infections. (Note that inoculum for such early-season infections come strictly from within the vineyard.) Epidemic disease development can then result from repeated cycles of new infections, which are caused by new spores produced within the white fungal growth on diseased tissues. These spores are produced only at night when the relative humidity is extremely high (>95%). They can be blown relatively long distances and cause infection when they land on susceptible tissues that remain wet for just a few hours. (Note that such disease spread can also originate from nearby vines outside the vineyard.)

The generation period for the fungus (time from spore germination and infection to the production of a new "crop" of secondary spores) is only 4 to 5 days at optimum temperatures in the mid- to upper-70s, allowing explosive disease development during extended periods of warm, humid weather with periodic rain showers. On some varieties, including all Vinifera varieties, this can be particularly destructive during the several week period before and after bloom, when fruit clusters are highly susceptible to infection. Young leaves remain highly susceptible to infection so long as they continue to be produced, although even older leaves can become diseased under high-pressure conditions. Uncontrolled infections can cause extensive defoliation in wet years, limiting both fruit ripening and

vine winter hardiness. Winter kill of buds or even entire vines is not uncommon when spraying stops too early on susceptible varieties in a bad downy mildew season. Disease can develop at a wide range of temperatures, from the low 50s to the mid-80s, although the rate of spread is slower while at the edges of the range.

Management
(Source: 2015 Organic Production and IPM Guide for Grapes. Cornell University Cooperative Extension.)

Downy mildew management programs should focus on:

- Preventing early disease establishment and destructive cluster infections during the pre-bloom and early post-bloom periods; and
- Limiting secondary spread on the foliage during the summer and early fall.

Any practice that improves air circulation and speeds drying within vine canopies will help to control downy mildew.

Because primary infections can first occur 2–3 weeks before bloom, protection may need to start at this time on Vinifera varieties and on highly susceptible hybrid and Labrusca varieties (e.g., Chancellor, Catawba, Niagara) if the weather is wet. This is particularly true if significant disease occurred the previous year which would contribute to high levels of overwintering inoculum within the vineyard. Clusters should be protected on all but the most highly resistant varieties from the immediate pre-bloom period through the first or second post-bloom spray, depending on the weather.

Continued protection against disease spread during the summer should be based on variety susceptibility, the extent of favorable weather conditions, and the amount of disease already in the vineyard (secondary inoculum). Downy mildew has the potential for "explosive" spread if the disease is active and weather conditions favor its development. However, in many years, hot, drier weather causes the downy mildew fungus to become inactive during mid-summer. Thus, it is worthwhile to scout vineyards during this time for the presence of active disease and to determine the need for protective sprays based on such findings. Also, recognize that fruit lose their susceptibility to infection by midsummer, although protection against leaf infections and consequent defoliation may need to continue throughout the summer, depending on weather conditions.

Downy Mildew Management Options (Source: 2015 Organic Production and IPM Guide for Grapes. Cornell University Cooperative Extension.)	
Scouting/thresholds	Scout vineyards in mid-summer for the presence of sporulating lesions that may spread infections to leaves during warm, wet weather.
Slightly susceptible varieties	Baco noir, Cascade, Chelois, Concord, Foch, Frontenac, Frontenac gris, Himrod, Marquette, Moore's Diamond, Steuben, and Valvin Muscat.
Cultural management	*Canopy management*. Prune and train the vines to promote air circulation, reduce humidity, and speed drying of the leaves and fruit. *Vineyard management*. Orient rows to improve air movement within the vineyard. Avoid sites prone to fog or heavily wooded areas.
Chemical treatment	Copper products are very effective, although they must be reapplied frequently (7-day to 10-day intervals) during periods of wet weather to provide continued protection.

2016 IR-4 Grower Priority

The most recent IR-4 Workshop for prioritization of research to address grower needs for disease control was held September 21, 2016 in Orlando, FL. Downy mildew control on grapes was identified as a grower need for prioritization (fruit category).

CROP GROUP 13: GRAPES: Phomopsis Fruit Rot (*Phomopsis viticola*)

Economic Importance
(Source: Wayne F. Wilcox, Grape Disease Control, 2015. Cornell University.)

Wayne F. Wilcox of Cornell University reported that over the years, he believes he has seen Phomopsis cause more pronounced economic loss on Concord and (especially) Niagara grapes than any other disease. Most hybrid and *V. vinifera* cultivars are susceptible as well, and whereas they tend to be less problematic in the vast majority of these commercial blocks for several reasons, that does not have to be true.

Biology
(Source: 2015 Organic Production and IPM Guide for Grapes. Cornell University Cooperative Extension.)

Phomopsis cane and leaf spot and fruit rot are most likely to become problems when the Phomopsis fungus is allowed to build up on dead canes or pruning stubs in the vines and effective early-season sprays for this disease are omitted. In conventionally managed vineyards, economic losses have been especially severe on Niagara, and to a lesser extent, Concord, although many other Labrusca, hybrid, and Vinifera varieties are susceptible as well.

Infected rachises and shoots develop black lesions that may split the green tissue (shoots) or appear sunken (rachises). Numerous lesions give the shoot surface a blackened, scabby appearance, and may coalesce to girdle the rachises. Severe infection weakens the tissues at these spots and can cause infected shoots to break off during high winds, or infected clusters to break before and during harvest. Small, pinprick-sized lesions, with brown or black centers surrounded by a small and often yellow margin, can be numerous on the leaves early in the season. These infections cause little harm themselves, but provide a good indication that the fungus is present in the vine and capable of causing more serious losses on other organs if not effectively managed.

Infected berries remain symptomless until late summer or pre-harvest, when they turn brown, often beginning at the point of attachment to the pedicel (berry stem) and become covered with black, pimple-like fruiting bodies. Such berries eventually shrivel up into raisin-like "mummies", at which time they look very similar to berries infected with black rot. On fruit, the two diseases are best distinguished by the initial location, timing, and development of symptoms. Phomopsis lesions typically (but not always) start where the berry is attached to its stem, whereas black rot lesions start at random locations on the fruit. Also, Phomopsis lesions do not appear until late summer or early fall on the fruit, often just before harvest. In contrast, most black rot symptoms appear by late July or early August, and all diseased berries should be evident by veraison. Finally, berries infected with Phomopsis are usually quite easy to detach from their stem by lightly touching them or giving a gentle pull, whereas those with black rot typically remain attached firmly to the berry stem.

Black fruiting bodies of the Phomopsis fungus overwinter in infected wood (diseased canes or pruning stubs) and rachises. During wet periods, spores ooze from the fruiting bodies and are distributed by raindrops onto nearby susceptible tissues. For this reason, young shoots and clusters directly beneath old canes and pruning stubs are at greater risk than those that are trained to grow above these sources.

Extended periods of wet weather are particularly favorable for disease development. Shoot and leaf infections can occur anytime between bud break and early summer, although they are most common during the first few weeks of growth. Shoot and leaf lesions appear within 3 to 4 weeks after infection, but they do not serve as a source of disease spread during the current season. Rachises can be infected anytime after the young clusters first emerge until fungal spores are depleted in early

summer, although infections that occur soon after cluster emergence in the early growing season are the most damaging. Infections that occur on the pedicels (berry stems) during this period can also move into the fruit, causing them to rot before harvest.

Fruit appear to be most susceptible to direct infection from bloom through pea-sized berries, after which few spores are available for new infections. Fruit infection occurs sporadically, since it requires extended periods of rain and wetness. However, serious losses can result if the growing season is excessively wet and protection is not maintained with an effective Phomopsis fungicide from the early shoot growth period through fruit set.

Disease Management
(Source: 2015 Organic Production and IPM Guide for Grapes. Cornell University Cooperative Extension.)

Diseased canes should be removed during pruning to reduce inoculum. Research has shown that dead canes and pruning stubs can produce extremely high levels of Phomopsis spores, and these sources should be specifically targeted for removal as part of a Phomopsis management program. Recent research from Ohio suggests that when inoculum is present, moderately-severe infection can develop after about 26 hours of wetness at an average temperature of 48°F, 16 hours at 54°F, and 12 hours at 60–68°F (shorter and longer periods of wetness should reduce and increase disease severity, respectively).

Copper and sulfur are only weakly effective; thus, organic growers should pay strict attention to the removal of infected wood from within the canopy.

Phomopsis Management Options (Source: 2015 Organic Production and IPM Guide for Grapes. Cornell University Cooperative Extension.)	
Scouting/thresholds	Note "hot spots" of disease activity within individual vines; try to identify the likely source of the fungus causing these infections (pruning stubs, dead canes) and target for removal.
Slightly susceptible varieties	Baco Noir, Cayuga White, Elvira, GR7, Marquette, Marquis, Vanessa, Ventura, and Vidal blanc.
Cultural management	*Sanitation*. Remove all dead wood, infected wood and pruning stubs from the canopy during dormant pruning operations. *Canopy management*. Prune and train the vines to promote air circulation and speed drying of the shoots and clusters. In some instances performing "cane pruning" rather than "spur or cordon pruning" in vinifera and hybrids will result in ensuring new wood is laid down on the fruiting wire every year. *Vineyard management*. Orient rows to improve air movement within the vineyard.
Chemical treatment	*Copper and sulfur are weakly effective and may cause injury on sensitive varieties.* Early-season copper use may also injure more tolerant varieties if applied under cool and/or humid, slow-drying conditions. (Emphasis added.)

2016 IR-4 Grower Priority
The most recent IR-4 Workshop for prioritization of research to address grower needs for disease control was held September 21, 2016 in Orlando, FL. Phomopsis control on grapes was identified as a grower need for prioritization (fruit category).

CROP GROUP 13: STRAWBERRIES: Anthracnose Fruit Rot (*Colletotrichum acutatum*)

Economic Importance
(Source: Averre, C.W., Jones, R.K., and Miholland, R.S., Strawberry Diseases and Their Control, North Carolina State Extension)

Anthracnose fruit rot (*Colletotrichum acutatum*) can be a very destructive disease on California cultivars grown on black plastic. It has been reported to cause 60-75% fruit loss. The disease is most destructive during warm, wet weather. During warm wet periods, on a highly susceptible cultivar such as Pajaro or Chandler, anthracnose can be extremely difficult to control.

Pathogens
(Source: Strawberry Anthracnose. U Massachusetts Extension. A. Madeiras, 2016)

Anthracnose is a general term for diseases caused by species of the fungus *Colletotrichum*. In the Northeast, anthracnose of strawberries is caused by *Colletotrichum acutatum*, which can infect all parts of the plant. *Colletotrichum acutatum* has become increasingly troublesome since it was first identified in the US in 1986. Fruit rot is of particular concern as the fruit is rendered unmarketable. *Colletotrichum fragariae* and *Colletotrichum. gloeosporioides* are more commonly associated with a lethal crown rot, but these species are more common in warmer climates. *Colletotrichum acutatum* is endemic in the Northeast, but may also be brought in on infected transplants.

Signs and Symptoms
(Source: Strawberry Anthracnose. U Massachusetts Extension. A. Madeiras, 2016)

All three *Colletotrichum* species associated with strawberry anthracnose can cause leaf spots and/or dark lesions on petioles and stolons, crown infections, flower blight, and fruit rot. Leaf spots caused by *Colletotrichum acutatum* are brown to black and often more numerous along leaf tips and margins. The spots differ somewhat from the randomly distributed gray to black spots caused by *Colletotrichum fragariae* or *Colletotrichum gloeosporioides*. Petioles and stolons may become girdled, causing death of leaves and daughter plants. Open flowers are more susceptible to blight than closed buds.

Anthracnose can also affect fruit at any stage of development from flowering to harvest. On fruit, symptoms may begin as small light colored or water-soaked lesions a few millimeters in diameter. These lesions grow progressively larger and darker as they mature and end as sunken black spots. After a few days, salmon-colored masses of conidia appear in the lesions. Fruit may eventually become shrunken and mummified. Crowns infected by *Colletotrichum* species will be firm and reddish-brown inside. The discoloration may be uniform or show light and dark brown streaks. *Colletotrichum acutatum* is capable of causing crown infections, but plants usually survive, remain stunted, and produce few berries. Crown infections may occur in the nursery, but can remain latent until well after planting. *Colletotrichum acutatum* can also cause root lesions.

Life Cycle
(Source: Strawberry Anthracnose. U Massachusetts Extension. A. Madeiras, 2016)

Colletotrichum acutatum survives winter in plant debris, particularly mummified fruit. Primary inoculum is produced in spring. The optimum temperature for disease development is about 27°C (80°F). However, the fungus can infect fruit at lower temperatures, and spring infections may remain latent until warm, wet conditions induce disease development. Lesions produce conidia that may continue the infection process throughout the growing season. The time from infection to first sporulation is 7-11 days at 5°C and 2-3 days at 25°C. The fungus can produce conidia at temperatures from 5-35°C, though production is most abundant at 22-26°C. An adequate period of surface

wetness is also required for infection. At 25-30°C, infection occurs in less than 24 hours, but at lower temperatures, a longer wetness period is required. Spores are most often spread by splashing rain, but they may also be transported by insects, animals, and farm workers. Although *Colletotrichum acutatum* has a wide host range that includes many fruit, vegetable, and weed species, research suggests that strains of *Colletotrichum acutatum* that are pathogenic on strawberries are relatively host specific.

Management

Strawberry/Anthracnose Management Options (Source: 2016 Organic production and IPM Guide for Strawberries, Cornell Cooperative Extension)	
Scouting/Thresholds	None established.
Variety susceptibility	No known resistance varieties. 'Jewel' shows little infection in field conditions.
Cultural management	• Provide good air circulation by controlling weeds and reducing planting density. • Use of protected production structures, such as low tunnels, reduces anthracnose occurrence by limiting fruit wetness. • The anthracnose fungus is spread throughout a planting by splashing raindrops or sprinkler irrigation. Straw mulch may reduce the rate of disease spread relative to bare ground (less rain splash).
Chemical treatment	See table below.

(Source: Strawberry Anthracnose. U Massachusetts Extension. A. Madeiras, 2016)

Both organic and conventional fungicides are more effective when applied preventatively. OMRI approved products include Cease (*Bacillus subtilis* QST 713), which has been shown to provide some protection from fruit rot. Copper and sulfur based compounds are also available. However, neither is very effective for anthracnose control and both can be phytotoxic under certain conditions.

CROP GROUP 13: STRAWBERRIES: Leather Rot (*Phytophthora cactorum*)

Economic Importance
(Source: Leather Rot of Strawberry, Michael A. Ellis, Department of Plant Pathology, Ohio State University Extension)

Leather rot of strawberry has been reported in many regions of the United States. In many areas, it is considered a minor disease of little economic importance. However, excessive rainfall during May, June and July can lead to severe losses in fruit yield and quality resulting from leather rot. Commercial growers in Ohio have lost up to 50 percent of their crop to leather rot. The leather rot fungus primarily attacks the fruit, but many also infect blossoms.

(Source: Leather Rot of Strawberry, NC State Extension, https://content.ces.ncsu.edu/leather-rot-of-strawberry)

Leather rot, caused by *Phytophthora cactorum*, may cause substantial losses of fruit yield in wet years, and is particularly troublesome for pick-your-own operations, where undetected diseased fruit mixed in with healthy fruit may result in bitter tasting jams and jellies. Leather rot has been recorded only once since 1997 in plasticulture systems but may be a problem in matted row systems. *Phytophthora* spp. may also cause crown rot of strawberry, although these two diseases do not necessarily occur together.

Description
(Source: 2016 Organic Production and IPM Guide for Strawberries, Cornell Cooperative Extension)

Leather rot is caused by *Phytophthora cactorum*. Infected areas on immature fruit are brown, whereas those on maturing fruit appear bleached out. On all fruit, the infected areas are tough, leathery, and discolored on the inside as well as the outside of the fruit. Diseased fruits have a pungent smell and bitter taste. Leather rot is most severe during periods of abundant warm rains during the fruiting period and in flooded soils. The cultural practices listed in the table below are the most effective control procedures.

Management Options
(Source: 2016 Organic Production and IPM Guide for Strawberries, Cornell Cooperative Extension)

Leather Rot Management Options	
Scouting/thresholds	None established.
Variety susceptibility	No known resistant varieties.
Cultural management	• Plant only on a well-drained site or provide supplemental drainage. Growing strawberries on raised beds will also reduce disease severity. • Minimize soil flooding through site selection; by avoiding planting in ruts; and by preventing or reducing soil compaction. • Provide an extra layer of straw mulch between rows throughout the fruiting season. The mulch provides a physical barrier between the soilborne pathogen and the susceptible fruit.

Listing a pest on a pesticide label does not assure the pesticide's effectiveness.

CROP GROUP 13: STRAWBERRIES: Phomopsis Leaf Spot/Blight and Fruit Rot (Soft Rot) (*Phomopsis obscurans*)

Economic Importance
(Source: N. A. Peres, 2015 Florida Plant Disease Management Guide: Strawberry, Univ. of Florida IFAS Extension)

Phomopsis leaf blight and Phomopsis soft rot, caused by *Phomopsis obscurans*, can occasionally cause serious problems on strawberry, especially on plants propagated in nurseries from the southeastern United States.

Biology
(Source: 2016 Organic Production and IPM Guide for Strawberries, Cornell University Cooperative Extension)

Leaf lesions begin as small, circular to irregular, reddish, or purplish spots. As they expand, lesion centers become necrotic and turn light brown with a dark purple halo. Older lesions along major leaf veins develop into large V-shaped lesions that eventually kill the leaf. Heavy leaf infections can inhibit the production of flower buds for the following year, predispose a plant to winter injury, and provide inoculum for infection of the fruit caps. Fruit may also be infected in some instances.

Management Options

Phomopsis Leaf Blight (*Phomopsis obscurans*) Management Options (Source: 2016 Organic Production and IPM Guide for Strawberries, Cornell University Cooperative Extension)	
Scouting/thresholds	None established
Variety susceptibility	There are no reports of cultivar resistance to leaf blight but Jewel shows low infection rates.
Cultural management	Destroying infected leaves at renovation (e.g., mowing and burying) will reduce the amount of carry-over inoculum. Promoting air circulation (plant spacing and weed control) will reduce foliage drying time and limit infection periods.
Chemical treatment	An early season fungicide application is recommended when carry-over inoculum from the previous year is high or conditions are favorable for disease development.

Listing a pest on a pesticide label does not assure the pesticide's effectiveness.

CROP GROUP 19: HERBS AND SPICES

CROP GROUP 19: BASIL: Downy Mildew (*Peronospora belbahrii*)

Economic Importance
[Source: Michelle Grabowski, Basil Downy Mildew, University of Minnesota Extension. (Not dated.)]

Basil downy mildew was first officially identified in Minnesota in 2012. Under the right weather conditions, basil downy mildew can spread rapidly and result in complete yield loss. Although *Peronospora belbahrii*, the pathogen that causes basil downy mildew, cannot survive MN's winters, it can be reintroduced on infected seed or transplants or by windblown spores.

Identification
[Source: Michelle Grabowski, Basil Downy Mildew, University of Minnesota Extension. (Not dated.)]

- Infected leaves first turn yellow in areas restricted by major veins. With time, the entire leaf turns yellow.
- Irregular black spots appear on infected leaves as they age.
- Fluffy gray spores grow on the underside of infected leaves.
- Infection starts on lower leaves and moves up the plant.

Biology
[Source: Michelle Grabowski, Basil Downy Mildew, University of Minnesota Extension. (Not dated.)]

Peronospora belbahrii, the pathogen that causes basil downy mildew, can be carried on seed, transplants, or fresh leaves. Infected transplants and leaves may not show symptoms if maintained in cool dry conditions. Spores of *Peronospora belbahrii* can also travel long distances on moist air currents. *Peronospora belbahrii* tolerates cool weather and can infect and produce spores in temperatures as low as 59°F. The pathogen, however, thrives in warm, humid conditions. As a result, the most devastating damage is often seen in late summer.

Peronospora belbahrii needs two different mating types to produce tough resting spores known as oospores. Currently, only one mating type has been found in the USA. As a result, no oospores are formed, and the pathogen will not be able to survive Minnesota's harsh winters. This may change if the second mating type is introduced.

Management
[Source: Michelle Grabowski, Basil Downy Mildew, University of Minnesota Extension. (Not dated.)]

Resistant Varieties
There are no resistant varieties of sweet basil (*Ocimum basilicum*) available. Commercially popular varieties are highly susceptible. Lower disease levels have been observed in red leaf basil varieties (*Ocimum basilicum purpurescens*) and in lemon flavored varieties (*Ocimum citridorum*). Only varieties of *Ocimum americanum* have shown no symptoms or sporulation when inoculated with downy mildew.

Varieties with no to low disease are not necessarily good substitutes for susceptible sweet basil varieties. They often have different leaf color and flavor, dramatically affecting the final product. Growers should choose the most resistant variety that is acceptable to their market. Breeders are working to combine the flavor and other characteristics of sweet basil with the resistance found in other species of *Ocimum*.

Cultural Control

Peronospora belbahrii is carried on seed. All seedlings and transplants should be monitored closely for yellowing leaves and gray downy growth on the lower surface of the leaf. If basil downy mildew is identified on any plant, it should be removed and destroyed immediately.

Increase row width and distance between plants to provide good air movement between plants to allow leaves to dry quickly after rain, dew or irrigation. Use drip irrigation if possible. If sprinkler irrigation is the only option, water deeply and infrequently early on a sunny day so leaves dry quickly in the sun. In greenhouse production, adjust ventilation to reduce humidity.

Diseased plants that are past harvest should be promptly tilled under to reduce the spread of the pathogen from one plant to another through spores produced on infected leaves.

Fungicides

Certain fungicides can protect plants from basil downy mildew but sprays must begin before infection occurs to be effective. *Peronospora belbahrii* is not a true fungus but rather a member of the Oomycota. As a result, many common fungicides provide no control against downy mildew. In one study, extreme periods or rainy wet weather resulted in no control by any fungicide combination.

2016 IR-4 Grower Priority

The most recent IR-4 Workshop for prioritization of research to address grower needs for disease control was held September 21, 2016 in Orlando, FL. Downy mildew control on basil was identified as a grower need for prioritization (vegetable category) and was selected as an "A priority" (highest priority category) for funding.

EFFICACY DATA FOR THE POLYOXIN D ZINC SALT 5SC FORMULATION

During the April 2013 public heading before the NOSB regarding polyoxin D zinc salt, a member of the NOSB commented that the NOSB needed to receive and review efficacy data for polyoxin D zinc salt to confirm that it works. Also, California registrations was *not* considered by the NOSB to be sufficient documentation of efficacy.

A "map" for the location of trial-by-trial efficacy summaries included in the May 31, 2017 petition and this addendum is provided below. Uses are organized by crop group number and then alphabetically by the disease common name. New efficacy trials have focused on berries and small fruits (Crop Group 13).

"Map" of Summarized Efficacy Trials that Included the Polyoxin D Zinc Salt 5SC Formulation						
Disease	Pathogen	Crop Tested and Trial Sequence No. for Crop/Disease	May 31, 2016 Petition		February 2, 2018 Addendum	
			Trial No.	Page No.	Trial No.	Page No.
Crop Group 1: Root and Tuber Vegetables						
Botrytis Vine Rot, Gray Mold, Tan Spot	*Botrytis cinerea*	Potatoes #1	CER-2011-029	148		
Early Blight	*Alternaria solani*	Potatoes #1	CER-2011-029	90		
		Potatoes #2	CER-2011-030	92		
		Potatoes #3	CER-2012-028	94		
Late Blight	*Phytophthora infestans*	Potatoes #1	CER-2012-027	321		
Crop Group 4: Leafy Vegetables (except Brassica Vegetables)						
Downy Mildew	*Bremia lactucae*	Lettuce #1	CER-2011-046	177		
		Lettuce #2	CER-2013-014	179		
		Lettuce #3	CER-2013-032	181		
Gray Mold	*Botrytis cinerea*	Lettuce #1	CER-2011-014	141		
Powdery Mildew	*Golovinomyces cichoracearum*	Lettuce #1	CER-2012-074	267		
White Rust	*Albugo occidentalis*	Spinach #1	CER-2014-063	81		
		Spinach #2			CER-2015-152	64
Crop Group 8: Fruiting Vegetables						
Early Blight	*Alternaria solani* and *A. tomatophila*	Tomatoes #1	CER-2014-095	102		
Late Blight	*Phytophthora infestans*	Tomatoes #1	CER-2011-027	326		
Powdery Mildew	*Leviellula taurica*	Tomatoes #1	CER-2012-016	270		
	Odium neolycopersici	Tomatoes (GH) #1	BCGGA-2015-03	310		
Target Spot	*Corynespora cassiicola*	Tomatoes #1	CER-2014-095	213		
Crop Group 9: Cucurbit Vegetables						
Anthracnose	*Colletotrichum orbiculare*	Cucurbits #1	CER-2014-057	209		
Downy Mildew	*Pseudoperonospora cubensis*	Cucumber #1	CER-2012-067	394		
		Pumpkin #1	CER-2015-145	396		
Gummy Stem Blight	*Didymella bryoniae*	Cantaloupe #1	IND-2012-125	219		
		Cucumber #1	BCGGA-2015-02	221		
		Watermelon #1	CER-2011-028	224		
		Watermelon #2	CER-2012-051	226		
Powdery Mildew	*Podosphaera xanthii*	Cucumber #1	R-14-10-0	381		
		Pumpkin #1	CER-2015-145	383		
		Pumpkin #2	CER-2015-149	385		
Southern Blight	*Sclerotinium rolfsii*	Squash #1	CER-2012-050	400		

"Map" of Summarized Efficacy Trials that Included the Polyoxin D Zinc Salt 5SC Formulation						
Disease	Pathogen	Crop Tested and Trial Sequence No. for Crop/Disease	May 31, 2016 Petition		February 2, 2018 Addendum	
			Trial No.	Page No.	Trial No.	Page No.
Crop Group 11: Pome Fruits						
Fly Speck	*Zygophiala jamaicensis*	Apples #1	CER-2012-025	415		
Powdery Mildew	*Podosphaera leucotricha*	Apples #1	CER-2012-020	362		
		Apples #2	CER-2015-012	364		
		Apples #3	CER-2015-034	366		
		Apples #4			CER-2015-033	66
Sooty Blotch Complex	Geastrumia polystigmatus, *Leptodontium elatus*, and *Peltaster fructicola*	Apples #1	CER-2012-025	258		
Scab	*Venturia inaequalis*	Apples #1	CER-2012-025	409		
Crop Group 12: Stone Fruits						
Brown Rot Blossom Blight	*Monilinia fructicola* and *Monilinia laxa*	Cherries #1	CER-2015-035	283		
		French Prune #1	CER-2013-121	285		
Fruit Brown Rot	*Monilinia fructicola* and *Monilinia laxa*	Nectarine #1 and Peach #1	CER-2013-119	287		
Powdery Mildew	*Podosphaera clandestina*	Cherries #1	CER-2015-032	352		
		Cherries #2			CER-2015-035	68
Crop Group 13: Berries and Small Fruits: Blueberries						
Alternaria Fruit Rot	*Alternaria* spp.	Blueberries #1	CER-2012-049	107		
Botrytis Blight	*Botrytis cinerea*	Blueberries #1	CER-2015-009	116		
Mummyberry	*Monilinia vaccinii-corymbosi*	Blueberries #1	CER-2015-008	299		
		Blueberries #2	CER-2015-143	301		
		Blueberries #3			KAK-2016-Blueberry-MI	70
		Blueberries #4			KAK-2016-Blueberry-WA-Conv	74
		Blueberries #5			KAK-2016-Blueberry-WA-Org	76
		Blueberries #6			KAK-2017-Blueberry-WA-Org	79
Crop Group 13: Berries and Small Fruits: Caneberries						
Botrytis Fruit Rot & Cane Botrytis	*Botrytis cinerea*	Raspberries #1	IND-2015-RASP	155		
		Raspberries #2			IND-2016-Rasp-WA	82
		Raspberries #3			KAK-2017-Rasp-MI	84
Powdery Mildew	*Podosphaera aphanis*	Blackberries #1	CER-2012-060	331		
		Raspberries #1			KAK-2017-Rasp-MI	86
Crop Group 13: Berries and Small Fruits: Cranberries						
Cottonball	*Monilinia oxycocci*	Cranberries #1	IND-2014-165	292		
		Cranberries #2	IND-2015-208	294		
		Cranberries #3			11:SMF011 (2016; WI)	88
Fruit Rot Complex	*Coleophoma empetri*, *Colletotrichum acutatum*, *Colletotrichum gloeosporioides*, *Phyllosticta vaccinii*, and *Physalospora vaccinii*, etc.	Cranberries #1	IND-2014-166	191		
		Cranberries #2	CER-2015-104	193		
		Cranberries #3			11:SMF011 (2016; WI)	90

"Map" of Summarized Efficacy Trials that Included the Polyoxin D Zinc Salt 5SC Formulation						
Disease	Pathogen	Crop Tested and Trial Sequence No. for Crop/Disease	May 31, 2016 Petition		February 2, 2018 Addendum	
			Trial No.	Page No.	Trial No.	Page No.
Crop Group 13: Berries and Small Fruits: Grapes						
Black Rot	*Guignardia bidwellii*	Grapes #1			KAK-2016-Grape-MI	31
		Grapes #2			KAK-2017-Grape-MI	33
		Grapes #3			KAK-2016-Grape-PA	35
		Grapes #4			KAK-2017-Grape-PA	37
Bunch Rot	*Botrytis cinerea*	Grapes #1	CER-2013-002	124		
		Grapes #2	CER-2013-021	126		
		Grapes #3	CER-2014-045	128		
		Grapes #4	CER-2015-115	131		
		Grapes #5	CER-2015-140	134		
		Grapes #6			9:SMF011	94
Downy Mildew	*Plasmopara viticola*	Grapes #1			KAK-2016-Grape-MI	39
		Grapes #2			KAK-2017-Grape-MI	41
Phomopsis Fruit Rot	*Phomopsis viticola*	Grapes #1			KAK-2016-Grape-MI	43
		Grapes #2			KAK-2017-Grape-MI	46
Powdery Mildew	*Erisyphe necator*	Grapes #1	CER-2011-013	241		
		Grapes #2	CER-2012-069	244		
		Grapes #3	CER-2013-021	247		
		Grapes #4	CER-2015-019	249		
		Grapes #5	CER-2015-140	252		
		Grapes #6			KAK-2016-Grape-MI	96
		Grapes #7			KAK-2017-Grape-MI	99
		Grapes #8			KAK-2017-Grape-PA	101
Crop Group 13: Berries and Small Fruits: Strawberries						
Anthracnose Fruit Rot	*Colletotrichum acutatum*	Strawberries #1			KAK-2016-SBerry-MI	48
		Strawberries #2			KAK-2017-SBerry-MI	50
Gray Mold	*Botrytis cinerea*	Strawberries #1	CER-2012-070	166		
		Strawberries #2	CER-2014-038	168		
		Strawberries #3	Review Article, Adaskaveg *et al.*, 2013	170		
		Strawberries #4			KAK-2016-SBerry-MD	104
		Strawberries #5			KAK-2016-SBerry-MI	106
		Strawberries #6			KAK-2017-SBerry-MI	108
Leather Rot	*Phytophthora cactorum*	Strawberries #1			KAK-2016-SBerry-MI	52
		Strawberries #2			KAK-2017-SBerry-MI	54
Phomopsis Leaf Spot	*Phomopsis obscurans*	Strawberries #1			KAK-2016-SBerry-MI	56
		Strawberries #2			KAK-2017-SBerry-MI	59
Powdery Mildew	*Podosphaera aphanis*, *Sphacelotheca* sp.	Strawberries #1	CER-2012-070	342		
		Strawberries #2	CER-2013-008	344		
Crop Group 19: Herbs and Spices						
Downy Mildew	*Peronospora belbahrii*	Basil #1			IND-2015-218	62

NEW EFFICACY DATA FOR NEWLY PETITIONED USES

CROP GROUP 13: BERRIES AND SMALL FRUITS: GRAPES / Black Rot (*Guignardia bidwellii*)

#1: Trial No. KAK-2016-Grape-MI

a. Design

<table>
<tr><th colspan="6">Grapes / Black Rot (Guignardia bidwellii) #1:
Trial No. KAK-2016-Grape-MI: Design</th></tr>
<tr><td>Title:</td><td colspan="5">Evaluation of fungicides for control of foliar and fruit diseases of juice grapes, 2016</td></tr>
<tr><td>Author and affiliation:</td><td colspan="5">A. M. Schilder, J. M. Gillett, and R. W. Sysak
Michigan State University</td></tr>
<tr><td>Publication:</td><td colspan="5">PDMR (planned for fall 2018 publication)</td></tr>
<tr><td>Location:</td><td colspan="5">Fennville, MI</td></tr>
<tr><td>Crop:</td><td colspan="5">Grape (Vitis labrusca “Niagara’)</td></tr>
<tr><td>Disease name:</td><td colspan="5">Black rot</td></tr>
<tr><td>Pathogen:</td><td colspan="5">Guignardia bidwellii</td></tr>
<tr><td>Test plot design:</td><td colspan="5">Randomized complete block</td></tr>
<tr><td>Number of replicates:</td><td colspan="5">4</td></tr>
<tr><td>Application equipment:</td><td colspan="5">Research sprayer with 5-foot spray boom</td></tr>
<tr><td>Spray volume:</td><td colspan="5">50 gal/acre (May 8, 2016 to July 1, 2016)
75 gal/acre (remainder of the season)</td></tr>
<tr><td>Application type(s):</td><td colspan="5">Preventative</td></tr>
<tr><td>Number of applications:</td><td colspan="5">7 (Oso at 10-day to 16-day intervals)</td></tr>
<tr><td rowspan="9">Chronology:</td><td colspan="3">Application</td><td rowspan="2">Growth Stage</td><td rowspan="2">Disease Assessment Date</td></tr>
<tr><td>No.</td><td>Date</td><td>Interval</td></tr>
<tr><td>1</td><td>05/23/2016</td><td></td><td>3-5 inch shoot</td><td>09/09/2016</td></tr>
<tr><td>2</td><td>06/08/2016</td><td>16 days</td><td>10-16 inch shoot</td><td></td></tr>
<tr><td>3</td><td>06/21/2016</td><td>13 days</td><td>Bloom</td><td></td></tr>
<tr><td>4</td><td>07/01/2016</td><td>10 days</td><td>Pea-size fruit</td><td></td></tr>
<tr><td>5</td><td>07/12/2016</td><td>11 days</td><td>2nd post-bloom</td><td></td></tr>
<tr><td>6</td><td>07/27/2016</td><td>15 days</td><td>3rd post bloom</td><td></td></tr>
<tr><td>7</td><td>08/03/2016 [A]</td><td>7 days</td><td></td><td></td></tr>
<tr><td>8</td><td>08/10/2016</td><td>7 days</td><td>4th post-bloom</td><td></td></tr>
<tr><td>Disease assessment methodology:</td><td colspan="5">• 25 randomly selected leaves and clusters from the center vine in each plot were visually rated.
• Incidence = Percent leaves or clusters with disease.
• Severity = Percent area symptomatic on diseased plants only.
• Overall Severity = (Incidence x Severity) / 100.</td></tr>
<tr><td colspan="6">A. 08/03/2016 application was limited to selected treatment programs that included Ridomil Gold SL to control downy mildew.</td></tr>
</table>

b. Results

Grapes / Black Rot (*Guignardia bidwellii*) #1: Trial No. KAK-2016-Grape-MI: Results (9/10/2016)									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App. Code	Incidence (%)	Severity (%)	Overall Severity (%)	Percent Control
Untreated control			Not Applicable			82.0 a	45.4 a	37.44 a	
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	1,2,3,4, 5,6,8	46.0 b	10.3 b	4.66 b	87
Oso 5%SC	13 fl oz	50	Polyoxin D zinc salt	19	1,2,3,4, 5,6,8	17.0 def	3.4 cd	0.64 c	98
Ranman	2.75 fl oz		Cyazofamid	21	1,2,3,4, 5,6,8	24.0 cd	2.2 de	0.63 c	98
Silwet L-77	2 fl oz		Nonionic surfactant	NA					
Manzate Pro-Stick	3 lb		Cymoxanil	27	1, 2	0.0 g	0.0 g	0.0 c	100
Pristine 38WG	12.5 oz		Boscalid	7	3,4,6,8				
			Pyraclostrobin	11					
Super Spread 90	0.125%		Non-ionic surfactant	NA					
Ziram 76DF	3 lb		Ziram	M3	5				
Ridomil Gold			Mefenoxam	4	7				
Treatment means followed by the same letter are not statistically different according to the Fischer's Protected SD test at $P \leq 0.05$.									

The first assessments were performed after the last treatment. Therefore, all treatments are assumed to be preventative.

The researchers reported the black rot disease pressure to be light on leaves and moderate on fruit.

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 6.5 fl oz/acre and 13 fl oz/acre provided 87% and 98% control, respectively, of black rot on grape clusters.

No OMRI-listed products were evaluated in this trial.

#2: Trial No. KAK-2017-Grape-MI

a. Design

Grapes / Black Rot (*Guignardia bidwellii*) #2: Trial No. KAK-2017-Grape-MI: Design					
Title:	Evaluation of fungicides for control of foliar diseases of juice grapes, 2017				
Author and affiliation:	A. M.C. Schilder, J. M. Gillett, and R. W. Sysak Michigan State University				
Publication:	PDMR (planned for fall 2018 publication)				
Location:	Fennville, MI				
Crop:	Grape ('Niagara')				
Disease name:	Black rot				
Pathogen:	*Guidnardia bidwellii*				
Test plot design:	Randomized complete block				
Number of replicates:	4				
Application equipment:	Research sprayer with 5-foot boom				
Spray volume:	40 gallons/acre (first 3 applications) 50 gallons/acre (later season applications)				
Application type(s):	Preventative				
Number of applications:	7				
Chronology:	App. Code	Application Dates	App. Interval (Days)	Growth Stage	Disease Assessment Dates
	A	05/16/2017		3-5 inch shoots	08/23/2017
	B	05/30/2017	14	7-17 inch shoots	
	C	06/10/2017	11	Pre-bloom/bloom	
	D	06/21/2017	11	1st post-bloom; bb-size fruit	
	E	07/11/2017	19	2nd post-bloom; pea-size fruit	
	F	07/25/2017	14	3rd post-bloom; pre-bunch closure	
	G	08/14/2017	20	4th post-bloom; bunch closure	
Disease assessment methodology:	Incidence: % of leaves or clusters with disease. Severity: % area symptomatic on diseased plant parts only. Overall severity: (Incidence x Severity) / 100.				

b. Results

Grapes / Black Rot (*Guignardia bidwellii*) #2: Trial No. KAK-2017-Grape-MI: Results: Leaves									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App Code	Incidence (%)	Severity (%)	Overall Severity (%)	Control (%)
Untreated control			Not Applicable			62.0 a	13.2 a	8.2 a	
Oso	13.0 fl oz	50	Polyoxin D zinc salt	19	ABCDEFG	26.0 c	3.9 c	1.1 c	87
Lifegard WG	4.5 oz/ 100 gal		*Bacillus mycoides* isolate J		ABCDEFG	40.0 b	6.5 b	2.6 b	68
Stargus	64 fl oz		*Bacillus amyloliquefaciencs* strain F727		ABCDEFG	35.0 b	6.5 b	2.3 b	72
Intuity 4SC	6 fl oz		Mandestrobin	11	ABCDEFG	40.0 b	5.6 b	2.3 b	72
Super Spread 90	0.125% (v/v)		Non-ionic surfactant	NA	ABCDEFG				
Treatment means followed by the same letter are not statistically different according to the Fischer's Protected LSD test at P ≤ 0.05.									

Grapes / Black Rot (*Guignardia bidwellii*) #2: Trial No. KAK-2017-Grape-MI: Results: Clusters									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App Code	Incidence (%)	Severity (%)	Overall Severity (%)	Control (%)
Untreated control			Not Applicable			66.0 a	36.9 a	36.9 a	
Oso	13.0 fl oz	50	Polyoxin D zinc salt	19	ABCDEFG	29.0 ef	5.2 bc	5.2 bcd	86
Lifegard WG	4.5 oz/ 100 gal		*Bacillus mycoides* isolate J	44	ABCDEFG	43.0 b	7.9 b	7.9 b	79
Stargus	64 fl oz		*Bacillus amyloliquefaciencs* strain F727	44	ABCDEFG	42.0 bc	6.0 bc	6.0 bc	84
Intuity 4SC	6 fl oz		Mandestrobin	11	ABCDEFG	41.0 bcd	7.4 b	7.4 b	80
Super Spread 90	0.125% (v/v)		Non-ionic surfactant	NA	ABCDEFG				
Treatment means followed by the same letter are not statistically different according to the Fischer's Protected LSD test at P ≤ 0.05.									

The researchers described the black rot disease pressure:

- On grape leaves as light; and
- On grape clusters as moderate.

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 13 fl oz/acre provided 87% and 86% control of black rot on grape leaves and clusters, respectively.

OMRI-listed products evaluated in this trial included Lifegard WG and Stargus. Oso applied at 13 fl oz/acre provided control of black rot on grapes that is numerically ***superior*** to that of Lifegard WG and Stargus.

#3: Trial No. KAK-2016-Grape-PA

a. Design

<table>
<tr><th colspan="7">Grapes / Black Rot (Guidnardia bidwellii) #3:
Trial No. KAK-2016-Grape-PA: Design</th></tr>
<tr><td>Title:</td><td colspan="6">Evaluation of OSO 5% and other alternative fungicides on Vitis labrusca ‘Concord’ grapes, 2016.</td></tr>
<tr><td>Author and affiliation:</td><td colspan="6">Bryan Hed
Lake Erie Regional Grape Research and Extension Center
Penn State University</td></tr>
<tr><td>Publication:</td><td colspan="6">PDMR 11:SMF009</td></tr>
<tr><td>Location:</td><td colspan="6">North East, PA</td></tr>
<tr><td>Crop:</td><td colspan="6">Grapes (Concord)</td></tr>
<tr><td>Disease name:</td><td colspan="6">Black rot</td></tr>
<tr><td>Pathogen:</td><td colspan="6">Guidnardia bidwellii</td></tr>
<tr><td>Test plot design:</td><td colspan="6">Randomized complete block</td></tr>
<tr><td>Number of replicates:</td><td colspan="6">4</td></tr>
<tr><td>Application equipment:</td><td colspan="6">Friend covered-boom plot sprayer</td></tr>
<tr><td>Spray volume:</td><td colspan="6">50 gallons/acre (100 psi)</td></tr>
<tr><td>Application type(s):</td><td colspan="6">Preventative assumed.
Mummies were placed in the trellis as a source of inoculum.</td></tr>
<tr><td>Number of applications:</td><td colspan="6">6 (Oso; no application C2 at 21 days after the first application.)</td></tr>
<tr><td rowspan="10">Chronology:</td><td colspan="3">Application</td><td rowspan="2">Days After First Application</td><td rowspan="2">Growth Stage</td><td rowspan="2">Disease Assessment Dates</td></tr>
<tr><td>Code</td><td>Dates</td><td>Interval (Days)</td></tr>
<tr><td>A</td><td>05/23/2016</td><td></td><td>0</td><td>3-6 inch shoots</td><td>08/08/2016</td></tr>
<tr><td>B</td><td>06/02/2016</td><td>9</td><td>9</td><td>10-12 inch shoots</td><td>08/30/2016</td></tr>
<tr><td>C_1</td><td>06/11/2016</td><td>9</td><td>18</td><td>Immediate pre-bloom</td><td></td></tr>
<tr><td>C_2*</td><td>06/14/2016</td><td>12*</td><td>21</td><td>Bloom
(not used for Oso)</td><td></td></tr>
<tr><td>D</td><td>06/21/2016</td><td>10**</td><td>28</td><td>1st post-bloom</td><td></td></tr>
<tr><td>E</td><td>06/30/2016</td><td>9</td><td>37</td><td>2nd post-bloom</td><td></td></tr>
<tr><td>F</td><td>07/12/2016</td><td>12</td><td>49</td><td>Pea-size berries</td><td></td></tr>
<tr><td colspan="6">* Included exclusively in the treatment program that began with Manzate. Not used for Oso and the other treatments.
** Application interval for Oso and other treatments excluding the Manzate treatment program.</td></tr>
<tr><td>Disease assessment methodology:</td><td colspan="6">Severity was rated using the Barratt-Horsfall scale and was converted to % area infected (0-100%) using Elanco conversion tables.
Incidence = Percent clusters diseased.
Severity = Percent area of clusters diseased.</td></tr>
</table>

b. Results

This trial was conducted during a local drought. Total rainfall for May, June, July, and September was 2.1, 1.9, 2.7, 4.5 and 5.2 inches, respectively. Dry weather during May, June, and July made for very unfavorable conditions for fungal infections and resulted in low levels of disease.

For clusters with no mummies in the trellis to serves as inoculum, the disease pressure was too low (2.0% incidence and 0.05% severity) for meaningful data. Statistical differences in incidence and severity were observed for clusters for which black rot mummies were included in the trellis.

Grapes / Black Rot (*Guidnardia bidwellii*) #3: Trial No. KAK-2016-Grape-PA: Results: Clusters									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App Code	With Mummies in the Trellis to Serve as Inoculum			
						Incidence		Severity	
						Measured (%)	% Control	Measured (%)	% Control
Untreated control			Not Applicable			55.0 ab		7.02 b	
OSO 5%	13.0 fl oz	50	Polyoxin D zinc salt	19	ABC_1DEFG	53.6 ab	2.5	7.26 b	-3.4
Fracture	36.6 fl oz		Banda de Lupinus albus doce (BLAD)	BM1	ABC_1DEFG	51.3 b	6.7	9.02 ab	-28.5
Double Nickel	3 qt		*Bacillus amyloliquefaciens* str. D747	44	ABC_1DEFG	76.7 a	-39.5	12.98 a	-84.9
Badge X2	1.75 lb		Copper hydroxide, Copper oxychloride	M1	ABC_1DEFG	15.0 c	72.7	1.29 c	81.6
Lime	1.75 lb		Calcium hydroxide	NA	ABC_1DEFG				
Conventional standard:									
• Manzate Prostik	3 lb		Cymoxanil	27	AB	0.8 c	98.5	0.02 c	99.7
• Ziram	4 lb		Zinc dimethyldithio-carbamate	M3	C_2DEF				
• Quintec	4 fl oz		Quinoxyfen	13	C_2 E				
• Vivando	10.3 fl oz		Metrafenone	U8	D				
• Toledo	4 oz		Tebuconazole	3	G				
Treatment means followed by the same letter are not statistically different according to Fisher's LDS test at $P \leq 0.05$.									

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 13 fl oz/acre provided very modest control of black rot incidence (2.5%) in grape clusters when cages with black rot mummies were attached to the trellis to serve as inoculum. In the absence of the mummies, no significant black rot was observed.

OMRI-listed products evaluated in this trial included Double Nickel and a tank-mixture of Badge X2 and lime. Based upon this trial, Oso provided:

- ***Superior*** performance compared to Double Nickel; and
- ***Inferior*** performance compared to Badge X2 tank-mixed with lime.

Fracture is a biopesticide. However, based upon the label posted to the Internet, Fracture is ***not*** OMRI-listed.

#4: Trial No. KAK-2017-Grape-PA

a. Design

<table>
<tr><th colspan="7">Grapes / Black Rot (Guidnardia bidwellii) #4:
Trial No. KAK-2017-Grape-PA: Design</th></tr>
<tr><td>Title:</td><td colspan="6">Evaluation of OSO 5% and other alternative fungicides on Vitis labrusca ‘Concord’ grapes, 2017.</td></tr>
<tr><td>Author and affiliation:</td><td colspan="6">Bryan Hed
Lake Erie Regional Grape Research and Extension Center
Penn State University</td></tr>
<tr><td>Publication:</td><td colspan="6">PDMR (submitted)</td></tr>
<tr><td>Location:</td><td colspan="6">North East, PA</td></tr>
<tr><td>Crop:</td><td colspan="6">Grapes (Concord)</td></tr>
<tr><td>Disease name:</td><td colspan="6">Black rot</td></tr>
<tr><td>Pathogen:</td><td colspan="6">Guidnardia bidwellii</td></tr>
<tr><td>Test plot design:</td><td colspan="6">Randomized complete block</td></tr>
<tr><td>Number of replicates:</td><td colspan="6">4</td></tr>
<tr><td>Application equipment:</td><td colspan="6">Friend covered-boom plot sprayer</td></tr>
<tr><td>Spray volume:</td><td colspan="6">50 gallons/acre (100 psi)</td></tr>
<tr><td>Application type(s):</td><td colspan="6">Preventative assumed.
Mummies were placed in the trellis as a source of inoculum.</td></tr>
<tr><td>Number of applications:</td><td colspan="6">7</td></tr>
<tr><td rowspan="9">Chronology:</td><td colspan="3">Application</td><td rowspan="2">Days After First Application</td><td rowspan="2">Growth Stage</td><td rowspan="2">Disease Assessment Dates</td></tr>
<tr><td>Code</td><td>Dates</td><td>Interval (Days)</td></tr>
<tr><td>A</td><td>05/10/2017</td><td></td><td>0</td><td>3-6 inch shoots</td><td>08/04/2017</td></tr>
<tr><td>B</td><td>05/19/2017</td><td>9</td><td>9</td><td>10-12 inch shoots</td><td>08/30/2017</td></tr>
<tr><td>C</td><td>05/28/2017</td><td>9</td><td>18</td><td>12-16 inch shoots</td><td></td></tr>
<tr><td>D</td><td>06/08/2017</td><td>11</td><td>29</td><td>Immediate pre-bloom</td><td></td></tr>
<tr><td>E</td><td>06/18/2017</td><td>10</td><td>39</td><td>1st post-bloom</td><td></td></tr>
<tr><td>F</td><td>06/28/2017</td><td>10</td><td>49</td><td>2nd post-bloom</td><td></td></tr>
<tr><td>G</td><td>07/09/2017</td><td>11</td><td>60</td><td>3rd post-bloom</td><td></td></tr>
<tr><td>Disease assessment methodology:</td><td colspan="6">Severity was rated using the Barratt-Horsfall scale and was converted to percent area infected (0-100%) using Elanco conversion tables.</td></tr>
</table>

For both the 2016 and 2017 trials conducted in North East, PA first applications were made when the grapes were at 3-6 inch shoot stage. The 2017 trial included one more application than the 2016 trial at the same location. The 2017 trial included an application at 12-16 inch shoot length that was not included in the 2016 trial. The 2017 trial included an application at 60 days after the last treatment, whereas the last application in the 2016 trial was made 49 days after the first application.

b. Results

This trial was conducted during the second year of a local drought. Total rainfall for May, June, July, August, and September was 5.70, 3.62, 0.84, 2.35, and 2.7 inches, respectively. Dry weather conditions greatly limited black rot development, particularly during July.

For clusters with no mummies in the trellis to serves as inoculum, the disease pressure was too low for meaningful data. Statistical differences in incidence and severity were observed for clusters for which black rot mummies were included in the trellis.

Grapes / Black Rot (*Guidnardia bidwellii*) #4:
Trial No. KAK-2017-Grape-PA: Results: Clusters

Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App Code	With Mummies in the Trellis to Serve as Inoculum			
						Incidence (%)		Severity (%)	
						Measured	% Control	Measured	% Control
Untreated control			Not Applicable			85.8 a		20.66 a	
OSO 5%	13.0 fl oz	50	Polyoxin D zinc salt	19	ABCDEFG	59.2 ab	31.0	12.16 ab	41.1
Fracture	36.6 fl oz		Banda de Lupinus albus doce (BLAD)	BM1	ABCDEFG	85.0 ab	1.2	20.13 a	2.6
Double Nickel	3 qt		*Bacillus amyloliquefaciens* str. D747	44	ABCDEFG	85.0 ab	1.2	22.44 a	-8.6
Badge X2	1.75 lb		Copper hydroxide, Copper oxychloride	M1	ABCDEFG	44.2 b	48.5	5.47 b	73.5
Lime	1.75 lb		Calcium hydroxide	NA	ABCDEFG				
Conventional standard:									
• Manzate Prostik	3 lb		Cymoxanil	27	ABCD	0.8 c	99.1	0.02 b	99.9
• Ziram	4 lb		Zinc dimethyldithio-carbamate	M3	EFG				
• Quintec	4 fl oz		Quinoxyfen	13	D G				
• Vivando	10.3 fl oz		Metrafenone	U8	E				
• Toledo	4 oz		Tebuconazole	3	F				

Treatment means followed by the same letter are not statistically different according to Fisher's LDS test at P ≤ 0.05.

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 13 fl oz/acre provided 41.1% control of black rot on grape clusters when cages with black rot mummies were attached to the trellis to serve as inoculum. In the absence of the mummies, no significant black rot was observed.

OMRI-listed products evaluated in this trial included Double Nickel and a tank-mixture of Badge X2 and lime.

Fracture is a biopesticide. However, based upon the label posted to the Internet, Fracture is ***not*** OMRI-listed.

Based upon this trial, Oso applied at 13 fl oz/acre provided control of black rot on grapes that was:

- ***Superior*** to that of Double Nickel; and
- ***Statistically equivalent*** to that of Badge X2 tank-mixed with lime.

CROP GROUP 13: GRAPES / Downy mildew (*Plasmopara viticola*)

#1: Trial No. KAK-2016-Grape-MI

a. Design

<table>
<tr><th colspan="6">Grapes / Downy Mildew (Plasmopara viticola) #1:
Trial No. KAK-2016-Grape-MI: Design</th></tr>
<tr><td>Title:</td><td colspan="5">Evaluation of fungicides for control of foliar and fruit diseases of juice grapes, 2016</td></tr>
<tr><td>Author and affiliation:</td><td colspan="5">A. M. Schilder, J. M. Gillett, and R. W. Sysak
Michigan State University</td></tr>
<tr><td>Publication:</td><td colspan="5">PDMR (planned for fall 2018 publication)</td></tr>
<tr><td>Location:</td><td colspan="5">Fennville, MI</td></tr>
<tr><td>Crop:</td><td colspan="5">Grape (Vitis labrusca “Niagara’)</td></tr>
<tr><td>Disease name:</td><td colspan="5">Downy mildew</td></tr>
<tr><td>Pathogen:</td><td colspan="5">Plasmopara viticola</td></tr>
<tr><td>Test plot design:</td><td colspan="5">Randomized complete block</td></tr>
<tr><td>Number of replicates:</td><td colspan="5">4</td></tr>
<tr><td>Application equipment:</td><td colspan="5">Research sprayer with 5-foot spray boom</td></tr>
<tr><td>Spray volume:</td><td colspan="5">50 gal/acre (May 8, 2016 to July 1, 2016)
75 gal/acre (remainder of the season)</td></tr>
<tr><td>Application type(s):</td><td colspan="5">Preventative</td></tr>
<tr><td>Number of applications:</td><td colspan="5">7 (Oso at 10-day to 16-day intervals)</td></tr>
<tr><td rowspan="10">Chronology:</td><td colspan="3">Application</td><td rowspan="2">Growth Stage</td><td rowspan="2">Disease Assessment Date</td></tr>
<tr><td>No.</td><td>Date</td><td>Interval</td></tr>
<tr><td>1</td><td>05/23/2016</td><td></td><td>3-5 inch shoot</td><td>09/12/2016</td></tr>
<tr><td>2</td><td>06/08/2016</td><td>16 days</td><td>10-16 inch shoot</td><td></td></tr>
<tr><td>3</td><td>06/21/2016</td><td>13 days</td><td>Bloom</td><td></td></tr>
<tr><td>4</td><td>07/01/2016</td><td>10 days</td><td>Pea-size fruit</td><td></td></tr>
<tr><td>5</td><td>07/12/2016</td><td>11 days</td><td>2nd post-bloom</td><td></td></tr>
<tr><td>6</td><td>07/27/2016</td><td>15 days</td><td>3rd post bloom</td><td></td></tr>
<tr><td>7</td><td>08/03/2016 [A]</td><td>7 days</td><td></td><td></td></tr>
<tr><td>8</td><td>08/10/2016</td><td>7 days</td><td>4th post-bloom</td><td></td></tr>
<tr><td>Disease assessment methodology:</td><td colspan="5">• 25 randomly selected leaves and clusters from the center vine in each plot were visually rated.
• Incidence = Percent leaves or clusters with disease.
• Severity = Percent area symptomatic on diseased plants only.
• Overall Severity = (Incidence x Severity) / 100.</td></tr>
<tr><td colspan="6">A. 08/03/2016 application was limited to selected treatment programs that included Ridomil Gold SL to control downy mildew.</td></tr>
</table>

b. Results

Grapes / Downy Mildew (*Plasmopara viticola*) #1: Trial No. KAK-2016-Grape-MI: Results (9/12/2016)									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App. Code	Incidence on Leaves (%)	Severity on Leaves (%)	Overall Severity on Leaves (%)	Percent Control on Leaves
Untreated control			Not Applicable			83.0 a	44.3 a	36.68 a	
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	1,2,3,4, 5,6,8	39.0 bc	7.6 b	2.89 b	92
Oso 5%SC	13 fl oz	50	Polyoxin D zinc salt	19	1,2,3,4, 5,6,8	6.0 e	1.3 d	0.10 d	99
Ranman	2.75 fl oz		Cyazofamid	21	1,2,3,4, 5,6,8	3.0 ef	1.0 de	0.06 d	99
Silwet L-77	2 fl oz		Nonionic surfactant	NA					
Manzate Pro-Stick	3 lb		Cymoxanil	27	1, 2	0.0 f	0.0 f	0.0 d	100
Pristine 38WG	12.5 oz		Boscalid	7	3,4,6,8				
			Pyraclostrobin	11					
Super Spread 90	0.125%		Non-ionic surfactant	NA					
Ziram 76DF	3 lb		Ziram	M3	5				
Ridomil Gold			Mefenoxam	4	7,8				
Treatment means followed by the same letter are not statistically different according to the Fischer's Protected SD test at $P \leq 0.05$.									

The first assessments were performed after the last treatment. Therefore, all treatments are assumed to be preventative.

The researchers reported the downy mildew disease pressure to be moderately high.

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 6.5 fl oz/acre and 13 fl oz/acre provided 92% and 99% control, respectively, of downy mildew on grape leaves.

No OMRI-listed products were evaluated in this trial.

#2: Trial No. KAK-2017-Grape-MI

a. Design

Grapes / Downy Mildew (*Plasmopara viticola*) #2: Trial No. KAK-2017-Grape-MI: Design					
Title:	Evaluation of fungicides for control of foliar diseases of juice grapes, 2017				
Author and affiliation:	A. M.C. Schilder, J. M. Gillett, and R. W. Sysak Michigan State University				
Publication:	PDMR (planned for fall 2018 publication)				
Location:	Fennville, MI				
Crop:	Grape ('Niagara')				
Disease name:	Downy mildew				
Pathogen:	*Plasmopara vitacola*				
Test plot design:	Randomized complete block				
Number of replicates:	4				
Application equipment:	Research sprayer with 5-foot boom				
Spray volume:	40 gallons/acre (first 3 applications) 50 gallons/acre (later season applications)				
Application type(s):	Preventative				
Number of applications:	7				
Chronology:	App. Code	Application Dates	App. Interval (Days)	Growth Stage	Disease Assessment Dates
	A	05/16/2017		3-5 inch shoots	09/21/2017
	B	05/30/2017	14	7-17 inch shoots	
	C	06/10/2017	11	Pre-bloom/bloom	
	D	06/21/2017	11	1st post-bloom; bb-size fruit	
	E	07/11/2017	19	2nd post-bloom; pea-size fruit	
	F	07/25/2017	14	3rd post-bloom; pre-bunch closure	
	G	08/14/2017	20	4th post-bloom; bunch closure	
Disease assessment methodology:	Incidence: % of leaves or clusters with disease. Severity: % area symptomatic on diseased plant parts only. Overall severity: (Incidence x Severity) / 100.				

b. Results

Grapes / Downy Mildew (*Plasmopara viticola*) #2: Trial No. KAK-2017-Grape-MI: Results: Clusters									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App Code	Incidence (%)	Severity (%)	Overall Severity (%)	Control (%)
Untreated control			Not Applicable			78.0 a	55.5 a	43.1 a	
Oso	13.0 fl oz	50	Polyoxin D zinc salt	19	ABCDEFG	36.0 c	5.7 bc	2.1 cd	95
Lifegard WG	4.5 oz/ 100 gal		*Bacillus mycoides* isolate J	44	ABCDEFG	42.0 b	6.9 b	2.9 b	93
Stargus	64 fl oz		*Bacillus amyloliquefaciencs* strain F727	44	ABCDEFG	38.0 bc	6.4 b	2.5 bc	94
Intuity 4SC	6 fl oz		Mandestrobin	11	ABCDEFG	38.0 bc	6.0 b	2.3 bc	94
Super Spread 90	0.125% (v/v)		Non-ionic surfactant	NA	ABCDEFG				
Treatment means followed by the same letter are not statistically different according to the Fischer's Protected LSD test at P ≤ 0.05.									

The researchers described the downy mildew disease pressure as moderately high.

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 13 fl oz/acre provided 95% control of downy mildew on grape clusters.

OMRI-listed products evaluated in this trial included Lifegard and Stargus. Oso applied at 13.0 fl oz/acre provided control of downy mildew on grape clusters that was numerically ***superior*** to that provided by Lifegard WG and Stargus.

CROP GROUP 13: GRAPES / Phomopsis Fruit Rot (*Phomopsis viticola*)

#1: Trial No. KAK-2016-Grape-MI

a. Design

Grapes / Phomopsis Fruit Rot (*Phomopsis viticola*) #1: Trial No. KAK-2016-Grape-MI: Design					
Title:	Evaluation of fungicides for control of foliar and fruit diseases of juice grapes, 2016				
Author and affiliation:	A. M. Schilder, J. M. Gillett, and R. W. Sysak Michigan State University				
Publication:	PDMR (planned for fall 2018 publication)				
Location:	Fennville, MI				
Crop:	Grape (Vitis labrusca "Niagara')				
Disease name:	Phomopsis fruit rot				
Pathogen:	*Phomopsis viticola*				
Test plot design:	Randomized complete block				
Number of replicates:	4				
Application equipment:	Research sprayer with 5-foot spray boom				
Spray volume:	50 gal/acre (May 8, 2016 to July 1, 2016) 75 gal/acre (remainder of the season)				
Application type(s):	Preventative				
Number of applications:	7 (Oso at 10-day to 16-day intervals)				
Chronology:	Application			Growth Stage	Disease Assessment Date
	No.	Date	Interval		
	1	05/23/2016		3-5 inch shoot	09/15/2016
	2	06/08/2016	16 days	10-16 inch shoot	
	3	06/21/2016	13 days	Bloom	
	4	07/01/2016	10 days	Pea-size fruit	
	5	07/12/2016	11 days	2nd post-bloom	
	6	07/27/2016	15 days	3rd post bloom	
	7	08/03/2016 [A]	7 days		
	8	08/10/2016	7 days	4th post-bloom	
Disease assessment methodology:	• 25 randomly selected leaves and clusters from the center vine in each plot were visually rated. • Incidence = Percent leaves or clusters with disease. • Severity = Percent area symptomatic on diseased plants only. • Overall Severity = (Incidence x Severity) / 100.				
A. 08/03/2016 application was limited to selected treatment programs that included Ridomil Gold SL to control downy mildew.					

b. Results

Grapes / Phomopsis Fruit Rot (*Phomopsis viticola*) #1: Trial No. KAK-2016-Grape-MI: Results: Rachis (9/15/2016)									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App. Code	Incidence (%)	Severity (%)	Overall Severity (%)	Percent Control
Untreated control			Not Applicable			57.0 a	22.4 a	12.64 a	
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	1,2,3,4, 5,6,8	39.0 b	10.4 b	3.98 b	68
Oso 5%SC	13 fl oz	50	Polyoxin D zinc salt	19	1,2,3,4, 5,6,8	14.0 fg	3.6 d	0.55 de	96
Ranman	2.75 fl oz		Cyazofamid	21	1,2,3,4, 5,6,8	20.0 ef	3.5 d	0.71 d	94
Silwet L-77	2 fl oz		Nonionic surfactant	NA					
Manzate Pro-Stick	3 lb		Cymoxanil	27	1, 2	2.0 l	1.0 ef	0.04 g	99
Pristine 38WG	12.5 oz		Boscalid	7	3,4,6,8				
			Pyraclostrobin	11					
Super Spread 90	0.125%		Non-ionic surfactant	NA					
Ziram 76DF	3 lb		Ziram	M3	5				
Ridomil Gold			Mefenoxam	4	7				
Treatment means followed by the same letter are not statistically different according to the Fischer's Protected SD test at P ≤ 0.05.									

The first assessments were performed after the last treatment. Therefore, all treatments are assumed to be preventative.

The researchers reported the Phomopsis disease pressure to be low to moderate.

No phytotoxicity was observed.

c. Comparison to OMRI-Listed Products

In this trial, Oso applied at 6.5 fl oz/acre and 13 fl oz/acre provided 68% and 96% control, respectively, of Phomopsis fruit rot on grape rachis (main axis of the cluster).

No OMRI-listed products were evaluated in this trial.

Grapes / Phomopsis Fruit Rot (*Phomopsis viticola*) #1: Trial No. KAK-2016-Grape-MI: Results: Fruit (9/15/2016)									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App. Code	Incidence (%)	Severity (%)	Overall Severity (%)	Percent Control
Untreated control			Not Applicable			57.0 a	41.7 a	23.62 a	
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	1,2,3,4, 5,6,8	39.0 b	20.3 b	7.68 b	67
Oso 5%SC	13 fl oz	50	Polyoxin D zinc salt	19	1,2,3,4, 5,6,8	14.0 fg	7.0 d	1.06 de	96
Ranman	2.75 fl oz		Cyazofamid	21	1,2,3,4, 5,6,8	20.0 ef	7.1 d	1.42 d	94
Silwet L-77	2 fl oz		Nonionic surfactant	NA					
Manzate Pro-Stick	3 lb		Cymoxanil	27	1, 2	2.0 l	1.3 ef	0.05 e	99
Pristine 38WG	12.5 oz		Boscalid	7	3,4,6,8				
			Pyraclostrobin	11					
Super Spread 90	0.125%		Non-ionic surfactant	NA					
Ziram 76DF	3 lb		Ziram	M3	5				
Ridomil Gold			Mefenoxam	4	7				
Treatment means followed by the same letter are not statistically different according to the Fischer's Protected SD test at $P \leq 0.05$.									

The first assessments were performed after the last treatment. Therefore, all treatments are assumed to be preventative.

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 6.5 fl oz/acre and 13 fl oz/acre provided 67% and 96% control, respectively, of Phomopsis fruit rot on grapes.

No OMRI-listed products were evaluated in this trial.

#2: Trial No. KAK-2017-Grape-MI

a. Design

Grapes / Phomopsis Fruit Rot (*Phomopsis viticola*) #2: Trial No. KAK-2017-Grape-MI: Design					
Title:	Evaluation of fungicides for control of foliar diseases of juice grapes, 2017				
Author and affiliation:	A. M.C. Schilder, J. M. Gillett, and R. W. Sysak Michigan State University				
Publication:	PDMR (planned for fall 2018 publication)				
Location:	Fennville, MI				
Crop:	Grape ('Niagara')				
Disease name:	Phomopsis fruit rot				
Pathogen:	*Phomopsis vitaola*				
Test plot design:	Randomized complete block				
Number of replicates:	4				
Application equipment:	Research sprayer with 5-foot boom				
Spray volume:	40 gallons/acre (first 3 applications) 50 gallons/acre (later season applications)				
Application type(s):	Preventative				
Number of applications:	7				
Chronology:	App. Code	Application Dates	App. Interval (Days)	Growth Stage	Disease Assessment Dates
	A	05/16/2017		3-5 inch shoots	09/25/2017
	B	05/30/2017	14	7-17 inch shoots	
	C	06/10/2017	11	Pre-bloom/bloom	
	D	06/21/2017	11	1st post-bloom; bb-size fruit	
	E	07/11/2017	19	2nd post-bloom; pea-size fruit	
	F	07/25/2017	14	3rd post-bloom; pre-bunch closure	
	G	08/14/2017	20	4th post-bloom; bunch closure	
Disease assessment methodology:	Incidence: % of leaves or clusters with disease. Severity: % area symptomatic on diseased plant parts only. Overall severity: (Incidence x Severity) / 100.				

b. Results

Grapes / Phomopsis Fruit Rot (*Phomopsis viticola*) #2: Trial No. KAK-2017-Grape-MI: Results: Clusters									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App Code	Incidence (%)	Severity (%)	Overall Severity (%)	Control (%)
Untreated control			Not Applicable			88.0 a	51.8 a	45.5 a	
Oso	13.0 fl oz	50	Polyoxin D zinc salt	19	ABCDEFG	28.0 cd	4.8 d	1.4 c	97
Lifegard WG	4.5 oz/ 100 gal		*Bacillus mycoides* isolate J	44	ABCDEFG	44.0 b	12.7 b	5.6 b	88
Stargus	64 fl oz		*Bacillus amyloliquefaciencs* strain F727	44	ABCDEFG	34.0 c	11.5 b	3.8 b	92
Intuity 4SC	6 fl oz		Mandestrobin	11	ABCDEFG	8.0 e	1.8 de	0.3 d	99
Super Spread 90	0.125% (v/v)		Non-ionic surfactant	NA	ABCDEFG				
Treatment means followed by the same letter are not statistically different according to the Fischer's Protected LSD test at P ≤ 0.05.									

The researchers described the Phomopsis fruit rot disease pressure as moderate.

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 13 fl oz/acre provided 97% control of Phomopsis fruit rot on grape clusters.

OMRI-listed products evaluated in this trial included Lifegard and Stargus. Oso applied at 13.0 fl oz/acre provided control of Phomopsis fruit rot on grapes that was statistically ***superior*** to that provided by Lifegard WG and Stargus.

CROP GROUP 13: STRAWBERRIES / Anthracnose Fruit Rot (*Colletotrichum acutatum*)

#1: Trial No. KAK-2016-SBerry-MI

a. Design

<table>
<tr><td colspan="6">Strawberries /Anthracnose Fruit Rot (Colletotrichum acutatum) #1:
Trial No. KAK-2016-Sberry-MI: Design</td></tr>
<tr><td>Title:</td><td colspan="5">Evaluations of fungicides for control of leaf and fruit rot diseases in matted-row strawberry, 2016</td></tr>
<tr><td>Author and affiliation:</td><td colspan="5">A. M. C. Schilder, N. M. Gillett, and R. W. Sysak
Michigan State University</td></tr>
<tr><td>Publication:</td><td colspan="5">PDMR (planned for fall 2018 publication)</td></tr>
<tr><td>Location:</td><td colspan="5">Camden, MI</td></tr>
<tr><td>Crop:</td><td colspan="5">Strawberry (Fragarias x ananassa ‘Wendy’)</td></tr>
<tr><td>Disease name:</td><td colspan="5">Anthracnose fruit rot</td></tr>
<tr><td>Pathogen:</td><td colspan="5">Colletotrichum acutatum</td></tr>
<tr><td>Test plot design:</td><td colspan="5">Randomized complete block</td></tr>
<tr><td>Number of replicates:</td><td colspan="5">4</td></tr>
<tr><td>Application equipment:</td><td colspan="5">Handheld Smith Contractor Sprayer (29 psi)</td></tr>
<tr><td>Spray volume:</td><td colspan="5">75 gal/acre</td></tr>
<tr><td>Application type(s):</td><td colspan="5">Preventative</td></tr>
<tr><td>Number of applications:</td><td colspan="5">7</td></tr>
<tr><td rowspan="9">Chronology:</td><td colspan="4">Application</td><td rowspan="2">Disease Assessment Dates</td><td rowspan="2">Harvest Dates</td></tr>
<tr><td>No.</td><td>Date</td><td>Interval</td><td>Growth Stage</td></tr>
<tr><td>1</td><td>05/09/2016</td><td></td><td>Green up</td><td rowspan="7">06/23/2016</td><td rowspan="7">06/16/2016
06/24/2016</td></tr>
<tr><td>2</td><td>05/18/2016</td><td>9 days</td><td>Bloom</td></tr>
<tr><td>3</td><td>05/24/2016</td><td>6 days</td><td>2nd bloom after frost</td></tr>
<tr><td>4</td><td>06/01/2016</td><td>7 days</td><td>Bloom and green fruit</td></tr>
<tr><td>5</td><td>06/07/2016</td><td>6 days</td><td>Green fruit</td></tr>
<tr><td>6</td><td>06/15/2016</td><td>7 days</td><td>Green and red fruit</td></tr>
<tr><td>7</td><td>06/23/2016</td><td>8 days</td><td>Red fruit</td></tr>
<tr><td>Disease assessment methodology:</td><td colspan="5">• Visual field ratings: 50 berries were selected randomly.
• Disposable gloves were used to pick berries and changed between plots to reduce cross-contamination.
• Harvest was from the center of plots.
• Post-harvest: 25 marketable berries from each plot were placed equidistant on metal screens in aluminum trays and incubated at 72°F and 100% relative humidity. After 4 days, the berries were inspected for fungal sporulation.</td></tr>
</table>

b. Results

Strawberries /Anthracnose Fruit Rot (*Colletotrichum acutatum*) #1: Trial No. KAK-2016-Sberry-MI: Results								
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	Field Incidence (%)		4-Day Post-Harvest Marketable Fruit [A] (1st Harvest; 6/16/2016)	
					Measured	Percent Control	Incidence (%)	Percent Increase
Untreated control			Not Applicable		27.0 a		7.5 a	
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	5.5 b	80	28.0 bc	273
Oso 5%SC	13 fl oz	50	Polyoxin D zinc salt	19	4.0 bc	85	25.0 b	233
Serifel	4 oz		*Bacillus amyloliquefanciens* strain MBI 600	44	5.0 b	80	27.0 bc	260
Serifel	4 oz		*Bacillus amyloliquefanciens* strain MBI 600	44	5.0 b	81	38.0 c	407
Pristine	11.5 oz		Boscalid	7				
			Pyraclostrobin	11				

Treatment means followed by the same letter are not statistically different according to Fisher's Protected LSD test at $P \leq 0.05$.
A. Harvested 1 day after last application. All berries used in the post-harvest incubation test appeared marketable (no visible disease or soft areas) before incubation started.

The first assessments were performed after the last treatment. Therefore, all treatments are assumed to be preventative.

The researchers reported that the Anthracnose incidence observed in the field on fruit was moderate.

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 6.5 fl oz/acre and 13 fl oz/acre provided:

- 80% and 85% control, respectively, of field incidence of anthracnose fruit rot on strawberries; and
- 273% and 233% increases, respectively, of 4-day post-harvest marketable fruit.

One OMRI-listed product was evaluated in this trial. Oso applied at 13 fl oz/acre provided *superior* field control of anthracnose on strawberries compared to Serifel.

#2: Trial No. KAK-2017-SBerry-MI

a. Design

Strawberries /Anthracnose Fruit Rot (*Colletotrichum acutatum*) #2: Trial No. KAK-2017-Sberry-MI: Design				
Title:	Evaluation of fungicides for control of leaf and fruit rot diseases in matted-row strawberry, 2017			
Author and affiliation:	A. M. C. Schilder, J. M. Gillett, and R. W. Sysak Michigan State University			
Publication:	PDMR (planned for fall 2018 publication)			
Location:	Camden, MI			
Crop:	Strawberry (*Fragaria* x *ananassa* 'Wendy')			
Disease name:	Anthracnose fruit rot			
Pathogen:	*Colletotrichum acutatum* and *Colletotrichum dematium*			
Test plot design:	Randomized complete block			
Number of replicates:	4			
Application equipment:	Smith Contractor Sprayer (29 psi)			
Spray volume:	75 gallons/acre			
Application type(s):	Preventative			
Number of applications:	5			
Chronology:	Application Dates	Application Interval (days)	Growth Stage	Disease Assessment Dates
	05/01/2017		Green up	06/22/2017 (field ratings)
	05/07/ 2017	7	50% bloom	06/26/2017 (post-harvest ratings)
	05/24/2017	17	Bloom	
	05/31/2017	7	Bloom and green fruit	
	06/14/2017	14	Red fruit	
Disease assessment methodology (post-harvest):	25 marketable berries from each plot were placed equidistantly on metal screens in aluminum trays and incubated at room temperature and 100% relative humidity. After 4 days, berries were visually assessed for final sporulation.			

b. Results

Strawberries /Anthracnose Fruit Rot (*Colletotrichum acutatum*) #2: Trial No. KAK-2017-Sberry-MI: Results									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App Code	4-Day Post-Harvest			
						Colletotrichum acutatum		*Colletotrichum dematium*	
						Incidence (%)	Control (%)	Incidence (%)	Control (%)
Untreated control			Not Applicable			10.0 a		43.0 a	
Oso 5%	13 fl oz	50	Polyoxin D zinc salt	19	ABCDE	1.0 b	90	5.0 b	88
Conventional standard:									
Topsin	4.5 fl oz		Thiophanate-methyl	1	A	2.0 b	80	9.0 b	79
Captan 4L	3 qt		Captan	M4	A				
Fontelis	24 fl oz		Penthiopyrad	7	BCE				
Switch 62.5	12 oz		Cyprodinil	9	D				
			Fludioxonil	12					
Treatment means followed by the same letter are not statistically different according to the Fisher's Protected LSD test at P ≤ 0.05.									
Overall Severity = [(Incidence) x (Severity)] / 100.									

The researchers described the Botrytis disease pressure as moderately high.

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 13 fl oz/acre provided 90% and 88% control, of anthracnose on 4-day post-harvested strawberries caused by *Colletotrichum acutatum* and *Colletotrichum dematium*, respectively.

No OMRI-listed products were evaluated in this trial.

CROP GROUP 13: STRAWBERRIES / Leather Rot (*Phytophthora cactorum*)

#1: Trial No. KAK-2016-SBerry-MI

a. Design

<table>
<tr><td colspan="6">Strawberries / Leather Rot (Phytophthora cactorum) #1:
Trial No. KAK-2016-Sberry-MI: Design</td></tr>
<tr><td>Title:</td><td colspan="5">Evaluations of fungicides for control of leaf and fruit rot diseases in matted-row strawberry, 2016</td></tr>
<tr><td>Author and affiliation:</td><td colspan="5">A. M.C. Schilder, N. M. Gillett, and R. W. Sysak
Michigan State University</td></tr>
<tr><td>Publication:</td><td colspan="5">PDMR (planned for fall 2018 publication)</td></tr>
<tr><td>Location:</td><td colspan="5">Camden, MI</td></tr>
<tr><td>Crop:</td><td colspan="5">Strawberry (Fragarias x ananassa ‘Wendy’)</td></tr>
<tr><td>Disease name:</td><td colspan="5">Leather rot</td></tr>
<tr><td>Pathogen:</td><td colspan="5">Phytophthora cactorum</td></tr>
<tr><td>Test plot design:</td><td colspan="5">Randomized complete block</td></tr>
<tr><td>Number of replicates:</td><td colspan="5">4</td></tr>
<tr><td>Application equipment:</td><td colspan="5">Handheld Smith Contractor Sprayer (29 psi)</td></tr>
<tr><td>Spray volume:</td><td colspan="5">75 gal/acre</td></tr>
<tr><td>Application type(s):</td><td colspan="5">Preventative</td></tr>
<tr><td>Number of applications:</td><td colspan="5">7</td></tr>
<tr><td rowspan="9">Chronology:</td><td colspan="4">Application</td><td rowspan="2">Disease Assessment Dates</td><td rowspan="2">Harvest Dates</td></tr>
<tr><td>No.</td><td>Date</td><td>Interval</td><td>Growth Stage</td></tr>
<tr><td>1</td><td>05/09/2016</td><td></td><td>Green up</td><td rowspan="7">06/23/2016</td><td rowspan="7">06/16/2016
06/24/2016</td></tr>
<tr><td>2</td><td>05/18/2016</td><td>9 days</td><td>Bloom</td></tr>
<tr><td>3</td><td>05/24/2016</td><td>6 days</td><td>2nd bloom after frost</td></tr>
<tr><td>4</td><td>06/01/2016</td><td>7 days</td><td>Bloom and green fruit</td></tr>
<tr><td>5</td><td>06/07/2016</td><td>6 days</td><td>Green fruit</td></tr>
<tr><td>6</td><td>06/15/2016</td><td>7 days</td><td>Green and red fruit</td></tr>
<tr><td>7</td><td>06/23/2016</td><td>8 days</td><td>Red fruit</td></tr>
<tr><td>Disease assessment methodology:</td><td colspan="5">• Visual field ratings: 50 berries were selected randomly.
• Disposable gloves were used to pick berries and changed between plots to reduce cross-contamination.
• Harvest was from the center of plots.
• Post-harvest: 25 marketable berries from each plot were placed equidistant on metal screens in aluminum trays and incubated at 72°F and 100% relative humidity. After 4 days, the berries were inspected for fungal sporulation.</td></tr>
</table>

b. Results

Strawberries / Leather Rot (*Phytophthora cactorum*) #1: Trial No. KAK-2016-Sberry-MI: Results									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App Code	Field Incidence on Fruit (%)		4-Day Post-Harvest Marketable Fruit [A] (1st Harvest; 6/1462016)	
						Measured	Percent Control	Incidence (%)	Percent Increase
Untreated control			Not Applicable			31.0 a		7.5 a	
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	1-7	5.0 b	84	28.0 bc	273
Oso 5%SC	13 fl oz	50	Polyoxin D zinc salt	19	1-7	0.5 cd	98	25.0 b	233
Serifel	4 oz		*Bacillus amyloliquefanciens* strain MBI 600	44	1-7	3.0 bc	90	27.0 bc	260
Serifel	4 oz		*Bacillus amyloliquefanciens* strain MBI 600	44	1-7	2.5 bc	92	38.0 c	407
Pristine	11.5 oz		Boscalid	7					
			Pyraclostrobin	11					
Treatment means followed by the same letter are not statistically different according to Fisher's Protected LSD test at $P \leq 0.05$. A. Harvested 1 day after last application. All berries used in the post-harvest incubation test appeared marketable (no visible disease or soft areas) before incubation started.									

The first assessments were performed after the last treatment. Therefore, all treatments are assumed to be preventative.

The researchers reported that the leather rot incidence observed on fruit in the field was moderate.

No phytotoxicity was observed.

c. Discussion

In this study, Oso applied at 6.5 fl oz/acre and 13 fl oz/acre provided:

- 84% and 98% control, respectively, of in-field incidence of leather rot on strawberries; and
- 273% and 233% increases, respectively, of 4-day post-harvest marketable fruit.

One OMRI listed product was evaluated in this trial. Oso applied at 13 fl oz/ acre provided *superior* control of field incidence of leather rot on strawberries compared to Serifel.

#2: Trial No. KAK-2017-SBerry-MI

a. Design

Strawberries / Leather Rot (*Phytophthora cactorum*) #2: Trial No. KAK-2017-Sberry-MI: Design				
Title:	Evaluation of fungicides for control of leaf and fruit rot diseases in matted-row strawberry, 2017			
Author and affiliation:	A. M. C. Schilder, J. M. Gillett, and R. W. Sysak Michigan State University			
Publication:	PDMR (planned for fall 2018 publication)			
Location:	Camden, MI			
Crop:	Strawberry (*Fragaria* x *ananassa* 'Wendy')			
Disease name:	Leather rot			
Pathogen:	*Phytophthora cactorum*			
Test plot design:	Randomized complete block			
Number of replicates:	4			
Application equipment:	Smith Contractor Sprayer (29 psi)			
Spray volume:	75 gallons/acre			
Application type(s):	Preventative			
Number of applications:	5			
Chronology:	Application Dates	Application Interval (days)	Growth Stage	Disease Assessment Dates
	05/01/2017		Green up	06/22/2017 (field ratings)
	05/07/ 2017	7	50% bloom	06/26/2017 (post-harvest ratings)
	05/24/2017	17	Bloom	
	05/31/2017	7	Bloom and green fruit	
	06/14/2017	14	Red fruit	
Disease assessment methodology (post-harvest):	25 marketable berries from each plot were placed equidistantly on metal screens in aluminum trays and incubated at room temperature and 100% relative humidity. After 4 days, berries were visually assessed for final sporulation.			

b. Results

Strawberries / Leather Rot (*Phytophthora cactorum*) #2: Trial No. KAK-2017-Sberry-MI: Results									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App Code	Field Rating of Leather Rot on Fruit		4-Day Post-Harvest Marketable Fruit	
						Incidence (%)	Control (%)	Incidence (%)	Increase (%)
Untreated control			Not Applicable			56.8 a		2.0 a	
Oso 5%	13 fl oz	50	Polyoxin D zinc salt	19	ABCDE	10.8 b	81	49.0 b	2350
Conventional standard:									
Topsin	4.5 fl oz		Thiophanate-methyl	1	A	7.5 b	87	40.0 b	1900
Captan 4L	3 qt		Captan	M4	A				
Fontelis	24 fl oz		Penthiopyrad	7	BC E				
Switch 62.5	12 oz		Cyprodinil	9	D				
			Fludioxonil	12					
Treatment means followed by the same letter are not statistically different according to the Fisher's Protected LSD test at P ≤ 0.05.									

The researchers described the leather rot disease pressure as moderately high.

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 13 fl oz/acre provided:

- 81% control of leather rot; and
- a 2350% increase in 4-day post-harvest marketable strawberries.

No OMRI-listed products were evaluated in this trial.

CROP GROUP 13: STRAWBERRIES / Phomopsis Leaf Spot *(Phomopsis obscurans)*

#1 Trial No. KAK-2016-SBerry-MI

a. Design

<table>
<tr><td colspan="6">Strawberries / Phomopsis Leaf Spot (Phomopsis obscurans) #1:
Trial No. KAK-2016-Sberry-MI: Design</td></tr>
<tr><td>Title:</td><td colspan="5">Evaluations of fungicides for control of leaf and fruit rot diseases in matted-row strawberry, 2016</td></tr>
<tr><td>Author and affiliation:</td><td colspan="5">A. M.C. Schilder, N. M. Gillett, and R. W. Sysak
Michigan State University</td></tr>
<tr><td>Publication:</td><td colspan="5">PDMR (planned for fall 2018 publication)</td></tr>
<tr><td>Location:</td><td colspan="5">Camden, MI</td></tr>
<tr><td>Crop:</td><td colspan="5">Strawberry (Fragarias x ananassa ‘Wendy’)</td></tr>
<tr><td>Disease name:</td><td colspan="5">Phomopsis leaf spot</td></tr>
<tr><td>Pathogen:</td><td colspan="5">Phomopsis obscurans</td></tr>
<tr><td>Test plot design:</td><td colspan="5">Randomized complete block</td></tr>
<tr><td>Number of replicates:</td><td colspan="5">4</td></tr>
<tr><td>Application equipment:</td><td colspan="5">Handheld Smith Contractor Sprayer (29 psi)</td></tr>
<tr><td>Spray volume:</td><td colspan="5">75 gal/acre</td></tr>
<tr><td>Application type(s):</td><td colspan="5">Preventative</td></tr>
<tr><td>Number of applications:</td><td colspan="5">7</td></tr>
<tr><td rowspan="9">Chronology:</td><td colspan="4">Application</td><td rowspan="2">Disease Assessment Dates</td><td rowspan="2">Harvest Dates</td></tr>
<tr><td>No.</td><td>Date</td><td>Interval</td><td>Growth Stage</td></tr>
<tr><td>1</td><td>05/09/2016</td><td></td><td>Green up</td><td rowspan="7">06/23/2016</td><td rowspan="7">06/16/2016
06/24/2016</td></tr>
<tr><td>2</td><td>05/18/2016</td><td>9 days</td><td>Bloom</td></tr>
<tr><td>3</td><td>05/24/2016</td><td>6 days</td><td>2nd bloom after frost</td></tr>
<tr><td>4</td><td>06/01/2016</td><td>7 days</td><td>Bloom and green fruit</td></tr>
<tr><td>5</td><td>06/07/2016</td><td>6 days</td><td>Green fruit</td></tr>
<tr><td>6</td><td>06/15/2016</td><td>7 days</td><td>Green and red fruit</td></tr>
<tr><td>7</td><td>06/23/2016</td><td>8 days</td><td>Red fruit</td></tr>
<tr><td>Disease assessment methodology:</td><td colspan="5">Visual field ratings: 25 leaves were randomly selected.
Post-harvest ratings: 25 marketable berries form each plot were placed equidistantly on metal screens on aluminum trays and incubated at 72°F and 100% relative humidity. After 4 days, berries were assessed visually for fungal sporulation and disease incidence for individual pathogens.</td></tr>
</table>

b. Results

Strawberries / Phomopsis Leaf Spot *(Phomopsis obscurans)* #1: Trial No. KAK-2016-Sberry-MI: Field Results								
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	Leaves			
					Incidence (%)	Severity (%)	Overall (%)	Control (%)
Untreated control			Not Applicable		10.3 a	39.5 a	4.1 a	
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	2.0 b	2.9 b	0.06 b	98
Oso 5%SC	13 fl oz	50	Polyoxin D zinc salt	19	0.0 c	0.0 c	0.0 b	100
Serifel	4 oz		*Bacillus amyloliquefanciens* strain MBI 600	44	1.0 bc	1.8 bc	0.03 b	99
Serifel	4 oz		*Bacillus amyloliquefanciens* strain MBI 600	44	0.5 c	0.8 bc	0.02 b	99
Pristine	11.5 oz		Boscalid	7				
			Pyraclostrobin	11				
Treatment means followed by the same letter are not statistically different according to Fisher's Protected LSD test at $P \leq 0.05$.								

The first assessments were performed after the last treatment. Therefore, all treatments are assumed to be preventative.

The researchers described the Phomopsis leaf spot incidence and severity on leaves as low.

No phytotoxicity was observed.

Strawberries / Phomopsis Fruit Rot *(Phomopsis obscurans)* #1: Trial No. KAK-2016-Sberry-MI: 4-Day Post-Harvest Results								
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	Marketable Fruit			
					Harvest 1		Harvest 2	
					Incidence (%)	Increase (%)	Incidence (%)	Increase (%)
Untreated control			Not Applicable		7.5 a		15.0 a	
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	28.0 bc	273	46.0 bc	207
Oso 5%SC	13 fl oz	50	Polyoxin D zinc salt	19	25.0 b	233	62.0 bc	313
Serifel	4 oz		*Bacillus amyloliquefanciens* strain MBI 600	44	27.0 bc	260	47.0 bc	213
Serifel	4 oz		*Bacillus amyloliquefanciens* strain MBI 600	44	38.0 c	407	68.0 bc	353
Pristine	11.5 oz		Boscalid	7				
			Pyraclostrobin	11				
Treatment means followed by the same letter are not statistically different according to Fisher's Protected LSD test at $P \leq 0.05$.								

c. Discussion

In this trial, Oso applied at 6.5 fl oz/acre and 13 fl oz/acre provided:

- 98% and 100% control, respectively, of Phomopsis leaf spot on strawberry leaves; and
- Up to 273% and 313% increase, respectively, in marketable strawberries.

One OMRI-listed products was evaluated in this trial. Oso applied at 13 fl oz/acre provided:

- *Superior* control of Phomopsis leaf spot compared to Serifel; and
- *Superior* control of Phomopsis fruit rot compared to Serifel.

#2 Trial No. KAK-2017-SBerry-MI

a. Design

Strawberries / Phomopsis Leaf Spot and Fruit Rot (*Phomopsis obscurans*) #2: Trial No. KAK-2017-Sberry-MI: Design				
Title:	Evaluation of fungicides for control of leaf and fruit rot diseases in matted-row strawberry, 2017			
Author and affiliation:	A. M. C. Schilder, J. M. Gillett, and R. W. Sysak Michigan State University			
Publication:	PDMR (planned for fall 2018 publication)			
Location:	Camden, MI			
Crop:	Strawberry (*Fragaria* x *ananassa* 'Wendy')			
Disease name:	Phomopsis leaf spot and fruit rot			
Pathogen:	*Phomopsis obscurans*			
Test plot design:	Randomized complete block			
Number of replicates:	4			
Application equipment:	Smith Contractor Sprayer (29 psi)			
Spray volume:	75 gallons/acre			
Application type(s):	Preventative			
Number of applications:	5			
Chronology:	Application Dates	Application Interval (days)	Growth Stage	Disease Assessment Dates
	05/01/2017		Green up	06/22/2017 (field ratings)
	05/07/ 2017	7	50% bloom	06/26/2017 (post-harvest ratings)
	05/24/2017	17	Bloom	
	05/31/2017	7	Bloom and green fruit	
	06/14/2017	14	Red fruit	
Disease assessment methodology (post-harvest):	25 marketable berries from each plot were placed equidistantly on metal screens in aluminum trays and incubated at room temperature and 100% relative humidity. After 4 days, berries were visually assessed for final sporulation.			

b. Results

Strawberries / Phomopsis Leaf Spot *(Phomopsis obscurans)* #2: Trial No. KAK-2017-Sberry-MI: Results: Field Ratings									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App Code	Field Rating of Leaves for Phomopsis Leaf Spot			
						Incidence (%)	Severity (%)	Overall Severity (%)	Control (%)
Untreated control			Not Applicable			35.1 a	15.5 a	5.4 a	
Oso 5%	13 fl oz	50	Polyoxin D zinc salt	19	ABCDE	17.4 b	4.6 b	0.8 b	83
Topsin	4.5 fl oz		Thiophanate-methyl	1	A	15.9 b	5.3 b	0.9 b	87
Captan 4L	3 qt		Captan	M4	A				
Fontelis	24 fl oz		Penthiopyrad	7	BC E				
Switch 62.5	12 oz		Cyprodinil	9	D				
			Fludioxonil	12					
Treatment means followed by the same letter are not statistically different according to the Fisher's Protected LSD test at P ≤ 0.05. Overall Severity = [(Incidence) x (Severity)] / 100.									

Strawberries / Phomopsis Fruit Rot *(Phomopsis obscurans)* #2: Trial No. KAK-2017-Sberry-MI: Post-Harvest Results									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App Code	4-Day Post-Harvest Phomopsis Fruit Rot		4-Day Post-Harvest Marketable Fruit	
						Incidence (%)	Control (%)	Incidence (%)	Increase (%)
Untreated control			Not Applicable			20.0 a		2.0 a	
Oso 5%	13 fl oz	50	Polyoxin D zinc salt	19	ABCDE	4.0 b	80	49.0 b	2350
Conventional standard:									
Topsin	4.5 fl oz		Thiophanate-methyl	1	A	3.0 b	85	40.0 b	1900
Captan 4L	3 qt		Captan	M4	A				
Fontelis	24 fl oz		Penthiopyrad	7	BC E				
Switch 62.5	12 oz		Cyprodinil	9	D				
			Fludioxonil	12					
Treatment means followed by the same letter are not statistically different according to the Fisher's Protected LSD test at P ≤ 0.05.									

The researchers described the Phomopsis *leaf spot* field incidence as moderate and the overall Phomopsis leaf spot severity as low.

The researchers described the post-harvest Phomopsis *fruit rot* incidence as moderately low.

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 13 fl oz/acre provided:

- 83% control of Phomopsis leaf spot on strawberry leaves;
- 80% control of 4-day post-harvest Phomopsis fruit rot; and
- a 2350% post-harvest increase in marketable fruit.

No OMRI-listed products were evaluated in this trial.

CROP GROUP 19: HERBS AND SPICES: BASIL / Downy Mildew (*Peronospora belbahrii*)

#1: Trial No. IND-2015-218

a. Design

Basil / Downy Mildew (*Peronospora belbahrii*) #1: Trial No. IND-2015-218: Design			
Title:	Evaluation of biopesticides for downy mildew in basil with a potted plant assay		
Author and affiliation:	Margaret Tuttle McGrath Cornell University		
Publication:	PDMR 10:V034		
Location:	Greenhouse, then field (Riverhead, New York)		
Crop:	Basil (variety not specified)		
Disease name:	Downy mildew		
Pathogen:	*Peronospora belbahrii*		
Test plot design:	Not applicable		
Number of replicates:	1 replicate; 10 seedlings/treatment		
Application equipment:	Not applicable		
Spray volume:	Seedling dipped into fungicide solutions		
Application type(s):	Preventative		
Number of applications:	1		
Chronology:	Application Dates	Application Interval	Disease Assessment Dates
	09/22/2015	NA	09/30/2015
Methodology:	Potted seedlings were dipped into treatment solutions instead of sprayed with treatment solution to ensure contact of the treatment solution with both sides of the basil leaves. The dipped potted seedlings were allowed to dry in the greenhouse overnight. During the next approximately 72 hours, the seedlings were outdoors during daytimes and in the greenhouse in garbage bags during nighttimes for high humidity to promote spore production.		

b. Results

Basil / Downy Mildew (*Peronospora belbahrii*) #1: Trial No. IND-2015-218: Results									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	Severity (%) 10/13/2015		Incidence (%) 10/09/2015		Mean Percent Control
					Measured	Percent Control	Measured	Percent Control	
Untreated control			Not Applicable		45.3		100		
Oso	13 fl oz	50	Polyoxin D zinc salt	19	16.7	63.1	60	40	52
Actinovate AG	12 oz		*Streptomyces lydicus* WYEC 108	NC	40.0	1.15	80	20	11
Double Nickel	1.5 lb		*Bacillus amyloliquefaciens* str. D747	44	35.7	21.2	80	20	21
MilStop	3 lb		Potassium bicarbonate	NC	38.3	15.5	30	70	43
Trilogy	1%		Neem oil	NC	18.3	59.6	50	50	55
Regalia	2 qt		*Reynoutria sachalinensis* extract	P5	28.8	36.4	20	80	58
Sil-Matrix	3 qt		Potassium silicate	NC	18.0	60.3	20	80	70
Cueva	4 qt		Copper octanoate	M1	NA	NA	0	100	100
Revus	8 fl oz		Mandipropamid	40	40.0	11.7	10	90	51
NC = Not classified.									

The researcher did not comment of the relative downy mildew disease incidence or severity.

No phytotoxicity was reported.

c. Discussion

In this trial, Oso applied at 13 fl oz/acre provided 52% control of downy mildew on basil.

With the exception of Revus, all of the alternative treatments are OMRI-listed. Based upon this trial, Oso applied at 13 fl oz/acre provided control of downy mildew on basil that was:

- *Superior* to that provided by Actinovate AG, Double Nickel, and MilStop;
- *Similar* to that provided by Trilogy; and
- Inferior to that provided by Regalia, Sil-Matrix, and Cueva.

NEW EFFICACY DATA FOR USES INCLUDED IN THE MAY 31, 2016 PETITION

CROP GROUP 4: LEAFY VEGETABLES: **SPINACH / White Rust (***Albugo occidentalis***)**

#2: Trial No. CER-2015-152

a. Design

Spinach / White Rust (*Albugo occidentalis*) #2: Trial No. CER-2015-152: Design			
Title:	2015-2016 Fungicide Trial for Control of Spinach White Rust		
Author and affiliation:	Larry Stein and Marcel Valdez, Texas A&M AgriLife Extension Service; and Devin Kerstetter and Tyler Knight, Del Monte Corporation		
Publication:	Not published		
Location:	Del Monte Research Farm near Crystal City, TX		
Crop:	Spinach (variety Viroflay)		
Disease name:	White rust		
Pathogen:	*Albugo occidentalis*		
Test plot design:	Not reported		
Number of replicates:	Not reported		
Application equipment:	Foliar spray		
Spray volume:	15 gallon/acre		
Application type(s):	Preventative		
Number of applications:	4		
Chronology:	Application Dates	Application Interval	Disease Assessment Dates
	2015/12/11		2016/01/19
	2015/12/23	14 days	2016/01/29
	2016/01/08	15 days	
	2016/01/19	11 days	
Disease assessment rating:	1 = No white rust. 10 = Blown out.		

b. Results

Spinach / White Rust (*Albugo occidentalis*) #2: Trial No. CER-2015-152: Results							
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App Code	Disease Rating [A] 01/29/2016	
						Measured	Percent Control
Untreated control			Not Applicable			4.5 c	
Oso	6.5 fl oz	25	Polyoxin D zinc salt	19	ABCD	2.3 a	49
Induce	4 oz		Non-ionic wetter/spreader	NA			
Orondis	4.8 oz		Mandipropamid	40	ABCD	2.0 a	55
Induce	4 oz		Non-ionic wetter/spreader	NA			
Actinovate	6 oz		*Streptomyces lydicus* WYEC 108	NC	ABCD	2.0 a	55
Induce	4 oz		Non-ionic wetter/spreader	NA			
Zampro	14 oz		Ametoctradin	45	ABCD	2.0 a	55
			Dimethomorph	40			
Induce	4 oz		Non-ionic wetter/spreader	NA			
Double Nickel LC	1 qt		*Bacillus amyloliquefaciens* str. D747	44	AC	3.5 b	22
Cueva	20 oz		Copper octanoate	M1	BD		
Induce	4 oz		Non-ionic wetter/spreader	NA	ABCD		
Treatment means followed by the same letter are not statistically different. She statistical test and significance criteria were was not reported. A. Disease rating: 1 = No white rust. 10 = Blown out.							

On January 19, 2015, the last application was made and disease was first observed. Therefore, the first three applications were preventative and the last application was curative.

The researchers indicated that the disease pressure was low.

Upon returning to the trial site on February 12, 2016 to make the final rating and to determine the main cause of the problems, the trial had been destroyed by feral hogs. Nonetheless, the data provide for comparison of disease control through January 29, 2016, *i.e.*, 10 days after the last treatment.

Please note that the no white rust rating is 1 in this trial and was 0 in the 2014 trial.

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 6.5 fl oz/acre tank-mixed with Induce (a non-ionic wetter/spreader) provided 49% control of white rust on spinach.

OMRI-listed products evaluated in this trial included Actinovate, Double Nickel LC, and Cueva. Based upon this trial, Oso applied at 6.5 fl oz/acre provided control of white rust on spinach that was:

- Statistically ***equivalent*** to that provided by Actinovate; and
- Statistically ***superior*** to that provided by alternate applications of Double Nickel and Cueva.

CROP GROUP 11: POME FRUITS

APPLE / Powdery Mildew Storage Rot (*Podosphaera leuotricha*)

#4: Trial No. CER-2015-033

a. Design

<table>
<tr><th colspan="5">Apple / Powdery Mildew Storage Rot (Podosphaera leuotricha) #4:
Trial No. CER-2015-033: Design</th></tr>
<tr><td>Title:</td><td colspan="4">Evaluation of the Efficacy of Oso 5%SC Fungicide, Cueva and Double Nickel LC Against Common Storage Rot Pathogens on Apples</td></tr>
<tr><td>Author and affiliation:</td><td colspan="4">Ron Britt
Ron Britt & Associates</td></tr>
<tr><td>Publication:</td><td colspan="4">Not published</td></tr>
<tr><td>Location:</td><td colspan="4">Wapato, Washington</td></tr>
<tr><td>Crop:</td><td colspan="4">Apples (Granny Smith)</td></tr>
<tr><td>Disease name:</td><td colspan="4">Powdery mildew storage rot</td></tr>
<tr><td>Pathogen:</td><td colspan="4">Podosphaera leucotricha</td></tr>
<tr><td>Test plot design:</td><td colspan="4">Randomized compete block</td></tr>
<tr><td>Number of replicates:</td><td colspan="4">4</td></tr>
<tr><td>Application equipment:</td><td colspan="4">Rears airblast sprayer (110 psi)</td></tr>
<tr><td>Spray volume:</td><td colspan="4">100 gallons/acre</td></tr>
<tr><td>Application type(s):</td><td colspan="4">Preventative (not evaluated for powdery mildew before application)</td></tr>
<tr><td>Number of applications:</td><td colspan="4">1</td></tr>
<tr><td rowspan="2">Chronology:</td><td>Application Dates</td><td>Application Interval</td><td>Harvest Date</td><td>Disease Assessment Dates</td></tr>
<tr><td>09/29/2015</td><td>NA</td><td>Not reported</td><td>12/14/2015
12/15/2015
02/03/2016
02/05/2016</td></tr>
<tr><td>Disease assessment methodology:</td><td colspan="4">For each treatment, 200 apples were harvested. The skin of 100 apples were punctured with a wire to facilitate infection. 100 apples were not punctured. Apples were placed into cold storage.
<u>Evaluation of punctured apples</u>:
0 = No infection.
1 = Infection at the site of the puncture.
2 = Infection spread past the puncture site.
<u>Evaluation of apples not punctured</u>:
0 = No infection.
1 = Less than 2% apple surface was infected.
2 = More than 2% apple surface was infected.</td></tr>
</table>

b. Results

Apple / Powdery Mildew Storage Rot (*Podosphaera leuotricha*) #4: Trial No. CER-2015-033: Results								
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	Incidence (%) Not Punctured 2/5/2016		Incidence (%) Punctured 2/3/2016	
					Measured	Percent Control	Measured	Percent Control
Untreated control			Not Applicable		55.5 a		96.0 a	
Oso	6.5	25	Polyoxin D zinc salt	19	49.2 a	11.4	87.0 a	9.4
R-56	0.25% (v/v)		Sticker/spreader	NA				
Cueva	2 qt		Copper octanoate	M1	56.0 a	-0.9	92.2 a	4.0
Double Nickel	1 qt		*Bacillus amyloliquefaciens* str. D747	44	57.5 a	-3.6	95.5 a	0.5
Double Nickel	2 qt		*Bacillus amyloliquefaciens* str. D747	44	52.5 a	5.4	96.5 a	0.5
Treatment means followed by the same letter are not statistically different according to the LSD test at P = 0.05.								

The researcher did not describe the relative powdery mildew storage rot disease pressure.

c. Discussion

Based upon this trial, Oso field applied at 6.5 fl oz/acre tank-mixed with R-56 (a sticker-spreader) provided 11.4% and 9.4% decreased incidence of powdery mildew storage rot of apples that were not punctured and punctured, respectively, before storage.

The OMNI-listed products evaluated in this trial included Cueva and Double Nickel. Based upon this trial:

- Oso provided *superior* control of powdery mildew storage rot of apples compared to both Cueva and Double Nickel.
- Cueva at 2 qt/acre and Double Nickel at 1 qt/acre were *ineffective* against powdery mildew storage rot of apples for apples not punctured prior to storage, *i.e.*, disease incidence for these treatments exceeded the disease incidence in the untreated control.

CROP GROUP 12: STONE FRUITS: CHERRIES / Powdery Mildew (*Podosphaera clandestina*)

Cherries #2: Trial No. CER-2015-035

a. Design

Cherries / Powdery Mildew (*Podosphaera clandestina*) #2: Trial No. CER-2015-035: Design					
Title:	Comparison of fungicides for management of cherry diseases, 2015				
Authors and affiliation:	J. W. Pscheidt, John P. Bassinette, and L. A. Jones Oregon State University				
Publication:	PDMR 10:STF009				
Location:	Corvallis, OR				
Crop:	Sweet cherry ('Bing')				
Disease name:	Powdery mildew				
Pathogen:	*Podosphaera clandestina*				
Test plot design:	Randomized complete block				
Number of replicates:	Not reported				
Application equipment:	Hydraulic handgun sprayer (100 psi)				
Spray volume:	164 gal/acre				
Application type:	Preventative and curative				
Number of applications:	7 (all pre-harvest)				
Chronology:	Application Dates	Growth Stage	Application Intervals	Brown Rot Blossom Blight Assessment Dates	Harvest Date
	03/26/2015	Popcorn		04/14/2015	06/10/2015
	04/02/2015	Full bloom	7 days		
	04/15/2015	Petal fall	13 days		
	04/29/2015	Fruit set	14 days		
	05/12/2015		13 days		
	05/26/2015		14 days		
	06/09/2015	Pre-harvest	14 days		

b. Results

Cherries / Powdery Mildew (*Podosphaera clandestina*) #2: Trial No. CER-2015-035: Results						
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	Powdery Mildew (Leaves) (%)	
					Measured	Percent Control
Untreated control			Not Applicable		53.5 a	
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	43.0 ab	19.6
Induce	32 fl oz/100 gal		Non-ionic wetter/spreader	NA		
Merivon	6 fl oz		Fluxapyroxad	7	17.5 cde	67.3
			Pyraclostrobin	11		
Induce	32 fl oz/100 gal		Non-ionic wetter/spreader	NA		

Symptoms of powdery mildew were first observed and confirmed on May 18, 2015, *i.e.*, after applications 1-5 and before applications 6-7. Therefore, the applications were preventative *and curative*.

The researchers described the disease pressure as low.

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 6.5 fl oz/acre tank-mixed with Induce (a non-ionic wetter/spreader) provided 19.6% control of powdery mildew on cherries.

No OMRI-listed products were evaluated in this trial.

CROP GROUP 13: BERRIES AND SMALL FRUITS: BLUEBERRIES / Mummyberry (*Monilinia vaccinii-corymbosi*)

#3: Trial No. KAK-2016-Blueberry-MI

a. Design

Blueberries / Mummyberry (*Monilinia vaccinii-corymbosi*) #3: Trial No. KAK-2016-Blueberry-MI: Design						
Title:	Evaluating fungicides for control of mummy berry and post-harvest fruit rot in blueberries, 2016.					
Author and affiliation:	A. M. C. Schilder, J. M. Gillett, and R. W. Sysak Michigan State University					
Publication:	PDMR (planned for fall 2018 publication)					
Location:	Bangor, MI					
Crop:	Blueberry (*Vaccinium corymbosum* 'Berkeley')					
Disease name:	Mummy berry					
Pathogen:	*Monilinia vaccinii-corymbosi*					
Test plot design:	Randomized complete block					
Number of replicates:	4					
Application equipment:	Hand-held Smith Contractor Sprayer (29 psi)					
Spray volume:	40 gallons/acre through May 19, 2016. 50 gallons/acre thereafter.					
Application type(s):	Preventative					
Number of applications:	4 (Shoot strike evaluations) 8 (Mummies per bush evaluations)					
Chronology:	Application			Growth Stage	Disease Assessment Dates	Harvest Date
	No.	Dates	Interval			
	1	04/18/2016		Early green tip; apothecia cup ave. diameter 1/8 inch	05/16/2016	07/14/2016
	2	04/26/2016	8 days	Late green tip with some early pink bud; apothecia cup ave. diameter 1/4 inch	05/25/2016	
	3	05/06/2016	13 days	Pink bud with some early bloom	07/08/2016	
	4	05/19/2016	13 days	Bloom, some apothecia sill present		
	6	05/31/2016	12 days	Petal fall		
	7	06/14/2016	15 days	Green fruit		
	8	07/07/2016	23 days	10% blue fruit		
Disease assessment methodology:	• Mummified berries on the ground were counted in a 6.5 x 6.5 foot section under the two center bush for each plot. • Fifty ripe berries per subplot were harvested, placed equidistantly on metal screens in aluminum trays and incubated at room temperature and 100% relative humidity. Ten days later, the berries were rated for post-harvest health by observing sporulation on the berries.					

b. Results

Blueberries / Mummyberry (*Monilinia vaccinii-corymbosi*) #3: Trial No. KAK-2016-Blueberry-MI: Results: Shoot Strikes							
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App. Code	No. Shoot Strikes per Bush (05/16/2016)	
						Measured	Percent Control
Untreated control			Not Applicable			57.8 a	
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	1,2,3,4	5.3 cde	90.8
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	1,2,3,4	7.0 bcde	87.9
LI 700	0.125% (v/v)		Penetrant, acidifier	NA			
Oso 5%SC	13 fl oz	50	Polyoxin D zinc salt	19	1,2,3,4	0.0 f	100
Double Nickel	1.06 qt		*Bacillus amyloliquefaciens* str. D747	44	1,2,3,4	12.0 b	79.2
Double Nickel	2.1 qt		*Bacillus amyloliquefaciens* str. D747	44	1,2,3,4	3.5 cdef	93.9
Kenja 400SC	13.5 fl oz		Isofetamid	7	1,2,3,4	7.0 bcde	87.9
Indar 2F	6 fl oz		Fenbuconazole	3	1,2,3,4	0.0 f	100
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	1,3	0.0 f	100
LI 700	0.125% (v/v)		Non-ionic surfactant	NA			
Indar 2F	6 fl oz		Fenbuconazole	3	2,4		
Treatment means followed by the same letter are not statistically different according to the Fisher's Protected LSD test at P ≤ 0.05.							

Blueberries / Mummyberry (*Monilinia vaccinii-corymbosi*) #3
Trial No. KAK-2016-Blueberry-MI: Results: Field and Post-Harvest

Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App. Code	No. Mummies per Bush		Percent Healthy 10 Days Post-Harvest	
						Measured	Percent Control	Measured	Percent Increase
Untreated control			Not Applicable			32.3 a		70.0 ns	
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	1,2,3,4,6,7,8	3.0 def	90.7	50.5	-27.9
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	1,2,3,4,6,7,8	3.8 de	88.2	73.5	5.0
LI 700	0.125% (v/v)		Non-ionic surfactant	NA					
Oso 5%SC	13 fl oz	50	Polyoxin D zinc salt	19	1,2,3,4,6,7,8	0.0 f	100	73.5	5.0
Double Nickel	1.06 qt		*Bacillus amyloliquefaciens* str. D747	44	1,2,3,4,6,7,8	8.0 bc	75.2	73.5	5.0
Double Nickel	2.1 qt		*Bacillus amyloliquefaciens* str. D747	44	1,2,3,4,6,7,8	4.0 de	87.6	78.0	11.4
Kenja 400SC	13.5 fl oz		Isofetamid	7	1,2,3,4,6,7,8	6.0 cd	81.4	71.5	2.1
Indar 2F	6 fl oz		Fenbuconazole	3	1,2,3,4,6,7,8	0.0 f	100	71.5	2.1
Bravo Weather Stik	4 qt		Chlorothalonil	M5	1,3	0.0 f	100	75.0	7.1
Indar 2F	6 fl oz		Fenbuconazole	3	2,4,6				
Pristine	23 oz		Boscalid	7	7,8				
			Pyraclostrobin	11					
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	1,3,6,8	0.0 f	100	75.0	7.1
LI 700	0.125% (v/v)		Non-ionic surfactant	NA					
Indar 2F	6 fl oz		Fenbuconazole	3	2,4				
Pristine	23 oz		Boscalid	7	7				
			Pyraclostrobin	11					

Treatment means followed by the same letter are not statistically different according to the Fisher's Protected LSD test at P ≤ 0.05.
ns. No significant differences were found according to the Fisher's Protected LSD test at P ≤ 0.05.

The first assessments were performed May 16, 2016, *i.e.*, after applications 1-3 and before applications 4-8. Disease was observed. Therefore:

- Applications 1 to 3 are assumed to be preventative, and
- Applications 4 to 8 were ***curative***.

No phytotoxicity was observed.

c. Discussion

In this trial:

- Oso applied at 6.5 fl oz/acre and 13 fl oz/acre provided 90.7% and 100% control, respectively, of Mummyberry on blueberry fruit.
- Oso was applied at 6.5 fl oz/acre with and without LI 700 (a non-ionic surfactant) as a tank-mix partner. Oso ***without*** LI 700 provided numerically ***superior*** control of the number of mummies per bush (90.7% control without LI 700 vs 88.2% control with LI 700).
- No statistical differences were observed in the 10-day post-harvest number of healthy blueberries.

The only OMRI-listed product evaluated in this trial was Double Nickel. Oso provided ***superior*** control the number of mummies per blueberry bush (90.7% and 100% control) compared to Double Nickel (75.2% and 87.6% control).

#4: Trial No. KAK-2016-Blueberry-WA-Conv

a. Design

Blueberries / Mummyberry (*Monilinia vaccinii-corymbosi*) #4: Trial No. KAK-2016-Blueberry-WA-Conv: Design				
Title:	Conventional Mummy Berry & Botrytis Control in Blueberries #2			
Author and affiliation:	Alan Schreiber Agricultural Development Group, Inc.			
Publication:	Not published; permission received.			
Location:	Mt. Vernon, Washington			
Crop:	Highbush Blueberry (variety: Reka)			
Disease name:	Mummy berry			
Pathogen:	*Monilinia vaccinii-corymbosi*			
Test plot design:	Randomized complete block			
Number of replicates:	4			
Application equipment:	Rears OverRo			
Spray volume:	100 gallons/acre			
Application type(s):	Preventative			
Number of applications:	6			
Chronology:	Application Dates	Application Intervals	Growth Stage	Disease Assessment Dates
	03/05/2016			05/03/2016
	03/16/2016	11 days		06/25/2016
	03/31/2016	15 days		
	04/15/2016	16 days	50% bloom	
	04/25/2016	10 days	80% bloom	
	05/06/2016	11 days		

b. Results

Blueberries / Mummyberry (*Monilinia vaccinii-corymbosi*) #4: Trial No. KAK-2016-Blueberry-WA-Conv: Results									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App. Code	Incidence: Flower/Leaf Strikes per Plot (05/03/2016)		Incidence: Mummified Berries (06/25/2016)	
						Measured	Percent Control	Measured	Percent Control
Untreated control			Not Applicable			13.5 a		17.8 a	
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	ABCDEF	2.3 b	83.0	2.8 b	84.3
Oso 5%SC	13 fl oz	50	Polyoxin D zinc salt	19	ABCDEF	2.3 b	83.0	2.3 b	87.1
Chlorothalonil	32 fl oz		Chlorothalonil	M5	A	0.8 b	94.1	0.3 b	98.3
Indar 2F	6 fl oz		Fenbuconazole	3	B				
Proline	5.7 fl oz		Prothioconazole	3	C				
Switch 62 WG	11 oz		Cyprodinil	9	D				
			Fludioxonil	12					
Pristine	18 oz		Boscalid	7	E				
			Pyraclostrobin	11					
Abound	10 fl oz		Azoxystrobin	11	F				
Elevate	1.5 lb		Fenhexamid	17	F				
Chlorothalonil	32 fl oz		Chlorothalonil	M5	A	0.8 b	94.1	2.8 b	84.3
Indar 2F	6 fl oz		Fenbuconazole	3	BC				
Switch	14 oz wt		Cyprodinil	9	D				
			Fludioxonil	12					
Indar 2F	6 fl oz		Fenbuconazole	3	AB	3.3 b	75.6	1.5 b	66.7
Pristine	20 oz		Boscalid	7	C				
			Pyraclostrobin	11					
Switch	14 oz wt		Cyprodinil	9	D				
			Fludioxonil	12					
Treatment means followed by the same letter are not statistically different according to Bartlett's X2 test at P = 0.05.									

The first treatment was applied March 5, 3016. Based upon feedback from Washington State University plant pathologists, this was prior to ascospore release (*i.e.*, prior to crop infection). Therefore, the treatments were applied preventatively.

The researcher described the mummyberry pressure as moderate.

No phytotoxicity was reported.

c. Discussion

In this trial, Oso applied at 6.5 fl oz/acre and 13 fl oz/acre provided:

- 83.0% control of flower/leaf strikes at both application rates; and
- 84.3% and 87.1% control, respectively, of the number of mummified berries.

No OMRI-listed products were evaluated in this trial.

#5: Trial No. KAK-2016-Blueberry-WA-Org

a. Design

Blueberries / Mummyberry (*Monilinia vaccinii-corymbosi*) #5: Trial No. KAK-2016-Blueberry-WA-Org: Design				
Title:	Organic Mummy Berry & Botrytis Control in Blueberries of Western Washington 2016			
Author and affiliation:	Alan Schreiber Agricultural Development Group, Inc.			
Publication:	Not published; permission received.			
Location:	Mt. Vernon, Washington			
Crop:	Highbush Blueberry (variety: Reka)			
Disease name:	Mummy berry			
Pathogen:	*Monilinia vaccinii-corymbosi*			
Test plot design:	Randomized complete block			
Number of replicates:	4			
Application equipment:	Rears OverRo			
Spray volume:	100 gallons/acre			
Application type(s):	Preventative			
Number of applications:	7			
Chronology:	Application Dates	Application Interval	Growth Stage	Evaluation Dates
	02/27/2016		Veg Bud	05/03/2016
	03/07/2016	9 days	Veg Tip	06/23/2016
	03/16/2016	9 days	Pre Bud	
	03/25/2016	9 days	Pink Bud	
	03/31/2016	6 days	10% Bloom	
	04/08/2016	9 days	30% Bloom	
	04/15/2016	7 days	50% Bloom	

b. Results

Blueberries / Mummyberry (*Monilinia vaccinii-corymbosi*) #5: Trial No. KAK-2016-Blueberry-WA-Org: Results									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	Appl Code	Incidence Leaf Strikes/Plot) (05/03/2016)		Incidence (Infected Fruit) (06/23/2016)	
						Measured	Percent Control	Measured	Percent Control
Untreated control			Not Applicable			16.0 abc		45.0 a	
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	ABCDEF	26.3 a	-64.4	37.0 a	17.8
Oso 5%SC	13 fl oz	50	Polyoxin D zinc salt	19	ABCDEF	10.8 c	32.5	31.5 a	30.0
Fracture	20 fl oz		Banda de Lupinus albus doce (BLAD)	M12	ABCDEFG	21.0 abc	-31.3	39.8 a	11.6
Zen-O-Spore	4 lb		*Ulocladium oudemansii* (U3 Strain)	NC	ABCDEFG	18.0 abc	-12.5	32.5 a	27.8
Actinovate AG	12 oz		*Streptomyces lydicus* WYEC 108	NC	ABCDEFG	16.8 abc	-5.0	39.0 a	13.3
Double Nickel LC	1 qt		*Bacillus amyloliquefaciens* str. D747	44	ABCDEFG	12.8 bc	20.0	33.5 a	25.6
Regalia	2 qt		*Reynoutria sachalinensis* extract	P5	ABCDEFG	12.0 c	25.0	39.0 a	13.3
NovaSource's Lime-Sulfur	2% v/v		Calcium polysulfide	M2	ABCD	9.8 c	38.8	36.0 a	20.0
Oso 5%SC	13 fl oz		Polyoxin D zinc salt	19	BDF	25.3 ab	-58.1	24.3 a	46.0
Actinovate AG	12 oz		*Streptomyces lydicus* WYEC 108	NC	ACEG				
Oso 5%SC	13 fl oz		Polyoxin D zinc salt	19	BDF	20.8 abc	-30.0	32.8 a	27.1
Regalia	2 qt		*Reynoutria sachalinensis* extract	P5	ACEG				
Actinovate AG	12 oz		*Streptomyces lydicus* WYEC 108	NC	ACEG				
Oso 5%SC	13 fl oz		Polyoxin D zinc salt	19	EFG	15.8 abc	1.3	29.3 a	34.9
NovaSource's Lime-Sulfur	2% v/v		Calcium polysulfide	M2	ABCD				
Oso 5%SC	13 fl oz		Polyoxin D zinc salt	19	ACEG	21.5 abc	-34.4	25.8 a	42.7
Regalia	2 qt		*Reynoutria sachalinensis* extract	P5	BDF				
Actinovate AG	12 oz		*Streptomyces lydicus* WYEC 108	NC	ACEG	22.0 abc	-37.5	39.0 a	13.3
Regalia	2 qt		*Reynoutria sachalinensis* extract	P5	ACEG				
Double Nickel LC	1 qt		*Bacillus amyloliquefaciens* str. D747	44	BDF				
Zen-O-Spore	4 lb		*Ulocladium oudemansii* (U3 Strain)	NC	BDF				
Treatment means followed by the same letter are not statistically different according to Bartlett's X2 test at P = 0.05.									

The first application was made on February 27, 2016. Based upon feedback from Washington State University plant pathologists, this was prior to ascospore release (i.e., prior to crop infection). Therefore, the treatments were applied preventatively.

The researcher described the mummyberry pressure as moderate.

No phytotoxicity was reported.

c. Discussion

In this trial:

- Oso applied at 6.5 fl oz/acre provided no control of mummyberry leaf strike incidence and 17.8% control of fruit mummies; and
- Oso applied at 13 fl oz/acre provided 32.5% control of leaf strike incidence and 30.0% control of fruit mummies.

The reduction in efficacy observed on this trial compared to the nearby trial using conventional pesticides (Trial No. KAK-2016-Blueberry-WA-Conv) is postulated to be due to the "re-inoculation" of the Oso subplots by the surrounding subplots for the organic treatments with no or lesser mummyberry control.

OMRI-listed products evaluated in this trial as single product treatments included Actinovate AG, Double Nickel LC, Regalia, NovaSource's Lime-Sulfur, and Zen-O-Spore. (Based upon information on the Internet, Zen-O-Spore is not EPA registered for use on blueberries.) In these single product evaluations, Oso applied at 13 fl oz/acre provided:

- *Superior* control of fruit mummies for all evaluated OMRI-listed products;
- *Superior* control of leaf strike incidence compared to Zen-O-Spore, Actinovate AG, Double Nickel LC, and Regalia; and
- *Slightly less* control of leaf strike incidence than provided by Nova-Sources Lime-Sulfur (32.5% vs 38.8% control).

Actinovate AG, Double Nickel LC, Regalia, NovaSource's Lime-Sulfur were also evaluated as rotation partners with Oso at 13 fl oz/acre. For all of the evaluated rotations with Oso, the control of fruit mummies by Oso rotated with the OMRI-listed rotation partner was *superior* to the control provided by the OMRI-listed product used alone. Oso used in rotation with:

- Actinovate provided *superior* control of fruit mummies compared to Oso used alone and compared to Actinovate used alone.
- Regalia and Actinovate provided *superior* control of fruit mummies compared to Regalia used alone and compared to Actinovate used alone.
- NovaSource's Lime-Sulfur provided *superior* control of fruit mummies compared to Oso used alone and compared to NovaSource's Lime-Sulfur used alone.
- Regalia provided *superior* control of fruit mummies compared to Oso used alone and compared to Regalia used alone.

Fracture was also evaluated in this trial. Fracture is a biopesticide. Based upon the label posted to the Internet, Fracture is not an OMRI-listed product.

#6: Trial No. KAK-2017-Blueberry-WA-Org

a. Design

<table>
<tr><th colspan="6">Blueberries / Mummyberry (Monilinia vaccinii-corymbosi) #6: Trial No. KAK-2017-Blueberry-WA-Org: Design</th></tr>
<tr><td>Title:</td><td colspan="5">Effect of Organic Fungicides on Blueberry Mummy Berry</td></tr>
<tr><td>Author and affiliation:</td><td colspan="5">T. Walters and A. Schreiber
Agricultural Development Group, Inc.</td></tr>
<tr><td>Publication:</td><td colspan="5">Not published; permission.</td></tr>
<tr><td>Location:</td><td colspan="5">Near Mt. Vernon, Washington</td></tr>
<tr><td>Crop:</td><td colspan="5">Blueberries (highbush)</td></tr>
<tr><td>Disease name:</td><td colspan="5">Mummy berry</td></tr>
<tr><td>Pathogen:</td><td colspan="5">Monilinia vaccinii-corymbosi</td></tr>
<tr><td>Test plot design:</td><td colspan="5">Randomized complete block</td></tr>
<tr><td>Number of replicates:</td><td colspan="5">4</td></tr>
<tr><td>Application equipment:</td><td colspan="5">Over the row spray mount</td></tr>
<tr><td>Spray volume:</td><td colspan="5">64 gallons/acre</td></tr>
<tr><td>Application type(s):</td><td colspan="5">Preventative</td></tr>
<tr><td>Number of applications:</td><td colspan="5">8 (trial); 7 (Oso)</td></tr>
<tr><td rowspan="10">Chronology:</td><td rowspan="2">Application Code</td><td rowspan="2">Application Dates</td><td colspan="2">Application Interval (Days)</td><td rowspan="2">Disease Assessment Dates</td></tr>
<tr><td>Trial</td><td>Oso</td></tr>
<tr><td>A</td><td>03/19/2017</td><td></td><td></td><td>07/07/2017</td></tr>
<tr><td>B</td><td>03/30/2017</td><td>11</td><td>11</td><td></td></tr>
<tr><td>C</td><td>04/04/2017</td><td>5</td><td>5</td><td></td></tr>
<tr><td>D</td><td>04/11/2017</td><td>7</td><td>7</td><td></td></tr>
<tr><td>E</td><td>04/18/2017</td><td>7</td><td>7</td><td></td></tr>
<tr><td>F</td><td>04/25/2017</td><td>7</td><td>7</td><td></td></tr>
<tr><td>G</td><td>05/02/2017</td><td>7</td><td rowspan="2">18</td><td></td></tr>
<tr><td>H</td><td>05/13/2017</td><td>11</td><td></td></tr>
<tr><td>Disease assessment methodology:</td><td colspan="5">Number of infections per 100 randomly picked berries.</td></tr>
</table>

b. Results

Blueberries / Mummyberry (*Monilinia vaccinii-corymbosi*) #6: Trial No. KAK-2017-Blueberry-WA-Org: Results							
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App. Code	Incidence (%)	
						Measured	Percent Control
Untreated control			Not Applicable			6.3 a	
Oso	6.5 fl oz	25	Polyoxin D zinc salt	19	ABCDEFH	2.3 de	63
Oso	13 fl oz	50	Polyoxin D zinc salt	19	ABCDEFH	2.0 de	68
Regalia	2 qt		*Reynoutria sachalinensis* extract	P5	ABCDEFGH	3.3 cde	48
Actinovate AG	12 oz		*Streptomyces lydicus* WYEC 108	NC	ABCDEFGH	3.8 bcde	40
Double Nickel LC	1 qt		*Bacillus amyloliquefaciens* str. D747	44	ABCDEFGH	5.5 ab	13
Oso	13 fl oz		Polyoxin D zinc salt	19	ABCDEFGH	2.0 de	68
Actinovate AG	12 oz		*Streptomyces lydicus* WYEC 108	NC	ABCDEFGH		
Stimplex	4.8 oz/10 gal		Cytokinin	NC	ABCDEFGH		
Oso	13 fl oz		Polyoxin D zinc salt	19	ABCDEFGH	1.8 e	71
Regalia	2 qt		*Reynoutria sachalinensis* extract	P5	ABCDEFGH		
Oso	13 fl oz		Polyoxin D zinc salt	19	BDF	3.3 cde	48
Regalia	2 qt		*Reynoutria sachalinensis* extract	P5	BDR		
Actinovate AG	12 oz		*Streptomyces lydicus* WYEC 108	NC	ACEGH		
Stimplex	4.8 oz/10 gal		Cytokinin	NC	ACEGH		
Oso	13 fl oz		Polyoxin D zinc salt	19	BDF	3.0 cde	52
Double Nickel LC	1 qt		*Bacillus amyloliquefaciens* str. D747	44	BDF		
Actinovate AG	12 oz		*Streptomyces lydicus* WYEC 108	NC	ACEGH		
Stimplex	4.8 oz/10 gal		Cytokinin	NC	ACEGH		
Oso	13 fl oz		Polyoxin D zinc salt	19	EFG	2.3 de	63
Lime-Sulfur Solution	2% v/v		Calcium polysulfide	M2	ABCDH		
Lime-Sulfur Solution	2 gal		Calcium polysulfide	M2	ABCD	4.0 bcd	37
Lime-Sulfur Solution	3.5 gal		Calcium polysulfide	M2	ABCD	4.0 bcd	37
Lime-Sulfur Solution	7.5 gal		Calcium polysulfide	M2	ABCD	2.5 de	60
Lime-Sulfur Solution	8 gal		Calcium polysulfide	M2	ABCD	1.8 e	71
Lime-Sulfur Solution	8 gal		Calcium polysulfide	M2	ACE	3.3 cde	48
Treatment means followed by the same letter are not statistically different (P = 0.05, LSD).							

Treatments were applied preventatively.

The researchers reported that the mummyberry disease pressure was low. Based upon communications with the lead researcher, the 2017 growing season was unusually dry.

No phytotoxicity was reported.

c. Discussion

In this trial, Oso applied at 6.5 fl oz/acre and 13 fl oz/acre provided 63% control and 68% control of blueberry mummies.

The following OMRI-listed products were also evaluated in this trial: Actinovate AG, Double Nickel LC, Regalia, and Lime-Sulfur Solution. Stimplex is an OMRI-listed biostimulant and was included in tank-mixes that were evaluated.

In this trial, Oso applied at 13 fl oz/acre provided:

- *Superior* control of mummyberry incidence compared to Actinovate AG, Double Nickel LC, Regalia, and Lime-Sulfur Solution (2 to 7.5 gal/acre) used alone; and
- Statistically *equivalent* control of mummyberry incidence compared to high dose Lime-Sulfur Solution (8 gal/acre).

In this trial, Oso applied at 13 fl oz/acre was used in rotation with Actinovate AG, Double Nickel LC, Regalia, and/or Lime-Sulfur Solution and sometimes Simplex. In these rotations, the efficacy of Oso in rotation with Actinovate AG, Double Nickel LC, Regalia, and/or Lime-Sulfur Solution was superior to the OMRI-listed products used alone.

CROP GROUP 13: BERRIES AND SMALL FRUITS: CANEBERRIES / Gray Mold (Botrytis sp.)

Raspberries #2: Trial No. IND-2016-Rasp-WA

a. Design

Raspberries /Botrytis Fruit Rot *(Botrytis* sp.) #2: Trial No. IND-2016-Rasp-WA: Design				
Title:	Raspberry Botrytis Field Efficacy Program - 2016			
Author and affiliation:	Tom Walters Agricultural Development Group, Inc.			
Publication:	Not published (permission)			
Location:	Everson, Washington			
Crop:	Raspberry (variety Meeker)			
Disease name:	Botrytis fruit rot			
Pathogen:	*Botrytis sp.*			
Test plot design:	Randomized complete block			
Number of replicates:	4			
Application equipment:	Rears OveRo (130 psi)			
Spray volume:	100 gal/acre			
Application type(s):	Preventative			
Number of applications:	6			
Chronology:	Application Date	Application Interval	Growth Stage	Disease Assessment Dates
	05/05/2016		10% bloom	07/09/2016
	05/16/2016	11 days	30% bloom	07/12/2016
	05/25/2016	9 days	50% bloom	
	06/07/2016	12 days	1st harvest	
	06/17/2016	10 days		
	06/29/2016	12 days	Mid-harvest	
Disease assessment methodology:	For each plot, all berries were inspected, and all infected berries were counted. A total of 5520 row feet (more than a mile) were examined at each evaluation.			

b. Results

Raspberries / Botrytis Fruit Rot *(Botrytis* sp.) #2: Trial No. IND-2016-Rasp-WA: Results						
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	Incidence (No. Infected Berries/Plot) (07/12/2016)	
					Measured	Percent Control
Untreated control			Not Applicable		21.0 abc	
Oso 5SC	12 fl oz	46	Polyoxin D zinc salt	19	10.0 c	52.4
Oxidate	32 fl oz/ 100 gal		Hydrogen dioxide	NC	27.8 a	-32.4
PH~D 11.3WDG	6.2 oz		Polyoxin D zinc salt	19	19.8 abc	5.7
Elevate 50	1.5 lb		Fenhexamid	17	17.0 abc	19.0
Switch 62.5	14 oz		Cyprodinil	9	16.8 abc	20.0
			Fludioxonil	12		
Iprodione 4	1 pt		Iprodione	2	14.0 abc	33.3
Pristine 38	23 oz		Boscalid	7	13.0 bc	38.1
			Pyraclostrobin	11		
Luna Tranquility 45	18 fl oz		Fluopyram	7	9.8 c	53.3
			Pyrimethalin	9		
Captan 80	2.5 lb		Captan	M4	7.8 c	62.9
Treatment means followed by the same letter are not statistically different according to the Bartlett's X2 test at P = 0.03						

The researchers described the Botrytis disease pressure as low. There was virtually no disease pressure until the end of the trial. Disease was first observed on July 9, 2016 (10 days after the last application). The treatments were therefore assumed to have been applied preventatively.

No phytotoxicity was reported.

c. Discussion

In this study, Oso applied at 12 fl oz/acre provided 52.4% control of Botrytis fruit rot on raspberries.

Oxidate was the only OMRI-listed product evaluated in this trial. Oso provided statistically *superior* control of Botrytis fruit rot on raspberries compared to Oxidate.

Oxidate was *ineffective* in this trial. More Botrytis fruit rot was observed in the Oxidate treatment than in the untreated control.

Two formulations of polyoxin D zinc salt were evaluated in this trial. Oso is the 5% suspension concentrate formulation. PH~D is the 11.3% water dispersible granular formulation. *Oso provided noticeably superior Botrytis fruit rot control compared to PH~D (52.4% compared to 5.7%).*

Raspberries #3: Trial No. KAK-2017-Rasp-MI

a. Design

Raspberries / Botrytis Fruit Rot (*Botrytis cinerea*) #3: Trial No. KAK-2017-Rasp-MI: Design				
Title:	Evaluation of fungicides for control of powdery mildew and Botrytis in tunnel-grown raspberries, 2017			
Author and affiliation:	A, M. C. Schilder, J. M. Gillett, and R. W. Sysak Michigan State University			
Publication:	PDMR (planned for fall 2018 publication)			
Location:	Haygrove tunnel in Lawton, MI			
Crop:	Raspberry (*Rubus idaeus*)			
Disease name:	Botrytis fruit rot			
Pathogen:	*Botrytis cinerea*			
Test plot design:	Randomized complete block			
Number of replicates:	4			
Application equipment:	Hand-held Smith Contractor Sprayer (29 psi)			
Spray volume:	50 gallons/acre on 05/16/2017 75 gallons/acre for the remainder of the season			
Application type(s):	Preventative			
Number of applications:	5			
Chronology:	Application Dates	Application Interval (days)	Growth Stage	Disease Assessment Dates
	05/16/2017		Green up	07/15/2017
	05/30/2017	14	40% bloom	
	06/13/2017	14	Bloom and green fruit	
	06/20/2017	7	Green fruit	
	06/29/2017	9	Red fruit	
Disease assessment methodology:	Incidence: % of leaves or fruit with disease. Severity: % area symptomatic on diseased plant parts only. Overall severity: (Incidence x Severity) / 100.			

b. Results

Raspberries / Botrytis Fruit Rot (*Botrytis cinerea*) #3: Trial No. KAK-2017-Rasp-MI: Results						
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	Field Incidence on Fruit (%)	
					Measured	Percent Control
Untreated control			Not Applicable		53.3 a	
Oso	6.5 fl oz	25	Polyoxin D zinc salt	19	10.0 de	81
Oso	13 fl oz	50	Polyoxin D zinc salt	19	0.0 f	100
Botector	10 oz		*Aureobasidium pullulans* strains DSM 14940 and DSM 14941	NC	21.1 b	60
Double Nickel LC	3 qt		*Bacillus amyloliquefaciens* str. D747	44	16.7 bc	69
Cueva	2 gal		Copper octanoate	M1	14.5 cd	73
Fracture	35 fl oz		Banda de Lupinus albus doce (BLAD)	M12	14.5 cd	73
Kenja 400SC	13.5 fl oz		Isofetamid	7	8.9 e	83
Kinetic	3 fl oz/100 gal		Non-ionic surfactant	NA		
Kenja 400SC	15.5 fl oz		Isofetamid	7	0.0 f	100
Kinetic	3 fl oz/100 gal		Non-ionic surfactant	NA		
Prolivo	4 fl oz		Pyriofenone	U8	8.9 e	83
Kinetic	3 fl oz/100 gal		Non-ionic surfactant	NA		
Prolivo	5 fl oz		Pyriofenone	U8	0.0 f	100
Kinetic	3 fl oz/100 gal		Non-ionic surfactant	NA		
Switch 62.5WG	14 oz		Cyprodinil	9	0.0 f	100
			Fludioxonil	12		
Kinetic	3 fl oz/100 gal		Non-ionic surfactant	NA		
Treatment means followed by the same letter are not statistically different according to the Fisher's Protected LSD test at $P \leq 0.05$.						

The researcher described the Botrytis disease pressure as high, especially for a field rating of Botrytis fruit rot.

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 6.5 fl oz/acre and 13 fl oz/acre provided 81% and 100% control of Botrytis fruit rot, respectively.

OMRI-listed products evaluated in this trial were Botector, Double Nickel LC and Cueva.

Based upon this trial, Oso applied at both 6.5 fl oz/acre and at 13 fl oz/acre provided *superior* control of Botrytis fruit rot on raspberries compared to Botector, Double Nickel and Cueva.

Fracture is a biopesticide, but based upon information on the Internet, is not OMRI-listed.

CROP GROUP 13: BERRIES AND SMALL FRUITS: CANEBERRIES / Powdery Mildew (*Podosphaera aphanis*)

Raspberries #1: Trial No. KAK-2017-Rasp-MI

a. Design

Raspberries / Powdery Mildew (*Podosphaera aphanis* var. *aphanis*) #1: Trial No. KAK-2017-Rasp-MI: Design				
Title:	Evaluation of fungicides for control of powdery mildew and Botrytis in tunnel-grown raspberries, 2017			
Author and affiliation:	A. M. C. Schilder, J. M. Gillett, and R. W. Sysak Michigan State University			
Publication:	PDMR (planned for fall 2018 publication)			
Location:	Haygrove tunnel in Lawton, MI			
Crop:	Raspberry (*Rubus idaeus*)			
Disease name:	Powdery mildew			
Pathogen:	*Podosphaera aphanis* var. *aphanis*			
Test plot design:	Randomized complete block			
Number of replicates:	4			
Application equipment:	Hand-held Smith Contractor Sprayer (29 psi)			
Spray volume:	50 gallons/acre on 05/16/2017 75 gallons/acre for the remainder of the season			
Application type(s):	Preventative			
Number of applications:	5			
Chronology:	Application Dates	Application Interval (days)	Growth Stage	Disease Assessment Dates
	05/16/2017		Green up	07/15/2017
	05/30/2017	14	40% bloom	
	06/13/2017	14	Bloom and green fruit	
	06/20/2017	7	Green fruit	
	06/29/2017	9	Red fruit	
Disease assessment methodology:	Incidence: % of leaves or clusters with disease. Severity: % area symptomatic on diseased plant parts only. Overall severity: (Incidence x Severity) / 100.			

b. Results

Raspberries / Powdery Mildew (*Podosphaera aphanis* var. *aphanis*) #1: Trial No. KAK-2017-Rasp-MI: Results								
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	Leaves (7/15/2017)			
					Incidence (%)	Severity (%)	Overall Severity (%)	Control (%)
Untreated control			Not Applicable		57.3 a	12.2 a	7.0 a	
Oso	6.5 fl oz	25	Polyoxin D zinc salt	19	13.3 ef	1.5 e	0.2 e	97
Oso	13 fl oz	50	Polyoxin D zinc salt	19	0.0 g	0.0 f	0.0 e	100
Cueva	2 gal		Copper octanoate	M1	41.3 b	7.3 b	3.0 b	57
Double Nickel LC	3 qt		*Bacillus amyloliquefaciens* str. D747	44	38.7 bc	7.8 b	3.0 b	57
Botector	10 oz		*Aureobasidium pullulans* strains DSM 14940 and DSM 14941	NC	33.3 cd	5.5 c	1.8 c	74
Fracture	35 fl oz		Banda de Lupinus albus doce (BLAD)	M12	28.0 d	3.4 d	1.0 d	86
Kenja 400SC	13.5 fl oz		Isofetamid	7	18.7 e	2.0 e	0.4 e	94
Kinetic	3 fl oz/100 gal		Non-ionic surfactant	NA				
Prolivo	4 fl oz		Pyriofenone	U8	8.0 f	0.7 ef	0.1 e	99
Kinetic	3 fl oz/100 gal		Non-ionic surfactant	NA				
Kenja 400SC	15.5 fl oz		Isofetamid	7	0.0 g	0.0 f	0.0 e	100
Kinetic	3 fl oz/100 gal		Non-ionic surfactant	NA				
Prolivo	5 fl oz		Pyriofenone	U8	0.0 g	0.0 f	0.0 e	100
Kinetic	3 fl oz/100 gal		Non-ionic surfactant	NA				
Switch 62.5WG	14 oz		Cyprodinil	9	0.0 g	0.0 f	0.0 e	100
			Fludioxonil	12				
Kinetic	3 fl oz/100 gal		Non-ionic surfactant	NA				
Treatment means followed by the same letter are not statistically different according to the Fisher's Protected LSD test at $P \leq 0.05$.								

The researchers reported that the powdery mildew disease pressure was moderate on leaves and not evident on fruit.

No phytotoxicity was observed.

c. Discussion

Based upon this trial, Oso applied at 6.5 fl oz/acre and 13 fl oz/acre provided 97% and 100% control, respectively, of powdery mildew on raspberry leaves.

OMRI-listed products evaluated in this trial included Cueva, Double Nickel LC, and Botector. Oso provided statistically *superior* control of powdery mildew on raspberry leaves compared to that provided by Cueva (57% control), Double Nickel LC (also 57% control), and Botector (74% control).

Fracture is a biopesticide, but based upon information on the Internet, is not OMRI-listed.

CROP GROUP 13: CRANBERRIES / Cottonball (*Monilinia oxycocci*)

#3: Trial No. 11:SMF011(2016; WI)

a. Design

Cranberries / Cottonball (*Monilinia oxycocci*) #3: Trial No. 11:SMF011(2016; WI): Design		
Title:	Evaluation of fungicides for control of cranberry cottonball in Wisconsin, 2016	
Authors and affiliation:	P. McManus and R.S. Perry University of Wisconsin	
Publication:	PDMR 11:SMF011	
Location:	Near City Point, WI	Near Warrens, WI
Crop:	Cranberry (cultivar Ben Lear)	Cranberry (cultivar Ben Lear)
Disease name:	Cottonball	
Pathogen:	*Monilinia oxycocci*	
Test plot design:	Randomized compete block	
Number of replicates:	5	
Application equipment:	CO_2 backpack sprayer (31 psi)	
Spray volume:	28.4 gal/acre	
Number of applications:	2	
Application interval:	8 days	12 days
Application dates:	07/07/2016 (10% bloom) 07/15/2016 (50% bloom)	07/06/2016 (10% bloom) 07/18/2016 (50% bloom)
Disease assessment date(s):	09/22/2016	09/13/2016
Yield calculation:	One barrel = 100 pounds (industry standard)	

b. Results

Cranberries / Cottonball (*Monilinia oxycocci*) #3: Trial No. 11:SMF011(2016; WI): Incidence on Fruit								
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	% Cottonball Incidence City Point, WI		% Cottonball Incidence Warrens, WI	
					Measured	Percent Control	Measured	Percent Control
Untreated control			Not Applicable		11.9 a		10.7 a	
Oso 5SC	6.5 fl oz	25	Polyoxin D zinc salt	19	4.0 cde	66	5.8 bcd	46
X77	0.25% (v/v)	NA	Non-ionic spreader	NA				
Regalia 5EC	2 pt		*Reynoutria sachalinensis* extract	P5	4.0 cde	66	5.2 cd	51
Kenja 400SC	15.5 fl oz		Isofetamid	7	6.1 bc	49	7.1 abc	34
Treatment means followed by the same letter are not statistically different according to Fisher's Protected LSD test at P = 0.05.								

Cranberries / Cottonball (*Monilinia oxycocci)* #3: Trial No. 11:SMF011(2016; WI): Yield								
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	Yield (Barrels/Acre) City Point, WI		Yield (Barrels/Acre) Warrens, WI	
					Measured	Percent Increase	Measured	Percent Increase
Untreated control			Not Applicable		265.3 b		318.3 b	
Oso 5SC	6.5 fl oz	25	Polyoxin D zinc salt	19	310.4 a	17.0	339.1 ab	6.53
X77	0.25% (v/v)	NA	Non-ionic spreader	NA				
Regalia 5EC	2 pt		*Reynoutria sachalinensis* extract	P5	313.6 a	18.2	353.8 ab	11.2
Kenja 400SC	15.5 fl oz		Isofetamid	7	300.9 ab	13.4	335.6 ab	5.4
Treatment means followed by the same letter are not statistically different according to Fisher's Protected LSD test at P = 0.05.								

The date of first observation of cottonball symptoms was not reported. Therefore, the treatments are assumed to have been preventative.

The researchers described the cottonball disease pressure as low at both sites.

No phytotoxicity was observed.

c. Discussion

In this trial report, Oso applied at 6.5 fl oz/acre tank-mixed with X77 (a non-ionic spreader) applied at 0.25% (v/v) at *two different trial sites* provided:

- 66% and 46% control, respectively, of cottonball on cranberries; and
- 17.0% and 6.53% increased cranberry yield, respectively.

Regalia was the only OMRI-listed product evaluated in this trial. In this trial, Oso and Regalia provided statistically *equivalent*:

- Control of cottonball on cranberries; and
- Increased yields.

CROP GROUP 13: CRANBERRIES / Cranberry Fruit Rot Complex (*Coleophoma empetri*, *Colletotrichum acutatum*, *Colletotrichum gloeosporioides*, *Phyllosticta vaccinii*, and *Physalospora vaccinii*, etc.)

#3: Trial No. 11:SMF012 (2016; WI)

a. Design

Cranberries / Fruit Rot Complex (*Coleophoma empetri*, etc.) #3: Trial No. 11:SMF012 (2016; WI): Design					
Title:	Evaluation of fungicides for control of cranberry fruit rot in Wisconsin, 2016				
Authors and affiliation:	P. McManus and R.S. Perry University of Wisconsin				
Publication:	PDMR 11:SMF012				
Location; Crop; Crop age	Oakdale; cranberry 'Stevens'; 30 years old				
	Valley Junction; cranberry 'Stevens'; 3 years old				
	Warrens; cranberry 'Mullica Queen'; 3 year old 3				
	Mather; cranberry 'GHI'; 3 years old				
	Tomah; cranberry 'Scarlet Knight'; 2 years old				
Disease name:	Cranberry fruit rot complex				
Pathogen:	Ripe rot: *Coleophoma empetri* Bitter rot: *Colletotrichum* spp. Viscid rot: *Phomopsis vaccinii* Early rot: *Phyllosticta vaccinii* Blotch rot: *Physalospora vaccinii*				
Test plot design:	Randomized complete block				
Number of replicates:	5				
Application equipment:	CO_2 backpack sprayer (31 psi)				
Spray volume:	28.4 gal/acre				
Number of applications:	2				
Chronology:	Site	App. Date	Growth Stage	App. Interval	Disease Assessment
	Oakdale	06/30/2016	Full bloom	11 days	09/29/2016
		07/11/2016	Late bloom/early fruit set		
	Valley Junction	06/30/2016	Full bloom	11 days	09/27/2016
		07/11/2016	Late bloom/early fruit set		
	Warrens	06/24/2016	Full bloom	14 days	09/08/2016
		07/08/2016	Late bloom/early fruit set		
	Mather	06/30/2016	Full bloom	11 days	09/27/2016
		07/11/2016	Late bloom/early fruit set		
	Tomah	06/24/2016	Full bloom	14 days	09/06/2016
		07/08/2016	Late bloom/early fruit set		
Disease assessment methodology:	Soft, discolored fruit				

b. Results

Cranberries / Fruit Rot Complex (*Coleophoma empetri*, etc.) #3a: Trial No. 11:SMF012 (2016; WI): Results: Oakdale								
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	Fruit Rot Incidence (%)		Yield (Barrels/Acre)	
					Measured	Percent Control	Measured	Percent Increase
Untreated control			Not Applicable		31.3 a		322 ab	
Oso 5SC	6.5 fl oz	25	Polyoxin D zinc salt	19	6.9 c	78.0	295 ab	-8.4
X77	0.25% (v/v)	NA	Non-ionic spreader	NA				
Regalia 5EC	2 pt		*Reynoutria sachalinensis* extract	P5	7.2 c	77.0	294 ab	-8.7
Kenja 400SC	15.5 fl oz		Isofetamid	7	24.6 b	21.4	343 a	6.5
Treatment means followed by the same letter are not statistically different according to the Fisher's Protected LSD test at P = 0.05.								

Cranberries / Fruit Rot Complex (*Coleophoma empetri*, etc.) #3b: Trial No. 11:SMF012 (2016; WI): Results: Valley Junction								
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	Fruit Rot Incidence (%)		Yield (Barrels/Acre)	
					Measured	Percent Control	Measured	Percent Increase
Untreated control			Not Applicable		35.2 a		141 d	
Oso 5SC	6.5 fl oz	25	Polyoxin D zinc salt	19	4.5 b	87.2	238 a-d	68.8
X77	0.25% (v/v)	NA	Non-ionic spreader	NA				
Regalia 5EC	2 pt		*Reynoutria sachalinensis* extract	P5	22.8 a	35.2	198 a-d	40.4
Kenja 400SC	15.5 fl oz		Isofetamid	7	35.9 a	-2.0	156 cd	10.6
Treatment means followed by the same letter are not statistically different according to the Fisher's Protected LSD test at P = 0.05.								

Cranberries / Fruit Rot Complex (*Coleophoma empetri*, etc.) #3c: Trial No. 11:SMF012 (2016; WI): Results: Warrens								
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	Fruit Rot Incidence (%)		Yield (Barrels/Acre)	
					Measured	Percent Control	Measured	Percent Increase
Untreated control			Not Applicable		40.5 a		443 a	
Oso 5SC	6.5 fl oz	25	Polyoxin D zinc salt	19	17.8 c	56.0	359 ab	-19.0
X77	0.25% (v/v)	NA	Non-ionic spreader	NA				
Regalia 5EC	2 pt		*Reynoutria sachalinensis* extract	P5	20.8 c	48.6	348 ab	-21.4
Kenja 400SC	15.5 fl oz		Isofetamid	7	31.3 b	22.7	394 ab	-11.1
Treatment means followed by the same letter are not statistically different according to the Fisher's Protected LSD test at P = 0.05.								

Cranberries / Fruit Rot Complex (*Coleophoma empetri*, etc.) #3d: Trial No. 11:SMF012 (2016; WI): Results: Mather								
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	Fruit Rot Incidence (%)		Yield (Barrels/Acre)	
					Measured	Percent Control	Measured	Percent Increase
Untreated control			Not Applicable		61.6 a		91 d	
Oso 5SC	6.5 fl oz	25	Polyoxin D zinc salt	19	44.3 ab	28.1	130 a-d	42.9
X77	0.25% (v/v)	NA	Non-ionic spreader	NA				
Regalia 5EC	2 pt		*Reynoutria sachalinensis* extract	P5	44.5 ab	27.8	138 a-d	51.6
Kenja 400SC	15.5 fl oz		Isofetamid	7	63.8 a	-3.6	91 d	0.0
Treatment means followed by the same letter are not statistically different according to the Fisher's Protected LSD test at P = 0.05.								

Cranberries / Fruit Rot Complex (*Coleophoma empetri*, etc.) #3e: Trial No. 11:SMF012 (2016; WI): Results: Tomah								
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	Fruit Rot Incidence (%)		Yield (Barrels/Acre)	
					Measured	Percent Control	Measured	Percent Increase
Untreated control			Not Applicable		33.3 a		374 bc	
Oso 5SC	6.5 fl oz	25	Polyoxin D zinc salt	19	19.1 c	42.6	317 b-e	-15.2
X77	0.25% (v/v)	NA	Non-ionic spreader	NA				
Regalia 5EC	2 pt		*Reynoutria sachalinensis* extract	P5	23.4 bc	29.7	305 b-e	-18.4
Kenja 400SC	15.5 fl oz		Isofetamid	7	33.8 a	-1.5	276 de	-26.2
Treatment means followed by the same letter are not statistically different according to the Fisher's Protected LSD test at P = 0.05.								

The diseases assessment date was after the last application treatment. Therefore, the treatments were assumed to be preventative.

The researchers described the cranberry fruit rot disease pressure at all sites to be high.

No phytotoxicity was observed on fruit or foliage.

c. Discussion

In this trial report which included *5 different trial sites*, Oso applied at 6.5 fl oz acre tank-mixed with X77 (a non-ionic spreader) applied at 0.25% (v/v) provided:

- 78.0%, 87.2%, 56.0%, 28.1%, and 42.6% (mean 58.4%) control of cranberry fruit complex; and
- -8.4%, 68.8%, -19.0%, 42.9%, and -15.2% (mean 13.8%) increased cranberry yield.

Regalia 5EC was the only OMRI-listed product that was also evaluated in this trial.

- For 4 of the 5 trials sites, Oso provided statistically *equivalent* control of cranberry fruit rot complex compared to Regalia;
- For the Valley Junction site, Oso provided statistically *superior* control of cranberry fruit rot complex compared to Regalia; and
- For all 5 trial sites, Oso provided statistically *equivalent* increased yield of cranberries.

CROP GROUP 13: BERRIES AND SMALL FRUITS: GRAPES / Bunch Rot (*Botrytis cinerea*)

#6: Trial No. 9:SMF001

a. Design

Grapes / Bunch Rot (*Botrytis cinerea*) #6: Trial No. 9:SMF001: Design				
Title:	Management of grape Botrytis bunch rot with experimental, organic and conventional fungicides, 2014			
Author and affiliation:	T. T. Nguyen, N. S. Morris, and W. D. Gubler University of California, Davis, CA			
Publication:	PDMR 9:SMF001			
Location:	Napa County, CA			
Crop:	Grape (*Vitis* 'Chardonnay')			
Disease name:	Bunch rot			
Pathogen:	*Botrytis cinerea*			
Test plot design:	Randomized complete block			
Number of replicates:	4			
Application equipment:	Nifty-Fifty pump tank/engine spray system			
Spray volume:	200 gal/acre			
Application type(s):	Preventative			
Number of applications:	3			
Chronology:	Application Dates	Application Interval (Days)	Growth Stage	Disease Assessment Dates
	05/08/2014		Bloom	10/06/2014
	06/12/2014	35	Pre-close	
	07/17/2014	35	Veraison	

b. Results

Grapes / Bunch Rot (*Botrytis cinerea*) #6: Trial No. 9:SMF001: Results								
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	Incidence (%)		Severity (%)	
					Measured	Percent Control	Measured	Percent Control
Untreated control			Not Applicable		22.8 a		4.4 a	
Tavano 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	4.0 cd	82.5	1.5 bc	59.1
Isofetamid	20 fl oz		Isofetamid	7	2.0 cd	91.2	0.0 c	100
Elevate	16 fl oz		Fenhexamid	17	4.0 cd	82.5	0.2 c	95.5
Double Nickel LC	2 qt		*Bacillus amyloliquefaciens* str. D747	44	1.0 d	95.6	0.3 bc	93.2
Double Nickel 55WDG	20 oz		*Bacillus amyloliquefaciens* str. D747	44	5.0 cd	78.1	1.3 bc	70.5
Treatment means followed by the same letter are not statistically different according to the Student's t test at α = 0.05.								

No phytotoxicity was reported.

c. Discussion

In this trial, Tavano (containing 5% polyoxin D zinc salt) applied at 6.5 fl oz/acre provided:

- 82.5% control of grape bunch rot incidence; and
- 59.1% control of grape bunch rot severity.

Double Nickel LC and Double Nickel 55WDG are OMRI-listed products evaluated in this trial. Tavano provided relative to these products:

- Statistically *equivalent* control of bunch rot incidence; and
- Statistically *equivalent* control of bunch rot severity.

CROP GROUP 13: BERRIES AND SMALL FRUITS: GRAPES / Powdery Mildew (*Erysiphe necator*)

#6: Trial No. KAK-2016-Grape-MI

a. Design

<table>
<tr><th colspan="6">Grapes / Powdery Mildew (Erysiphe necator) #6:
Trial No. KAK-2016-Grape-MI: Design</th></tr>
<tr><td>Title:</td><td colspan="5">Evaluation of fungicides for control of foliar and fruit diseases of juice grapes, 2016</td></tr>
<tr><td>Author and affiliation:</td><td colspan="5">A. M. Schilder, J. M. Gillett, and R. W. Sysak
Michigan State University</td></tr>
<tr><td>Publication:</td><td colspan="5">PDMR (planned for fall 2018 publication)</td></tr>
<tr><td>Location:</td><td colspan="5">Fennville, MI</td></tr>
<tr><td>Crop:</td><td colspan="5">Grape (Vitis labrusca “Niagara’)</td></tr>
<tr><td>Disease name:</td><td colspan="5">Powdery mildew</td></tr>
<tr><td>Pathogen:</td><td colspan="5">Erysiphe necator</td></tr>
<tr><td>Test plot design:</td><td colspan="5">Randomized complete block</td></tr>
<tr><td>Number of replicates:</td><td colspan="5">4</td></tr>
<tr><td>Application equipment:</td><td colspan="5">Research sprayer with 5-foot spray boom</td></tr>
<tr><td>Spray volume:</td><td colspan="5">50 gal/acre (May 8, 2016 to July 1, 2016)
75 gal/acre (remainder of the season)</td></tr>
<tr><td>Application type(s):</td><td colspan="5">Preventative</td></tr>
<tr><td>Number of applications:</td><td colspan="5">7 (Oso at 10-day to 16-day intervals)</td></tr>
<tr><td rowspan="10">Chronology:</td><td colspan="3">Application</td><td rowspan="2">Growth Stage</td><td rowspan="2">Disease Assessment Date</td></tr>
<tr><td>No.</td><td>Date</td><td>Interval</td></tr>
<tr><td>1</td><td>05/23/2016</td><td></td><td>3-5 inch shoot</td><td>09/10/2016</td></tr>
<tr><td>2</td><td>06/08/2016</td><td>16 days</td><td>10-16 inch shoot</td><td></td></tr>
<tr><td>3</td><td>06/21/2016</td><td>13 days</td><td>Bloom</td><td></td></tr>
<tr><td>4</td><td>07/01/2016</td><td>10 days</td><td>Pea-size fruit</td><td></td></tr>
<tr><td>5</td><td>07/12/2016</td><td>11 days</td><td>2nd post-bloom</td><td></td></tr>
<tr><td>6</td><td>07/27/2016</td><td>15 days</td><td>3rd post bloom</td><td></td></tr>
<tr><td>7</td><td>08/03/2016 [A]</td><td>7 days</td><td></td><td></td></tr>
<tr><td>8</td><td>08/10/2016</td><td>7 days</td><td>4th post-bloom</td><td></td></tr>
<tr><td>Disease assessment methodology:</td><td colspan="5">• 25 randomly selected leaves and clusters from the center vine in each plot were visually rated.
• Incidence = Percent leaves or clusters with disease.
• Severity = Percent area symptomatic on diseased plants only.
• Overall Severity = (Incidence x Severity) / 100.</td></tr>
<tr><td colspan="6">A. 08/03/2016 application was limited to selected treatment programs that included Ridomil Gold SL to control downy mildew.</td></tr>
</table>

Grapes / Powdery Mildew (*Erysiphe necator*) #6: Trial No. KAK-2016-Grape-MI: Results: Leaves (9/10/2016)									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App. Code	Incidence on Leaves (%)	Severity on Leaves (%)	Overall Severity on Leaves (%)	Percent Control on Leaves
Untreated control			Not Applicable			63.0 a	38.4 a	24.23 a	
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	1,2,3,4, 5,6,8	30.0 b	8.2 b	2.45 bc	90
Oso 5%SC	13 fl oz	50	Polyoxin D zinc salt	19	1,2,3,4, 5,6,8	5.0 de	1.5 de	0.10 d	99
Ranman	2.75 fl oz		Cyazofamid	21	1,2,3,4, 5,6,8	1.0 e	0.5 ef	0.02 d	99
Silwet L-77	2 fl oz		Nonionic surfactant	NA					
Manzate Pro-Stick	3 lb		Cymoxanil	27	1, 2	0.0 e	0.0 f	0.0 d	100
Pristine 38WG	12.5 oz		Boscalid	7	3,4,6,8				
			Pyraclostrobin	11					
Super Spread 90	0.125%		Non-ionic surfactant	NA					
Ziram 76DF	3 lb		Ziram	M3	5				
Ridomil Gold			Mefenoxam	4	7,8				
Treatment means followed by the same letter are not statistically different according to the Fischer's Protected SD test at P ≤ 0.05.									

Grapes / Powdery Mildew (*Erysiphe necator*) #6: Trial No. KAK-2016-Grape-MI: Results: Cluster (9/10/2016)									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App. Code	Incidence on Cluster (%)	Severity on Cluster (%)	Overall Severity on Cluster (%)	Percent Control on Cluster
Untreated control			Not Applicable			58.0 a	15.8 a	9.20 a	
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	1,2,3,4, 5,6,8	25.0 b	4.3 b	1.11 b	88
Oso 5%SC	13 fl oz	50	Polyoxin D zinc salt	19	1,2,3,4, 5,6,8	5.0 ef	1.8 cde	0.13 c-f	99
Ranman	2.75 fl oz		Cyazofamid	21	1,2,3,4, 5,6,8	1.0 f	0.5 de	0.02 ef	99
Silwet L-77	2 fl oz		Nonionic surfactant	NA					
Manzate Pro-Stick	3 lb		Cymoxanil	27	1, 2	0.0 f	0.0 e	0.0 f	100
Pristine 38WG	12.5 oz		Boscalid	7	3,4,6,8				
			Pyraclostrobin	11					
Super Spread 90	0.125%		Non-ionic surfactant	NA					
Ziram 76DF	3 lb		Ziram	M3	5				
Ridomil Gold			Mefenoxam	4	7,8				
Treatment means followed by the same letter are not statistically different according to the Fischer's Protected SD test at P ≤ 0.05.									

The first assessments were performed after the last treatment. Therefore, all treatments are assumed to be preventative.

The researchers reported the powdery mildew disease pressure to be moderate on leaves and low on clusters.

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 6.5 fl oz/acre and 13 fl oz/acre provided:

- 90% and 99% control, respectively, of powdery mildew on grape leaves; and
- 88% and 99% control, respectively, of powdery mildew on grape clusters.

No OMRI-listed products were evaluated in this trial.

#7: Trial No. KAK-2017-Grape-MI

a. Design

Grapes / Powdery Mildew (*Erysiphe necator*) #7: Trial No. KAK-2017-Grape-MI: Design					
Title:	Evaluation of fungicides for control of foliar diseases of juice grapes, 2017				
Author and affiliation:	A. M.C. Schilder, J. M. Gillett, and R. W. Sysak Michigan State University				
Publication:	PDMR (planned for fall 2018 publication)				
Location:	Fennville, MI				
Crop:	Grape ('Niagara')				
Disease name:	Powdery mildew				
Pathogen:	*Erysiphe necator*				
Test plot design:	Randomized complete block				
Number of replicates:	4				
Application equipment:	Research sprayer with 5-foot boom				
Spray volume:	40 gallons/acre (first 3 applications) 50 gallons/acre (later season applications)				
Application type(s):	Preventative				
Number of applications:	7				
Chronology:	App. Code	Application Dates	App. Interval (Days)	Growth Stage	Disease Assessment Dates
	A	05/16/2017		3-5 inch shoots	09/18/2017
	B	05/30/2017	14	7-17 inch shoots	
	C	06/10/2017	11	Pre-bloom/bloom	
	D	06/21/2017	11	1st post-bloom; bb-size fruit	
	E	07/11/2017	19	2nd post-bloom; pea-size fruit	
	F	07/25/2017	14	3rd post-bloom; pre-bunch closure	
	G	08/14/2017	20	4th post-bloom; bunch closure	
Disease assessment methodology:	Incidence: % of leaves or clusters with disease. Severity: % area symptomatic on diseased plant parts only. Overall severity: (Incidence x Severity) / 100.				

b. Results

Grapes / Powdery Mildew (*Erysiphe necator*) #7: Trial No. KAK-2017-Grape-MI: Results: Leaves									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App Code	Incidence (%)	Severity (%)	Overall Severity (%)	Control (%)
Untreated control			Not Applicable			79.0 a	44.0 a	34.9 a	
Oso	13.0 fl oz	50	Polyoxin D zinc salt	19	ABCDEFG	28.0 d	4.4 c	1.2 b	97
Lifegard WG	4.5 oz/ 100 gal		*Bacillus mycoides* isolate J		ABCDEFG	36.0 b	5.5 c	2.0 b	94
Stargus	64 fl oz		*Bacillus amyloliquefaciencs* strain F727		ABCDEFG	42.0 b	6.9 b	2.9 b	96
Intuity 4SC	6 fl oz		Mandestrobin	11	ABCDEFG	39.0 b	4.9 c	1.9 b	95
Super Spread 90	0.125% (v/v)		Non-ionic surfactant	NA	ABCDEFG				
Treatment means followed by the same letter are not statistically different according to the Fischer's Protected LSD test at P ≤ 0.05.									

Grapes / Powdery Mildew (*Erysiphe necator*) #7: Trial No. KAK-2017-Grape-MI: Results: Clusters									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App Code	Incidence (%)	Severity (%)	Overall Severity (%)	Control (%)
Untreated control			Not Applicable			85.0 a	43.0 a	36.6 a	
Oso	13.0 fl oz	50	Polyoxin D zinc salt	19	ABCDEFG	8.0 e	2.5 cd	0.3 d	99
Lifegard WG	4.5 oz/ 100 gal		*Bacillus mycoides* isolate J	44	ABCDEFG	25.0 bc	4.2 b	1.1 b	97
Stargus	64 fl oz		*Bacillus amyloliquefaciencs* strain F727	44	ABCDEFG	29.0 b	3.8 bc	1.1 b	97
Intuity 4SC	6 fl oz		Mandestrobin	11	ABCDEFG	27.0 bc	3.9 bc	1.1 b	97
Super Spread 90	0.125% (v/v)		Non-ionic surfactant	NA	ABCDEFG				
Treatment means followed by the same letter are not statistically different according to the Fischer's Protected LSD test at P ≤ 0.05.									

The researchers described the powdery mildew disease pressure as moderate.

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 13 fl oz/acre provided 97% and 99% control of powdery mildew on grape leaves and clusters, respectively.

Lifegard WG and Stargus are OMRI-listed products evaluated in this trial. Oso provided:

- Numerically ***superior*** control of powdery mildew on grape leaves compared to Lifegard WG and compared to Stargus.
- Statistically ***superior*** control of powdery mildew on grape clusters compared to Lifegard WG and compared to Stargus.

#8: Trial No. KAK-2017-Grape-PA

a. Design

<table>
<tr><th colspan="7">Grapes / Powdery Mildew (Erysiphe necator) #8:
Trial No. KAK-2017-Grape-PA: Design</th></tr>
<tr><td>Title:</td><td colspan="6">Evaluation of OSO 5% and other alternative fungicides on Vitis labrusca ‘Concord’ grapes, 2017.</td></tr>
<tr><td>Author and affiliation:</td><td colspan="6">Bryan Hed
Lake Erie Regional Grape Research and Extension Center
Penn State University</td></tr>
<tr><td>Publication:</td><td colspan="6">PDMR (submitted)</td></tr>
<tr><td>Location:</td><td colspan="6">North East, PA</td></tr>
<tr><td>Crop:</td><td colspan="6">Grapes (Concord)</td></tr>
<tr><td>Disease name:</td><td colspan="6">Powdery mildew</td></tr>
<tr><td>Pathogen:</td><td colspan="6">Podosphaera xanthii</td></tr>
<tr><td>Test plot design:</td><td colspan="6">Randomized complete block</td></tr>
<tr><td>Number of replicates:</td><td colspan="6">4</td></tr>
<tr><td>Application equipment:</td><td colspan="6">Friend covered-boom plot sprayer</td></tr>
<tr><td>Spray volume:</td><td colspan="6">50 gallons/acre (100 psi)</td></tr>
<tr><td>Application type(s):</td><td colspan="6">Preventative</td></tr>
<tr><td>Number of applications:</td><td colspan="6">7</td></tr>
<tr><td rowspan="11">Chronology:</td><td colspan="3">Application</td><td rowspan="2">Days After First Application</td><td rowspan="2">Growth Stage</td><td rowspan="2">Disease Assessment Dates</td></tr>
<tr><td>Code</td><td>Dates</td><td>Interval (Days)</td></tr>
<tr><td>A</td><td>05/10/2017</td><td></td><td>0</td><td>3-6 inch shoots</td><td></td></tr>
<tr><td>B</td><td>05/19/2017</td><td>9</td><td>9</td><td>10-12 inch shoots</td><td></td></tr>
<tr><td>C</td><td>05/28/2017</td><td>9</td><td>18</td><td>12-16 inch shoots</td><td></td></tr>
<tr><td>D</td><td>06/08/2017</td><td>11</td><td>29</td><td>Immediate pre-bloom</td><td></td></tr>
<tr><td>E</td><td>06/18/2017</td><td>10</td><td>39</td><td>1st post-bloom</td><td></td></tr>
<tr><td>F</td><td>06/28/2017</td><td>10</td><td>49</td><td>2nd post-bloom</td><td></td></tr>
<tr><td>G</td><td>07/09/2017</td><td>11</td><td>60</td><td>3rd post-bloom</td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td>08/03/2017 (clusters)</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td>08/15/2017 (leaves)</td></tr>
<tr><td>Disease assessment methodology:</td><td colspan="6">Severity was rated using the Barratt-Horsfall scale and was converted to % area infected (0-100%) using Elanco conversion tables.</td></tr>
</table>

b. Results

Grapes / Powdery Mildew (*Erysiphe necator*) #8: Trial No. KAK-2017-Grape-PA: Results: Clusters								
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App Code	Incidence (%)	Severity (%)	
							Measured	% Control
Untreated control			Not Applicable			90.0 ab	6.29 a	
OSO 5%	13.0 fl oz	50	Polyoxin D zinc salt	19	ABCDEFG	42.0 d	1.03 e	84
Fracture	24.4 fl oz		Banda de Lupinus albus doce (BLAD)	BM1	ABCDEFG	90.0 a	3.91 bcd	38
Fracture	36.6 fl oz		Banda de Lupinus albus doce (BLAD)	BM1	ABCDEFG	92.0 a	3.42 bcd	46
Double Nickel	1.5 qt		*Bacillus amyloliquefaciens* str. D747	44	ABCDEFG	89.0 ab	4.78 bc	24
Double Nickel	3 qt		*Bacillus amyloliquefaciens* str. D747	44	ABCDEFG	91.0 a	5.20 ab	17
Badge X2	1.75 lb		Copper hydroxide, Copper oxychloride	M1	ABCDEFG	69.0 bc	2.57 cde	59
Lime	1.75 lb		Calcium hydroxide	NA	ABCDEFG			
Conventional standard:								
• Manzate Prostik	3 lb		Cymoxanil	27	ABCD	61.0 cd	1.64 de	74
• Ziram	4 lb		Zinc dimethyldithiocarbamate	M3	EFG			
• Quintec	4 fl oz		Quinoxyfen	13	D G			
• Vivando	10.3 fl oz		Metrafenone	U8	E			
• Toledo	4 oz		Tebuconazole	3	F			
Treatment means followed by the same letter are not statistically different according to Fisher's LDS test at P ≤ 0.05.								

Grapes / Powdery Mildew (*Erysiphe necator*) #8: Trial No. KAK-2017-Grape-PA: Results: Leaves								
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App Code	Incidence (%)	Severity (%)	
						Measured	Measured	Percent Control
Untreated control			Not Applicable			98.0 a	16.32 a	
OSO 5%	13.0 fl oz	50	Polyoxin D zinc salt	19	ABCDEFG	75.0 bc	3.09 bc	81
Fracture	24.4 fl oz		Banda de Lupinus albus doce (BLAD)	BM1	ABCDEFG	85.0 bc	5.74 bc	65
Fracture	36.6 fl oz		Banda de Lupinus albus doce (BLAD)	BM1	ABCDEFG	86.0 abc	8.66 abc	47
Double Nickel	1.5 qt		*Bacillus amyloliquefaciens* str. D747	44	ABCDEFG	89.0 ab	7.18 bc	56
Double Nickel	3 qt		*Bacillus amyloliquefaciens* str. D747	44	ABCDEFG	91.0 ab	9.98 ab	39
Badge X2	1.75 lb		Copper hydroxide, Copper oxychloride	M1	ABCDEFG	19.0 e	0.54 c	97
Lime	1.75 lb		Calcium hydroxide	NA	ABCDEFG			
Conventional standard:								
• Manzate Prostik	3 lb		Cymoxanil	27	ABCD	42.0 d	1.27 e	92
• Ziram	4 lb		Zinc dimethyldithiocarbamate	M3	EFG			
• Quintec	4 fl oz		Quinoxyfen	13	D G			
• Vivando	10.3 fl oz		Metrafenone	U8	E			
• Toledo	4 oz		Tebuconazole	3	F			
Treatment means followed by the same letter are not statistically different according to Fisher's LDS test at P ≤ 0.05.								

The researcher described the powdery mildew development on grape clusters and grape leaves as moderately high.

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 13 fl oz/acre provided:

- 84% control of powdery mildew severity on grape clusters; and
- 81% control of powdery mildew severity on grapes leaves.

OMRI-listed products evaluated in this trial included Double Nickel and Badge X2 tank-mixed with Lime. Oso provided:

- Numerically ***superior*** control of powdery mildew severity on grape clusters and leaves compared to Double Nickel; and
- Statistically ***equivalent*** control of powdery mildew severity on grape clusters and leaves compared to Badge X2 tank-mixed with lime.

CROP GROUP 13: BERRIES AND SMALL FRUITS: STRAWBERRIES / Botrytis Fruit Rot (*Botrytis cinerea*)

#4: Trial No. KAK-2016-Sberry-MD

a. Design

Strawberries / Botrytis Fruit Rot (*Botrytis cinerea*) #4: Trial No. KAK-2016-Sberry-MD: Design					
Title:	Evaluation of organic and conventional fungicides for the control of Botrytis fruit rot in strawberries, 2016				
Author and affiliation:	E. E. Koivunen and C. L. Swett Univ. of Maryland				
Publication:	Submitted to Plant Disease Management Reports				
Location:	Queenstown, MD				
Crop:	Strawberry (*Fragaria x ananassa* 'Chandler')				
Disease name:	Botrytis Fruit Rot				
Pathogen:	*Botrytis cinerea*				
Test plot design:	Randomized complete block				
Number of replicates:	4				
Application equipment:	Twin TeeJet nozzles (60 psi)				
Spray volume:	93 gal/acre				
Application type(s):	Preventative				
Number of applications:	9				
Chronology:	Application Dates	Application Interval	Assessment Dates		
			AUDPC	Incidence	Marketable Fruit
	03/30/2016		05/06/2016	05/06/2016	05/18/2016
	04/06/2016	7 days	05/18/2016	05/18/2016	05/25/2016
	04/13/2016	7 days	05/25/2016	05/25/2016	06/01/2016
	04/20/2016	7 days	06/01/2016	06/01/2016	
	05/25/2016	5 days			
	05/30/2016	5 days			
	05/04/2016	5 days			
	05/10/2016	6 days			
	05/18/2016	8 days			
Soil:	Not fumigated.				

Strawberries / Botrytis Fruit Rot (*Botrytis cinerea*) #4: Trial No. KAK-2016-Sberry-MD: Results												
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App. No.	Incidence (%)		Marketable Fruit				
								Percent		Grams/Plant		
						Measured	Percent Control	Measured	Percent Increase	Measured	Percent Increase	
Untreated control (Water)			Not Applicable			14.4 b		67.5 a		114.3 a		
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	1-9	5.6 ab	61.1	66.3 a	-1.88	114.1 a	-0.17	
Oso 5%SC	13 fl oz	50	Polyoxin D zinc salt	19	1-9	4.4 a	69.4	80.0 a	18.5	143.1 a	25.2	
Organic Std: • Regalia	4 qt		*Reynoutria sachalinensis* extract	P5	1-9	9.4 ab	34.7	67.5 a	0.00	115.9 a	1.34	
• Actinovate	12 oz		*Streptomyces lydicus*	NC	2,4,6,8							
• Silwet	0.8 qt		Non-ionic surfactant	NA	2-9							
• Serenade ASO	4 qt		*Bacillus subtilis* str. QST 713	44	3,5,7,9							
Treatment means followed by the same letter are not statistically different according to ANOVA and Tukey's multiple means comparison test at P = 0.05.												

Treatments were applied preventatively. Foliage remained healthy.

The researchers described the Botrytis fruit rot disease pressure as relatively low due to the cool spring.

No phytotoxicity was observed.

c. Discussion

This trial was conducted on the eastern shore of Maryland where humidity is high, pick-your-own strawberry farms are common, and soil fumigation is not used due to the close proximity of the Chesapeake Bay.

In this trial, Oso applied at 6.5 fl oz/acre and 13 fl oz/acre, in the absence of soil fumigation for pest control, provided:

- 61.1% and 69.4% control, respectively, of Botrytis fruit rot incidence; and
- -1.88% and 18.5% increased strawberry marketable fruit, respectively.

The local standard treatment program of organic strawberries includes Regalia, Actinovate, Silwet, and Serenade ASO and was evaluated in this trial. Treatment with Oso provided:

- *Superior* control of Botrytis fruit rot incidence compared to the organic standard treatment program; and
- *Superior* marketable strawberry yield compared to the organic standard treatment program.

#5: Trial No. KAK-2016-Sberry-MI

a. Design

<table>
<tr><th colspan="7">Strawberries / Botrytis Gray Mold (Botrytis cinerea) #5:
Trial No. KAK-2016-Sberry-MI: Design</th></tr>
<tr><td>Title:</td><td colspan="6">Evaluations of fungicides for control of leaf and fruit rot diseases in matted-row strawberry, 2016</td></tr>
<tr><td>Author and affiliation:</td><td colspan="6">A. M.C. Schilder, N. M. Gillett, and R. W. Sysak
Michigan State University</td></tr>
<tr><td>Publication:</td><td colspan="6">PDMR (planned for fall 2018 publication)</td></tr>
<tr><td>Location:</td><td colspan="6">Camden, MI</td></tr>
<tr><td>Crop:</td><td colspan="6">Strawberry (Fragarias x ananassa ‘Wendy’)</td></tr>
<tr><td>Disease name:</td><td colspan="6">Botrytis gray mold</td></tr>
<tr><td>Pathogen:</td><td colspan="6">Botrytis cinerea</td></tr>
<tr><td>Test plot design:</td><td colspan="6">Randomized complete block</td></tr>
<tr><td>Number of replicates:</td><td colspan="6">4</td></tr>
<tr><td>Application equipment:</td><td colspan="6">Handheld Smith Contractor Sprayer (29 psi)</td></tr>
<tr><td>Spray volume:</td><td colspan="6">75 gal/acre</td></tr>
<tr><td>Application type(s):</td><td colspan="6">Preventative</td></tr>
<tr><td>Number of applications:</td><td colspan="6">7</td></tr>
<tr><td rowspan="9">Chronology:</td><td colspan="4">Application</td><td rowspan="2">Disease Assessment Dates (Berries)</td><td rowspan="2">Harvest Dates</td></tr>
<tr><td>No.</td><td>Date</td><td>Interval</td><td>Growth Stage</td></tr>
<tr><td>1</td><td>05/09/2016</td><td></td><td>Green up</td><td rowspan="7">06/23/2016</td><td rowspan="7">06/16/2016
06/24/2016</td></tr>
<tr><td>2</td><td>05/18/2016</td><td>9 days</td><td>Bloom</td></tr>
<tr><td>3</td><td>05/24/2016</td><td>6 days</td><td>2nd bloom after frost</td></tr>
<tr><td>4</td><td>06/01/2016</td><td>7 days</td><td>Bloom and green fruit</td></tr>
<tr><td>5</td><td>06/07/2016</td><td>6 days</td><td>Green fruit</td></tr>
<tr><td>6</td><td>06/15/2016</td><td>7 days</td><td>Green and red fruit</td></tr>
<tr><td>7</td><td>06/23/2016</td><td>8 days</td><td>Red fruit</td></tr>
<tr><td>Disease assessment methodology:</td><td colspan="6">• Visual field ratings: 50 berries were selected randomly.
• Disposable gloves were used to pick berries and changed between plots to reduce cross-contamination.
• Harvest was from the center of plots.
• Post-harvest: 25 marketable berries from each plot were placed equidistant on metal screens in aluminum trays and incubated at 72°F and 100% relative humidity. After 4 days, the berries were inspected for fungal sporulation.</td></tr>
</table>

b. Results

Strawberries / Botrytis Gray Mold (*Botrytis cinerea*) #5: Trial No. KAK-2016-Sberry-MI: Results										
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	Field Incidence (%)		4-Day Post-Harvest [A] Incidence (%) (1st Harvest; 6/16/2016)		4-Day Post-Harvest [A] Marketable Fruit(%) (1st Harvest; 6/16/2016)	
					Measured	Percent Control	Measured	Percent Control	Measured	Percent Increase
Untreated control			Not Applicable		39.0 a		39.0 a		7.5 a	
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	6.0 b	85	27.0 cd	31	28.0 bc	273
Oso 5%SC	13 fl oz	50	Polyoxin D zinc salt	19	5.5 bc	86	25.0 cd	36	25.0 b	233
Serifel	4 oz		*Bacillus amyloliquefanciens* strain MBI 600	44	3.5 bc	91	35.0 bc	10	27.0 bc	260
Serifel	4 oz		*Bacillus amyloliquefanciens* strain MBI 600	44	6.5 b	83	21.0 d	46	38.0 c	407
Pristine	11.5 oz		Boscalid	7						
			Pyraclostrobin	11						

Treatment means followed by the same letter are not statistically different according to Fisher's Protected LSD test at $P \leq 0.05$.
A. Harvested 1 day after last application. All berries used in the post-harvest incubation test appeared marketable (no visible disease or soft areas) before incubation started.

The first assessments were performed after the last treatment. Therefore, all treatments are assumed to be preventative.

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 13 fl oz/acre provided:

- 86% control of field incidence of Botrytis fruit rot on strawberries; and
- 233% increased 4-day post-harvest marketable strawberries.

OMRI-listed products evaluated in this trial included Serifel. Oso applied at both 6.5 fl oz/acre and at 13 fl oz/acre provided control of Botrytis on strawberries that was statistically *equivalent* to the field and post-harvest control of Botrytis provided by Serifel.

#6: Trial No. KAK-2017-Sberry-MI

a. Design

Strawberries / Botrytis Gray Mold (*Botrytis cinerea*) #6: Trial No. KAK-2017-Sberry-MI: Design				
Title:	Evaluation of fungicides for control of leaf and fruit rot diseases in matted-row strawberry, 2017			
Author and affiliation:	A. M. C. Schilder, J. M. Gillett, and R. W. Sysak Michigan State University			
Publication:	PDMR (planned for fall 2018 publication)			
Location:	Camden, MI			
Crop:	Strawberry (*Fragaria* x *ananassa* 'Wendy')			
Disease name:	Botrytis gray mold			
Pathogen:	*Botrytis cinerea*			
Test plot design:	Randomized complete block			
Number of replicates:	4			
Application equipment:	Smith Contractor Sprayer (29 psi)			
Spray volume:	75 gallons/acre			
Application type(s):	Preventative			
Number of applications:	5			
Chronology:	Application Dates	Application Interval (days)	Growth Stage	Disease Assessment Dates
	05/01/2017		Green up	06/22/2017 (field ratings)
	05/07/ 2017	7	50% bloom	06/26/2017 (post-harvest ratings)
	05/24/2017	17	Bloom	
	05/31/2017	7	Bloom and green fruit	
	06/14/2017	14	Red fruit	
Disease assessment methodology (post-harvest):	25 marketable berries from each plot were placed equidistantly on metal screens in aluminum trays and incubated at room temperature and 100% relative humidity. After 4 days, berries were visually assessed for final sporulation.			

b. Results

Strawberries / Botrytis Gray Mold (*Botrytis cinerea*) #6: Trial No. KAK-2017-Sberry-MI: Results									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App Code	Field Rating of Botrytis Gray Mold on Fruit		4-Day Post-Harvest Marketable Fruit	
						Incidence (%)	Control (%)	Incidence (%)	Increase (%)
Untreated control			Not Applicable			53.5 a		2.0 a	
Oso 5%	13 fl oz	50	Polyoxin D zinc salt	19	ABCDE	3.3 b	94	49.0 b	2350
Standard program:									
Topsin	4.5 fl oz		Thiophanate-methyl	1	A	3.3 b	94	40.0 b	1900
Captan 4L	3 qt		Captan	M4	A				
Fontelis	24 fl oz		Penthiopyrad	7	BCE				
Switch 62.5	12 oz		Cyprodinil	9	D				
			Fludioxonil	12					
Treatment means followed by the same letter are not statistically different according to the Fisher's Protected LSD test at P ≤ 0.05.									

The researchers described the Botrytis disease pressure in the field as moderately high.

No phytotoxicity was observed.

c. Discussion

In this trial, Oso applied at 13 fl oz/acre provided:

- 94% control of Botrytis fruit rot on strawberries; and
- 2350% increased 4-day post-harvest marketable strawberries.

No OMRI-listed products were evaluated in this trial.

EVALUATION OF ORGANIC GROWER NEED

STEP 1: Cumulative Efficacy Data Summary for Polyoxin D Zinc Salt Petitioned Uses

Efficacy data for the polyoxin D zinc salt 5SC formulation summarized in the May 31, 2016 petition and this addendum for which polyoxin D zinc salt was used in the absence of other fungicide products is further summarized below. The table below includes mean percent control data based upon the application rate. Curative treatments are highlighted. Non-ionic surfactants and other adjuvants are noted when used.

Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051) Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inocu-lated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
CROP GROUP 1: ROOT AND TUBER VEGETABLES																		
Early Blight	*Alternaria solani*	Potatoes #1	CER-2011-029	MI	CX-10440	8	7	3.8	15	19.3	NA	26.4	Preventative and curative	No	45.0	No	PDMR 6:V107	
								7.5	29	22.2	NA	6.9						
		Potatoes #2	CER-2011-030	PA	CX-10440	4	14 - 18	3.75	14	18.1	NA	NA	Preventative and curative	Yes	AUDPC = 922.6	No	PDMR 6:V113	
								7.5	29	39.7	NA	NA						
		Potatoes #3	CER-2012-028	PA	CX-10440	7	7 - 8	6.5	25	41.9	NA	13.5	Preventative and curative	Yes	AUDPC = 340	No	PDMR 7:V105	
								13	50	41.9	NA	6.5						
							Mean	3.75 - 3.8	14 - 15	18.7	NA	26.4						
								6.5 - 7.5	25 - 29	34.6	NA	10.2						
								13	50	41.9	NA	6.5						
Late Blight	*Phytophthora infestans*	Potatoes #1	CER-2012-027	PA	CX-10440	5	7	13	50	10.1	NA	13.9	Preventative and curative	Yes	AUDPC = 1612	No	PDMR 7:V094	
Tan Spot	*Botrytis cinerea*	Potatoes #1	CER-2011-029	MI	CX-10440	8	7	3.8	15	74.9	NA	26.4	Preventative	No	35.0	No	PDMR 6:V107	
								7.5	29	71.4	NA	6.9						
CROP GROUP 4: LEAFY VEGETABLES (EXCEPT BRASSICA VEGETABLES)																		
Downy Mildew	*Bremia lactucae*	Lettuce #1	CER-2011-046	CA	CX-10440	4	14 - 15	3.75	14	47.5	NA	NA	Preventative and curative	No	100	No	Certis data; not published.	
								7.5	29	33.7	NA	NA						
		Lettuce #2	CER-2013-014	CA	Oso	8	7	6.5	25	50	NA	NA	Preventative and curative	No	12.58 lesions/ head	No	Certis data; not published.	
								13	50	62	NA	NA						
		Lettuce #3	CER-2013-032	CA	Oso + Syl-Tak (surfactant; 4 fl oz/A)	4	6 - 10	13	50	46.2	NA	NA	Preventative	No	4.26 lesions/ head	No	Not published. Permission received.	
							Mean	3.75	14	47.5	NA	NA						
								6.5 -7.5	25 -29	42	NA	NA						
								13	50	54	NA	NA						
Gray Mold	*Botrytis cinerea*	Lettuce #1	CER-2011-014	CA	CX-10440	4	10 - 11	3.75	14	30.0	NA	6.1	Preventative	No	52.62	No	Certis data; not published.	
								7.5	29	41.7	NA	6.5						

Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051) Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inocu-lated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
Powdery Mildew	*Golovinomyces cichoracearum*	Lettuce #1	CER-2012-074	AZ	CX-10440	4	8 - 11	3.75	14	69	NA	NA	Preventative and curative	No	3.9 (0-5 scale)	No	PMDR 8:V199	
								6.5	25	69	NA	NA						
White Rust	*Albugo occidentalis*	Spinach #1	CER-2014-063	TX	Oso	4	5 - 9	6.5	25	53	NA	NA	Curative	No	100	No	Not published. Permission received.	Disease present before first application.
		Spinach #2	CER-2015-152	TX	Oso + Induce (non-ionic surfactant; 4 oz/A)	4	11 - 15	6.5	25	49	NA	NA	Preventative	No	4.5 on 1 to 10 scale	No	Not published. Permission received.	New data.
							Mean	6.5	25	51	NA	NA						
CROP GROUP 8: FRUITING VEGETABLES																		
Early Blight	*Alternaria solani*	Tomatoes #1	CER-2014-095	FL	Oso	8	6 - 9	6.5	50	38.4	NA	NA	Preventative and curative	Yes	55.0	No	PDMR 9:V072	
Late Blight	*Phytophthora infestans*	Tomatoes #1	CER-2011-027	FL	CX-10440	4	6 - 8	7.5	29	64.3	NA	NA	Preventative	No	546.0 lesions/ plot	No	Not published. Permission received.	
Powdery Mildew	*Leviellula taurica*	Tomatoes #1	CER-2012-016	CA	CX-10440	3	9 - 14	13	50	47.3	NA	14.5	Curative	No	93.5	No	Not published. Permission received.	See also *Odium neolycopersici*.
Powdery Mildew	*Odium neoplycopersici*	Tomatoes #1	BCGGA-2015-03	Green-house	Oso	4	7	4.1	15	84.8	NA	3.5	Preventative and curative	Yes	62.5	No	Canadian Journal Plant Pathology	See also *Leviellula taurica*.
								6.8	26.2	86.9	NA	11.4						
								13.7	52.7	90.2	NA	14.8						
						2	14	13.7	52.7	82.5	NA	-6.3						
								20.5	75	82.9	NA	19.3						
							Mean	4.1	15	84.8	NA	3.5						
								6.8	26.2	86.9	NA	11.4						
								13.7	52.7	86.4	NA	4.3						
								20.5	75	82.9	NA	19.3						
Target Spot	*Corynespora cossiicola*	Tomatoes #1	CER-2014-095	FL	Oso	8	6 - 9	6.5	25	38.4	NA	NA	Preventative and curative	Yes	55.0	No	PDMR 9:V072	

Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051) Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inocu-lated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
CROP GROUP 9: CUCURBIT VEGETABLES																		
Anthracnose	*Colletotrichum orbiculare*	Watermelon #1	CER-2014-057	TX	Oso + Capsil (surfactant; 12 fl oz/100 gal)	7	6 - 11	6.5	25	82	NA	3.3	Preventative and curative	No	1.38 (Scale of 0 to 5)	No	Not published. Permission received.	Phytotoxicity observed in alternative treatment program: chlorothalonil + mancozeb + zoxamide.
Gummy Stem Blight	*Didymella bryoniae*	Cantaloupe #1	IND-2012-125	Green-house	CX-10440	1	Not Applicable	14	54	86.7	NA	NA	Preventative	Yes	100		Permission received. Submitted to Plant Health Progress.	Phytotoxicity observed for alternatives: Armicarb and Organocide.
		Cucumber #1	BCGGA-2015-02	Green-house	Oso	4	7	13.7	52.7	61.0	NA	20.3	Preventative and curative	Yes	90.8	No	Canadian Journal Plant Pathology	20.5 fl oz/acre exceeds labeled rate.
						2	14	13.7	52.7	60.7	NA	15.8						
						2	14	20.5	75	58.9	NA	21.9						
		Watermelon #1	CER-2011-028	SC	CX-10440	7	7 - 12	27	27	33.6	NA	NA	Preventative and curative	Yes	99.9	No	PDMR 6:V023	Exceeds labeled rate.
								54	51	62.5	NA	NA						
		Watermelon #2	CER-2012-051	GA	CX-10440	7	5 - 9	6.5	25	25.7	NA	NA	Curative	Yes	85.0	No	Submitted to Plant Health Congress. Permission received.	Inoculated 20 days before first fungicide treatment.
								13.0	50	30.6	NA	NA						
							Mean	6.5	25	25.7	NA	NA						
								13.0 - 14	50 - 54	57	NA	18.1						
								20.5	75	58.9	NA	21.9						
Powdery Mildew	*Podosphaera xanthii*	Cucumbers #1	R-14-10-0	Green-house	Veggieturbo 5SC	2	7	6.5	25	80	NA	NA	Curative	Yes	80.0	No	Kaken data; not published.	Disease confirmed before first treatment.
								13	50	81	NA	NA						
		Pumpkins #1	CER-2015-145	IL	Oso + Activator (non-ionic surfactant; 0.125%)	7	6 - 8	6.5	25	67	NA	NA	Preventative and curative	No	30	No	Not published. Permission received.	
		Pumpkin #2	CER-2015-149	GA	Oso	5	7	6.5	25	51.7	NA	NA	Preventative	No	72.5 (0 to 100 scale; 100 = Plant mortality.	No	Not published. Permission received.	
							Mean	6.5	25	66	NA	NA						
								13	50	81	NA	NA						

Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051) Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inocu-lated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
Downy Mildew	*Pseudo-peronospora cubensis*	Cucumber #1	CER-2012-067	DE	CX 10440	5	5 - 7	6.5	25	57.1	NA	37.1	Preventative	No	17.5	No	Not published. Permission received.	
								13	50	37.1	NA	18.0						
		Pumpkin #1	CER-2015-145	IL	Oso + Activator (non-ionic surfactant; 0.125%)	7	6 - 8	6.5	25	78	NA	NA	Preventative and curative	No	20.75	No	Not published. Permission received.	
							Mean	6.5	25	68	NA	37.1						
								13	50	37.1	NA	18.0						
Southern Blight	*Sclerotinium rolfsii*	Squash #1	CER-2012-050	GA	CX-10440	9	7	6.5	25	NA	59	482	Preventative	No	2 on a 1 to 10 scale	No	Certis data; not published.	Foliar treatment.
								13	50	NA	82	552						
CROP GROUP 11: POME FRUITS																		
Fly Speck	*Zygophiala jamaicensis*	Apples #1	CER-2012-025	VA	CX-10440	9	12 - 20	6.5	25	NA	93	NA	Preventative and curative	No	87	No	PDMR 7:PF034	
								13	50	NA	70	NA						
Powdery Mildew	*Podosphaera leucotricha*	Apples #1	CER-2012-020	WA	CX-10440	5	6 - 14	6.5	25	56	NA	NA	Preventative and curative	No	35.5	No	Certis data; not published.	
								13.0	50	54	NA	NA						
		Apples #2	CER-2015-012	WA	Oso	5	8 - 27	6.5	25	14.4	78.2	NA	Preventative and curative	No	61.3	No	Certis data; not published.	
		Apples #3	CER-2015-034	WA	Oso + sticker/ spreader (R-56 or SB56; not specified; rate not reported)	6	13 - 19	6.5	25	40.5	NA	NA	Preventative and curative	No	30.8	No	Certis data; not published.	
		Apples #4	CER-2015-033	WA	Oso + R-56 (sticker/ spreader; 0.25%; v/v)	1	NA	6.5	25	NA	10.4	NA	Preventative	No	96.0	No	Certis data; not published.	New data. Storage rot; fruit punctured and not punctured.
							Mean	6.5	25	37	44.3	NA						
								13.0	50	54	NA	NA						
Scab	*Venturia inaequalis*	Apples #1	CER-2012-025	VA	CX-10440	9	12 - 28	6.5	25	53	62	NA	Curative	No	87	No	PDMR 7:PF034	Scab was present before the first fungicide application.
								13	50	13	46	NA						
Sooty Blotch Complex	*Geastrumia polystigmatus*, etc.	Apples #1	CER-2012-025	VA	CX-10440	9	12 - 28	6.5	25	NA	79	NA	Preventative and curative	No	94	No	PDMR 7:PF034	
								13	50	NA	56	NA						

Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051) Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inocu-lated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
CROP GROUP 12: STONE FRUITS																		
Brown Rot Blossom Blight	*Monilinia fructicola* and *Monilinia laxa*	Cherries #1	CER-2015-035	OR	Oso + Induce (wetter/ sticker; 32 fl oz/100 gal)	7	7 - 14	6.5	25	96.5	NA	NA	Preventative and curative	No	14.3	No	PDMR 10:STF009	Applications initiated before bloom.
		French prunes #1	CER-2013-121	CA	CX-10440	1	NA	6	23	85.9	NA	NA	Curative	Yes	65.1	No	UC Repository 07 CPB 6	Inoculated 24 hr before first treatment.
										97.3	NA	NA	Preventative	Yes	63.8			Inoculated 4 hr after first treatment.
							Mean	6 - 6.5	23 - 25	93.2	NA	NA						
Brown Rot Fruit Rot	*Monilinia fructicola*	Nectarines #1	CER-2013-119	CA	CX-10440	1	NA	3.5	13	NA	18	NA	Preventative	Yes (post-har-vest)	85.3	No	Internet (Adaskaveg, 2013)	Pre-harvest treatment. Post-harvest inoculation and evaluation.
								13	50	NA	20	NA						
		Peaches #1						3.5	13	NA	13	NA			67.9			
								13	50	NA	19	NA						
		Cherries #1	CER-2015-035	OR	Oso + Induce (wetter/ sticker; 32 fl oz/100 gal)	7	7 - 14	6.5	25	NA	78	NA	Preventative and curative	No	6.0	No	PDMR 10:STF009	Pre-harvest treatment. Post-harvest evaluation.
							Mean	3.5	13	NA	16	NA						
								6.5	25	NA	19	NA						
								13	50	NA	20	NA						
Powdery Mildew	*Podosphaera clandestina*	Cherries #1	CER-2015-032	WA	Oso + R-56 (spreader/ sticker; 32 fl oz/100 gal)	4	14 - 15	6.5	25	60.0	NA	NA	Preventative and curative	No	89.0	No	Certis data; not published.	
		Cherries #2	CER-2015-035	OR	Oso + Induce (wetter/ sticker; 32 fl oz/100 gal)	7	7 - 14	6.5	25	19.6	NA	NA	Preventative	No	53.3	No	PDMR 10:STF009	New data. Applications initiated before bloom.
							Mean	6.5	25	39.8	NA	NA						

Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051) Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inocu-lated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
CROP GROUP 13: BERRIES AND SMALL FRUITS: BLUEBERRIES																		
Alternaria Fruit Rot	Alternaria spp.	Blueberries #1	CER-2012-049	MI	CX-10440	5	10 - 39	6.5	25	NA	31	NA	Preventative	No	48.5	No	PDMR 7:SMF014	Pre-harvest treatment. Post-harvest evaluation.
								13.0	50	NA	51	NA						
Gray Mold	*Botrytis cinerea*	Blueberries #1	CER-2015-009	OR	Oso + Kinetic (sticker/ spreader; 6 fl oz/100 gal)	12	Typically 6-8	5.6	22	NA	72	NA	Preventative	No	7.8	No	PDMR 10:SMF027	
						7	13-15	5.6	22	NA	87	NA						
							Mean	5.6	22	NA	80	NA						
Mummyberry	*Monilinia vaccinii-corymbosi*	Blueberries #1	CER-2015-008	OR	Oso + Induce (wetter/ sticker; 6 fl oz/100 gal)	9	4 - 8	5.6	21.6	NA	21.3	NA	Preventative and curative	No	34.8	No	PDMR 10:SMF026	
		Blueberries #2	CER-2015-143	MI	Oso + LI 700 (penetrant, acidifier; 0.125% v/v)	5	7 - 14	6.5	25	89	94	NA	Preventative	No	46.5 mummies/ bush	No	PDMR 10:SMF009	
		Blueberries #3	KAK-2016-Blueberry-MI	MI	Oso	8	8 - 23	6.5	25	90.8	90.7	NA	Preventative and curative	No	57.8 shoot strikes/ bush	No	PDMR (Planned fall 2018 publication) (Permission)	New data.
								13	50	100	100	NA						
					Oso + LI 700 (penetrant, acidifier; 0.125% v/v)			6.5	25	87.9	88.2	NA						
		Blueberries #4	KAK-2016-Blueberry-WA-Conv	WA	Oso	6	10 - 16	6.5	25	83.0	84.3	NA	Preventative	No	17.8 Mummies/ bush	No	Permission.	New data.
								13	50	83.0	87.1							
		Blueberries #5	KAK-2016-Blueberry-WA-Org	WA	Oso	7	6 - 9	6.5	25	-64.4	17.8	NA	Preventative	No	45.0 (fruit)	No	Permission.	New data. Includes Oso with microbial pesticides.
								13	50	32.5	30.0	NA						
		Blueberries #6	KAK-2017-Blueberry-WA-Org	WA	Oso	7	5 - 11	6.5	25	NA	63	NA	Preventative	No	6.3	No	Permission.	New data. Includes Oso with microbial pesticides.
								13	50	NA	68	NA						
							Mean Conven-tional	5.6 - 6.5	21.6 - 25	88	77	NA						
								13	20	91.5	93.6	NA						
							Mean Organic	6.5	25	-64.4	40	NA						
								13	50	32.5	49	NA						

Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051) Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inocu-lated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
CROP GROUP 13: BERRIES AND SMALL FRUITS: CANEBERRIES																		
Botrytis Fruit Rot	*Botrytis cinerea*	Raspberries #1	IND-2015-rasp	WA	Oso	6	10	12	46	NA	51.1	NA	Preventative	No	19.0	No	Permission.	
		Raspberries #2	IND-2016-Rasp-WA	WA	Oso	6	9 - 12	12	46	NA	52.4	NA	Preventative	No	21.0	No	Permission.	New data.
		Raspberries #3	KAK-2017-Rasp-MI	MI	Oso	5	7 - 14	6.5	25	NA	81	NA	Preventative	No	53.3	No	PDMR (Planned fall 2018 publication) (Permission)	New data.
								13	50	NA	100	NA						
							Mean	12	46	NA	51.8	NA						
Powdery Mildew	*Podosphaera aphanis*	Blackberries #1	CER-2012-060	OR	CX-10440	3	12 - 14	3.75	12.5	NA	42	NA	Preventative	No	60.0	No	Certis data; not published.	
								6.5	25	NA	58	NA						
		Raspberries #1	KAK-2017-Rasp-MI	MI	Oso	5	7 - 14	6.5	25	97	NA	NA	Preventative	No	57.3	No	PDMR (Planned fall 2018 publication) (Permission)	New data.
								13	50	100	NA	NA						
							Mean	3.75	12.5	NA	42	NA						
								6.5	25	97	58	NA						
								13	50	100	NA	NA						
CROP GROUP 13: BERRIES AND SMALL FRUITS: CRANBERRIES																		
Cottonball	*Monilinia oxycocci*	Cranberries #1	IND-2014-165	WI	Tavano 5SC	2	14	6.5	25	NA	16	NA	Preventative	No	32	No	PDMR 9:SMF014	City Point
								6.5	25	NA	38	NA			21			Warrens
		Cranberries #2	IND-2015-208	WI	Oso	2	9	6.5	25	NA	68.1	22.0	Preventative	No	16.6	No	PDMR 10:SMF007	
					Oso + X77 (non-ionic spreader; 0.25% v/v)	2	9	6.5	25	NA	54.8	17.3	Preventative	No	16.6	No		
		Cranberries #3	11:SMF011 (2016; WI)	WI	Oso + X77 (non-ionic spreader; 0.25% v/v)	2	8	6.5	25	NA	66	17.0	Preventative	No	11.9	No	PDMR 11:SMF011	New data; City Point.
					Oso + X77 (non-ionic spreader; 0.25% v/v)	2	12	6.5	25	NA	46	6.53	Preventative	No	10.7	No		New data; Warrens.
							Mean	6.5	25	NA	48	15.7						

Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051) Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inocu-lated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
Fruit rot complex	*Coleophoma empetri*, *Colletotrichum acutatum*, *Colletotrichum gloeosporioides*, *Phyllosticta vaccinii*, and *Physalospora vaccinii*, etc.	Cranberries #1	IND-2014-166	WI	Tavano 5SC	2	9	6.5	25	NA	50	0	Preventative	No	18.1	No	PDMR 9:SMF015	
		Cranberries #2a	CER-2015-104	WI	Oso + X77 (Non-ionic spreader; 0.25%)	2	19	6.5	25	NA	84.3	0	Preventative	No	23.6	No	PDMR 10:SMF008	Warrens
					Oso	2	19	13	50	NA	60.6	-1.9						
		Cranberries #2b	CER-2015-104	WI	Oso + X77 (Non-ionic spreader; 0.25%)	2	14	6.5	25	NA	90.2	34.9	Preventative	No	45.0	No	PDMR 10:SMF008	Valley Junction
		Cranberries #2c	CER-2015-104	WI	Oso + X77 (Non-ionic spreader; 0.25%)	2	9	6.5	25	NA	68.5	2.1	Preventative	No	30.5	No	PDMR 10:SMF008	Plainfield
					Oso			13	50	NA	63.9	-2.4						
		Cranberries #2d	CER-2015-104	WI	Oso + X77 (Non-ionic spreader; 0.25%)	2	19	6.5	25	NA	78.4	29.0	Preventative	No	22.2	No	PDMR 10:SMF008	Oakdale
					Oso			13	50	NA	81.1	29.5						
		Cranberries #3	11:SMF012 (2016; WI)	WI	Oso + X77 (non-ionic spreader; 0.25% v/v)	2	11	6.5	25	NA	78.0	-84	Preventative	No	31.3	No	PDMR 11:SMF012	New data; Oakdale.
					Oso + X77 (non-ionic spreader; 0.25% v/v)	2	11	6.5	25	NA	87.2	68.8	Preventative	No	35.2	No	PDMR 11:SMF012	New data; Valley Junction.
					Oso + X77 (non-ionic spreader; 0.25% v/v)	2	14	6.5	25	NA	56.0	-19.0	Preventative	No	40.5	No	PDMR 11:SMF012	New data; Warrens.
					Oso + X77 (non-ionic spreader; 0.25% v/v)	2	11	6.5	25	NA	28.1	42.9	Preventative	No	61.6	No	PDMR 11:SMF012	New data; Mather.
					Oso + X77 (non-ionic spreader; 0.25% v/v)	2	14	6.5	25	NA	42.6	-15.2	Preventative	No	33.3	No	PDMR 11:SMF012	New data; Tomah.
							Mean	6.5	25	NA	66	6						
								13	30	NA	68.5	8.4						

Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051) Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inocu-lated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
CROP GROUP 13: BERRIES AND SMALL FRUITS: GRAPES																		
Black Rot	*Guignardia bidwellii*	Grapes #1	KAK-2016-Grape-MI	MI	Oso	7	10 - 16	6.5	25	NA	87	NA	Preventative	No	82.0	No	PDMR (Planned fall 2018 publication) (Permission)	New data.
								13	50	NA	98							
		Grapes #2	KAK-2017-Grape-MI	MI	Oso	7	11 - 20	13	50	87	86	NA	Preventative	No	66.0	No	PDMR (Planned fall 2018 publication) (Permission)	New data.
		Grapes #3	KAK-2016-Grape-PA	PA	Oso	6	9 - 12	13	50	NA	2.5	NA	Preventative	Yes	55.0	No	PDMR 11:SMF009	New data. Mummies in the trellis.
		Grapes #4	KAK-2017-Grape-PA	PA	Oso	7	9 - 11	13	50	NA	36.1	NA	Preventative	Yes	85.8	No	PDMR (Submitted)	New data. Mummies in the trellis.
							Mean	6.5	25	NA	87	NA						
								13	50	87	55.7	NA						
Bunch Rot	*Botrytis cinerea*	Grapes #1	CER-2013-002	CA	Tavano 5% SC	4	37 - 56	6.5	25	NA	89.0	NA	Preventative	No	30.00	No	Certis data; not published.	
								13	50	NA	92.8							
		Grapes #2	CER-2013-021	CA	Tavano 5% SC	6	18 - 21	6.5	25	NA	83.2	NA	Preventative and curative	No	20.8	No	Certis data; not published.	
								13	50	NA	78.1							
		Grapes #3	CER-2014-045	NY	Tavano 5% SC	4	13 - 43	6.5	25	NA	37	NA	Preventative and curative	No	76.3	No	Not published. Permission received.	
		Grapes #4	CER-2015-115	NY	OSO	4	14 - 41	6.5	25	NA	69	NA	Preventative	No	96	No	Not published. Permission received.	
		Grapes #5	CER-2015-140	MI	Oso 5%SC + Super Spread 90 (non-ionic surfactant; 0.125% v/v)	4	20 - 29	6.5	25	NA	56	NA	Preventative	No	25	No	PDMR 10:SMF011	
		Grapes #6	9:SMF001	CA	Tavano 5% SC	3	35	6.5	25	NA	61.1	NA	Preventative	No	22.8	No	PDMR 9:SMF001	New data.
							Mean	6.5	25	NA	66	NA						
								13	50	NA	85	NA						

Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051) Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inocu-lated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
Downy Mildew	*Plasmopara viticola*	Grapes #1	KAK-2016-Grape-MI	MI	Oso	7	7 - 16	6.5	25	92	NA	NA	Preventative	No	83.0	No	PDMR (Planned fall 2018 publication) (Permission)	New data.
								13	50	99	NA	NA						
		Grapes #2	KAK-2017-Grape-MI	MI	Oso	7	11 - 20	13	50	NA	95	NA	Preventative	No	78.0	No	PDMR (Planned fall 2018 publication) (Permission)	New data.
							Mean	6.5	25	92	NA	NA						
								13	50	99	95	NA						
Phomopsis Fruit Rot	*Phomopsis viticola*	Grapes #1	KAK-2016-Grape-MI	MI	Oso	7	10 - 16	6.5	25	Rachis: 6.8	67	NA	Preventative	No	57.0	No	PDMR (Planned fall 2018) (Permission)	New data.
								13	50	9.6	96	NA						
		Grapes #2	KAK-2017-Grape-MI	MI	Oso	7	11 - 20	13	50	NA	97	NA	Preventative	No	88.0	No	PDMR (Planned fall 2018) (Permission)	New data.
							Mean	6.5	25	Rachis: 6.8	Fruit: 67	NA						
								13	50	9.6	97	NA						

Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051) Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inocu-lated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
Powdery mildew	*Erysiphe necator*	Grapes #1	CER-2011-013	CA	CX-10440	8	10 - 11	3.75	14	78.1	78.6	NA	Preventative and curative	No	70.3	No	Certis data; not published.	
								7.5	29	80.4	68.8							
		Grapes #2	CER-2012-069	CA	CX-10440	8	9 - 11	13	50	NA	96.67	NA	Preventative and curative	No	30.00	No	Certis data; not published.	Wine was analyzed.
		Grapes #3	CER-2013-021	CA	Tavano	5	18 - 21	6.5	25	NA	44.2	NA	Preventative and curative	No	100	No	Certis data; not published.	
								13	50	NA	73.6	NA						
		Grapes #4	CER-2015-019	OR	Oso + Sylguard (silicone surfactant; 0.025% v/v)	6	13 - 15	6.5	25	86.1	47.9	NA	Preventative and curative	No	87.5	No	Certis data; not published.	
		Grapes #5	CER-2015-140	MI	Oso 5%SC + Super Spread 90 (non-ionic surfactant; 0.125% v/v)	4	20 - 29	6.5	25	55	56	NA	Preventative	No	37	No	PDMR 10:SMF011	
		Grapes #6	KAK-2016-Grape-MI	MI	Oso	7	10 - 16	6.5	25	90	88	NA	Preventative	No	63.0	No	PDMR (Planned fall 2018) (Permission)	New data.
								13	50	99	99							
		Grapes #7	KAK-2017-Grape-MI	MI	Oso	7	11 - 20	13	50	97	99	NA	Preventative	No	85.0	No	PDMR (Planned fall 2018) (Permission)	New data.
		Grapes #8	KAK-2017-Grape-PA	PA	Oso	7	9 - 11	13	50	81	84	NA	Preventative	No	98.0	No	PDMR (Planned fall 2018) (Permission)	New data.
							Mean	3.75	14	78.1	78.6	NA						
								6.5 - 7.5	25 - 29	78	61	NA						
								13	50	92	90	NA						

Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051) Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inocu-lated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
CROP GROUP 13: BERRIES AND SMALL FRUITS: STRAWBERRIES																		
Anthracnose Fruit Rot	*Colletotrichum acutatum*	Strawberries #1	KAK-2016-SBerry-MI	MI	Oso	7	6 - 9	6.5	25	NA	Field: 80	4-day post-harvest: 273	Preventative	No	27.0	No	PDMR (Planned fall 2018) (Permission)	New data.
								13	50	NA	85	233						
	Colletotrichum acutatum and	Strawberries #2	KAK-2017-SBerry-MI	MI	Oso	5	7 - 14	13	50	NA	4-day post-harvest: 90	NA	Preventative	No	10.0	No	PDMR (Planned fall 2018) (Permission)	New data.
	Colletotrichum dematium							13	50	NA	88	NA			43.0			
							Mean	6.5	25	NA	80	273						
								13	50	NA	88	233						
Gray mold	*Botrytis cinerea*	Strawberries #1	CER-2012-070	CA	CX-10440	5	7 - 8	3.75	14	40.22	NA	NA	Preventative and curative	No	17.79	No	Certis data; not published.	
								6.5	25	25.44	NA	NA						
		Strawberries #2	CER-2014-038	FL	Oso	14	7	6.5	25	NA	27.2	28.1	Preventative and curative	No	49.5	No	PDMR 9:SMF020	
		Strawberries #3	Adaskaveg, 2013	CA	Tavano	NR	NR	NR	NR	Moder-ate and Vari-able	NA	NA	Not reported	NR	NR	NR	Internet (Adaskaveg)	
		Strawberries #4	KAK-2016-SBerry-MD	MD	Oso	9	5 - 8	6.5	25	NA	61.1	-1.88	Preventative	No	14.4	No	PDMR 11:SMF020	New data. No soil fumigation.
								13	50	NA	69.4	18.5						
		Strawberries #5	KAK-2016-SBerry-MI	MI	Oso	7	6 - 9	6.5	25	NA	85	4-day post-harvest: 273	Preventative	No	39.0	No	PDMR (Planned fall 2018 publication) (Permission)	New data.
								13	50	NA	86	233						
		Strawberries #6	KAK-2017-SBerry-MI	MI	Oso	5	7 - 14	13	50	NA	94	4-day post-harvest: 2350	Preventative	No	53.5	No	PDMR (Planned fall 2018 publication) (Permission)	New data.
							Mean	3.75	14	40.2	NA	NA						
								6.5	25	NA	43	15						
								13	50	NA	90	4-day post-harvest: 1292						

Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051) Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inoculated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
Leather rot	*Phytophthora cactorum*	Strawberries #1	KAK-2016-SBerry-MI	MI	Oso	7	6 - 9	6.5	25	NA	84	4-day post-harvest: 273	Preventative	No	31.0	No	PDMR (Planned fall 2018 publication) (Permission)	New data.
								13	50	NA	98	233						
		Strawberries #2	KAK-2017-SBerry-MI	MI	Oso	5	7 - 14	13	50	NA	81	4-day post-harvest: 2350	Preventative	No	56.8	No	PDMR (Planned fall 2018 publication; permission)	New data.
							Mean	6.5	25	NA	84	4-day post-harvest: 273						
								13	50	NA	90	1292						
Phomopsis Leaf Spot and Fruit Rot	*Phomopsis obscurans*	Strawberries #1	KAK-2016-SBerry-MI	MI	Oso	7	6 - 9	6.5	25	98	NA	4-day post-harvest: 240	Preventative	No	39.5	No	PDMR (Planned fall 2018 publication) (Permission)	New data.
								13	50	100	NA	273						
		Strawberries #2	KAK-2017-SBerry-MI	MI	Oso	5	7 - 14	13	50	83	80	4-day post-harvest: 2350	Preventative	No	35.1	No	PDMR (Planned fall 2018 publication) (Permission)	New data.
							Mean	6.5	25	98	NA	4-day post-harvest: 240						
								13	50	92	80	1312						
Powdery mildew	*Sphacelotheca* sp.	Strawberries #1	CER-2013-008	CA	CX-10440	7	7 - 10	6.5	25	94	NA	NA	Preventative and curative	No	70	No	Certis data; not published	
								13	50	80	NA							
		Strawberries #2	CER-2012-070	CA	CX-10440	5	7 - 8	3.75	14	26.31	NA	NA	Preventative and curative	No	100	No	Certis data; not published.	
								6.5	25	23.75	NA							
		Strawberries #3	CER-2013-008	CA	CX-10440	7	6 - 43	6.5	25	93.5	NA	NA	Preventative and curative	No	70	No	Certis data; not published.	
								13	50	80	NA							
							Mean	3.75	14	26.31	NA	NA						
								6.5	25	70	NA	NA						
								13	50	80	NA	NA						

Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051) Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inocu-lated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
CROP GROUP 19: HERBS AND SPICES																		
Downy Mildew	*Peronospora belbahrii*	Basil #1	IND-2015-218	NY	Oso	1	NA	13	50	52	NA	NA	Preventative	No	100	No	PDMR 10:V034	New data.

1. "Veggieturbo 5SC Suspension Concentrate Fungicide" is Kaken's EPA registered brand name for Polyoxin D Zinc Salt 5SC Fungicide.
"Oso 5%SC Fungicide" and "Tavano 5%SC Fungicide" are Certis USA, L.L.C. supplemental distributor brand names for Polyoxin D Zinc Salt 5SC Fungicide.
"CX-10440" is the Certis USA, L.L.C. formulation code for Polyoxin D Zinc Salt 5SC Fungicide.

NR. Not reported.

Preventative and curative: Treatments include at least one application after disease was observed.
Curative: Disease was confirmed to be present before the first treatment was applied.

STEP 2: Identification of OMRI-List Alternative Products, Efficacy Data, Product Hazards, and Restrictions

METHODOLOGY

Polyoxin D Zinc Salt 5SC Formulation
The first row of each table below in highlighted in yellow and is based upon the data from Step 1. Mean percent control values are based upon mean control values for each trial *separately*, then averaged to determine the mean for the available trials for each crop/diseases combination.

Identification of EPA Registered OMRI-Listed Alternative Products for Crop Groups 13 and 19
The initial identification of EPA registered OMRI-listed alternative products, was achieved using the Cornell University Extension documents, when available:

- 2015 Organic Production and IPM Guide for Blueberries;
- 2015 Organic Production and IPM Guide for Grapes;
- 2016 Organic Production and IPM Guide for Raspberries and Blackberries; and
- 2016 Organic Production and IPM Guide for Strawberries.

The final identification was determined via manual inspection of EPA registered labels for OMRI-listed products. There are many "me-too" copper and sulfur products. Some products are possibly omitted, but the commercially most significant products are believed to have been identified.

The manual inspection of each label included confirmation of the label claim (*e.g.*, suppression vs control) for each crop/disease combination included in this petition addendum.

Efficacy data were reviewed and EPA's Pesticide Product Label System was consulted to identify recently EPA registered OMRI-listed products registered for identified uses.

Published Efficacy Data for OMRI-Listed Alternative Products
Plant Disease Management Reports (PDMR) is a low cost, subscription-based, on-line journal for the publication of efficacy trials. It is the journal of choice for most university efficacy researchers.

For each crop/disease combination, searches were conducted for the crop in combination with the disease. Separate searches were conducted for the crop (singular) and the crop (plural). For example, the search criteria for grapes / bunch rot (caused by Botrytis) included:

- "grape" and "Botrytis"; and
- "grapes" and "Botrytis".

Each article was then reviewed to determine if the article is applicable, *i.e.*,

- The trial included an untreated control; *and*
- One or more OMRI-listed EPA registered alternative for the crop/disease (pathogen) combination was included in the trial in the *absence* of other pesticide products.
    - Tank-mixes and treatment programs with other products were *excluded*.
    - Treatments of a single OMRI-listed pesticide product with, *e.g.*, a surfactant or sticker-spreader were *included*.

For each identified relevant Plant Disease Management Reports article and treatment, the data were summarized. Some trials include data for only a single percent control determination, while others contained more, *e.g.*:

- Incidence and severity; and/or
- Leaves and fruit.

For each trial, the *overall* mean (average) percent control was determined.

If the OMRI-listed alternative had *more* disease than the untreated control (treatment failure), then the percent control was reported and calculated as *0% control* instead of a negative percent control. This provided some bias in favor of the OMRI-listed alternatives but helps with visual comparisons of data sets.

Generally, the Plant Disease Management Reports articles report the data for only one trial location. When more than one trial location is reported in a single article, as in most of the articles regarding cranberries, *each trial location was treated separately* for the calculation of trial averages.

When an OMRI-listed alternative product was evaluated in more then one trial, the average percent control was determined used the *average* percent control for *each* trial. This gives equal weight to each trial and does not favor trials for which more data points were reported.

The mean percent control values are paired with the number of trials included in the calculation of the mean. Mean percent control values supported by a larger number of trials provide greater confidence to the calculated mean. Also higher mean values supported by a larger number of trials reflect greater *consistency* of disease control.

Efficacy Data for the Polyoxin D Zinc Salt 5SC Formulation

For efficacy trials of the polyoxin D zinc salt 5SC formulation (a.k.a. Oso), the selection criteria and method of calculation of averages were the same as above with the *exception* that *all* available data are considered, *i.e.*, published and unpublished data are included in the May 31, 2016 petition or this addendum. An example of included unpublished efficacy data are data from blueberry and raspberry trials that were developed by private (non-university affiliated) researchers.

Comparison of Average Percent Control

The average percent control for the polyoxin D zinc salt 5SC formulation and for the OMRI-listed alternatives are included in the summary tables below. To facilitate comparisons, the average percent control columns are color coded:

- *Green* indicates that the OMRI-listed alternative has similar, equal, or greater average percent control compared to Oso.
- *Orange* indicates that the OMRI-listed alternative provides less than similar percent control compared to Oso but generally more that 50% of the percent control provided by Oso.
- *Red* indicates that the OMRI-listed alternative provides substantially less control than Oso (0% control to approximately 50% of the control provided by Oso).
- *Brown* indicates that no relevant data were found in Plant Disease Management Reports.

Comparison of Hazards and Restrictions

Human and environmental hazard statements on the EPA registered label are summarized. Please note that products that are exempt from regulation as a pesticide under section 25(b) of FIFRA do not have uniform criteria for labels statements. Nonetheless, statements have been summarized based upon the commercial label. The statements are color coded:

- *Red* indicates:
  - EPA's highest hazard categories (*e.g.*, permanent injury);
  - EPA's highest environmental hazard category ("highly toxic"); and
  - Physical hazards that can result in injury (*e.g.*, fire).
- *Orange* indicates:
  - EPA's next most hazardous category for humans (*e.g.*, severe but not permanent injury); and
  - EPA's next most hazardous category for environmental hazards ("toxic").
- *Blue* indicates critical temperature restrictions for use and/or storage for products with a live microorganism as the active ingredient. Please see the product label for details.

OMRI-Listed Product Comparison Table Header Row

OMRI-listed product comparison table header rows have a color background. There is ***no meaning*** to the color. Instead, the color is included as a visual clue to indicate a new table when the color is different. The color helps to visually link the summarized efficacy data with the corresponding list of OMRI-listed alternative products and the associated crop/disease combination.

OMRI-LISTED ALTERNATIVES: CROP GROUP 13: BERRIES AND SMALL FRUITS: BLUEBERRIES / Alternaria Fruit Rot (*Alternaria* spp.)

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Blueberries / Alternaria Fruit Rot (*Alternaria* spp.)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	41	1	See Oso efficacy summary table.	Control.	0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain MBI 600	Serifel	71840-18	No data	NA	NA	Control. Preventative only. Not for use in California.	0	4	None.	Moderate eye irritation. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	None.
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if inhaled. May cause dermal sensitization. [F] Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Spray solution pH restrictions.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Optiva	264-1160	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if inhaled.	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151	No data	NA	NA	Control. Preventative only.	0	4	None.	May cause dermal sensitization. [F]	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Optimum	264-1160	No data	NA	NA	Suppression only. Preventative only.	0	4	None.	May cause dermal sensitization. [F]	None.	None.
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation.	None.	Avoid freezing.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Blueberries / Alternaria Fruit Rot (*Alternaria* spp.)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Non-synthetic	NC; Biological	*Streptomyces lydicus* WYEC 108	Actinovate AG	73314-1	No data	NA	NA	Alternaria claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Field uses: Control vs suppression only is not specified. Greenhouse uses: Suppression only.	0	1 or until dry	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live bacterium. Use and storage temperature restrictions.
Non-synthetic	NC; Botanical oil	Neem oil	Trilogy	70051-2	No data	NA	NA	Alternaria control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	4	Yes.	Moderate eye irritation.	Toxic to fish, aquatic organisms, and bees.	Use and storage temperature restrictions.
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate 2.0	70299-2	No data	NA	NA	Control.	0	Until dry	None.	Irreversible eye damage. May be fatal if swallowed. Skin irritation.	Highly toxic to bees and other beneficial insects. Toxic to fish.	Chemical instabilities. Strong oxidizing agent. Use and storage temperature restrictions.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative environmental toxicity descriptors, lowest toxicity to highest toxicity: Practically non-toxic < Moderately toxic < Toxic < Highly toxic.

OMRI-LISTED ALTERNATIVES: CROP GROUP 13: BERRIES: BLUEBERRIES / Botrytis Blight (*Botrytis cinerea*)

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Blueberries / Botrytis Blight (*Botrytis cinerea*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	80	1	See Oso efficacy summary table.	Control.	0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel 55	70051-108	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel LC	70051-114	58	1	5:SMF027	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain F727	Stargus	84059-28	No data			Control. Preventative only.	0	4	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Not for sale or use after 18 months from the date of manufacture. Avoid freezing.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain MBI 600	Serifel	71840-18	No data	NA	NA	Control. Preventative only. Not for use in California.	0	4	None.	Moderate eye irritation. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	None.
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if inhaled. May cause dermal sensitization. [F] Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Spray solution pH restrictions.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Optiva	264-1160	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if inhaled.	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151	28	1	5:SMF001	Control. Preventative only.	0	4	None.	May cause dermal sensitization. [F]	None.	None.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Blueberries / Botrytis Blight (*Botrytis cinerea*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Optimum	264-1160	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	None.
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3	0	1	7:SMF031	Control. Preventative only.	0	4	None.	Moderate eye irritation.	None.	Avoid freezing.
Non-synthetic	NC; Biological	*Aureobasidium pullulans* strains DSM 14940 and DSM 14941	Botector	86174-3	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if swallowed or absorbed through skin. May cause dermal sensitization. [F] Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live yeast-like fungus. Use and storage temperature restrictions. Not compatible with many fungicides.
Non-synthetic	NC; Biological	*Streptomyces lydicus* WYEC 108	Actinovate AG	73314-1	No data	NA	NA	Botrytis claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Field uses: Control vs suppression only is not specified. Greenhouse uses: Suppression only.	0	1 or until dry	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live bacterium. Use and storage temperature restrictions.
Non-synthetic	NC; Botanical oil	Neem oil	Trilogy	70051-2	No data	NA	NA	Botrytis control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	4	Yes.	Moderate eye irritation.	Toxic to fish, aquatic organisms, and bees.	Use and storage temperature restrictions.
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)	No data	NA	NA	Control.	0	0	Yes.	Harmful if swallowed.	Toxic to bees.	Not for use near heat or open flames.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1	No data	NA	NA	Botrytis control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Blueberries / Botrytis Blight (*Botrytis cinerea*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541	No data	NA	NA	Control.	0	4	None.	Harmful if swallowed. Moderate eye irritation.	None.	Avoid contamination by pesticides and fertilizers. Final spray solution must have pH ≥7.0.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539	No data	NA	NA	Botrytis control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.
Synthetic	NC; Inorganic salt	Potassium silicate	Sil-Matrix	82100-1	No data	NA	NA	Control.	0	4	None.	Moderate eye irritation	None.	Damages glass surfaces. Chemical instabilities.
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate 2.0	70299-2	No data	NA	NA	Control.	0	Until dry	None.	Irreversible eye damage. May be fatal if swallowed. Skin irritation.	Highly toxic to bees and other beneficial insects. Toxic to fish.	Chemical instabilities. Strong oxidizing agent. Use and storage temperature restrictions.
Synthetic	NC; Oxidizing agent	Hydrogen peroxide, Hydrogen dioxide	Perpose Plus	86729-1	No data	NA	NA	Botrytis control claim for all agricultural crops. Preventative only.	0	Until dry	None.	Irreversible eye damage and skin burns. May be fatal if absorbed through skin. Harmful if swallowed.	Toxic to birds, mammals, fish, and aquatic life.	Chemical instabilities. Strong oxidizing agent. Storage restrictions.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative environmental toxicity descriptors, lowest toxicity to highest toxicity: Practically non-toxic < Moderately toxic < Toxic < Highly toxic.

Plant Disease Management Reports citations and data summaries:

7:SMF031. J.W. Pscheidt and J.P. Bassinette, Oregon State University. Fungicide Management of blueberry fruit rots, 2012.
Regalia at 12 gal/A beginning at pre-bloom: No control. Less disease control than the untreated control.

5:SMF001. J.W. Pscheidt and J.P. Bassinette, Oregon State University. Management of *Botrytis* fruit rot and mummy berry, 2010.
Serenade Max at 3 lb/A + Nu-Film-P at 6 fl oz/100 gal/A: 28% control of Botrytis fruit rot.

5:SMF027. J.W. Pscheidt, J.P. Bassinette and L. A. Jones, Oregon State University. Fungicide Management of blueberry fruit rots, 2015.
Double Nickel LC at 2 qt/A, beginning at floral rosette with 1 or 2 open blooms: 70.5% control of Botrytis blight.
Double Nickel LC at 2 qt/A, beginning at floral rosette with 1 or 2 open blooms: 44.9% control of Botrytis blight.
Trial mean: 57.7% control.

OMRI-LISTED ALTERNATIVES: CROP GROUP 13: BERRIES AND SMALL FRUITS: BLUEBERRIES / Mummyberry *(Monilinia vaccinii-corymbosi)*

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Blueberries / Mummyberry (*Monilinia vaccinii-corymbosi*)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	64	6	See Oso efficacy summary table.	Control.	0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel 55	70051-108	No data	NA	NA	Suppression only. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel LC	70051-114	50	2	10:SMF026; 9:SMF038.	Suppression only. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain MBI 600	Serifel	71840-18	No data	NA	NA	Control. Preventative only. Not for use in California.	0	4	None.	Moderate eye irritation. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	None.
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata ASO	264-1153	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if inhaled. May cause dermal sensitization. [F] Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Spray solution pH restrictions.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Optiva	264-1160	78	1	7:SMF013.	Suppression only. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152	21	2	2:SMF013; F&N 59:SMF023	Control. Preventative only.	0	4	None.	Harmful if inhaled.	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151	41	2	5:SMF001; F&N 61: SMF023.	Control. Preventative only.	0	4	None.	May cause dermal sensitization. [F]	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Optimum	264-1160	28	3	10:SMF026; 9:SMF038; 8:SMF003.	Suppression only. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	None.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Blueberries / Mummyberry (*Monilinia vaccinii-corymbosi*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3	27	5	8:SMF003; 8:SMF023; 7:SMF005; 7:SMF007; 7:SMF030.	Control. Preventative only.	0	4	None.	Moderate eye irritation.	None.	Avoid freezing.
Non-synthetic	NC; Biological	*Streptomyces lydicus* WYEC 108	Actinovate AG	73314-1	No data	NA	NA	Monilinia claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Field uses: Control vs suppression only is not specified. Greenhouse uses: Suppression only.	0	1 or until dry	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live bacterium. Use and storage temperature restrictions.
Non-synthetic	NC; Botanical oil	Clove oil, Rosemary oil, Peppermint oil	BacStop	NA; 25(b)	No data	NA	NA	Control.	0	0	None.	Temporary eye and skin irritation	No FIFRA statements.	Storage temperature restrictions.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541	No data	NA	NA	Control.	0	4	None.	Harmful is swallowed. Moderate eye irritation.	None.	Avoid contamination by pesticides and fertilizers. Final spray solution must have pH ≥7.0.
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate 2.0	70299-2	No data	NA	NA	Control.	0	Until dry	None.	Irreversible eye damage. May be fatal if swallowed. Skin irritation.	Highly toxic to bees and other beneficial insects. Toxic to fish.	Chemical instabilities. Strong oxidizing agent. Use and storage temperature restrictions.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative environmental toxicity descriptors, lowest toxicity to highest toxicity: Practically non-toxic < Moderately toxic < Toxic < Highly toxic.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Blueberries / Mummyberry (*Monilinia vaccinii-corymbosi*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical

Plant Disease Management Reports citations and data summaries:

10:SMF026. J.W. Pscheidt, J.P. Bassinette, and S. Heckert, Oregon State University. Evaluation of various fungicides for management of mummy berry, 2015.
Double Nickel LC at 2 qt/A beginning at floral bud break (8 applications): No control of floral strikes, vegetative strikes and mummyberries (less disease control than untreated control).
Serenade Opti at 20 oz/A beginning at floral bud break (8 applications): 9.9% control of floral strikes. No control of vegetative strikes (less disease control than untreated control). 8.9% control of mummyberries. Trial mean: 6.3% control (n = 3).

9:SMF038. A. M.C. Schilder, J. M. Gillett, and W. Sysaks, Michigan State University. Evaluation of fungicides and biocontrol products for control of mummy berry in blueberries, 2014.
Serenade Optimum at 20 oz/A + NuFilm P at 0.125% (v/v) beginning at green tip, apothecia present: 66% control of shoot strikes. 42% control on fruit. Trial mean: 54% control (n = 2).
Double Nickel LC at 1.06 qt/A beginning at green tip, apothecia present: 100% control of shoot strikes. 98% control on fruit.
Double Nickel LC at 2.1 qt/A beginning at green tip, apothecia present: 100% control of shoot strikes. 100% control on fruit. Trial mean: 99.5% control (n = 4).

8:SMF003. J.W. Pscheidt, J.P. Bassinette, and J. Florance, Oregon State University. Evaluation of various products for management of mummy berry, 2013.
Serenade Optimum at 16 oz/A + Nu-Film-P at 32 fl oz/100 gal/A beginning at floral bud break: 35% control of floral strikes and 10% control on fruit. Trial mean: 22.5% control (n = 2).
Regalia at 1 gal/A beginning at floral bud break: 43% control of floral strikes and 38% control on fruit. Trial mean = 40.5% control (n = 2).

8:SMF023. F. Connelly, Univ. of Georgia. Mummy berry management in rabbiteye blueberry with chemical and organic fungicides, 2013.
Regalia at 4 qt/A beginning at green tip: 0.7% control of mummyberry incidence.

7:SMF005. W. O. Cline and B. K. Bloodworth, North Carolina State University. Fungicides for mummy berry and blueberry rust control on 'Rebel' in North Carolina, 2012.
Regalia at 2 qt/A beginning March 16, 2012: 3% control of mummyberries per bush.

7:SMF007. W. O. Cline and B. K. Bloodworth, North Carolina State University. Fungicides for mummy berry control on 'Powderblue', 'Vernon' and 'Ochlockonee' in North Carolina, 2012.
Regalia at 2 Qt/A: Average 36% (range 14% to 50%) control of number of shoot strikes.

7:SMF013. A.M.C. Schilder, J. M. Gillett, and W. Sysaks, Michigan State University. Evaluating fungicides and biocontrol products for control of mummyberry in blueberries, 2012.
Optiva at 1 lb/A + Nu Film P at 0.25%(v/v) beginning at pink bud: 79.0% control of shoot strikes and 76.3% control of mummies. Trial mean: 77.7% control (n = 2).

7:SMF030. J.W. Pscheidt and J.P. Bassinette, Oregon State University. Evaluation of materials for management of mummy berry, 2012.
Regalia at 1 gal/A beginning at floral bud break: 71% control of floral strikes. 58% control of vegetative strikes. 29% control on fruit. Trial mean: 52.7% control (n = 3).

5:SMF001. J.W. Pscheidt and J.P. Bassinette, Oregon State University. Management of *Botrytis* fruit rot and mummy berry, 2010.
Serenade Max at 3 lb/A + Nu-Film-P at 6 fl oz/100 gal/A: 19% control of mummy berry floral and vegetative strikes. 19% control of mummy berry fruit rot. Trial mean: 19% control (n = 2).

2:SMF013. J.W. Pscheidt and J.P. Bassinette, Oregon State University. Fungicidal control of mummy berry, 2007
Serenade ASO at 256 fl oz/A beginning at floral bud break: 28% control on floral clusters. 8% control on shoots. No control on green fruit (less effective than untreated control). Trial mean: 12% control (n = 3).

F&N Vol 61: SMF023. A.M.C. Schilder, J. M. Gillett, and W. Sysaks, Michigan State University. Evaluation of fungicides for control of mummy berry in 'Rubel' blueberries, 2005.
Serenade Max at 3 lb/A beginning at green tip: 95% control of shoot strikes. 31% control on fruit. Trial mean: 63% control (n = 2).

F&N Vol 59:SMF023. A.M.C. Schilder, J. M. Gillett, and W. Sysaks, Michigan State University. Evaluation of fungicides for control of mummy berry in blueberries, 2003.
Serenade (formulation and rate not specified; ASO assumed) beginning at early green tip: 16% control of shoot strikes. 45% control on fruit. Trial mean: 30.5% control (n = 2).

OMRI-LISTED ALTERNATIVES: CROP GROUP 13: BERRIES AND SMALL FRUITS: CANEBERRIES / Botrytis Fruit Rot (*Botrytis cinerea*) (add citations)

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Caneberries / Botrytis Fruit Rot (*Botrytis cinerea*)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	65	3	See Oso efficacy summary table.	Control.	0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	44	Bacillus amylo-liquefaciens strain D747	Double Nickel 55	70051-108	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain MBI 600	Serifel	71840-18	No data	NA	NA	Control. Preventative only. Not for use in California.	0	4	None.	Moderate eye irritation. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	None.
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if inhaled. May cause dermal sensitization. [F] Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Spray solution pH restrictions.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152	14	4	F&N 58:SMF048; F&N 57;SMF31; F&N 57:SMF32; F&N 56:SMF38.	Control. Preventative only.	0	4	None.	Harmful if inhaled.	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151	No data	NA	NA	Control. Preventative only.	0	4	None.	May cause dermal sensitization. [F]	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Optimum	264-1160	No data	NA	NA	Suppression only. Preventative only.	0	4	None.	May cause dermal sensitization. [F]	None.	None.
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3	37	1	7:SMF008	Control. Preventative only.	0	4	None.	Moderate eye irritation.	None.	Avoid freezing.

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Caneberries / Botrytis Fruit Rot (*Botrytis cinerea*)													
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Non-synthetic	NC; Bio-chemical	Rhamnolipid biosurfactant	Zonix	72431-1	23	1	8:V2017	Botrytis control claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Preventative use only.	0	4	None.	Irreversible eye damage.	None.	Do not use at ambient temperatures over 80°F. Keep from overheating or freezing. Store out of direct sunlight.
Non-synthetic	NC; Biological	*Aureobasidium pullulans* strains DSM 14940 and DSM 14941	Botector	86174-3	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if swallowed or absorbed through skin. May cause dermal sensitization. [F] Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live yeast-like fungus. Use and storage temperature restrictions. Not compatible with many fungicides.
Non-synthetic	NC; Biological	*Streptomyces lydicus* WYEC 108	Actinovate AG	73314-1	7	1	2:SMF003	Botrytis claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Field uses: Control vs suppression only is not specified. Greenhouse uses: Suppression only.	0	1 or until dry	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live bacterium. Use and storage temperature restrictions.
Non-synthetic	NC; Botanical oil	Neem oil	Trilogy	70051-2	No data	NA	NA	Botrytis control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	4	Yes.	Moderate eye irritation.	Toxic to fish, aquatic organisms, and bees.	Temperature restrictions. Storage restrictions.
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)	No data	NA	NA	Control.	0	0	Yes.	Harmful if swallowed.	Toxic to bees.	Not for use near heat or open flames.

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Caneberries / Botrytis Fruit Rot (*Botrytis cinerea*)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	M1	Copper octanoate	Cueva	67702-2-70051	No data	NA	NA	Control.	0	4	Yes.	Harmful if swallowed or absorbed through skin.	Toxic to fish and aquatic organisms.	Do not store below 4°C (39°F). Tank-mix restrictions.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1	No data	NA	NA	Botrytis control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541	No data	NA	NA	Control.	0	4	None.	Harmful if swallowed. Moderate eye irritation.	None.	Avoid contamination by pesticides and fertilizers. Final spray solution must have pH ≥7.0.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539	No data	NA	NA	Botrytis control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate 2.0	70299-2	9	1	2:SMF003	Control.	0	Until dry	None.	Irreversible eye damage. May be fatal if swallowed. Skin irritation.	Highly toxic to bees and other beneficial insects. Toxic to fish.	Chemical instabilities. Strong oxidizing agent. Use and storage temperature restrictions.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative environmental toxicity descriptors, lowest toxicity to highest toxicity: Practically non-toxic < Moderately toxic < Toxic < Highly toxic.

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Caneberries / Botrytis Fruit Rot (*Botrytis cinerea*)													
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical

Plant Disease Management Reports citations and data summaries.

7:SMF008. A.M.C. Schilder, J. M. Gillett, and R. W. Sysak, Michigan State University. Evaluation of fungicides for control of foliar and fruit diseases in red raspberries, 2012.
Regalia at 1 qt/acre + Nu Film P at 0.25%: 64% control of post-harvest Botrytis, harvest 1. 21% control of post-harvest Botrytis, harvest 2.
Regalia at 1 qt/acre + Nu Film P at 0.25%: 64% control of post-harvest Botrytis, harvest 1. 15% control of post-harvest Botrytis, harvest 2.
Regalia at 1 qt/acre + Nu Film P at 0.25%: 33% control of post-harvest Botrytis, harvest 1. 17% control of post-harvest Botrytis, harvest 2.
Regalia at 1 qt/acre + Nu Film P at 0.25%: 51% control of post-harvest Botrytis, harvest 1. 33% control of post-harvest Botrytis, harvest 2.
Trial mean: 37% control (n = 8).

2:SMF003. A.M.C. Schilder, J. M. Gillett, and R. W. Sysak, Michigan State University. Evaluation of fungicides for control of fruit diseases of red raspberries, 2007.
Actinovate at 12 oz/acre: 7% control of post-harvest Botrytis fruit rot incidence.
Oxidate at 4 pt/acre: 9% control of post-harvest Botrytis fruit rot incidence.

F&N 58:SMF048. P. R. Bristow and G. E. Windom, Washington State University. Evaluation of fungicides for control of fruit rot and red raspberry, 2002.
Serenade (specific formulation not specified; ASO assumed) at 8.0 lb/acre: 8% control of all fungi (mostly Botrytis), fresh market. 4% control of Botrytis, processing.
Trial mean: 6% control (n = 2).

F&N 57:SMF31. P. R. Bristow and G. E. Windom, Washington State University. Use of fungicides to control fruit diseases of red raspberry, 2001.
Serenade ASO at 2 gal/A: 13% control of Botrytis fruit rot, fresh market. 5% control of Botrytis fruit rot, processing.
Serenade ASO at 2 gal/A: 25% control of Botrytis fruit rot, fresh market. 15% control of Botrytis fruit rot, processing.
Trial mean: 15% control (n = 4).

F&N 57:SMF32. J. DeFrancesco and G. Koskela, Oregon State University. Evaluation of fungicides for control of fruit rot on raspberries, 2001.
Serenade ASO at 1.335 gal/acre: 38% control of Botrytis fruit rot incidence (July 2). 4% control of Botrytis fruit rot incidence (July 9).
Trial mean: 21% control (n = 2).

F&N 56:SMF38. P. R. Bristow and G. E. Windom, Washington State University. Evaluation of fungicides for control of cane and fruit diseases of red raspberry, 1999.
Serenade (specific formulation not specified; ASO assumed) at 8 lb/acre: 7% control of Botrytis fruit rot, fresh market. 16% control of Botrytis fruit rot, post-harvest.
Trial mean: 12% control (n = 2).

OMRI-LISTED ALTERNATIVES: CROP GROUP 13: BERRIES AND SMALL FRUITS: CANEBERRIES / Powdery Mildew (*Podosphaera aphanais*)

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Caneberries / Powdery Mildew (*Podosphaera aphanis*)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	74	2	See Oso efficacy summary table.	Control.	0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain MBI 600	Serifel	71840-18	No data	NA	NA	Control. Preventative only. Not for use in California.	0	4	None.	Moderate eye irritation. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	None.
Non-synthetic	44	*Bacillus pumilis* strain QST 2808	Sonata ASO	264-1153	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if inhaled. May cause dermal sensitization. [F] Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Spray solution pH restrictions.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151	No data	NA	NA	Control. Preventative only.	0	4	None.	May cause dermal sensitization. [F]	None.	None.
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation.	None.	Avoid freezing.
Non-synthetic	NC; Bio-chemical	Rhamnolipid biosurfactant	Zonix	72431-1	No data			Powdery mildew control claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Preventative use only.	0	4	None.	Irreversible eye damage.	None.	Do not use at ambient temperatures over 80°F. Keep from overheating or freezing. Store out of direct sunlight.

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Caneberries / Powdery Mildew (*Podosphaera aphanis*)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Non-synthetic	NC; Biological	*Streptomyces lydicus* WYEC	Actinovate	73314-1	No data	NA	NA	Powdery mildew claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Field uses: Control vs suppression only is not specified. Greenhouse uses: Suppression only.	0	1 or until dry	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live bacterium. Use and storage temperature restrictions.
Non-synthetic	NC; Botanical oil	Neem oil	Trilogy	70051-2	No data	NA	NA	Powdery mildew control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	4	Yes.	Moderate eye irritation.	Toxic to fish, aquatic organisms, and bees.	Temperature restrictions. Storage restrictions.
Non-synthetic	NC; Botanical oil	Cinnamon oil	Cinnerate	NA; 25(b)	No data	NA	NA	Control.	0	0	None.	Eye and skin irritation. May cause dermal sensitization. [F]	None.	Do not expose to light.
Non-synthetic	NC; Botanical oil	Garlic oil, Cottonseed oil, Corn oil	Mildew Cure	NA; 25(b)	No data	NA	NA	General powdery mildew claim; not crop specific.	0	0	None.	Avoid contact with skin, eyes, and clothing.	No FIFRA statement.	None.
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)	No data	NA	NA	Control.	0	0	Yes.	Harmful if swallowed.	Toxic to bees.	Not for use near heat or open flames.
Non-synthetic	NC; Organic acid	Citric acid	Nuke Em	NA; 25(b)	No data	NA	NA	General mildew claim; not crop specific.	0	0	None.	No FIFRA statement.	No FIFRA statement.	Store away from direct sunlight.
Synthetic	M2	Sulfur	Acoidal	62562-4	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin.	Toxic to fish and aquatic organisms.	Suspended dust ignites easily.
Synthetic	M2	Sulfur	Cosavet-DF	70905-1	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin. Moderate eye irritation.	None.	Suspended dust ignites easily.
Synthetic	M2	Sulfur	Defend DF	62562-8	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin.	Toxic to fish and aquatic organisms.	Suspended dust ignites easily.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Caneberries / Powdery Mildew (*Podosphaera aphanis*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	M2	Sulfur	Kumulus DF	51306-352-66330	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed. Avoid contact with eyes, skin, and clothing.	None.	Do not store above 104°F.
Synthetic	M2	Sulfur	Micro Sulf	55146-75	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin. Eye irritation.	None.	Keep away from heat, sparks, or flames.
Synthetic	M2	Sulfur	Microthiol Disperss	70506-187	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin.	None.	Do not store near flammable materials.
Synthetic	M2	Sulfur	Thiolux	34704-1079	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin. Eye irritation.	None.	Suspended dust ignites easily.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1	No data	NA	NA	Powdery mildew control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Kaligreen	70231-1	No data	NA	NA	General powdery mildew control claim.	1	4	None.	Harmful if swallowed.	None.	Chemical incompatibilities.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539	No data	NA	NA	Powdery mildew control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541	No data	NA	NA	Control.	0	4	None.	Harmful if swallowed. Moderate eye irritation.	None.	Avoid contamination by pesticides and fertilizers. Final spray solution pH must be ≥7.0.
Synthetic	NC; Inorganic salt	Potassium silicate	Sil-Matrix	82100-1	No data	NA	NA	General powdery mildew control claim. Preventative only.	0	4	None.	Moderate eye irritation.	None	Chemical incompatibilities.
Synthetic	NC; Organic salt	Potassium salts of fatty acids	M-Pede	10163-324	No data	NA	NA	Control.	0	12	Yes.	Substantial eye injury. Skin irritation.	Harmful to aquatic invertebrates	If water has high mineral content, check for compatibility.

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Caneberries / Powdery Mildew (*Podosphaera aphanis*)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	NC; Organic salt	Insecticidal soap	Des-X	67702-22-70051	No data	NA	NA	Control.	0	12	Yes.	Substantial eye injury. Skin irritation.	Harmful to aquatic invertebrates	If water has high mineral content, check for compatibility.
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate	70299-2	No data	NA	NA	Control.	0	Until dry	None.	Irreversible eye damage. May be fatal if swallowed. Skin irritation.	Highly toxic to bees and other beneficial insects. Toxic to fish.	Chemical instabilities. Strong oxidizing agent. Use and storage temperature restrictions.
Synthetic	NC; Oxidizing agent	Hydrogen peroxide, Hydrogen dioxide	Perpose Plus	86729-1	No data	NA	NA	Powdery mildew control claim for all agricultural crops. Preventative only.	0	Until dry	None.	Irreversible eye damage and skin burns. May be fatal if absorbed through skin. Harmful if swallowed.	Toxic to birds, mammals, fish, and aquatic life.	Chemical instabilities. Strong oxidizing agent. Storage restrictions.
Synthetic	NC; Petroleum oil	Mineral oil	Glacial Spray Liquid	34704-849	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed, inhaled, or absorbed through skin. Eye irritation. May cause dermal sensitization. [F]	Hazardous to aquatic organisms.	None.
Synthetic	NC; Petroleum oil	Mineral oil	JMS Stylet Oil	65564-1	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed.	Toxic to fish.	None.
Synthetic	NC; Petroleum oil	Mineral oil	Omni Supreme Spray	5905-368	No data	NA	NA	Control.	0	12	Yes (with sulfur).	Harmful if absorbed through skin. May cause dermal sensitization. [F]	Toxic to fish and aquatic organisms.	Chemical incompatibilities.
Synthetic	NC; Petroleum oil	Mineral oil	PureSpray Green	69526-9	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed or absorbed through skin. May cause dermal sensitization. [F]	Toxic to aquatic organisms.	None.
Synthetic	NC; Petroleum oil	Mineral oil	TriTek	48813-1	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed or absorbed through skin. May cause dermal sensitization. [F]	Toxic to aquatic organisms.	None.
Synthetic	NC; Petroleum oil	Aliphatic petroleum solvent	SuffOil-X	48813-1-68539	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed. May cause dermal sensitization. [F]	Toxic to aquatic organisms.	None.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Caneberries / Powdery Mildew (*Podosphaera aphanis*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides.
https://www.plantmanagementnetwork.org/pub/trial/pdmr/
Search terms included raspberry, raspberries, blackberry, blackberries, caneberry, and caneberries in combination with "powdery mildew".
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative environmental toxicity descriptors, lowest toxicity to highest toxicity: Practically non-toxic < Moderately toxic < Toxic < Highly toxic.
D. Serenade formulation not specified.

OMRI-LISTED ALTERNATIVES: CROP GROUP 13: BERRIES AND SMALL FRUITS: CRANBERRIES / Cottonball (*Monilinia oxycocci*)

There are no OMRI-listed products that are EPA registered for use on cranberries for treatment of cottonball.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Cranberries / Cottonball (*Monilinia oxycocci*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	46	5	See Oso efficacy summary table.	Control.	0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative environmental toxicity descriptors, lowest toxicity to highest toxicity: Practically non-toxic < Moderately toxic < Toxic < Highly toxic.

OMRI-LISTED ALTERNATIVES: CROP GROUP 13: BERRIES: CRANBERRIES / Fruit Rot Complex (*Coleophoma empetri*, *Colletotrichum acutatum*, *Colletotrichum gloeosporioides*, *Phyllosticta vaccinii*, and *Physalospora vaccinii*, etc.)

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Cranberries / Fruit Rot Complex
(*Coleophoma empetri*, *Colletotrichum acutatum*, *Colletotrichum gloeosporioides*, *Phyllosticta vaccinii*, and *Physalospora vaccinii*, etc.)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	65	10	See Oso efficacy summary table.	Control (most pathogens).	0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Synthetic	M1	Copper hydroxide	Nu-Cop 50 WP	42002-7	No data	NA	NA	Control.	0	24	Yes.	Irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. May cause dermal sensitization. [F]	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	M1	Copper hydroxide	Champ WG	55146-1	7	1	2:SMF022	Control.	0	48	Yes.	Irreversible eye damage. Harmful if swallowed. May cause dermal sensitization. [F]	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	M1	Copper hydroxide, Copper oxychloride	Badge X2	80289-12	No data	NA	NA	Control.	0	48	Yes.	May be fatal if swallowed. Substantial eye injury.	Toxic to fish and aquatic organisms.	May damage aluminum.
Synthetic	M1	Copper sulfate pentahydrate	CS 2005	66675-3	No data	NA	NA	Control.	0	48	Yes.	Irreversible eye damage. Skin irritation. Harmful if swallowed, inhaled or absorbed through skin.	Toxic to fish and aquatic organisms.	Incompatible with galvanized pipe and nylon equipment.
Synthetic	M1	Cupric hydroxide	Nu-Cup HB	42750-132	No data	NA	NA	Control.	1	24	Yes.	Irreversible eye damage. Harmful if swallowed or absorbed through skin.	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	M1	Cuprous oxide	Nordox 75 WG	48142-4	No data	NA	NA	Control.	0	12	Yes.	Harmful if swallowed or absorbed through skin. Eye irritation.	None.	Water pH restrictions.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative environmental toxicity descriptors, lowest toxicity to highest toxicity: Practically non-toxic < Moderately toxic < Toxic < Highly toxic.

Plant Disease Management Reports citations and data summaries:

2:SMF002. P. McManus and R. S. Perry, University of Wisconsin. Evaluation of fungicides for control of cranberry fruit rot in Wisconsin, 2007.
Champ at 5.33 pt/A, applied June 19 and 26, 2007: 10% and 12% control.
Champ at 5.33 pt/A, applied June 6 and July 9, 2007: No control. Disease control was less than in the untreated control.
Trial mean: 7.3% control (n = 3).

OMRI-LISTED ALTERNATIVES: CROP GROUP 13: BERRIES: GRAPES / Black Rot (*Guignardia bidwellii*)

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Grapes / Black Rot (*Guignardia bidwellii*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	54	4	See Oso efficacy summary table.	Suppression.	0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain F727	Stargus	84059-28	No data	NA	NA	Control. Preventative only.	0	4	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Not for sale or use after 18 months from the date of manufacture. Avoid freezing.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151	No data	NA	NA	Control. Preventative only.	0	4	None.	May cause dermal sensitization. [F]	None.	None.
Non-Synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3	8	3	8:SMF014; 7:SMF003; 6:SMF008.	Control. Preventative only.	0	4	None.	Moderate eye irritation.	None.	Avoid freezing.
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)	No data	NA	NA	Control.	0	0	Yes.	Harmful if swallowed.	Toxic to bees.	Not for use near heat or open flames.
Synthetic	M1	Basic copper sulfate	Basic Copper 53	45002-8	No data	NA	NA	Suppression.	0	24	Yes.	Substantial eye injury.	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	M1	Copper oxychloride, Copper hydroxide	Badge X2	50289-12	54	2	8:SMF014; 6:SMF008.	Control.	0	48	Yes.	May be fatal if swallowed. Substantial eye injury.	Toxic to fish and aquatic organisms.	May damage aluminum.
Synthetic	M1	Copper hydroxide	Champ WG	55146-1	No data	NA	NA	Control.	0	48	Yes.	Irreversible eye damage. Harmful if swallowed. May cause dermal sensitization. [F]	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	M1	Copper hydroxide	Nu-Cop 50 WP	42002-7	78	2	6:SMF008.	Control.	0	24	Yes.	Irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. May cause dermal sensitization. [F]	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	M1	Copper octanoate	Cueva	67702-2-70051	32	3	3:SMF030; 3:SMF031; 2:SMF004.	Control.	0	4	Yes.	Harmful if swallowed or absorbed through skin.	Toxic to fish and aquatic organisms.	Do not store below 4°C (39°F). Tank-mix restrictions.
Synthetic	M1	Copper sulfate pentahydrate	CS 2005	66675-3	No data	NA	NA	Control.	0	48	Yes.	Irreversible eye damage. Skin irritation. Harmful if swallowed, inhaled or absorbed through skin.	Toxic to fish and aquatic organisms.	Incompatible with galvanized pipe and nylon equipment.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Grapes / Black Rot (*Guignardia bidwellii*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	M1	Cupric hydroxide	NuCop 50 DF	45002-4	No data	NA	NA	Control.	1	24	Yes.	Irreversible eye damage. Harmful if swallowed or absorbed through skin. May cause dermal sensitization. [F]	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	M1	Cupric hydroxide	Nu-Cop HB	42750-132	No data	NA	NA	Control.	1	24	Yes.	Irreversible eye damage. Harmful if swallowed or absorbed through skin.	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	M1	Cuprous oxide	Nordox 75 WG	48142-4	No data	NA	NA	Control.	0	12	Yes.	Harmful if swallowed or absorbed through skin. Eye irritation.	None.	Water pH restrictions.
Synthetic	NC; oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate 2.0	70299-2	0	1	F&N 56:SMF19.	Control.	0	Until dry	None.	Irreversible eye damage. May be fatal if swallowed. Skin irritation.	Highly toxic to bees and other beneficial insects. Toxic to fish.	Chemical instabilities. Strong oxidizing agent. Use and storage temperature restrictions.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative environmental toxicity descriptors, lowest toxicity to highest toxicity: Practically non-toxic < Moderately toxic < Toxic < Highly toxic.

Plant Disease Management Reports citations and data summaries for non-synthetic alternatives:

8:SMF014. Grape/black rot. Bryan Hed. Penn State University. Evaluation of organic fungicides for control of black rot and powdery and downy mildew of Concord grapes, 2013.
Regalia 5% at 6 quarts/A; *without* mummies: 46% control on fruit.
Regalia 5% at 6 quarts/A; *with* mummies: 0% control on fruit.
Trial mean: 23% control (n = 2).

7:SMFF003. Grape/black rot. Bryan Hed. Penn State University. Evaluation of organic fungicides for control of black rot and powdery mildew of Concord grapes, 2012.
Regalia 5% at 6 quarts/A, *without* mummies: Insufficient pest pressure.
Regalia 5% at 6 quarts/A, *with* mummies: No control. More disease than in the untreated control on fruit.

6:SMF008. Grape/black rot. Bryan Hed. Penn State University. Evaluation of conventional and organic fungicides for control of black rot and powdery mildew of Concord grapes, 2011.
Regalia 5% at 6 quarts/A + NuFilm P at 0.0625%; *without* mummies: Insufficient pest pressure.
Regalia 5% at 6 quarts/A + NuFilm P at 0.0625%; *with* mummies: 1.8% control of diseased clusters. No control of diseased area on clusters.
Trial mean: 1% control (n = 2).

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Grapes / Black Rot (*Guignardia bidwellii*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical

Plant Disease Management Reports citations and data summaries for synthetic alternatives:

8:SMF014. Bryan Hed, Penn State University. Evaluation of organic fungicides for control of black rot and powdery and downy mildew of Concord grapes, 2013.
Badge X2 1.75 lb/A + lime 1.75 lb/A, 5 or more applications, different timings; *without* mummies: 64%, 77%, 81%, and 90% control on fruit.
Badge X2 1.75 lb/A + lime 1.75 lb/A, 5 or more applications, different timings; *with* mummies: 4%, 5%, 15%, and 22% control on fruit.
Badge X2 1.75 lb/A + lime 1.75 lb/A + Nu-Film-P, 5 or more applications, different timings; *without* mummies: 66.5%, and 71% control on fruit.
Badge X2 1.75 lb/A + lime 1.75 lb/A + Nu-Film-P, 5 or more applications, different timings; *with* mummies: 9% and 9% control on fruit.
Trial mean: 43% control (n = 12).

6:SMF008. B. Hed and N. K. Ngugi, Penn State University. Evaluation of conventional and organic fungicides for control of black rot and powdery mildew of Concord grapes, 2011.
NuCop 50 WP at 1 lb/A + Lime at 1 lb/A + Nufilm P at 0.0625%: 67% control of diseased clusters; 85% control of diseased area.
NuCop 50 WP at 2 lb/A + Lime at 2 lb/A + Nufilm P at 0.0625%: 65% control of diseased clusters; 91% control of diseased area.
NuCop 50 WP trial mean: 77% control (n = 4).
Badge X2 at 1.75 lb/A + Lime at 1.75 lb/A + Nufilm P at 0.0625%: 52% control of diseased clusters; 75% control of diseased area.
Badge X2 trial mean: 64% control (n = 2).

3:SMF030. Bryan Hed, Penn State University. Evaluation of organic fungicides for control of black rot and powdery mildew, 2008.
Cueva 1%; 6 applications beginning intermediate pre-bloom: 39% control on fruit.

3:SMF031. Bryan Hed, Penn State University. Evaluation of alternative fungicides of black rot, powdery mildew, and downy mildew of grapes, 2008.
Cueva 1%; 7 applications beginning at immediate pre-bloom.
Cane inoculum plus mummies: 23% control on fruit.
Wood inoculum only: 0% control on fruit.
Trial mean: 12% control (n = 2).

2:STF004. Bryan Hed, Penn State University. Evaluation of organic fungicides for control of black rot and powdery mildew of Concord grapes, 2007.
Cueva at 1 gal/A; 4 applications beginning June 6, 2017: 45% control on fruit.
Cueva at 2 gal/A; 4 applications beginning June 6, 2017: 44% control on fruit.
Trial mean: 45% control (n =2).

F&N Test 56:SMF19. M. Ellis *et al.* Ohio State University. Evaluations of fungicides for control of Grape Black Rot, 2000.
Oxidate 27% L at 128 fl oz/A; 7 applications: No control of leaf infections. No control of fruit infections. More disease than in the untreated control.

OMRI-LISTED ALTERNATIVES: CROP GROUP 13: BERRIES: GRAPES / Bunch Rot (*Botrytis cinerea*)

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Grapes / Bunch Rot (*Botrytis cinerea*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	66	6	See Oso efficacy summary table.	Control.	0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel 55	70051-108	74	1	9:SMF001.	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel LC	70051-114	95	1	9:SMF001.	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain F727	Stargus	84059-28	No data	NA	NA	Control. Preventative only.	0	4	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Not for sale or use after 18 months from the date of manufacture. Avoid freezing.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain MBI 600	Serifel	71840-18	No data	NA	NA	Control. Preventative only. Not for use in California.	0	4	None.	Moderate eye irritation. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	None.
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if inhaled. May cause dermal sensitization. [F] Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Spray solution pH restrictions.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Optiva	264-1160	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152	22	4	5:SMF010; F&N 61:SMF034; F&N 58:SMF026.	Control. Preventative only.	0	4	None.	Harmful if inhaled.	None.	None.

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Grapes / Bunch Rot (*Botrytis cinerea*)													
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151	39	4	6:SMF047; 5:SMF049; 5:SMF057; 2:SMF009.	Control. Preventative only.	0	4	None.	May cause dermal sensitization. [F]	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Optimum	264-1160	32	1	9:SMF023.	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	None.
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3	38	1	9:SMF023.	Control. Preventative only.	0	4	None.	Moderate eye irritation.	None.	Avoid freezing.
Non-synthetic	NC; Biological	*Aureobasidium pullulans* strains DSM 14940 and DSM 14941	Botector	86174-3	23	4	10:SMF030; 9:SMF013; 9:SMS023; 8:SMF015.	Control. Preventative only.	0	4	None.	Harmful if swallowed or absorbed through skin. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live yeast-like fungus. Use and storage temperature restrictions. Not compatible with many fungicides.
Non-synthetic	NC; Biological	*Streptomyces lydicus*	Actinovate AG	73314-1	No data	NA	NA	Botrytis claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Field uses: Control vs suppression only is not specified. Greenhouse uses: Suppression only.	0	1 or until dry	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live bacterium. Use and storage temperature restrictions.
Non-synthetic	NC; Biological	*Ulacladium ouderansii* strain U3	Zen-O-Spore	75747-2	No data	NA	NA	Control.	0	4	None.	Harmful if inhaled. Moderate eye irritation. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live fungal spores. Store below 68°F.
Non-synthetic	NC; Botanical oil	Neem oil	Trilogy	70051-2	No data	NA	NA	Botrytis control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	4	Yes.	Moderate eye irritation.	Toxic to fish, aquatic organisms, and bees.	Temperature restrictions. Storage restrictions.

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Grapes / Bunch Rot (*Botrytis cinerea*)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Non-synthetic	NC; Botanical oil	Clove oil, Rosemary oil, Peppermint oil	BacStop	NA; 25(b)	No data	NA	NA	Control.	0	0	None.	Temporary eye and skin irritation	No FIFRA statements.	Storage temperature restrictions.
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)	No data	NA	NA	Control.	0	0	Yes.	Harmful if swallowed.	Toxic to bees.	Not for use near heat or open flames.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1	No data	NA	NA	Botrytis control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541	20	1	F&N 55:SMF116	Control.	0	4	None.	Harmful is swallowed. Moderate eye irritation.	None.	Avoid contamination by pesticides and fertilizers. Final spray solution pH must be ≥7.0.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539	No data	NA	NA	Botrytis control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	1	None.	Harmful is swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate 2.0	70299-2	26	2	5:SMF049; 5:SMF057.	Control.	0	Until dry	None.	Irreversible eye damage. May be fatal if swallowed. Skin irritation.	Highly toxic to bees and other beneficial insects. Toxic to fish.	Chemical instabilities. Strong oxidizing agent. Use and storage temperature restrictions.
Synthetic	NC; Oxidizing agent	Hydrogen peroxide, Hydrogen dioxide	Perpose Plus	86729-1	No data	NA	NA	Botrytis control claim for all agricultural crops. Preventative only.	0	Until dry	None.	Irreversible eye damage and skin burns. May be fatal if absorbed through skin. Harmful if swallowed.	Toxic to birds, mammals, fish, and aquatic life.	Chemical instabilities. Strong oxidizing agent. Storage restrictions.
Synthetic	NC; Petroleum oil	Mineral oil	JMS Stylet Oil	65564-1	10	2	2:SMF036; F&N 61:SMF038	Control.	0	4	Yes. (with sulfur).	Harmful if swallowed.	Toxic to fish.	None.
Synthetic	NC; Petroleum oil	Mineral oil	PureSpray Green	69526-9	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed or absorbed through skin. May cause dermal sensitization. [F]	Toxic to aquatic organisms.	None.
Synthetic	NC; Petroleum oil	Aliphatic petroleum solvent	SuffOil-X	48813-1-68539	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed. May cause dermal sensitization. [F]	Toxic to aquatic organisms.	None.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Grapes / Bunch Rot (*Botrytis cinerea*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	NC; Petroleum oil	Mineral oil	TriTek	48813-1	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed or absorbed through skin. May cause dermal sensitization. [F]	Toxic to aquatic organisms.	None.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative environmental toxicity descriptors, lowest toxicity to highest toxicity: Practically non-toxic < Moderately toxic < Toxic < Highly toxic.

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Grapes / Bunch Rot (*Botrytis cinerea*)													
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Plant Disease Management Reports citations and data summaries for non-synthetic alternatives: 10:SMF030. J.W. Pscheidt and J. P. Bassinette, Oregon State University. Efficacy of Fungicides for Management of Grape Bunch Rot, 2015. Botector at 10 oz/A: 80.1%, 61.8%, 43.2%, and 82.1% control of incidence (9/13/2015, 9/22/2015, 9/28/2015) and Severity (9/28/2015), respectively. Trial mean: 66.8% control (n = 4). 9:SMF001. T. T. Nguyen, N.S. Morris, and W. D. Gubler, University of California, Davis. Management of Grape Botrytis Bunch Rot with experimental, organic and conventional fungicides, 2014. Double Nickel LC at 2 qt/A: 93% and 96% control of Botrytis bunch rot (severity and incidence, respectively). Trial mean: 95% control (n = 2). Double Nickel 55WDG at 20 oz/A: 70% and 78% control of Botrytis bunch rot (severity and incidence, respectively). Trial mean: 74% control (n = 2). 9:SMF013. B. Hed, Pennsylvania State University. Evaluation of Leaf Removal, Botector, Foliar Nutrients, and Fungicides for Control of Botrytis Bunch Rot of Grapes, 2014. Botector at 5 oz/A: 1.7% control of Botrytis incidence on clusters. 11.2% control of Botrytis severity on clusters. Trial mean: 6.5% control (n = 2). 9:SMF023. L. J. Bettiga, University of California Cooperative Extension (Salinas). Evaluation of fungicides for the control of Botrytis bunch rot of grape, 2014. Regalia at 2 qt/A + Kinetic at 0.05%: 29% control of Botrytis bunch rot incidence. 47% control of Botrytis bunch rot severity. Trial mean: 38% control (n = 2). Serenade Optimum at 1 lb/A + Kinetic at 0.05%: 26% control of Botrytis bunch rot incidence. 38% control of Botrytis bunch rot severity. Trial mean: 32% control (n = 2). Botector at 7 oz/A + Kinetic at 0.05%: 30% control of Botrytis bunch rot incidence. 53% control of Botrytis bunch rot severity. Trial mean: 42% control (n = 2). 8:SMF015. B. Hed, Pennsylvania State University. Evaluation of Leaf Removal, ProGibb, Vapor Gard, and Fungicides for the Control of Botrytis Bunch Rot of Grapes, 2013. Botector at 5 oz/A: 16.7% control of Botrytis bunch rot incidence. 37.5% control of Botrytis bunch rot severity. Trial mean: 27.1% control (n = 2). 6:SMF047. W. F. Wilcox and D. G. Riegel, Cornell University. Evaluation of fungicide programs for control of Botrytis bunch rot of grapes, 2010. Serenade Max at 1.5 lb/A: 36% control of Botrytis on clusters. 34% control of diseased area on clusters. Trial mean: 35% control (n = 2). 5:SMF010. I.S. Bay, J. D. Eynard, and W. D. Gubler, University of California, Davis. Fungicide programs for control of Botrytis bunch rot of grape, 2010. Serenade (formulation not specified; assume ASO = liquid) at 4 qt/A: 39% and 30% control of Botrytis bunch rot incidence and severity, respectively. Trial mean: 35% control (n = 2). 5:SMF049. A. M.C. Schilder, J. M. Gillett, and R. W. Sysak, Michigan State University. Evaluation of fungicide programs for control of bunch rots and downy mildew in 'Vignoles' grapes, 2008. Serenade Max at 3 lb/A + NuFilm-17 at 0.5 pt/A: 37% control of Botrytis bunch rot. 5:SMF057. A. M.C. Schilder, J. M. Gillett, and R. W. Sysak, Michigan State University. Evaluation of fungicide programs for control of bunch rots in 'Vignoles' grapes, 2009. Serenade Max at 3 lb/A + Nu-Film P at 0.5 pt/A: 55% control of Botrytis bunch rot. 2:SMF009. W. F. Wilcox and D. G. Riegel, Cornell University. Evaluation of fungicide programs for control of Botrytis bunch rot of grapes, 2007. Serenade Max 2.0 lb + Biotune (adjuvant) at 0.13%: 13% control of Botrytis bunch rot on clusters. 45% control of infected cluster area. Trial mean: 29% control (n = 2). F&N 61:SMF034. W. F. Wilcox and D. G. Riegel, Cornell University. Evaluation of fungicide programs for control of Botrytis bunch rot of grapes, 2005. Serenade (unspecified formulation; assume ASO = liquid) at 4.0 qt/A + Biotune (adjuvant) at 0.125% (v/v): 36% control of Botrytis on clusters. 33% control of diseased area on clusters. Trial mean: 35% control (n = 2). F&N 58:SMF026. A. Baudoin, Virginia Polytechnic Institute and State University. Evaluation of fungicides for control of grape bunch and other late-season rots, 2002. Serenade (formulation not specified) at 6 lb/A, Stanardsville trial: No control of Botrytis incidence and severity. More disease than in the untreated control. Serenade (formulation not specified) at 6 lb/A, Linden trial: 18% control of Botrytis incidence. 20% control of Botrytis severity. Trial mean: 19% control (n =2).													

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Grapes / Bunch Rot (*Botrytis cinerea*)													
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Plant Disease Management Reports citations and data summaries for synthetic alternatives: 5:SMF049. A. M.C. Schilder, J. M. Gillett, and R. W. Sysak, Michigan State University. Evaluation of fungicide programs for control of bunch rots and downy mildew in 'Vignoles' grapes, 2008. Oxidate at 1% (v/v)/A: 43% control of Botrytis bunch rot. 5:SMF057. A. M.C. Schilder, J. M. Gillett, and R. W. Sysak, Michigan State University. Evaluation of fungicide programs for control of bunch rots in 'Vignoles' grapes, 2009. Oxidate at 1% (v/v)/A: 8.0% control of Botrytis bunch rot. 2:SMF036. J. Hashim-Buckey, University of California (Bakersfield). Evaluation of vineyard fungicide applications to control postharvest rot of table grapes, 2006. JMS Stylet-Oil at 1 gal/A: 0% control of post-harvest Botrytis bunch rot. Untreated control has less disease. F&N 61:SMF038. B. Hed and J.W. Travis, Penn State Research and Extension Centers. Evaluation of cultural methods and oils for improving control of Botrytis bunch rot of grapes, 2005. JMS Stylet-Oil at 2% (v/v), 2 treatments with 2 applications each, different timing: 0% and 39% control of Botrytis bunch rot. Trial mean: 20% control (n = 2). F&N 55:116. W. F. Wilcox and D. G. Riegel. Evaluation of fungicide programs for control of Botrytis bunch rot of grapes, 1999. Armicarb 100 at 2.5 lb/A: 20% control of Botrytis bunch rot on clusters. Armicarb 100 at 4.8 lb/A: 20% control of Botrytis bunch rot on clusters. Trial mean: 20% control (n = 2). References with especially low disease pressure in the untreated control are not summarized (F&N 58:SMF035).													

OMRI-LISTED ALTERNATIVES: CROP GROUP 13: BERRIES: GRAPES / Downy Mildew (*Plasmopara viticola*)

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Grapes / Downy Mildew (*Plasmopara viticola*)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	95	2	See Oso efficacy summary table.	Control.	0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel 55	70051-108	No data	NA	NA	Suppression only. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization.	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel LC	70051-114	No data	NA	NA	Suppression only. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain F727	Stargus	84059-28	No data	NA	NA	Control. Preventative only.	0	4	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Not for sale or use after 18 months from the date of manufacture. Avoid freezing.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain MBI 600	Serifel	71840-18	No data	NA	NA	Control. Preventative only. Not for use in California.	0	4	None.	Moderate eye irritation. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	None.
Non-synthetic	44	*Bacillus mycoides*, isolate J	LifeGard WG	70051-119	No data	NA	NA	No direct effect on plant pathogen; plant protectant; preventative.	0	4	None.	Harmful if inhaled. Moderate eye irritation. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Store at temperatures below 77°F.
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if inhaled. May cause dermal sensitization. [F] Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None	Spray solution pH restrictions.

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Grapes / Downy Mildew (*Plasmopara viticola*)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152	No data	NA	NA	Suppression only. Preventative only.	0	4	None.	Harmful if inhaled.	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151	42	1	3:SMF031	Suppression only. Preventative only.	0	4	None.	May cause dermal sensitization. [F]	None.	None.
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3	37	1	8:SMF014.	Control. Preventative only.	0	4	None.	Moderate eye irritation.	None.	Avoid freezing.
Non-synthetic	NC; Biological	*Streptomyces lydicus*	Actinovate AG	73314-1	No data	NA	NA	Downy mildew claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Field uses: Control vs suppression only is not specified. Greenhouse uses: Suppression only.	0	1 or until dry	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live bacterium. Use and storage temperature restrictions.
Non-synthetic	NC; Botanical oil	Neem oil	Trilogy	70051-2	No data	NA	NA	Downy mildew control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	4	Yes.	Moderate eye irritation.	Toxic to fish, aquatic organisms, and bees.	Temperature restrictions. Storage restrictions.
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)	No data	NA	NA	Control.	0	0	Yes.	Harmful if swallowed.	Toxic to bees.	Not for use near heat or open flames.
Synthetic	M1	Basic copper sulfate	Basic Copper 53	45002-8	No data	NA	NA	Control.	0	24	Yes.	Substantial eye injury.	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	M1	Copper oxychloride, Copper hydroxide	Badge X2	80289-12	99 (with lime)	1	8:SMF014	Control.	0	48	Yes.	May be fatal if swallowed. Substantial eye injury.	Toxic to fish and aquatic organisms.	May damage aluminum.
Synthetic	M1	Copper hydroxide	Champ WG	55146-1	No data	NA	NA	Control.	0	48	Yes.	Irreversible eye damage. Harmful if swallowed. May cause dermal sensitization. [F]	Toxic to fish and aquatic organisms.	Damages aluminum.

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Grapes / Downy Mildew (*Plasmopara viticola*)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	M1	Copper hydroxide	Nu-Cop 50 WP	42002-7	No data	NA	NA	Control.	0	24	Yes.	Irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. May cause dermal sensitization. [F]	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	M1	Copper octanoate	Cueva	67702-2-70051	93	1	3:SMF031	Control.	0	4	Yes.	Harmful if swallowed or absorbed through skin.	Toxic to fish and aquatic organisms.	Do not store below 4°C (39°F). Tank-mix restrictions.
Synthetic	M1	Copper sulfate pentahydrate	CS 2005	66675-3	No data	NA	NA	Control.	0	48	Yes.	Irreversible eye damage. Skin irritation. Harmful if swallowed, inhaled or absorbed through skin.	Toxic to fish and aquatic organisms.	Incompatible with galvanized pipe and nylon equipment.
Synthetic	M1	Copper sulfate pentahydrate	Copper Sulfate Crystals	56576-1	No data	NA	NA	Control.	0	24	Yes.	Corrosive. Causes eye damage. Skin irritation.	Toxic to fish.	None.
Synthetic	M1	Copper sulfate pentahydrate	Quimag Quimicos Arguila Copper Sulfate Crystals	73385-3	No data	NA	NA	Control.	0	24	Yes.	Irreversible eye damage. Maybe fatal if swallowed. RESTRICTED USE PESTICIDE.	Toxic to fish and aquatic invertebrates. ENDANGERED SPECIES RESTRICTIONS.	Possible incompatibility with aluminum, rubber, etc.
Synthetic	M1	Cupric hydroxide	NuCop 50 DF	45002-4	No data	NA	NA	Control.	1	24	Yes.	Irreversible eye damage. Harmful if swallowed or absorbed through skin. May cause dermal sensitization. [F]	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	M1	Cupric hydroxide	Nu-Cop HB	42750-132	No data	NA	NA	Control.	1	24	Yes.	Irreversible eye damage. Harmful if swallowed or absorbed through skin.	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	M1	Cuprous oxide	Nordox 75 WG	48142-4	No data	NA	NA	Control.	0	12	Yes.	Harmful if swallowed or absorbed through skin. Eye irritation.	None.	Water pH restrictions.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1	No data	NA	NA	Downy mildew control claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Not for use in California.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank- mix restrictions.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Grapes / Downy Mildew (*Plasmopara viticola*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541	No data	NA	NA	Control.	0	4	None.	Harmful is swallowed. Moderate eye irritation.	None.	Avoid contamination by pesticides and fertilizers. Final spray solution pH must be ≥7.0.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539	No data	NA	NA	Downy mildew control claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Not for use in California.	0	1	None.	Harmful is swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate 2.0	70299-2	92 (leaves)	1	5:SMF049.	Control.	0	Until dry	None.	Irreversible eye damage. May be fatal if swallowed. Skin irritation.	Highly toxic to bees and other beneficial insects. Toxic to fish.	Chemical instabilities. Strong oxidizing agent. Use and storage temperature restrictions.
Synthetic	NC; Oxidizing agent	Hydrogen peroxide, Hydrogen dioxide	Perpose Plus	86729-1	No data	NA	NA	Downy mildew control claim for all agricultural crops. Preventative only.	0	Until dry	None.	Irreversible eye damage and skin burns. May be fatal if absorbed through skin. Harmful if swallowed.	Toxic to birds, mammals, fish, and aquatic life.	Chemical instabilities. Strong oxidizing agent. Storage restrictions.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative environmental toxicity descriptors, lowest toxicity to highest toxicity: Practically non-toxic < Moderately toxic < Toxic < Highly toxic.

8:SMF014. B. Hed, Penn State University. Evaluation of organic fungicides for control of black rot and powdery and downy mildew of Concord grapes, 2013.
Regalia 5% at 6 quarts/A; 6 applications beginning May 20, 2013: 37% control on fruit.
Badge X2 at 1.75 lb/A + lime at 1.75 lb/A, different application timings: 96%, 99%, 100%, and 100% control of downy mildew on grapes (fruit).
Badge X2 at 1.75 lb/A + lime at 1.75 lb/A + Nu-Film-P at 0.0625%, different application timings: 100% and 100% control of downy mildew on grapes (fruit).
Badge X2 trial mean: 99% control (n = 6).

5:SMF049. A. Schilder, *et al*. Michigan State University. Evaluation of fungicide programs for control of bunch rots and downy mildew in 'Vignoles' grapes, 2008.
Oxidate 1% (v/v): 92% control on grape leaves.

3:SMF031. B. Hed. Penn State Univ. Evaluation of alternative fungicides for control of black rot, powdery mildew, and downy mildew of grapes, 2008.
Serenade at 1%/A + NuFilm P at 0.12%/A (formulation not specified; MAX assumed): 42% control on fruit.
Cueva 1%: 93% control of downy mildew on grapes (fruit).

OMRI-LISTED ALTERNATIVES: CROP GROUP 13: BERRIES: GRAPES / Phomopsis (*Phomopsis viticola*)

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Grapes / Phomopsis (*Phomopsis viticola*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	71	2	See Oso efficacy summary table.	Control.	0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel 55	70051-108	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel LC	70051-114	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain F727	Stargus	84059-28	No data	NA	NA	Control. Preventative only.	0	4	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Not for sale or use after 18 months from the date of manufacture. Avoid freezing.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain MBI 600	Serifel	71840-18	No data	NA	NA	Control. Preventative only. Not for use in California.	0	4	None.	Moderate eye irritation. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	None.
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if inhaled. May cause dermal sensitization. [F] Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Spray solution pH restrictions.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if inhaled.	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151	No data	NA	NA	Control. Preventative only.	0	4	None.	May cause dermal sensitization. [F]	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Optiva	264-1160	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	None.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Grapes / Phomopsis (*Phomopsis viticola*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation.	None.	Avoid freezing.
Non-synthetic	NC; Botanical oil	Clove oil, Rosemary oil, Peppermint oil	BacStop	NA; 25(b)	No data	NA	NA	Control.	0	0	None.	Temporary eye and skin irritation	No FIFRA statements.	Storage temperature restrictions.
Synthetic	M1	Copper oxychloride, Copper hydroxide	Badge X2	80289-12	No data	NA	NA	Control.	0	48	Yes.	May be fatal if swallowed. Substantial eye injury.	Toxic to fish and aquatic organisms.	May damage aluminum.
Synthetic	M1	Copper hydroxide	Champ WG	55146-1	No data	NA	NA	Control.	0	48	Yes.	Irreversible eye damage. Harmful if swallowed. May cause dermal sensitization. [F]	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	M1	Copper octanoate	Cueva	67702-2-70051	No data	NA	NA	Control.	0	4	Yes.	Harmful if swallowed or absorbed through skin.	Toxic to fish and aquatic organisms.	Do not store below 4°C (39°F). Tank-mix restrictions.
Synthetic	M1	Copper sulfate pentahydrate	CS 2005	66675-3	No data	NA	NA	Control.	0	48	Yes.	Irreversible eye damage. Skin irritation. Harmful if swallowed, inhaled or absorbed through skin.	Toxic to fish and aquatic organisms.	Incompatible with galvanized pipe and nylon equipment.
Synthetic	M1	Cupric hydroxide	Nu Cop 50 DF	45002-4	No data	NA	NA	Control.	1	24	Yes.	Irreversible eye damage. Harmful if swallowed or absorbed through skin. May cause dermal sensitization. [F]	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	M1	Cupric hydroxide	Nu Cop HB	42750-132	No data	NA	NA	Control.	1	24	Yes.	Irreversible eye damage. Harmful if swallowed or absorbed through skin.	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	M1	Cuprous oxide	Nordox	48142-4	No data	NA	NA	Control.	0	12	Yes.	Harmful if swallowed or absorbed through skin. Eye irritation.	None.	Water pH restrictions.
Synthetic	M2	Sulfur	Acoidal	62562-4	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin.	Toxic to fish and aquatic organisms.	Suspended dust ignites easily.
Synthetic	M2	Sulfur	Defend DF	62562-8	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin.	Toxic to fish and aquatic organisms.	Suspended dust ignites easily.
Synthetic	M2	Sulfur	Kumulus DF	51306-352-66330	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed. Avoid contact with eyes, skin, and clothing.	None.	Do not store above 104°F.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Grapes / Phomopsis (*Phomopsis viticola*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	M2	Sulfur	Micro Sulf	55146-75	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin. Eye irritation.	None.	Keep away from heat, sparks, or flames.
Synthetic	M2	Sulfur	Microthiol Disperss	70506-187	23	1	4:SMF047	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin.	None.	Do not store near flammable materials.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1	No data	NA	NA	Phomopsis control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539	No data	NA	NA	Phomopsis control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative environmental toxicity descriptors, lowest toxicity to highest toxicity: Practically non-toxic < Moderately toxic < Toxic < Highly toxic.

4:SMF047. W. F. Wilcox *et al.*, Cornell University. Evaluation of fungicide programs for control of Phomopsis in grapes, 2008. Results:
Microthiol Disperse at 5 lb/A; 4 applications beginning at 1-inch shoots:
Shoot infections: 13% control of incidence. 40% control of severity.
Rachis infections: 13% control of incidence. 26% control of girdling.
Trial mean: 23% control (n = 4).

OMRI-LISTED ALTERNATIVES: CROP GROUP 13: BERRIES: GRAPES / Powdery Mildew (*Erisyphe necator*)

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Grapes / Powdery Mildew (*Erisyphe necator*)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	79	8	See Oso efficacy summary table.	Control.	0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel 55	70051-108	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel LC	70051-114	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain F727	Stargus	84059-28	No data			Control. Preventative only.	0	4	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Not for sale or use after 18 months from the date of manufacture. Avoid freezing.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain MBI 600	Serifel	71840-18	No data	NA	NA	Control. Preventative only. Not for use in California.	0	4	None.	Moderate eye irritation. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	None.
Non-synthetic	44	*Bacillus mycoides*, isolate J	LifeGard WG	70051-119	No data			No direct effect on plant pathogen; plant protectant; preventative.	0	4	None.	Harmful if inhaled. Moderate eye irritation. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Store at temperatures below 77°F.
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if inhaled. May cause dermal sensitization. [F] Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Spray solution pH restrictions.

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Grapes / Powdery Mildew (*Erisyphe necator*)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Optiva	264-1160	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152	34	3	3:SMF031; 1:SMF005.	Control. Preventative only.	0	4	None.	Harmful if inhaled.	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151	1	1	6:SMF048.	Control. Preventative only.	0	4	None.	May cause dermal sensitization. [F]	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Optimum	264-1160	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	None.
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3	26	4	8:SMF014; 6:SMF049; 4:SMF054; 4:SMF055.	Control. Preventative only.	0	4	None.	Moderate eye irritation.	None.	Avoid freezing.
Non-synthetic	NC; Biological	*Streptomyces lydicus* WYEC	Actinovate	73314-1	6	2	4:SMF054; 4:SMF055.	Powdery mildew claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Field uses: Control vs suppression only is not specified. Greenhouse uses: Suppression only.	0	1 or until dry	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live bacterium. Use and storage temperature restrictions.
Non-synthetic	NC; Botanical oil	Cinnamon oil	Cinnerate	NA; 25(b)	No data	NA	NA	Control.	0	0	None.	Eye and skin irritation. May cause dermal sensitization. [F]	None.	Do not expose to light.
Non-synthetic	NC; Botanical oil	Garlic oil, Cottonseed oil, Corn oil	Mildew Cure	NA; 25(b)	No data	NA	NA	General powdery mildew claim; not crop specific	0	0	None.	Avoid contact with skin, eyes, and clothing.	No FIFRA statement.	None.
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)	No data	NA	NA	Control.	0	0	Yes.	Harmful if swallowed.	Toxic to bees.	Not for use near heat or open flames.
Non-synthetic	NC; Botanical oil	Neem oil	Trilogy	70051-2	No data	NA	NA	Powdery mildew control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	4	Yes.	Moderate eye irritation.	Toxic to fish, aquatic organisms, and bees.	Temperature restrictions. Storage restrictions.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Grapes / Powdery Mildew (*Erisyphe necator*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)	No data	NA	NA	Control.	0	0	Yes.	Harmful if swallowed.	Toxic to bees.	Not for use near heat or open flames.
Non-synthetic	NC; Organic acid	Citric acid	Nuke Em	NA; 25(b)	No data	NA	NA	General mildew claim; not crop specific.	0	0	None.	No FIFRA statement.	No FIFRA statement.	Store away from direct sunlight.
Synthetic	M1	Copper hydroxide	Nu-Cop 50 WP	42002-7	62	1	6:SMF008	Control.	0	24	Yes.	Irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. May cause dermal sensitization. [F]	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	M1	Copper hydroxide	Champ WG	55146-1	No data	NA	NA	Control.	0	48	Yes.	Irreversible eye damage. Harmful if swallowed. May cause dermal sensitization. [F]	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	M1	Copper hydroxide	Nu-Cop HB	42750-132	No data	NA	NA	Control.	1	24	Yes.	Irreversible eye damage. Harmful if swallowed or absorbed through skin.	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	M1	Copper hydroxide, Copper oxychloride	Badge X2	80289-12	50	2	8:SMF014 6:SMF008	Control.	0	48	Yes.	May be fatal if swallowed. Substantial eye injury.	Toxic to fish and aquatic organisms.	May damage aluminum.
Synthetic	M1	Copper octanoate	Cueva	67702-2-70051	19	4	6:SMF048; 3:SMF030; 3:SMF031; 2:SMF004.	Control.	0	4	Yes.	Harmful if swallowed or absorbed through skin.	Toxic to fish and aquatic organisms.	Do not store below 4°C (39°F). Tank-mix restrictions.
Synthetic	M1	Copper sulfate pentahydrate	CS 2005	66675-3	No data	NA	NA	Control.	0	48	Yes.	Irreversible eye damage. Skin irritation. Harmful if swallowed, inhaled or absorbed through skin.	Toxic to fish and aquatic organisms.	Incompatible with galvanized pipe and nylon equipment.
Synthetic	M1	Copper sulfate pentahydrate	Copper Sulfate Crystals	56576-1	No data	NA	NA	Control. Dormant only.	0	24	Yes.	Corrosive. Causes eye damage. Skin irritation.	Toxic to fish.	None.
Synthetic	M1	Cupric hydroxide	Nu-Cop 50 DF	45002-4	No data	NA	NA	Control.	1	24	Yes.	Irreversible eye damage. Harmful if swallowed or absorbed through skin. May cause dermal sensitization. [F]	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	M1	Cuprous oxide	Nordox	48142-4	No data	NA	NA	Control.	0	12	Yes.	Harmful if swallowed or absorbed through skin. Eye irritation.	None.	Water pH restrictions.

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Grapes / Powdery Mildew (*Erisyphe necator*)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	M2	Sulfur	Acoidal	62562-4	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin.	Toxic to fish and aquatic organisms.	Suspended dust ignites easily.
Synthetic	M2	Sulfur	Cosavet-DF	70905-1	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin. Moderate eye irritation.	None.	Suspended dust ignites easily.
Synthetic	M2	Sulfur	Defend DF	62562-8	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin.	Toxic to fish and aquatic organisms.	Suspended dust ignites easily.
Synthetic	M2	Sulfur	Kumulus DF	51306-352-66330	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed. Avoid contact with eyes, skin, and clothing.	None.	Do not store above 104°F.
Synthetic	M2	Sulfur	Micro Sulf	55146-75	88	1	6:SMF025	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin. Eye irritation.	None.	Keep away from heat, sparks, or flames.
Synthetic	M2	Sulfur	Microthiol Disperss	70506-187	40	6	6:SMF044; 6:SMF048; 6:SMF049; 4:SMF046; 4:SMF054; 4:SMF055.	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin.	None.	Do not store near flammable materials.
Synthetic	M2	Sulfur	Thiolux	34704-1079	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin. Eye irritation.	None.	Suspended dust ignites easily.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541	No data	NA	NA	Control.	0	4	None.	Harmful if swallowed. Moderate eye irritation.	None.	Avoid contamination by pesticides and fertilizers. Final spray solution pH must be ≥7.0.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Kaligreen	70231-1	No data	NA	NA	General powdery mildew control claim.	1	4	None.	Harmful if swallowed.	None.	Chemical incompatibilities.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70871-1-68539	0	1	3:SMF030.	Powdery mildew control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	1	4	None.	Harmful if swallowed. Moderate eye irritation	None.	Chemical incompatibilities.

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Grapes / Powdery Mildew (*Erisyphe necator*)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	NC; Inorganic salt	Potassium silicate	Sil-Matrix	82100-1	No data	NA	NA	General powdery mildew control claim. Preventative only.	0	4	None.	Moderate eye irritation.	None	Chemical incompatibilities.
Synthetic	NC; Organic salt	Potassium salts of fatty acids	M-Pede	10163-324	No data	NA	NA	Control.	0	12	Yes.	Substantial eye injury. Skin irritation.	Harmful to aquatic invertebrates	If water has high mineral content, check for compatibility.
Synthetic	NC; Organic salt	Insecticidal soap	Des-X	67702-22-70051	No data	NA	NA	Control.	0	12	Yes.	Substantial eye injury. Skin irritation.	Harmful to aquatic invertebrates	If water has high mineral content, check for compatibility.
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate	70299-2	No data	NA	NA	Control.	0	Until dry	None.	Irreversible eye damage. May be fatal if swallowed. Skin irritation.	Highly toxic to bees and other beneficial insects. Toxic to fish.	Chemical instabilities. Strong oxidizing agent. Use and storage temperature restrictions.
Synthetic	NC; Oxidizing agent	Hydrogen peroxide, Hydrogen dioxide	Perpose Plus	86729-1	No data	NA	NA	Powdery mildew control claim for all agricultural crops. Preventative only.	0	Until dry	None.	Irreversible eye damage and skin burns. May be fatal if absorbed through skin. Harmful if swallowed.	Toxic to birds, mammals, fish, and aquatic life.	Chemical instabilities. Strong oxidizing agent. Storage restrictions.
Synthetic	NC; Petroleum oil	Mineral oil	Glacial Spray Liquid	34704-849	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed, inhaled, or absorbed through skin. Eye irritation. May cause dermal sensitization. [F]	Hazardous to aquatic organisms.	None.
Synthetic	NC; Petroleum oil	Mineral oil	JMS Stylet Oil	65564-1	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed.	Toxic to fish.	None.
Synthetic	NC; Petroleum oil	Mineral oil	Omni Supreme Spray	5905-368	No data	NA	NA	Control.	0	12	Yes (with sulfur).	Harmful if absorbed through skin. May cause dermal sensitization. [F]	Toxic to fish and aquatic organisms.	Chemical incompatibilities.
Synthetic	NC; Petroleum oil	Mineral oil	PureSpray Green	69526-9	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed or absorbed through skin. May cause dermal sensitization. [F]	Toxic to aquatic organisms.	None.
Synthetic	NC; Petroleum oil	Mineral oil	SuffOil-X	48813-1-68539	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed. May cause dermal sensitization. [F]	Toxic to aquatic organisms.	None.
Synthetic	NC; Petroleum oil	Mineral oil	TriTek	48813-1	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed or absorbed through skin. May cause dermal sensitization. [F]	Toxic to aquatic organisms.	None.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Grapes / Powdery Mildew (*Erisyphe necator*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative environmental toxicity descriptors, lowest toxicity to highest toxicity: Practically non-toxic < Moderately toxic < Toxic < Highly toxic.

Plant Disease Management Reports citations and data summaries for non-synthetic alternatives:

8:SMF014. B, Hed, Penn State University. Evaluation of organic fungicides for control of black rot and powdery and downy mildew on Concord grapes, 2013.
Regalia at 6 qt/A: 61% control of powdery mildew on fruit.

6:SMF048. W. F. Wilcox and D. G. Riegel, Cornell University. Evaluation of fungicide programs for control of grapevine powdery mildew, 2010.
Serenade Max: 0% control on leaves. 0% control on leaf area. 0% control on clusters. 5% control on cluster area. Trial mean: 1% control (n = 4).

6:SMF049. W. F. Wilcox and D. G. Riegel, Cornell University. Evaluation of fungicide programs for control of grapevine powdery mildew, 2010.
Regalia at 2 qt/A + Cohere at 0.031% (v/v): 0% control on leaves. 24% control on leaf area. 0% control on clusters. 12% control on cluster area. Trial mean: 9% control (n = 4).

4:SMF054. W. F. Wilcox and D. G. Riegel, Cornell University. Evaluation of fungicide programs for control of grapevine powdery mildew, 2009.
Regalia Max at 0.25% + NuFilm at 0.03%: 0% control on leaves. 25% control on leaf area. 0% control on clusters. 3% control on cluster area. Trial mean: 2% control (n = 4).
Actinovate at 12 oz/A: 0% control on leaves. 4% control on leaf area. 0% control on clusters. 1% control on cluster area. Trial mean: 1% control (n = 4).

4:SMF055. W. F. Wilcox and D. G. Riegel, Cornell University. Evaluation of fungicide programs for control of powdery mildew on Rosette grapes, 2009.
Regalia Max at 0.25% + NuFilm at 0.03%: 0% control on leaves. 56% control on leaf area. 0% control on clusters. 81% control on cluster area. Trial mean: 34% control (n = 4).
Actinovate at 6 oz/A: 0% control on leaves. 6% control on leaf area. 0% control on clusters. 48% control on cluster area.
Actinovate at 12 oz/A: 0% control on leaves. 2% control on leaf area. 0% control on clusters. 24% control on cluster area.
Actinovate trial mean: 10% control (n = 8).

3:SMF030. B. Hed and J. W. Travis, Penn State University. Evaluation of organic fungicides for control of black rot and powdery mildew of Concord grapes, 2008.
Serenade (formulation not specified; ASO assumed) at 1% + NuFilm P 0.12%: 1% control on leaves. 32% control on leaf area. Trial mean: 17% control (n = 2).

3:SMF031. B. Hed and J. W. Travis, Penn State University. Evaluation of alternative fungicides for control of black rot, powdery mildew, and downy mildew of grapes, 2008.
Serenade (formulation not specified; ASO assumed) at 1% + NuFilm P 0.12%: 75% control.

1:SMF005. W. F. Wilcox and D. G. Riegel, Cornell University. Evaluation of fungicide programs for control of grapevine powdery mildew, 2006.
Serenade (formulation not specified; ASO assumed) at 4 qt/A: 0% control on leaves. 18% control on leaf area. 26% control on clusters. 14% control on cluster area. Trial mean: 14% control (n = 4).

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Grapes / Powdery Mildew (*Erisyphe necator*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical

Plant Disease Management Reports citations and data summaries for synthetic alternatives:

8:SMF014. B, Hed, Penn State University. Evaluation of organic fungicides for control of black rot and powdery and downy mildew on Concord grapes, 2013.
Badge X2 at 1.75 lb/A + lime at 1.75 lb/A, different application timings: 34%, 44%, 55%, and 58% control of powdery mildew on fruit
Badge X2 at 1.75 lb/A + lime at 1.75 lb/A + Nu-Film-P at 0.0625%, different application timings: 47% and 54% control of powdery mildew on fruit.
Trial mean: 40% control (n = 6).

6:SMF008. B. Hed and H. K. Ngugi, Penn State University. Evaluation of conventional and organic fungicides for control of black rot and powdery mildew of Concord grapes, 2011.
NuCop 50 WP at 1 lb/A + Lime at 1 lb/A + NuFilm P at 0.0625%: 86% control of powdery mildew on fruit. 33% control of powdery mildew on leaves.
NuCop 50 WP at 2 lb/A + Lime at 2 lb/A + NuFilm P at 0.0625%: 73% control of powdery mildew on fruit. 56% control of powdery mildew on leaves.
Trial mean: 62% (n = 4).
Badge X2 at 1.75 lb/A + Lime at 1075 lb/A + NuFilm P at 0.0625%: 69% control of powdery mildew on fruit. 49% control of powdery mildew on leaves. Trial mean: 59% (n = 2).

6:SMF025. N. O. Halbrendt, H.K. Ngugi, and J. M. Halbrendst, Penn State University. Performance of organic and conventional programs for powdery mildew management on wine grapes in PA, 2011.
Micro Sulf at 5 lb/A: 10.0%, 99.7%, 94.7%, and 99.7% control on leaves (incidence and severity, respectively; Chamboucin and Traminette, respectively).
Micro Sulf at 5 lb/A: 100%, 100%, 100%, and 100% control on clusters (incidence and severity, respectively; Chamboucin and Traminette, respectively).
Trial mean: 88% (n = 8).

6:SMF044. W. F. Wilcox and D. G. Riegel, Cornell University. Evaluation of fungicide programs for control of grapevine powdery mildew, 2011.
Microthiol 80DF at 5.0 lb/A: 0% control on leaves. 82% control on leaf area. 0% control on clusters. 86% control on cluster area.
Microthiol 80DF at 10.0 lb/A: 4% control on leaves. 88% control on leaf area. 12% control on clusters. 92% control on cluster area.
Trial mean: 46% (n = 8).

6:SMF048. W. F. Wilcox and D. G. Riegel, Cornell University. Evaluation of fungicide programs for control of grapevine powdery mildew, 2010.
Microthiol 80DF at 5.0 lb/A: 0% control on leaves. 62% control on leaf area. 0% control on clusters. 51% control on cluster area.
Microthiol 80DF at 10.0 lb/A: 0% control on leaves. 71% control on leaf area. 14% control on clusters. 90% control on cluster area.
Trial mean: 36% (n = 8).
Cueva at 1.0 % (v/v): 0% control on leaves. 71% control on leaf area. 4% control on clusters. 56% control on cluster area.
Trial mean: 33% (n = 4).

6:SMF049. W. F. Wilcox and D. G. Riegel, Cornell University. Evaluation of fungicide programs for control of grapevine powdery mildew, 2010.
Microthiol 80DF at 5.0 lb/A: 0% control on leaves. 64% control on leaf area. 0% control on clusters. 16% control on cluster area.
Microthiol 80DF at 10.0 lb/A: 0% control on leaves. 77% control on leaf area. 0% control on clusters. 41% control on cluster area.
Trial mean: 25% (n = 8).

5:SMF053. A. M. C. Schilder, J. M. Gillett, *et al*. Michigan State University. Evaluation of fungicides for control of powdery mildew in 'Chardonnay' grapes, 2008.
JMS Stylet Oil 1 gal/A: 12% overall control.

4:SMF046. W. F. Wilcox and D. G. Riegel, Cornell University. Evaluation of fungicide programs for control of powdery mildew on Chardonnay grapes, 2008.
Microthiol 80DF at 5.0 lb/A: 5% control on leaves. 76% control on leaf area. 14% control on clusters. 90% control on cluster area.
Microthiol 80DF at 10.0 lb/A: 17% control on leaves. 91% control on leaf area. 36% control on clusters. 71% control on cluster area.
Trial mean: 50% (n = 8).

4:SMF054. W. F. Wilcox and D. G. Riegel, Cornell University. Evaluation of fungicide programs for control of grapevine powdery mildew, 2009.
Microthiol 80DF at 5.0 lb/A: 0% control on leaves. 70% control on leaf area. 0% control on clusters. 4% control on cluster area.
Microthiol 80DF at 10.0 lb/A: 1% control on leaves. 83% control on leaf area. 0% control on clusters. 93% control on cluster area.
Trial mean: 31% (n = 8).

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Grapes / Powdery Mildew (*Erisyphe necator*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical

4:SMF055. W. F. Wilcox and D. G. Riegel, Cornell University. Evaluation of fungicide programs for control of powdery mildew on Rosette grapes, 2009.
Microthiol 80DF at 5.0 lb/A: 0% control on leaves. 74% control on leaf area. 0% control on clusters. 84% control on cluster area.
Microthiol 80DF at 10.0 lb/A: 13% control on leaves. 90% control on leaf area. 43% control on clusters. 93% control on cluster area.
Trial mean: 50% (n = 8).

3:SMF030. B. Hed and J. W. Travis, Penn State University. Evaluation of organic fungicides for control of black rot and powdery mildew of Concord grapes, 2008.
Cueva at 1%: 0% control. More disease than in the untreated control.
Milstop at 2.5 lb/A and 5 lb/A: 0% control. Same as the untreated control.

3:SMF031. B. Hed and J. W. Travis, Penn State University. Evaluation of alternative fungicides for control of black rot, powdery mildew, and downy mildew of grapes, 2008.
Cueva at 1%: 0% control. More disease than in the untreated control.

2:SMF004. B. Hed and J. W. Travis, Penn State University. Evaluation of organic fungicides for control of black rot and powdery mildew of Concord grapes, 2007.
Cueva at 1 gal/A: 26% and 39% control (fruit and rachis, respectively).
Cueva at 2 gal/A: 60% and 47% control (fruit and rachis, respectively).
Trial mean: 43% (n = 4).

Older studies are not cited and summarized.

OMRI-LISTED ALTERNATIVES: CROP GROUP 13: BERRIES AND SMALL FRUITS: STRAWBERRIES / Anthracnose Fruit Rot (*Colletotrichum acutatum*)

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Strawberries / Anthracnose Fruit Rot (*Colletotrichum acutatum*)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	86	2	See Oso efficacy summary table.	Control.	0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel 55	70051-108	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel LC	70051-114	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain MBI 600	Serifel	71840-18	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	None.
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if inhaled. May cause dermal sensitization. [F] Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None	Spray solution pH restrictions.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if inhaled.	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Optimum	264-1160	No data	NA	NA	Control. Preventative only. Not for use in California.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	None.
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3	No data	NA	NA	Suppression only. Preventative only.	0	4	None.	Moderate eye irritation.	None.	Avoid freezing.

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Strawberries / Anthracnose Fruit Rot (*Colletotrichum acutatum*)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Non-synthetic	NC; Biological	*Aureobasidium pullulans* strains DSM 14940 and DSM 14941	Botector	86174-3	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if swallowed or absorbed through skin. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live yeast-like fungus. Use and storage temperature restrictions. Not compatible with many fungicides.
Non-synthetic	NC; Biological	*Streptomyces lydicus* WYEC	Actinovate	73314-1	12	4	9:SMF007; 3:SMF019; 3:SMF023; 2:SMF045.	Anthracnose claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Field uses: Control vs suppression only is not specified. Greenhouse uses: Suppression only.	0	1 or until dry	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live bacterium. Use and storage temperature restrictions.
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)	No data	NA	NA	Control.	0	0	Yes.	Harmful if swallowed.	Toxic to bees.	Not for use near heat or open flames.
Synthetic	M1	Copper octanoate	Cueva	67702-25-70051	No data	NA	NA	Control.	0	4	Yes.	Harmful if swallowed or absorbed through skin.	Toxic to fish and aquatic organisms.	Do not store below 4°C (39°F). Tank-mix restrictions.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1	No data	NA	NA	Anthracnose control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541	No data	NA	NA	Control.	0	4	None.	Harmful if swallowed. Moderate eye irritation.	None.	Avoid contamination by pesticides and fertilizers. Final spray solution pH must be ≥7.0.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539	No data	NA	NA	Anthracnose control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Strawberries / Anthracnose Fruit Rot (*Colletotrichum acutatum*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	NC; Oxidizing agent	Hydrogen peroxide, Hydrogen dioxide	Perpose Plus	86729-1	No data	NA	NA	Anthracnose control claim for all agricultural crops. Preventative only.	0	Until dry	None.	Irreversible eye damage and skin burns. May be fatal if absorbed through skin. Harmful if swallowed.	Toxic to birds, mammals, fish, and aquatic life.	Chemical instabilities. Strong oxidizing agent. Storage restrictions.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative environmental toxicity descriptors, lowest toxicity to highest toxicity: Practically non-toxic < Moderately toxic < Toxic < Highly toxic.

Plant Disease Management Reports citations and data summaries:

9:SMF007. J. Mertely et al. Univ. Of Florida. Evaluation of products for anthracnose and Botrytis fruit rot control in annual strawberry, 2013-14.
Actinovate at 6 oz/A: 8% control of Anthracnose incidence.

3:SMF019. M. Rahman et al. North Carolina State Univ. Evaluation of fungicides to control anthracnose fruit rot on strawberry cultivar Chandler, 2008.
Actinovate WTEC at 108 (units?)/: 15% control of Anthracnose incidence.

3:SMF023. H. Su and W.D. Dubler. University of California. Fungicide control of Botrytis and anthracnose fruit rot on strawberry in California, 2008—trial II.
Actinovate at 6 oz/A: 28% control of Anthracnose incidence.

2:SMF045. J. Mertely et al. Univ. Of Florida. Evaluation of fungicides to control anthracnose fruit rot in annual strawberry, 2007-08.
Actinovate at 12 oz/A: 7% control of Anthracnose incidence.

OMRI-LISTED ALTERNATIVES: CROP GROUP 13: BERRIES AND SMALL FRUITS: STRAWBERRIES / Gray Mold (*Botrytis cinerea*)

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Strawberries / Gray Mold (*Botrytis cinerea*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	61	5	See Oso efficacy summary table.	Control.	0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel 55	70051-108	No data	NA	NA	Suppression only. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel LC	70051-114	2	2	9:SMF021; 9:SMF035.	Suppression only. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain F727	Stargus	84059-28	No data	NA	NA	Control. Preventative only. Not for use in California.	0	4	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Not for sale or use after 18 months from the date of manufacture. Avoid freezing.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain MBI 600	Serifel	71840-18	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	None.
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if inhaled. May cause dermal sensitization. [F] Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Spray solution pH restrictions.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Optiva	264-1160	No data	NA	NA	Suppression only. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152	0	1	9:SMF021.	Suppression only. Preventative only.	0	4	None.	Harmful if inhaled.	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151	19	1	F&N 59:SMF030.	Suppression only. Preventative only.	0	4	None.	May cause dermal sensitization. [F]	None.	None.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Strawberries / Gray Mold (*Botrytis cinerea*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Optimum	264-1160	16	5	11:SMF002; 10:SMF040; 9:SMF021; 9:SMF035; 8:SMF028.	Suppression only. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	None.
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3	2	2	11:SMF022; 9:SMF035.	Control. Preventative only.	0	4	None.	Moderate eye irritation.	None.	Avoid freezing.
Non-synthetic	NC; Bio-chemical	Rhamnolipid biosurfactant	Zonix	72431-1	No data			Botrytis control claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Preventative use only.	0	4	None.	Irreversible eye damage.	None.	Do not use at ambient temperatures over 80°F. Keep from overheating or freezing. Store out of direct sunlight.
Non-synthetic	NC; Biological	*Aureobasidium pullulans* strains DSM 14940 and DSM 14941	Botector	86174-3	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if swallowed or absorbed through skin. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live yeast-like fungus. Use and storage temperature restrictions. Not compatible with many fungicides.
Non-synthetic	NC; Biological	*Gliocladium catenulatum* strain J1446	Prestop	64137-11	0	1	11:SMF022	Botrytis claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	0	None.	Harmful if swallowed. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live organism. Store refrigerated. Tank-mix restrictions.
Non-synthetic	NC; Biological	*Streptomyces lydicus*	Actinovate AG	73314-1	17	3	11:SMF002; 9:SMF021; 3:SMF014.	Botrytis control claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Field uses: Control vs suppression only is not specified. Greenhouse uses: Suppression only.	0	1 or until dry	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live bacterium. Use and storage temperature restrictions.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Strawberries / Gray Mold (*Botrytis cinerea*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Non-synthetic	NC; Botanical oil	Cinnamon oil	Cinnerate	NA; 25(b)	No data	NA	NA	Control.	0	0	None.	Eye and skin irritation. May cause dermal sensitization. [F]	None.	Do not expose to light.
Non-synthetic	NC; Botanical oil	Clove oil, Rosemary oil, Peppermint oil	BacStop	NA; 25(b)	No data	NA	NA	Control.	0	0	None.	Temporary eye and skin irritation	No FIFRA statements.	Storage temperature restrictions.
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)	No data	NA	NA	Control.	0	0	Yes.	Harmful if swallowed.	Toxic to bees.	Not for use near heat or open flames.
Non-synthetic	NC; Botanical oil	Neem oil	Trilogy	70051-2	No data	NA	NA	Botrytis control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	4	Yes.	Moderate eye irritation.	Toxic to fish, aquatic organisms, and bees.	Temperature restrictions. Storage restrictions.
Synthetic	M1	Copper octanoate	Cueva	67702-2-70051	0	1	9:SMF035.	Control.	0	4	Yes.	Harmful if swallowed or absorbed through skin.	Toxic to fish and aquatic organisms.	Do not store below 4°C (39°F). Tank-mix restrictions.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1	No data	NA	NA	Botrytis control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541	No data	NA	NA	Control.	0	4	None.	Harmful is swallowed. Moderate eye irritation.	None.	Avoid contamination by pesticides and fertilizers. Final spray solution pH must be ≥7.0.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539	No data	NA	NA	Botrytis control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	1	None.	Harmful is swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate 2.0	70299-2	4	3	9:SMF021; F&N 59:SMF033; F&N 59:SMF048.	Control.	0	Until dry	None.	Irreversible eye damage. May be fatal if swallowed. Skin irritation.	Highly toxic to bees and other beneficial insects. Toxic to fish.	Chemical instabilities. Strong oxidizing agent. Use and storage temperature restrictions.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Strawberries / Gray Mold (*Botrytis cinerea*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	NC; Oxidizing agent	Hydrogen peroxide, Hydrogen dioxide	Perpose Plus	86729-1	No data	NA	NA	Botrytis control claim for all agricultural crops. Preventative only.	0	Until dry	None.	Irreversible eye damage and skin burns. May be fatal if absorbed through skin. Harmful if swallowed.	Toxic to birds, mammals, fish, and aquatic life.	Chemical instabilities. Strong oxidizing agent. Storage restrictions.
Synthetic	NC; Petroleum oil	Mineral oil	JMS Stylet Oil	65564-1	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed.	Toxic to fish.	None.
Synthetic	NC; Petroleum oil	Mineral oil	PureSpray Green	69526-9	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed or absorbed through skin. May cause dermal sensitization. [F]	Toxic to aquatic organisms.	None.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative environmental toxicity descriptors, lowest toxicity to highest toxicity: Practically non-toxic < Moderately toxic < Toxic < Highly toxic.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Strawberries / Gray Mold (*Botrytis cinerea*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical

Plant Disease Management Reports citations and data summaries for non-synthetic alternatives.

11:SMF002. R. C. Brantley, K.L. Ivors, and G. J. Holmes, California Polytechnic State University. Evaluation of biofungicides for Botrytis fruit rot management on strawberries, 2016.
Actinovate SP at 6 oz/A: No control of Botrytis fruit rot incidence for the season.
Actinovate SP at 12 oz/A: No control of Botrytis fruit rot incidence for the season.
Serenade Optimum at 20 oz/A: No control of Botrytis fruit rot incidence for the season.

11:SMF022. L. Cordova, A. Zuniga, *et al.*, University of Florida. Evaluation of biorational products for control of Botrytis fruit rot in annual strawberry, 2016-17.
Regalia at 52 fl oz/A: 3% control of Botrytis fruit rot for the season.
Prestop WG at 12.5 oz/A: No control of Botrytis fruit rot for the season. Botrytis fruit rot incidence was higher than in the untreated control.

10:SMF040. L. Cordova, J. Mertely, and N.A. Peres, University of Florida. Evaluation of biorational products for control of Botrytis fruit rot in annual strawberry, 2015-2016.
Serenade Optimum at 16 oz/A weekly: 38% control of Botrytis incidence on fruit during the growing season.
Serenade Optimum at 16 oz/A twice weekly: 62% control of Botrytis incidence on fruit during the growing season.
Trial mean: 50% control (n = 2).

9:SMF021. L. Cordova, J. Mertely, and N.A. Peres, University of Florida. Evaluation of biorational products for control of Botrytis fruit rot in annual strawberry, 2014-2015.
Actinovate 6 oz/A: No control of Botrytis Fruit rot. More Botrytis than in the untreated control for the season.
Double Nickel (formulation not specified; LC assumed) at 1.5 qt/A : 4% control of Botrytis fruit rot for the season.
Regalia at 2 qt/A: 9% control of Botrytis fruit rot for the season.
Serenade ASO at 4 qt/A: No control of Botrytis fruit rot. More Botrytis than in the untreated control for the season.
Serenade Optimum at 1 lb/A: 5% control of Botrytis fruit rot for the season.

9:SMF035. A. M. Schilder. J. M. Gillett, and R. W. Sysak, Michigan State University. Evaluation of organic fungicides for control of strawberry foliar and fruit diseases, 2014.
Double Nickel LC at 1 gal/acre: No control. More post-harvest Botrytis than in the untreated control.
Serenade Optimum at 20 oz/A + NuFilm P at 0.125% (v/v): No control. More post-harvest Botrytis than in the untreated control.
Regalia at 2 qt/acre: No control. More post-harvest Botrytis than in the untreated control.

8:SMF028. L. Cordova, A. Zuniga, *et al.*, University of Florida. Evaluation of products for the control of Botrytis fruit rot in annual strawberry, 2013-14.
Serenade Optimum at 20 fl oz/A: 13% control of Botrytis at peak period. 34% control of Botrytis for season. Trial mean: 24% control (n = 2).

3:SMF014. J. Mertley, T. Seijo, *et al.*, University of Florida. Evaluation of fungicides for control of Botrytis and other fruit rots in annual strawberry, 2007-08.
Actinovate at 12 oz/A at 7-day intervals: 52% control of Botrytis incidence. (6% incidence in the untreated control; low disease pressure.)

F&N 59:SMF030. A. M. Schilder. J. M. Gillett, and R. W. Sysak, Michigan State University. Evaluation of fungicides for control of foliar and fruit diseases of strawberry, 2003.
Serenade (formulation not specified; Max assumed based upon units) at 8 lb/A: 49%, 9.1% and No control (at 3 harvest times). Trial mean = 19% control (n = 3).

Data for trials with very low disease pressure in the untreated control are not summarized (F&N 60:SMF021, 1:SMF028).

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Strawberries / Gray Mold (*Botrytis cinerea*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical

Plant Disease Management Reports citations and data summaries for synthetic alternatives.

9:SMF021. L. Cordova, J. Mertely, and N. A. Peres, University of Florida. Evaluation of biorational products for control of Botrytis fruit rot in annual strawberry, 2014-2015.
Oxidate at 128 fl oz/A: No control of Botrytis fruit rot incidence for the season. More disease than in the untreated control.

9:SMF035. A. M. Schilder. J. M. Gillett, and R. W. Sysak, Michigan State University. Evaluation of organic fungicides for control of strawberry foliar and fruit diseases, 2014.
Cueva at 1 gal/acre: No control. More post-harvest Botrytis than in the untreated control.

F&N 59:SMF033. W. W. Turechek, N.A. Werner, and M.C. Heidenreich, Cornell University. Evaluation of fungicides for control of Botrytis fruit rot on strawberry, 2003.
Oxidate at 128 fl oz/A: No control post-harvest. More Botrytis than in the untreated control.

F&N 59:SMF048. F. J. Louws and J. G. Driver, North Carolina Stat University. Evaluation of fungicides for anthracnose fruit rot and gray mold management, 2003.
Oxidate at 128 fl oz/100 gal and 128 fl oz/300 gal: 11% control of Botrytis.

Data for trials with very low disease pressure in the untreated control are not summarized (F&N 60:SMF021, 1:SMF028).

OMRI-LISTED ALTERNATIVES: CROP GROUP 13: BERRIES: STRAWBERRIES / Leather Rot (*Phytophthora cactorum*)

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Strawberries / Leather Rot (*Phytophthora cactorum*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	86	2	See Oso efficacy summary table.	Control.	0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	BM2	*Trichoderma asperellum, Trichoderma gamsii*	Bio-Tam	80289-9	No data.	NA	NA	Phytophthora control claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Preventative only.	0	1	None.	Harmful if absorbed through skin or swallowed.	Toxic to beneficial beetle species.	Use and storage temperature restrictions.15-month shelf-life.
Non-synthetic	BM2	*Trichoderma harzianum* strain R-22, *Trichoderma virens* strain G41	Rootshield Plus+ Granules	68539-10	No data.	NA	NA	Phytophthora control claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Preventative only.	0	0	None.	Moderate eye irritation. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live spores. Use temperature restrictions. Store refrigerated.
Non-synthetic	BM2	*Trichoderma harzianum* strain R-22, *Trichoderma virens* strain G41	Rootshield Plus+ WP	68539-9	No data.	NA	NA	Phytophthora control claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Preventative only.	0	4	None.	Moderate eye irritation. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live spores. Use temperature restrictions. Store refrigerated.
Non-synthetic	NC; Biological	*Aureobasidium pullulans* strains DSM 14940 and DSM 14941	Botector	86174-3	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if swallowed or absorbed through skin. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live yeast-like fungus. Use and storage temperature restrictions. Not compatible with many fungicides.
Non-synthetic	NC; Biological	*Gliocladium catenulatum*	Prestop	64137-11	No data.	NA	NA	Soil treatment only.	0	0	None.	Harmful if swallowed. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live organism. Store refrigerated. Tank-mix restrictions.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Strawberries / Leather Rot (*Phytophthora cactorum*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative environmental toxicity descriptors, lowest toxicity to highest toxicity: Practicaly non-toxic < Moderately toxic < Toxic < Highly toxic.

OMRI-LISTED ALTERNATIVES: CROP GROUP 13: BERRIES: STRAWBERRIES / Phomopsis Leaf Spot (Blight) (*Phomopsis obscurans*)

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Strawberries / Phomopsis Leaf Spot (Blight) (*Phomopsis obscurans*)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	91	2	See Oso efficacy summary table.		0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3	54	1	9:SMF035	Control.	0	4	None.	Moderate eye irritation.	None.	Avoid freezing.
Non-synthetic	NC; Biological	*Aureobasidium pullulans* strains DSM 14940 and DSM 14941	Botector	86174-3	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if swallowed or absorbed through skin. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live yeast-like fungus. Use and storage temperature restrictions. Not compatible with many fungicides.
Synthetic	M1	Copper octanoate	Cueva	67702-2-70051	94	1	9:SMF035	Control.	0	4	Yes.	Harmful if swallowed or absorbed through skin.	Toxic to fish and aquatic organisms.	Do not store below 4°C (39°F). Tank-mix restrictions.
Synthetic	M1	Cupric hydroxide	Nu-Cop 50 DF	45002-4	No data	NA	NA	Control.	1	24	Yes.	Irreversible eye damage. Harmful if swallowed or absorbed through skin. May cause dermal sensitization. [F]	Toxic to fish and aquatic organisms.	Damages aluminum.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1	No data	NA	NA	Phomopsis control claim. Leaf vs fruit not specified. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539	No data	NA	NA	Phomopsis control claim. Leaf vs fruit not specified. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Strawberries / Phomopsis Leaf Spot (Blight) (*Phomopsis obscurans*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative environmental toxicity descriptors, lowest toxicity to highest toxicity: Practically non-toxic < Moderately toxic < Toxic < Highly toxic.

Plant Disease Management Reports citations and data summaries:

9:SMF035. A. Schilder *et al.*, Michigan State University. Evaluation of organic fungicides for control of strawberry foliar and fruit diseases, 2014.
Regalia at 2 qt/A: 54% control of Phomopsis leaf blight.
Cueva at 1 gal/A: 94% control of Phomopsis leaf blight.

OMRI-LISTED ALTERNATIVES: CROP GROUP 13: BERRIES: STRAWBERRIES / Phomopsis Fruit Rot (Soft Rot) (*Phomopsis obscurans*)

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Strawberries / Phomopsis Fruit Rot (*Phomopsis obscurans*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	80	1	See Oso efficacy summary table.		0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	NC; Biological	*Aureobasidium pullulans* strains DSM 14940 and DSM 14941	Botector	86174-3	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if swallowed or absorbed through skin. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live yeast-like fungus. Use and storage temperature restrictions. Not compatible with many fungicides.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1	No data	NA	NA	Phomopsis control claim. Leaf vs fruit not specified. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539	No data	NA	NA	Phomopsis control claim. Leaf vs fruit not specified. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative environmental toxicity descriptors, lowest toxicity to highest toxicity: Practically non-toxic < Moderately toxic < Toxic < Highly toxic.

OMRI-LISTED ALTERNATIVES: CROP GROUP 13: BERRIES: STRAWBERRIES / Powdery Mildew (*Podosphaera aphanis*)

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 13: Berries and Small Fruits: Strawberries / Powdery Mildew (*Podosphaera aphanis*, *Sphacelotheca* sp.)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	66	3	See Oso efficacy summary table.		0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel 55	70051-108	No data	NA	NA	Suppression only. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel LC	70051-114	No data	NA	NA	Suppression only. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain MBI 600	Serifel	71840-18	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	None.
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153	No data	NA	NA	Control. Preventative only.	0	4	None.	Harmful if inhaled. May cause dermal sensitization. [F] Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Spray solution pH restrictions.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152	No data	NA	NA	Suppression only. Preventative only.	0	4	None.	Harmful if inhaled.	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151	2	1	3:SMF016.	Suppression only. Preventative only.	0	4	None.	May cause dermal sensitization. [F]	None.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Optimum	264-1160	No data	NA	NA	Suppression only. Preventative only. Not for use in California.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	None.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Strawberries / Powdery Mildew (*Podosphaera aphanis*, *Sphacelotheca* sp.)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Non-synthetic	NC; Bio-chemical	Rhamnolipid biosurfactant	Zonix	72431-1	No data	NA	NA	Powdery mildew control claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Preventative use only.	0	4	None.	Irreversible eye damage.	None.	Do not use at ambient temperatures over 80°F. Keep from overheating or freezing. Store out of direct sunlight.
Non-synthetic	NC; Biological	*Streptomyces lydicus* WYEC	Actinovate	73314-1	No data	NA	NA	Powdery mildew claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Field uses: Control vs suppression only is not specified. Greenhouse uses: Suppression only.	0	1 or until dry	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live bacterium. Use and storage temperature restrictions.
Non-synthetic	NC; Botanical oil	Neem oil	Trilogy	70051-2	No data	NA	NA	Powdery mildew control. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	4	Yes.	Moderate eye irritation.	Toxic to fish, aquatic organisms, and bees.	Temperature restrictions. Storage restrictions.
Non-synthetic	NC; Botanical oil	Cinnamon oil	Cinnerate	NA; 25(b)	No data	NA	NA	Control.	0	0	None.	Eye and skin irritation. May cause dermal sensitization. [F]	None.	Do not expose to light.
Non-synthetic	NC; Botanical oil	Garlic oil, Cottonseed oil, Corn oil	Mildew Cure	NA; 25(b)	No data	NA	NA	General powdery mildew claim; not crop specific.	0	0	None.	Avoid contact with skin, eyes, and clothing.	No FIFRA statement.	None.
Non-synthetic	NC; Botanical oil	Clove oil, Rosemary oil, Peppermint oil	BacStop	NA; 25(b)	No data	NA	NA	Control.	0	0	None.	Temporary eye and skin irritation	No FIFRA statements.	Storage temperature restrictions.
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)	No data	NA	NA	Control.	0	0	Yes.	Harmful if swallowed.	Toxic to bees.	Not for use near heat or open flames.
Non-synthetic	NC; Botanical oil	Soybean oil	Golden Pest Spray	57538-11	No data	NA	NA	Control.	0	4	Yes.	Harmful if swallowed, absorbed through skin, or inhaled. Moderate eye irritation	None.	Temperature restrictions on use.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Strawberries / Powdery Mildew (*Podosphaera aphanis*, *Sphacelotheca* sp.)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	M1	Copper octanoate	Cueva	67702-2-70051	No data	NA	NA	Control.	0	4	Yes.	Harmful if swallowed or absorbed through skin.	Toxic to fish and aquatic organisms.	Do not store below 4°C (39°F). Tank-mix restrictions.
Synthetic	M2	Sulfur	Acoidal	62562-4	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin.	Toxic to fish and aquatic organisms.	Suspended dust ignites easily.
Synthetic	M2	Sulfur	Cosavet-DF	70905-1	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin. Moderate eye irritation.	None.	Suspended dust ignites easily.
Synthetic	M2	Sulfur	Defend DF	62562-8	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin.	Toxic to fish and aquatic organisms.	Suspended dust ignites easily.
Synthetic	M2	Sulfur	Kumulus DF	51306-352-66330	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed. Avoid contact with eyes, skin, and clothing.	None.	Do not store above 104°F.
Synthetic	M2	Sulfur	Micro Sulf	55146-75	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin. Eye irritation.	None.	Keep away from heat, sparks, or flames.
Synthetic	M2	Sulfur	Microthiol Disperss	70506-187	64	4	3:SMF016; 2:SMF042; F&N 61:SMF009; F&N 60:SMF006.	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin.	None.	Do not store near flammable materials.
Synthetic	M2	Sulfur	Thiolux	34704-1079	No data	NA	NA	Control.	0	24	Yes.	Harmful if swallowed, inhaled, or absorbed through skin. Eye irritation.	None.	Suspended dust ignites easily.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1	No data	NA	NA	Powdery mildew control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541	No data	NA	NA	Control.	0	4	None.	Harmful if swallowed. Moderate eye irritation.	None.	Avoid contamination by pesticides and fertilizers. Final spray solution pH must be ≥7.0.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Kaligreen	70231-1	23	1	F&N 56:SMF47	General powdery mildew control claim.	1	4	None.	Harmful if swallowed.	None.	Chemical incompatibilities.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Strawberries / Powdery Mildew (*Podosphaera aphanis*, *Sphacelotheca* sp.)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70871-1-68539	No data	NA	NA	Powdery mildew control claim. Mix-and-match directions for use. [E] No specific crop/disease claims.	1	4	None.	Harmful if swallowed. Moderate eye irritation	None.	Chemical incompatibilities.
Synthetic	NC; Inorganic salt	Potassium silicate	Sil-Matrix	82100-1	No data	NA	NA	General powdery mildew control claim. Preventative only.	0	4	None.	Moderate eye irritation.	None.	Chemical incompatibilities.
Synthetic	NC; Organic salt	Potassium salts of fatty acids	M-Pede	10163-324	No data	NA	NA	Control.	0	12	Yes.	Substantial eye injury. Skin irritation.	Harmful to aquatic invertebrates	If water has high mineral content, check for compatibility.
Synthetic	NC; Organic salt	Insecticidal soap	Des-X	67702-22-70051	No data	NA	NA	Control.	0	12	Yes.	Substantial eye injury. Skin irritation.	Harmful to aquatic invertebrates	If water has high mineral content, check for compatibility.
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate	70299-2	10	1	2:SMF042	Control.	0	Until dry	None.	Irreversible eye damage. May be fatal if swallowed. Skin irritation.	Highly toxic to bees and other beneficial insects. Toxic to fish.	Chemical instabilities. Strong oxidizing agent. Use and storage temperature restrictions.
Synthetic	NC; Oxidizing agent	Hydrogen peroxide, Hydrogen dioxide	Perpose Plus	86729-1	No data	NA	NA	Powdery mildew control claim for all agricultural crops. Preventative only.	0	Until dry	None.	Irreversible eye damage and skin burns. May be fatal if absorbed through skin. Harmful if swallowed.	Toxic to birds, mammals, fish, and aquatic life.	Chemical instabilities. Strong oxidizing agent. Storage restrictions.
Synthetic	NC; Petroleum oil	Mineral oil	Glacial Spray Liquid	34704-849	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed, inhaled, or absorbed through skin. Eye irritation. May cause dermal sensitization. [F]	Hazardous to aquatic organisms.	None.
Synthetic	NC; Petroleum oil	Mineral oil	JMS Stylet Oil	65564-1	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed.	Toxic to fish.	None.
Synthetic	NC; Petroleum oil	Mineral oil	Omni Supreme Spray	5905-368	No data	NA	NA	Control.	0	12	Yes (with sulfur).	Harmful if absorbed through skin. May cause dermal sensitization. [F]	Toxic to fish and aquatic organisms.	Chemical incompatibilities.
Synthetic	NC; Petroleum oil	Mineral oil	PureSpray Green	69526-9	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed or absorbed through skin. May cause dermal sensitization. [F]	Toxic to aquatic organisms.	None.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Strawberries / Powdery Mildew (*Podosphaera aphanis*, *Sphacelotheca* sp.)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	NC; Petroleum oil	Mineral oil	SuffOil-X	48813-1-68539	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed. May cause dermal sensitization. [F]	Toxic to aquatic organisms.	None.
Synthetic	NC; Petroleum oil	Mineral oil	TriTek	48813-1	No data	NA	NA	Control.	0	4	Yes (with sulfur).	Harmful if swallowed or absorbed through skin. May cause dermal sensitization. [F]	Toxic to aquatic organisms.	None.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative environmental toxicity descriptors, lowest toxicity to highest toxicity: Practically non-toxic < Moderately toxic < Toxic < Highly toxic.

Plant Disease Management Reports citations and data summaries:

3:SMF016. J. Mertely, T. Seijo, *et al.*, University of Florida. Evaluation of fungicides to control powdery mildew on annual strawberry, 2007-08.
Serenade Max at 1 lb/A: No control of powdery mildew on fruit (more disease than in the untreated control). No control and 5% control of powdery mildew on leaves. Mean control: 2% (n = 3.
Microthiol Disperss 80 WP at 7.5 lb/A: 81% and 95% control of powdery mildew on fruit. 26%, 30%, 33%, and 60% control of powdery mildew on leaves. Mean control: 54% (n = 6).

2:SMF042. J. Mertely, T. Seijo, *et al.*, University of Florida. Evaluation of fungicides to control powdery mildew on annual strawberry, 2006-07.
Microthiol Disperss 80WP at 7.5 lb/A: 71% control of powdery mildew on fruit.
Oxidate at 84 fl oz/A: 10% control of powdery mildew on fruit.

F&N 61:SMF009. J. Mertely, T. Seijo, *et al.*, University of Florida. Evaluation of fungicides to control powdery mildew on annual strawberry, 2004-05.
Microthiol Disperss 80 WP at 7.5 lb/A: 12% control of powdery mildew on foliage. 71% control of powdery mildew on fruit. Mean control: 41% (n = 5).

F&N 60:SMF006. J. Mertely, T. Seijo, and N. A. Peres, University of Florida. Evaluation of fungicides to control powdery mildew on annual strawberry, 2003-04.
Microthiol Disperss 80 WP at 7.5 lb/A: 90% control of powdery mildew incidence on fruit.

F&N 56:SMF47. D. E. Legard, C. L. Xiao, et al., University of Florida. Evaluation of fungicides to control powdery mildew of strawberry, 2000
Kaligreen 82WP at 3 lb/A at 7-day intervals: 23% control of powdery mildew.

OMRI-LISTED ALTERNATIVES: CROP GROUP 19: HERBS AND SPICES: BASIL / Downy Mildew (*Peronospora belbahrii*)

Comparative Overview of Efficacy, Hazards, and Use Restrictions Crop Group 19: Herbs and Spices : Basil / Downy Mildew (*Peronospora belbahrii*)														
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	52	1	See Oso efficacy summary table.	Control.	0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel 55	70051-108	40	1	11:V030	Suppression only. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel LC	70051-114	No data	NA	NA	Suppression only. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3	14	6	9:V001; 7:V015; 6:V059; 6:V099; 5:V098; 5:V155.	Control. Preventative only.	0	4	None.	Moderate eye irritation.	None.	Avoid freezing.
Non-synthetic	NC; Biological	*Streptomyces lydicus* WYEC	Actinovate	73314-1	No data	NA	NA	Downy mildew claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Field uses: Control vs suppression only is not specified. Greenhouse uses: Suppression only.	0	1 or until dry	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Live bacterium. Use and storage temperature restrictions.
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1	No data	NA	NA	Downy mildew control claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Not for use in California.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 19: Herbs and Spices : Basil / Downy Mildew (*Peronospora belbahrii*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539	13	2	7:V045; 6:V073.	Downy mildew control claim. Mix-and-match directions for use. [E] No specific crop/disease claims. Not for use in California.	0	1	None.	Harmful if swallowed. Moderate eye irritation.	None.	Mild alkaline solution; tank-mix restrictions.
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate	70299-2	20	1	6:V073	Control.	0	Until dry	None.	Irreversible eye damage. May be fatal if swallowed. Skin irritation.	Highly toxic to bees and other beneficial insects. Toxic to fish.	Chemical instabilities. Strong oxidizing agent. Use and storage temperature restrictions.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative environmental toxicity descriptors, lowest toxicity to highest toxicity: Practically non-toxic < Moderately toxic < Toxic < Highly toxic.

Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 19: Herbs and Spices : Basil / Downy Mildew (*Peronospora belbahrii*)

NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Plant Disease Management Reports Citations and data summaries for non-synthetic alternatives:														
11:V030. M. T. McGrath and Z. F. Sexton, Cornell University. Evaluation of biopesticides and an organic copper fungicide for downy mildew in sweet basil, 2016. Double Nickel 55 at 3 lb/acre, August 2, 2016: 41.9%, 25.9%, and 52.8% control of incidence. Trial mean: 40.2% control (n = 3).														
9:V001. S. B. Scheufel et al., Univ. of Massachusetts. Evaluation of copper fungicides for management of basil downy mildew in organic systems, 2014. Regalia at 4 qt/A: 0.8% control of downy mildew on basil.														
7:V015. M.T. McGrath and K. A Lamarsh, Cornell University. Evaluation of fungicides for managing downy mildew in basil, 2012. Regalia at 0.5%: 15.6% control of downy mildew on basil leaves.														
6:V059. Z. Mercha et al., Univ. Of Florida, Evaluation of biologicals and biorationals for control of basil downy mildew under greenhouse conditions, 2010. Regalia SC at 1%: 10.3% and 26.0% control of downy mildew severity on basil leaves in two different experiments. Trial mean: 18% control (n = 2).														
6:V099. M.T. McGrath and L.K. Hunsberger, Cornell University. Evaluation of biopesticides for managing downy mildew in basil, 2011. Regalia (1%): 28.4% control of downy mildew incidence on basil.														
5:V098. M.T. McGrath and L.K. Nunsberger, Cornell University. Evaluation of biopesticides for managing downy mildew in basil, 2010. Regalia (1% v/v): No control of downy mildew on basil. Disease severity exceeded that in the untreated control.														
5:V155. R. N. Raid, University of Florida. Evaluation of Regalia, alone and in tank-mixture, for control of basil downy mildew, Fall 2010. Regalia (1% v/v)/A: 23% control of downy mildew severity.														
Plant Disease Management Reports Citations and data summaries for synthetic alternatives:														
7:V045. J.E. Allen and M. Saska, University of Connecticut. Basil downy mildew control using organic fungicides and nitrogen fertilization rate, 2012. Milstop at 2.5 lb/A, 5 or 6 application beginning August 2 or 3, 2012: 0% to 2% control of downy mildew on basil. Trial mean: 1% control (n = 2).														
6:V073. J.E. Allen and A. Patrie, University of Connecticut. Evaluation of organic control products for basil downy mildew, 2011. Milstop at 2.5 lb/A, 5 applications: 16.8% and 33.8% control of downy mildew on basil. Trial mean: 25.3% control (n = 2). Oxidate at 0.6 gal/A with Yucca Ag-Aide at 0.125% (v/v)/A: 13.9% and 25.8% control of down mildew on basil. Trial mean: 19.9% control (n = 2).														

STEP 3: Identification of Relative Efficacy for Non-Synthetic and Synthetic OMRI-Listed Alternative Products

METHODOLOGY

The tables from Step 2 were reviewed to separately quantify for non-synthetic and synthetic OMRI-listed alternative products the number of OMRI-listed products for each crop/disease combination having:

- Mean efficacy comparable to greater than the polyoxin D zinc salt 5SC formulation (a.k.a. Oso);
- Mean efficacy less than comparable to Oso but more than 50% to mean efficacy of Oso;
- Mean efficacy less than 50% of the mean efficacy of Oso; and
- No efficacy data published in Plant Disease Management Reports (going back to 2000).

Products with mean efficacy comparable or greater than the polyoxin D zinc salt 5SC formulation were identified for further consideration.

Overview of Efficacy Comparisons of Oso to OMRI-Listed Alternatives

Disease (Pathogen)	EPA Registered, OMRI-Listed Alternative Products											
	Non-Synthetic						Synthetic					
	FRAC Codes (Modes of Action) or Non-Classified AI Type		Number of Alternative Products				FRAC Codes (Modes of Action) or Non-Classified AI Type		Number of Alternative Products			
	Total	FRAC Code [A]	Mean Efficacy Comparable to or Greater than Oso	Mean Efficacy Less than Comparable to Oso to 50% Oso	Mean Efficacy Less than 50% Oso	No Efficacy Data	Total	FRAC Code [A]	Mean Efficacy Comparable to or Greater than Oso	Mean Efficacy Less than Comparable to Oso to 50% Oso	Mean Efficacy Less than 50% Oso	No Efficacy Data
Crop Group 13: Blueberries												
Alternaria fruit rot (*Alternaria* spp.)	4	44 (*Bacillus*); P5 (Regalia); Biological; Botanical oil.	0	0	0	9	1	Oxidizing agent.	0	0	0	1
Botrytis blight (*Botrytis cinerea*)	4	44 (*Bacillus*); P5 (Regalia); Biological; Botanical oil.	0	1	2	11	2	Inorganic salt; Oxidizing agent.	0	0	0	6
Mummyberry (*Monilinia vaccinii-corymbosi*)	4	44 (*Bacillus*); P5 (Regalia); Biological; Botanical oil.	1 (Optiva)	2	3	5	2	Inorganic salt; Oxidizing agent.	0	0	0	2

Overview of Efficacy Comparisons of Oso to OMRI-Listed Alternatives

Disease (Pathogen)	EPA Registered, OMRI-Listed Alternative Products											
	Non-Synthetic						Synthetic					
	FRAC Codes (Modes of Action) or Non-Classified AI Type		Number of Alternative Products				FRAC Codes (Modes of Action) or Non-Classified AI Type		Number of Alternative Products			
	Total	FRAC Code [A]	Mean Efficacy Comparable to or Greater than Oso	Mean Efficacy Less than Comparable to Oso to 50% Oso	Mean Efficacy Less than 50% Oso	No Efficacy Data	Total	FRAC Code [A]	Mean Efficacy Comparable to or Greater than Oso	Mean Efficacy Less than Comparable to Oso to 50% Oso	Mean Efficacy Less than 50% Oso	No Efficacy Data
Crop Group 13: Caneberries												
Botrytis fruit rot (*Botrytis cinerea*)	5	44 (*Bacillus*); P5 (Regalia); Biochemical; Biological; Botanical oil.	0	1	3	8	3	M1 (copper); Inorganic salt; Oxidizing agent.	0	0	1	4
Powdery mildew (*Podosphaera aphanais*)	6	44 (*Bacillus*); P5 (Regalia); Biochemical; Biological; Botanical oil; Organic acid.	0	0	0	11	5	M2 (sulfur); Inorganic salt; Organic salt; Oxidizing agent; Petroleum oil.	0	0	0	22
Crop Group 13: Cranberries												
Cottonball (*Monilinia oxycocci*)	0	No applicable.	0	0	0	0	0	No applicable.	0	0	0	0
Fruit rot complex (*Coleophoma empetri*, *Colletotrichum acutatum*, *Colletotrichum gloeosporioides*, *Phyllosticta vaccinii*, and *Physalospora vaccinii*, etc.)	0	No applicable.	0	0	0	0	1	M1 (copper).	0	0	1	5

Overview of Efficacy Comparisons of Oso to OMRI-Listed Alternatives

Disease (Pathogen)	EPA Registered, OMRI-Listed Alternative Products											
	Non-Synthetic						Synthetic					
	FRAC Codes (Modes of Action) or Non-Classified AI Type		Number of Alternative Products				FRAC Codes (Modes of Action) or Non-Classified AI Type		Number of Alternative Products			
	Total	FRAC Code [A]	Mean Efficacy Comparable to or Greater than Oso	Mean Efficacy Less than Comparable to Oso to 50% Oso	Mean Efficacy Less than 50% Oso	No Efficacy Data	Total	FRAC Code [A]	Mean Efficacy Comparable to or Greater than Oso	Mean Efficacy Less than Comparable to Oso to 50% Oso	Mean Efficacy Less than 50% Oso	No Efficacy Data
Crop Group 13: Grapes												
Black rot (*Guignardia bidwellii*)	3	44 (*Bacillus*); P5 (Regalia); Botanical oil	0	0	1	3	1	M1(copper).	2 (Badge X2, Nu-Cop 50 WP)	1	1	6
Bunch rot (*Botrytis cinerea*)	4	44 (*Bacillus*); P5 (Regalia); Biological; Botanical oil	2 (Double Nickel 55 and LC)	2	3	9	3	Inorganic salt; Oxidizing agent; Petroleum oil.	0	0	3	6
Downy mildew (*Plasmopara viticola*)	4	44 (*Bacillus*); P5 (Regalia); Biological; Botanical oil	0	1	1	10	3	M1 (copper); Inorganic salt; Oxidizing agent.	3 (Badge X2, Cueva, Oxidate)	0	0	13
Phomopsis fruit rot (*Phomopsis viticola*)	3	44 (*Bacillus*); P5 (Regalia); Botanical oil	0	0	0	10	3	M1 (copper); M2 (sulfur); Inorganic salt	0	0	1	13
Powdery mildew (*Erisyphe necator*)	5	44 (*Bacillus*); P5 (Regalia); Biological; Botanical oil; Organic acid.	0	0	4	14	6	M1 (copper); M2 (sulfur); Inorganic salt; Organic salt; Oxidizing agent; Petroleum oil.	1 (Micro Sulf)	3	2	24

Overview of Efficacy Comparisons of Oso to OMRI-Listed Alternatives

Disease (Pathogen)	EPA Registered, OMRI-Listed Alternative Products											
	Non-Synthetic						Synthetic					
	FRAC Codes (Modes of Action) or Non-Classified AI Type		Number of Alternative Products				FRAC Codes (Modes of Action) or Non-Classified AI Type		Number of Alternative Products			
	Total	FRAC Code [A]	Mean Efficacy Comparable to or Greater than Oso	Mean Efficacy Less than Comparable to Oso to 50% Oso	Mean Efficacy Less than 50% Oso	No Efficacy Data	Total	FRAC Code [A]	Mean Efficacy Comparable to or Greater than Oso	Mean Efficacy Less than Comparable to Oso to 50% Oso	Mean Efficacy Less than 50% Oso	No Efficacy Data
Crop Group 13: Strawberries												
Anthracnose fruit rot (*Colletotrichum acutatum*)	4	44 (*Bacillus*); P5 (Regalia); Biological; Botanical oil.	0	0	1	9	3	M1 (copper); Inorganic salt; Oxidizing agent.	0	0	0	5
Gray mold (*Botrytis cinerea*)	5	44 (*Bacillus*); P5 (Regalia); Biochemical; Biological; Botanical oil.	0	0	7	11	4	M1 (copper); Inorganic salt; Oxidizing agent; Petroleum oil.	0	0	2	6
Leather rot (*Phytophthora cactorum*)	2	BM2; Biological.	0	0	0	5	0	No applicable.	0	0	0	0
Phomopsis leaf spot (blight) (*Phomopsis obscurans*)	2	P5 (Regalia); Biological.	0	1	0	1	2	M1 (copper); Inorganic salt.	1 (Cueva)	0	0	3
Phomopsis fruit rot (Soft rot) (*Phomopsis obscurans*)	1	Biological.	0	0	0	1	1	Inorganic salt.	0	0	0	2
Powdery mildew (*Podosphaera aphanis*)	4	44 (*Bacillus*); Biochemical; Biological; Botanical oil.	0	0	1	14	6	M1 (copper); M2 (sulfur); Inorganic salt; Organic salt; Oxidizing agent; Petroleum oil.	1 (Microthiol Disperss)	1	1	20
Crop Group 19: Basil												
Downy mildew (*Peronospora belbahrii*)	3	44 (*Bacillus*); P5 (Regalia); Biological	0	1	1	2	2	Inorganic salt; Oxidizing agent.	0	0	2	1

A. Examples of active ingredients with listed FRAC Code or not classified active ingredient types:

Biochemical:	*Rhamnolipdi* biosurfactant (Zonix).
Biological:	*Aureobasidium pullulans* (Botector), *Gliocladium catenulatum* (Prestop) *Streptomyces lydicus* (Actinovate), and *Ulacladium ouderansii* (Zen-O-Spore).
Botanical oil:	Cinnamon oil, Clove oil, Corn oil, Cotton seed oil, Garlic oil, Neem oil, Rosemary oil, and Thyme oil.
BM2:	*Trichoderma* spp. (Bio-Tam and Rootshield).
Inorganic salt:	Potassium bicarbonate and Potassium silicate.
Organic acid:	Citric acid.
Organic salt:	Insecticidal soap and Potassium salts of fatty acids.
Oxidizing agent:	Hydrogen dioxide, Hydrogen peroxide, and Peroxyacetic acid.
Petroleum oil:	Aliphatic petroleum solvent and Mineral oil.

CONCLUSIONS: Based upon *disease economic significant and efficacy data alone*, there is organic grower need for the polyoxin D zinc salt 5SC formulation for treatment of:

- **Blueberries for control of:**
  - **Alternaria blight (*Alternaria* spp.); and**
  - **Botrytis blight (*Botrytis cinerea*);**
- **Caneberries for control of:**
  - **Botrytis fruit rot (*Botrytis cinerea*); and**
  - **Powdery mildew (*Podosphaera aphanais*);**
- **Cranberries for control of:**
  - **Cottonball (Monilinia oxycocci); and**
  - **Fruit rot complex (*Coleophoma empetri*, *Colletotrichum acutatum*, *Colletotrichum gloeosporioides*, *Phyllosticta vaccinii*, and *Physalospora vaccinii*, etc.);**
- **Grapes for control of:**
  - **Phomopsis fruit rot (*Phomopsis viticola*);**
- **Strawberries for control of:**
  - **Anthracnose fruit rot (*Colletotrichum acutatum*);**
  - **Gray mold (*Botrytis cinerea*);**
  - **Leather rot (*Phytophthora cactorum*); and**
  - **Phomopsis fruit rot (soft rot) (*Phomopsis obscurans*); and**
- **Basil for control of:**
  - **Downy mildew (*Peronospora belbahrii*).**

Please note:

- For scheduling reasons, this analysis is limited to berries and small fruits and basil. Similar results are anticipated if other crop/disease combinations were analyzed.
- There is no EPA registered, OMRI-listed alternative for treatment of cranberries for control of cottonball (*Monilinia oxycocci*).

STEP 4: Further Consideration of OMRI-listed Products with Comparable or Greater Mean Efficacy Compared to the Polyoxin D Zinc Salt 5SC Formulation

METHODOLOGY

Step 3 summarizes disease/crop combinations for which one or more OMRI-listed products has comparable for superior efficacy based upon he mean of trial means. These OMRI-listed alternatives were noted in Step 2 using a *green background* to indicate comparable or superior mean trial efficacy.

For each crop/disease combination with an OMRI-listed identified in Step 2 and Step 3 as comparable or superior to that of the polyoxin D zinc salt 5SC formulation:

- The relevant table from Step 2 was copied and reduced in scope to focus on OMRI-listed alternative products with comparable or greater than that for the polyoxin D zinc salt.
  - Rows with efficacy information highlighted with a green background were retained.
  - All other rows for OMRI-listed alternatives (less than comparable efficacy or no data) were deleted.
  - Summaries of the data published in PDMR for the subject OMRI-listed alternatives were retained. Others were deleted.
- Table 1 was copied and reduced in scope to focus on crop/disease combinations with one or more OMRI-listed alternative products with comparable or greater than that for the polyoxin D zinc salt 5SC formulation.
  - Rows for the crop/disease combination under consideration were retained.
  - Rows for other crop/disease combinations were deleted.

The reduced scope tables from Step 2 and Step 1 are provided below.

Step 4 examined and provided commentary on:

- The *individual* efficacy trial results for the trials in the reduced scope Step 1 tables; and
- Phytotoxicity, human hazards, and environmental hazards label statements summarized in the reduced scope Step 2 tables.

BLUEBERRIES / Mummyberry (*Monilinia vaccinii-corymbosi*)

Please see the tables below.

From Step 2:
Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Blueberries / Mummyberry (*Monilinia vaccinii-corymbosi*)

NOP Status	FRAC [A] Code(s)	Active Ingredient (s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	64	6	See Oso efficacy summary table.	Control.	0	4	None	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Optiva	264-1160	78	1	7:SMF013.	Suppression only. Preventative only.	0	4	None	Moderate eye irritation. May cause dermal sensitization. [F]	None.	None.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative toxicity descriptors, lowest toxicity to highest toxicity: Practically nontoxic < Moderately toxic < Toxic < Highly toxic.

Plant Disease Management Reports citations and data summaries:

7:SMF013. A.M.C. Schilder, J. M. Gillett, and W. Sysaks, Michigan State University. Evaluating fungicides and biocontrol products for control of mummyberry in blueberries, 2012.
Optiva at 1 lb/A + Nu Film P at 0.25%(v/v) beginning at pink bud: 79.0% control of shoot strikes and 76.3% control of mummies. Trial mean: 77.7% control (n = 2).

From Step 1:
Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051)
Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inocu-lated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
CROP GROUP 13: BERRIES AND SMALL FRUITS: BLUEBERRIES																		
Mummyberry	*Monilinia vaccinii-corymbosi*	Blueberries #1	CER-2015-008	OR	Oso + Induce (wetter/ sticker; 6 fl oz/100 gal)	9	4 - 8	5.6	21.6	NA	21.3	NA	Preventative and curative	No	34.8	No	PDMR 10:SMF026	
		Blueberries #2	CER-2015-143	MI	Oso + LI 700 (penetrant, acidifier; 0.125% v/v)	5	7 - 14	6.5	25	89	94	NA	Preventative	No	46.5 mummies/ bush	No	PDMR 10:SMF009	
		Blueberries #3	KAK-2016-Blueberry-MI	MI	Oso	8	8 - 23	6.5	25	90.8	90.7	NA	Preventative and curative	No	57.8 shoot strikes/ bush	No	PDMR (Planned fall 2018 publication) (Permission)	New data.
								13	50	100	100	NA						
					Oso + LI 700 (penetrant, acidifier; 0.125% v/v)			6.5	25	87.9	88.2	NA						
		Blueberries #4	KAK-2016-Blueberry-WA-Conv	WA	Oso	6	10 - 16	6.5	25	83.0	84.3	NA	Preventative	No	17.8 Mummies/ bush	No	Permission.	New data.
								13	50	83.0	87.1							
		Blueberries #5	KAK-2016-Blueberry-WA-Org	WA	Oso	7	6 - 9	6.5	25	-64.4	17.8	NA	Preventative	No	45.0 (fruit)	No	Permission.	New data. Includes Oso with microbial pesticides.
								13	50	32.5	30.0	NA						
		Blueberries #6	KAK-2017-Blueberry-WA-Org	WA	Oso	7	5 - 11	6.5	25	NA	63	NA	Preventative	No	6.3	No	Permission.	New data. Includes Oso with microbial pesticides.
								13	50	NA	68	NA						
							Mean Conven-tional	5.6 - 6.5	21.6 - 25	88	77	NA						
								13	20	91.5	93.6	NA						
							Mean Organic	6.5	25	-64.4	40	NA						
								13	50	32.5	49	NA						

1. "Veggieturbo 5SC Suspension Concentrate Fungicide" is Kaken's EPA registered brand name for Polyoxin D Zinc Salt 5SC Fungicide.
"Oso 5%SC Fungicide" and "Tavano 5%SC Fungicide" are Certis USA, L.L.C. supplemental distributor brand names for Polyoxin D Zinc Salt 5SC Fungicide.
"CX-10440" is the Certis USA, L.L.C. formulation code for Polyoxin D Zinc Salt 5SC Fungicide.

NR. Not reported.

Preventative and curative: Treatments include at least one application after disease was observed.
Curative: Disease was confirmed to be present before the first treatment was applied.

Comparison with Optiva (Non-Synthetic)
A *single trial* with Optiva demonstrated 78% control of blueberry/mummyberry.

Six trials with Oso provided a mean of 64% control of blueberry/mummyberry. This 64% control value includes:

- One trial (CER-2015-008) which was conducted at a rate that was *below* the minimum application rate permitted by the label; and
- Two trials (KAK-2016-Blueberry-WA-Org and KAK-2017-Blueberry-WA-Org) for which the other treatments were organic products that provided inferior disease control. It is believed that the poor control of the nearby organic product sub-plots facilitated re-infection of the Oso treated sub-plot and reduced the control observed in the Oso sub-plot.

Please note that three trials (CER-2015-143, KAK-2016-Blueberry-MI, and KAK-2016-Blueberry-WA-Conv) provided 91.5%, 92.9% and 84.4% mean control of blueberry/mummyberry, respectively. The currently available data do not include a side-by-side comparison of Oso and Optiva. However, Kaken is optimistic that a side-by-side trial would demonstrate superior control of blueberry/mummyberry by Oso compared to Optiva.

Kaken also notes that the label for Optiva specifies that the product needs to be used *preventatively*, *i.e.*, before disease is present. The Oso labels does not have this restriction. Furthermore, 100% control of blueberry/mummyberry was observed in Trial No. KAK-2016-Blueberry-MI which included *curative* applications, *i.e.*, Oso was applied *after* disease was observed in the untreated control.

CONCLUSION: The polyoxin D zinc salt 5SC formulation offers organic blueberry growers:

- **Competitive efficacy for control of mummyberry;**
- **A treatment option *after* mummyberry is first observed;**
- **Competitive worker and environmental safety;**
- **A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and**
- **Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.**

GRAPES / Black Rot (*Guignardia bidwellii*)

Please see the tables below.

From Step 2:
Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Grapes / Black Rot (*Guignardia bidwellii*)

NOP Status	FRAC [A] Code(s)	Active Ingredient (s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	54	4	See Oso efficacy summary table.	Suppression.	0	4	None	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Synthetic	M1	Copper oxychloride, Copper hydroxide	Badge X2	50289-12	54	2	8:SMF014; 6:SMF008.	Control.	0	48	Yes	May be fatal if swallowed. Substantial eye injury.	Toxic to fish and aquatic organisms.	May damage aluminum.
Synthetic	M1	Copper hydroxide	Nu-Cop 50 WP	42002-7	78	2	6:SMF008.	Control.	0	24	Yes	Irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. May cause dermal sensitization. [F]	Toxic to fish and aquatic organisms.	Damages aluminum.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative toxicity descriptors, lowest toxicity to highest toxicity: Practically nontoxic < Moderately toxic < Toxic < Highly toxic.

Plant Disease Management Reports citations and data summaries for synthetic alternatives:

8:SMF014. Bryan Hed, Penn State University. Evaluation of organic fungicides for control of black rot and powdery and downy mildew of Concord grapes, 2013.
Badge X2 1.75 lb/A + lime 1.75 lb/A, 5 or more applications, different timings; *without* mummies: 64%, 77%, 81%, and 90% control on fruit.
Badge X2 1.75 lb/A + lime 1.75 lb/A, 5 or more applications, different timings; *with* mummies: 4%, 5%, 15%, and 22% control on fruit.
Badge X2 1.75 lb/A + lime 1.75 lb/A + Nu-Film-P, 5 or more applications, different timings; *without* mummies: 66.5%, and 71% control on fruit.
Badge X2 1.75 lb/A + lime 1.75 lb/A + Nu-Film-P, 5 or more applications, different timings; *with* mummies: 9% and 9% control on fruit.
Trial mean: 43% control (n = 12).

6:SMF008. B. Hed and N. K. Ngugi, Penn State University. Evaluation of conventional and organic fungicides for control of black rot and powdery mildew of Concord grapes, 2011.
NuCop 50 WP at 1 lb/A + Lime at 1 lb/A + Nufilm P at 0.0625%: 67% control of diseased clusters; 85% control of diseased area.
NuCop 50 WP at 2 lb/A + Lime at 2 lb/A + Nufilm P at 0.0625%: 65% control of diseased clusters; 91% control of diseased area.
NuCop 50 WP trial mean: 77% control (n = 4).
Badge X2 at 1.75 lb/A + Lime at 1.75 lb/A + Nufilm P at 0.0625%: 52% control of diseased clusters; 75% control of diseased area.
Badge X2 trial mean: 64% control (n = 2).

From Step 1:
Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051)
Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inocu-lated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
CROP GROUP 13: BERRIES AND SMALL FRUITS: GRAPES																		
Black Rot	*Guignardia bidwellii*	Grapes #1	KAK-2016-Grape-MI	MI	Oso	7	10 - 16	6.5	25	NA	87	NA	Preventative	No	82.0	No	PDMR (Planned fall 2018 publication) (Permission)	New data.
								13	50	NA	98							
		Grapes #2	KAK-2017-Grape-MI	MI	Oso	7	11 - 20	13	50	87	86	NA	Preventative	No	66.0	No	PDMR (Planned fall 2018 publication) (Permission)	New data.
		Grapes #3	KAK-2016-Grape-PA	PA	Oso	6	9 - 12	13	50	NA	2.5	NA	Preventative	Yes	55.0	No	PDMR 11:SMF009	New data. Mummies in the trellis.
		Grapes #4	KAK-2017-Grape-PA	PA	Oso	7	9 - 11	13	50	NA	36.1	NA	Preventative	Yes	85.8	No	PDMR (Submitted)	New data. Mummies in the trellis.
							Mean	6.5	25	NA	87	NA						
								13	50	87	55.7	NA						

1. "Veggieturbo 5SC Suspension Concentrate Fungicide" is Kaken's EPA registered brand name for Polyoxin D Zinc Salt 5SC Fungicide.
"Oso 5%SC Fungicide" and "Tavano 5%SC Fungicide" are Certis USA, L.L.C. supplemental distributor brand names for Polyoxin D Zinc Salt 5SC Fungicide.
"CX-10440" is the Certis USA, L.L.C. formulation code for Polyoxin D Zinc Salt 5SC Fungicide.

NR. Not reported.

Preventative and curative: Treatments include at least one application after disease was observed.
Curative: Disease was confirmed to be present before the first treatment was applied.

Comparison with Badge X2 and Nu-Cop 50 WP (Synthetic)

Oso provided mean 54% control of grape/black rot in 4 trials. Badge X2 also provided mean 54% control on two trials, and Nu-Cop 50 WP provided mean 78% control in 2 trials.

Please note the following:

- Two trials conducted in Michigan (KAK-2016-Grape-MI and KAK-2017-Grape-MI) provided mean 93% control and 87% control of grape/black rot, respectively. *No mummies* were tied into the trellis to serve as inoculum. Naturally occurring inoculum was the source of disease. The dilution water was tap water (*not softened*).
- Two trials conducted in Pennsylvania (KAK-2016-Grape-PA and KAK-2017-Grape-PA) had disappointing results with only 2.35% control and 36.1% control, respectively. In the two Pennsylvania trials, *mummies* were tied into the trellis to serve as inoculum. The dilution water was *softened* tap water. Both the 2016 and 2017 trials were conducted during a local drought.
- Research strategies to better understand how to achieve dependable control of grape/black rot are under discussion.
- Black rot control is a high priority for organic grape growers. Many organic grape growers in Pennsylvania, New York, and nearby areas in Canada have converted back to convention production because of the high crop losses in organic vineyards due to black rot and insufficient organic black rot control options.

- Badge X2 and Nu-Cop 50 WP are the two OMRI-listed products with comparable or better control of black rot compared to Oso.
  - There are no available side-by-side trials for comparison of the efficacy with the polyoxin D zinc salt 5SC formulation.
  - Both Badge X2 and Nu-Cop 50 WP:
    - Are copper products with the same mode of action.
    - Have significantly higher hazards to humans (may be fatal is swallowed; irreversible eye damage) than the polyoxin D zinc salt 5SC formulation.
    - Have higher toxicity to fish as aquatic organisms (toxic) than the polyoxin D zinc salt 5SC formulation (moderately toxic).
- No phytotoxicity has been observed for Oso. The Badge X2 label has phytotoxicity warning statements.

CONCLUSION: The polyoxin D zinc salt 5SC formulation offers organic grape growers:

- **Competitive efficacy for control of black rot;**
- **Greater crop, worker, and environmental safety;**
- **An opportunity to reduce the amount of copper applied to their vineyards and thereby reduce the negative effects of copper on soil;**
- **Reduced (EPA's minimum) personal protective equipment requirement;**
- **Greater flexibility in growing the crop (0-day PHI instead of 1-day; 4-hour worker re-entry interval instead of 48-hours or 24-hours);**
- **A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and**
- **Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.**

GRAPES / Bunch Rot (*Botrytis cinerea*)

Please see the tables below.

Serenade Optimum is retained in the reduce table from Step 2 based upon efficacy data from an unpublished trial summarized in the May 31, 2016 petition.

From Step 2:
Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Grapes / Bunch Rot (*Botrytis cinerea*)

NOP Status	FRAC [A] Code(s)	Active Ingredient (s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	66	6	See Oso efficacy summary table.	Control.	0	4	None.	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel 55	70051-108	74	1	9:SMF001.	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel LC	70051-114	95	1	9:SMF001.	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Optimum	264-1160	32	1	9:SMF023.	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	None.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative toxicity descriptors, lowest toxicity to highest toxicity: Practically nontoxic < Moderately toxic < Toxic < Highly toxic.

Plant Disease Management Reports citations and data summaries for non-synthetic alternatives:

9:SMF001. T. T. Nguyen, N.S. Morris, and W. D. Gubler, University of California, Davis. Management of Grape Botrytis Bunch Rot with experimental, organic and conventional fungicides, 2014.
Double Nickel LC at 2 qt/A: 93% and 96% control of Botrytis bunch rot (severity and incidence, respectively). Trial mean: 95% control (n = 2).
Double Nickel 55WDG at 20 oz/A: 70% and 78% control of Botrytis bunch rot (severity and incidence, respectively). Trial mean: 74% control (n = 2).

From Step 1:
Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051)
Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inocu-lated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
CROP GROUP 13: BERRIES AND SMALL FRUITS: GRAPES																		
Bunch Rot	*Botrytis cinerea*	Grapes #1	CER-2013-002	CA	Tavano 5% SC	4	37 - 56	6.5	25	NA	89.0	NA	Preventative	No	30.00	No	Certis data; not published.	
								13	50	NA	92.8							
		Grapes #2	CER-2013-021	CA	Tavano 5% SC	6	18 - 21	6.5	25	NA	83.2	NA	Preventative and curative	No	20.8	No	Certis data; not published.	
								13	50	NA	78.1							
		Grapes #3	CER-2014-045	NY	Tavano 5% SC	4	13 - 43	6.5	25	NA	37	NA	Preventative and curative	No	76.3	No	Not published. Permission received.	
		Grapes #4	CER-2015-115	NY	OSO	4	14 - 41	6.5	25	NA	69	NA	Preventative	No	96	No	Not published. Permission received.	
		Grapes #5	CER-2015-140	MI	Oso 5%SC + Super Spread 90 (non-ionic surfactant; 0.125% v/v)	4	20 - 29	6.5	25	NA	56	NA	Preventative	No	25	No	PDMR 10:SMF011	
		Grapes #6	9:SMF001	CA	Tavano 5% SC	3	35	6.5	25	NA	61.1	NA	Preventative	No	22.8	No	PDMR 9:SMF001	New data.
							Mean	6.5	25	NA	66	NA						
								13	50	NA	85	NA						

1. "Veggieturbo 5SC Suspension Concentrate Fungicide" is Kaken's EPA registered brand name for Polyoxin D Zinc Salt 5SC Fungicide.
"Oso 5%SC Fungicide" and "Tavano 5%SC Fungicide" are Certis USA, L.L.C. supplemental distributor brand names for Polyoxin D Zinc Salt 5SC Fungicide.
"CX-10440" is the Certis USA, L.L.C. formulation code for Polyoxin D Zinc Salt 5SC Fungicide.

NR. Not reported.

Preventative and curative: Treatments include at least one application after disease was observed.
Curative: Disease was confirmed to be present before the first treatment was applied.

The polyoxin D zinc salt 5SC formulation provided 66% mean control of grape/bunch rot in 6 trials.

- Individual trial means were 90.9%, 80.7%, 37%, 69%, 56%, and 61.1% control of grape bunch rot in trial numbers CER-2013-002, CER-20123-021, CER-2014-045, CER-2015-115, CER-2015-140, and 9:SMF-001, respectively.
- Trial numbers CER-2013-002, CER-20123-021, CER-2014-045, CER-2015-115 are *not* published.
- Trial numbers CER-2015-140 and 9:SMF-001 are published.

Comparison with Serenade Optimum (Non-Synthetic)

Trial number CER-2013-002 (not published) was summarized in the May 31, 2016 petition and includes direct comparison of Tavano 5%SC (containing 5% polyoxin D zinc salt) with Serenade Optimum.

- Tavano applied at 13 fl oz/acre had numerically *superior* control grape bunch rot incidence compared to Serenade Optimum (98.1% control vs 93.3% control). Both products provided 87.5% control of grape bunch rot disease severity.
- Serenade Optimum is required to be applied preventatively. Oso can be applied after disease is first observed.

Comparison with Double Nickel LC (Non-Synthetic):

Direct comparisons of the efficacy of polyoxin D zinc salt 5SC formulation (a.k.a. Tavano) with Double Nickel LC are included in three trials:

Trial No.	Treatment	Rate/acre	Label Rate/Acre Range	Bunch Rot Incidence		Bunch Rot Severity		Publication
				Percent	Percent Control	Percent	Percent Control	
CER-2014-045	Untreated control			76.3 a		31.6 a		Not published; summarized in the May 31, 2016 petition
	Tavano 5SC	6.5 fl oz	6.5 - 13	60.0 a-f	21	14.9 b-e	53	
	Double Nickel LC	2.0 qt	0.5 - 6	62.5 a-d	18	14.8 b-e	54	
CER-2015-115	Untreated control			96 a		44 ab		Not published; summarized in the May 31, 2016 petition
	Tavano 5SC	6.5 fl oz	6.5 - 13	50 gh	50	12 d-f	88	
	Double Nickel LC	1 qt	0.5 - 6	86 a-d	14	23 de	77	
	Double Nickel LC	2 qt	0.5 - 6	48 h	53	11 ef	89	
9:SMF001	Untreated control			22.8a		4.4 a		PDMR 9:SMF001
	Tavano 5SC	6.5 fl oz	6.5 - 13	4.0 cd	82.5	1.5 bc	59.1	
	Double Nickel LC	2 qt	0.5 - 6	1.0 d	95.6	0.3 bc	93.2	

For trials with direct comparison of the polyoxin D zinc salt 5SC formulation (a.k.a. Tavano) with Double Nickel LC, the efficacy of the polyoxin D zinc salt 5SC formulation applied at the minimum label rate of 6.5 fl oz/acre was:

- Statistically *superior* to Double Nickle LC at 1 qt/acre (1 trial); and
- Statistically *equivalent* to Double Nickle LC at 2 qt/acre (each of 3 trials).

Double Nickle LC is required to be applied preventatively. Oso can be applied after disease is first observed.

Comparison with Double Nickel 55 (Non-Synthetic):
Direct comparisons of the efficacy of polyoxin D zinc salt 5SC formulation (a.k.a. Tavano) with Double Nickel 55 are included in one trial (9:SMF001):

Trial No.	Treatment	Rate/acre	Label Rate/Acre Range	Bunch Rot Incidence		Bunch Rot Severity		Publication
				Percent	Percent Control	Percent	Percent Control	
9:SMF001	Untreated control			22.8a		4.4 a		PDMR 9:SMF001
	Tavano 5SC	6.5 fl oz	6.5 - 13	4.0 cd	82.5	1.5 bc	59.1	
	Double Nickel 55	20 oz	0.3 - 3 lb = 4.8 - 48 oz	5.0 cd	78.1	1.3 bc	70.5	

In this direct comparison of the polyoxin D zinc salt 5SC formulation (a.k.a. Tavano) with Double Nickel 55, the efficacy of the polyoxin D zinc salt 5SC formulation applied at the *minimum* label rate of 6.5 fl oz/acre was statistically *equivalent* to that of the Double Nickel applied at 20 oz/acre (approximately the *middle* of the application rate range on the label).

Double Nickle 55 is required to be applied preventatively. Oso can be applied after disease is first observed.

CONCLUSION: The polyoxin D zinc salt 5SC formulation offers organic grape growers:

- **Competitive or superior efficacy for control of bunch rot;**
- **A treatment option *after* bunch rot is first observed;**
- **Competitive worker and environmental safety;**
- **A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and**
- **Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.**

GRAPES / Downy Mildew (*Plasmopara viticola*)

Please see the tables below.

From Step 2:
Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Grapes / Downy Mildew (*Plasmopara viticola*)

NOP Status	FRAC [A] Code(s)	Active Ingredient (s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	95	2	See Oso efficacy summary table.	Control.	0	4	None	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Synthetic	M1	Copper oxychloride, Copper hydroxide	Badge X2	80289-12	99 (with lime)	1	8:SMF014	Control.	0	48	Yes	May be fatal if swallowed. Substantial eye injury.	Toxic to fish and aquatic organisms.	May damage aluminum.
Synthetic	M1	Copper octanoate	Cueva	67702-2-70051	93	1	3:SMF031	Control.	0	4	Yes	Harmful if swallowed or absorbed through skin.	Toxic to fish and aquatic organisms.	Do not store below 4°C (39°F). Tank-mix restrictions.
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate 2.0	70299-2	92 (leaves)	1	5:SMF049.	Control.	0	Until dry	None	Irreversible eye damage. May be fatal if swallowed. Skin irritation.	Highly toxic to bees and other beneficial insects. Toxic to fish.	Chemical instabilities. Strong oxidizing agent. Use and storage temperature restrictions.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative toxicity descriptors, lowest toxicity to highest toxicity: Practically nontoxic < Moderately toxic < Toxic < Highly toxic.

8:SMF014. B. Hed, Penn State University. Evaluation of organic fungicides for control of black rot and powdery and downy mildew of Concord grapes, 2013.
Badge X2 at 1.75 lb/A + lime at 1.75 lb/A, different application timings: 96%, 99%, 100%, and 100% control of downy mildew on grapes (fruit).
Badge X2 at 1.75 lb/A + lime at 1.75 lb/A + Nu-Film-P at 0.0625%, different application timings: 100% and 100% control of downy mildew on grapes (fruit).
Badge X2 trial mean: 99% control (n = 6).

5:SMF049. A. Schilder, *et al*. Michigan State University. Evaluation of fungicide programs for control of bunch rots and downy mildew in 'Vignoles' grapes, 2008.
Oxidate 1% (v/v): 92% control on grape leaves.

3:SMF031. B. Hed. Penn State Univ. Evaluation of alternative fungicides for control of black rot, powdery mildew, and downy mildew of grapes, 2008.
Cueva 1%: 93% control of downy mildew on grapes (fruit).

From Step 1:
Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051)
Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inocu-lated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
CROP GROUP 13: BERRIES AND SMALL FRUITS: GRAPES																		
Downy Mildew	*Plasmopara viticola*	Grapes #1	KAK-2016-Grape-MI	MI	Oso	7	7 - 16	6.5	25	92	NA	NA	Preventative	No	83.0	No	PDMR (Planned fall 2018 publication) (Permission)	New data.
								13	50	99	NA	NA						
		Grapes #2	KAK-2017-Grape-MI	MI	Oso	7	11 - 20	13	50	NA	95	NA	Preventative	No	78.0	No	PDMR (Planned fall 2018 publication) (Permission)	New data.
							Mean	6.5	25	92	NA	NA						
								13	50	99	95	NA						

1. "Veggieturbo 5SC Suspension Concentrate Fungicide" is Kaken's EPA registered brand name for Polyoxin D Zinc Salt 5SC Fungicide.
"Oso 5%SC Fungicide" and "Tavano 5%SC Fungicide" are Certis USA, L.L.C. supplemental distributor brand names for Polyoxin D Zinc Salt 5SC Fungicide.
"CX-10440" is the Certis USA, L.L.C. formulation code for Polyoxin D Zinc Salt 5SC Fungicide.

NR. Not reported.

Preventative and curative: Treatments include at least one application after disease was observed.
Curative: Disease was confirmed to be present before the first treatment was applied.

Based upon the mean of two trials, the polyoxin D zinc salt 5SC formulation provided comparable efficacy for the efficacy of downy mildew of grapes (95% control) compared to Badge X2 with lime (99% control), Cueva (93% control), and Oxidate (92% control).

Comparison to Badge X2, Cueva, and Oxidate (Synthetic)

The polyoxin D zinc salt 5SC formulation is a reduced risk product compared to Badge X2, Cueva, and Oxidate.

- Badge X2 is phytotoxic, has higher human toxicity (may be fatal if swallowed), and has higher environmental toxicity (toxic fish and aquatic organisms).
- Cueva has a phytotoxicity warning on its label ("may cause some copper toxicity on some plant species"), has higher acute toxicity (harmful if swallowed or absorbed through skin, and has higher environmental toxicity (toxic to fish and aquatic organisms).
- Oxidate is significantly more toxic to humans and environment. Oxidate causes irreversible eye damage and may be fatal if swallowed. Oxidate is highly toxic to bees and other beneficial insects and is toxic to fish.

CONCLUSION: The polyoxin D zinc salt 5SC formulation offers organic grape growers:

- **Competitive or superior efficacy for control of downy mildew;**
- **An opportunity to reduce the amount of copper applied to their vineyards and thereby reduce the negative effects of copper on soil;**
- **Greater to significantly greater crop, worker, and environmental safety;**
- **Reduced (EPA's minimum) personal protective equipment requirement;**
- **Greater flexibility in growing the crop [0-day PHI instead of 1-day PHI; 4-hour worker re-entry interval instead of 48 hours (Badge X2)];**
- **A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and**
- **Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.**

GRAPES / Powdery Mildew (*Erisyphe necator*)

Please see the tables below.

Rows for Double Nickel LC, Stargus, Lifegard WG, and Badge X2 are retained in the table from Step 2 to facilitate comparisons with these products based upon unpublished data.

From Step 2:
Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Grapes / Powdery Mildew (*Erisyphe necator*)

NOP Status	FRAC [A] Code(s)	Active Ingredient (s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	79	8	See Oso efficacy summary table.	Control.	0	4	None	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain D747	Double Nickel LC	70051-114	No data	NA	NA	Control. Preventative only.	0	4	None.	Moderate eye irritation. May cause dermal sensitization. [F]	None.	Water pH restrictions.
Non-synthetic	44	*Bacillus amylo-liquefaciens* strain F727	Stargus	84059-28	No data			Control. Preventative only.	0	4	None.	Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Not for sale or use after 18 months from the date of manufacture. Avoid freezing.
Non-synthetic	44	*Bacillus mycoides*, isolate J	LifeGard WG	70051-119	No data			No direct effect on plant pathogen; plant protectant; preventative.	0	4	None.	Harmful if inhaled. Moderate eye irritation. Respirator required; repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.	None.	Store at temperatures below 77°F.
Synthetic	M1	Copper hydroxide, Copper oxychloride	Badge X2	80289-12	50	2	8:SMF014 6:SMF008	Control.	0	48	Yes.	May be fatal if swallowed. Substantial eye injury.	Toxic to fish and aquatic organisms.	May damage aluminum.
Synthetic	M2	Sulfur	Micro Sulf	55146-75	88	1	6:SMF025	Control.	0	24	Yes	Harmful if swallowed, inhaled, or absorbed through skin. Eye irritation.	None.	Keep away from heat, sparks, or flames.

From Step 2:
Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Grapes / Powdery Mildew (*Erisyphe necator*)

NOP Status	FRAC [A] Code(s)	Active Ingredient (s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative toxicity descriptors, lowest toxicity to highest toxicity: Practically nontoxic < Moderately toxic < Toxic < Highly toxic.

Plant Disease Management Reports citations and data summaries for synthetic alternatives:

6:SMF025. N. O. Halbrendt, H.K. Ngugi, and J. M. Halbrendst, Penn State University. Performance of organic and conventional programs for powdery mildew management on wine grapes in PA, 2011.
Micro Sulf at 5 lb/A: 10.0%, 99.7%, 94.7%, and 99.7% control on leaves (incidence and severity, respectively; Chamboucin and Traminette, respectively).
Micro Sulf at 5 lb/A: 100%, 100%, 100%, and 100% control on clusters (incidence and severity, respectively; Chamboucin and Traminette, respectively).
Trial mean: 88% (n = 8).

From Step 1:
Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051)
Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inoculated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
CROP GROUP 13: BERRIES AND SMALL FRUITS: GRAPES																		
Powdery mildew	*Erysiphe necator*	Grapes #1	CER-2011-013	CA	CX-10440	8	10 - 11	3.75	14	78.1	78.6	NA	Preventative and curative	No	70.3	No	Certis data; not published.	
								7.5	29	80.4	68.8							
		Grapes #2	CER-2012-069	CA	CX-10440	8	9 - 11	13	50	NA	96.67	NA	Preventative and curative	No	30.00	No	Certis data; not published.	Wine was analyzed.
		Grapes #3	CER-2013-021	CA	Tavano	5	18 - 21	6.5	25	NA	44.2	NA	Preventative and curative	No	100	No	Certis data; not published.	
								13	50	NA	73.6	NA						
		Grapes #4	CER-2015-019	OR	Oso + Sylguard (silicone surfactant; 0.025% v/v)	6	13 - 15	6.5	25	86.1	47.9	NA	Preventative and curative	No	87.5	No	Certis data; not published.	
		Grapes #5	CER-2015-140	MI	Oso 5%SC + Super Spread 90 (non-ionic surfactant; 0.125% v/v)	4	20 - 29	6.5	25	55	56	NA	Preventative	No	37	No	PDMR 10:SMF011	
		Grapes #6	KAK-2016-Grape-MI	MI	Oso	7	10 - 16	6.5	25	90	88	NA	Preventative	No	63.0	No	PDMR (Planned fall 2018) (Permission)	New data.
								13	50	99	99							
		Grapes #7	KAK-2017-Grape-MI	MI	Oso	7	11 - 20	13	50	97	99	NA	Preventative	No	85.0	No	PDMR (Planned fall 2018) (Permission)	New data.
		Grapes #8	KAK-2017-Grape-PA	PA	Oso	7	9 - 11	13	50	81	84	NA	Preventative	No	98.0	No	PDMR (Planned fall 2018) (Permission)	New data.
							Mean	3.75	14	78.1	78.6	NA						
								6.5 - 7.5	25 - 29	78	61	NA						
								13	50	92	90	NA						

1. "Veggieturbo 5SC Suspension Concentrate Fungicide" is Kaken's EPA registered brand name for Polyoxin D Zinc Salt 5SC Fungicide.
"Oso 5%SC Fungicide" and "Tavano 5%SC Fungicide" are Certis USA, L.L.C. supplemental distributor brand names for Polyoxin D Zinc Salt 5SC Fungicide.
"CX-10440" is the Certis USA, L.L.C. formulation code for Polyoxin D Zinc Salt 5SC Fungicide.

NR. Not reported.

Preventative and curative: Treatments include at least one application after disease was observed.
Curative: Disease was confirmed to be present before the first treatment was applied.

The polyoxin D zinc salt 5SC formulation provided mean 79% control powdery mildew in grapes based upon *8 efficacy trials*. Individual trial means were 76.5%, 96.67%, 58.9%, 67%, 56%, 94%, 98%, and 83% control in trial numbers CER-2011-013, CER-2012-069, CER-2013-021, CER-2015-019, CER-2015-140, KAK-2016-Grape-MI, KAK-2017-Grape-MI, and KAK-2017-Grape-PA, respectively.

Comparison with Micro Sulf (Synthetic)

In a single trial, Micro Sulf provided mean 88% control of powdery mildew on grapes. This is:

- Within the range of the 8 trials for Oso; and
- Less than the 96.67%, 94%, and 98% control by Oso observed in trial numbers CER-2012-069, KAK-2016-Grape-MI, and KAK-2017-Grape-MI.

The polyoxin D zinc salt 5 SS formulation:

- Is not phytotoxic, whereas Micro Sulf is phytotoxic.
- Has lower mammalian toxicity. Micro Sulf is harmful if swallowed, inhaled, or absorbed through skin and causes eye irritation.

Other OMRI-Listed Alternatives

For the first 6 listed trials, no OMRI-listed alternatives were included in the trial.

Two trials which are not yet published for which summaries are included in this document each include direct comparisons of the polyoxin D zinc salt 5SC formulation to two OMRI-listed products:

- Trial No. KAK-2017-Grape-MI includes Lifegard WG and Stargus; and
- Trial No. KAK-2017-Grape-PA includes Double Nickel LC and Badge X2 with lime.

Comparison with Lifegard WG and Stargus (Non-Synthetic)

In Trial No. KAK-2017-Grape-MI, the polyoxin D zinc salt 5SC formulation provided:

- Statistically *equivalent* control of powdery mildew on grapes *leaves* compared to Lifegard WG and Stargus (97%, 94%, and 96% control, respectively); and
- Statistically *superior* control of powdery mildew on grapes *clusters* compared to Lifegard WG and Stargus (99%, 97%, and 97% control, respectively).

For both Lifeguard WG and Stargus:

- The US EPA registration is limited to preventative use only; and
- Applicators are required to wear a respirator.

The polyoxin D zinc salt 5SC formulation does not have either of these limitations.

Comparison with Double Nickel LC (Non-Synthetic)

In Trial No. KAK-2017-Grape-PA, the polyoxin D zinc salt 5SC formulation provided:

- Numerically *superior* control of powdery mildew on grape *leaves* (81%) compared to Double Nickel LC at 1.5 qt/acre and 3 qt/acre (56% and 39%), respectively; and
- Numerically *superior* control of powdery mildew on grape *clusters* (84%) compared to Double Nickel LC at 1.5 qt/acre and Double Nickel LC at 3 qt/acre (24%, and 17%, respectively).

Double Nickel is required to be used preventatively. Oso can be applied after disease is first observed.

Comparison with Badge X2 Tank-Mixed with Lime (Synthetic)

In Trial No. KAK-2017-Grape-PA, the polyoxin D zinc salt 5SC formulation provided:

- Statistically *equivalent* control of powdery mildew on grape *leaves* (81%) compared to Badge X2 tank-mixed with lime (97%); and
- Numerically *superior* control of powdery mildew on grape *clusters* (84%) compared to Badge X2 tank-mixed with lime (59%).

The polyoxin D zinc salt 5SC formulation is a reduced risk product relative to Badge X2. The polyoxin D zinc salt 5SC formulation:

- Is not phytotoxic, whereas Badge X2 is phytotoxic.
- Is practically non-toxic in all acute toxicity categories, whereas Badge X2 is harmful if swallowed, inhaled, or absorbed through skin and is an eye irritant. This difference is partially off-set by the polyoxin D zinc salt 5SC formulation's moderate toxicity to fish and aquatic organisms and no similar label statement for Badge X2.

CONCLUSION: The polyoxin D zinc salt 5SC formulation offers organic grape growers:

- **Competitive or superior efficacy for control of powdery mildew;**
- **A treatment option *after* powdery mildew is first observed;**
- **An opportunity to reduce the amount of copper applied to their vineyards and thereby reduce the negative effects of copper on soil;**
- **Competitive or superior crop, worker, and environmental safety;**
- **Greater flexibility in growing the crop [0-day PHI instead of 1-day PHI; 4-hour worker re-entry interval instead of 48 hours (Badge X2)];**
- **Increased applicator comfort (no respirator is required as is required for Lifegard WG and Stargus);**
- **A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and**
- **Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.**

STRAWBERRIES / Phomopsis Leaf Spot (Blight) (*Phomopsis obscurans*)

Please see the tables below.

From Step 2:
Comparative Overview of Efficacy, Hazards, and Use Restrictions
Crop Group 13: Berries and Small Fruits: Strawberries / Phomopsis Leaf Spot (Blight) (*Phomopsis obscurans*)

NOP Status	FRAC [A] Code(s)	Active Ingredient (s)	Product	EPA Reg. No.	Efficacy [B]			Label Claim	PHI (Days)	REI (Hrs)	Hazards and Restrictions Noted on the Product Label			
					Mean % Control	n [C]	PDMR [D] Citations				Phyto-toxicity	Human	Environmental [G]	Physical
Synthetic	19	Polyoxin D zinc salt	Oso	68173-4	91	2	See Oso efficacy summary table.		0	4	None	May cause dermal sensitization. [F]	Moderately toxic to fish and aquatic invertebrates.	None.
Synthetic	M1	Copper octanoate	Cueva	67702-2-70051	94	1	9:SMF035	Control.	0	4	Yes	Harmful if swallowed or absorbed through skin.	Toxic to fish and aquatic organisms.	Do not store below 4°C (39°F). Tank-mix restrictions.

A. FRAC = Fungicide Resistance Action Committee. Products with the same mode of action have the same FRAC Code. NC = Not classified; no FRAC code has been assigned.
B. For Polyoxin D zinc salt (Oso), from summarizes trials, published and unpublished. For OMRI-listed alternatives, from Plant Disease Management Reports (PDMR).
C. Number of trials included in the calculation of the mean.
D. PDMR = Plant Disease Management Reports (on-line journal generally used for publication of efficacy research conducted at universities). Preceded by F&N = Fungicides and Nematicides. https://www.plantmanagementnetwork.org/pub/trial/pdmr/
E. Mix-and-match directions for use. Label has a list of crops and a separate list of diseases with no claim for specific crop/disease combinations.
F. Complete label statement: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
G. EPA relative toxicity descriptors, lowest toxicity to highest toxicity: Practically nontoxic < Moderately toxic < Toxic < Highly toxic.

Plant Disease Management Reports citations and data summaries:

9:SMF035. A. Schilder *et al.*, Michigan State University. Evaluation of organic fungicides for control of strawberry foliar and fruit diseases, 2014.
Cueva at 1 gal/A: 94% control of Phomopsis leaf blight.

From Step 1:
Cumulative Summary of the Efficacy of the Polyoxin D Zinc Salt 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051) Applied as a Foliar Spray to Growing Food Crops Using Ground Application Equipment

Disease	Pathogen	Crop Tested & Sequence No.	Trial No.	State	Formulation [1]	No. App.	Application Interval (Days)	Application Rate		Mean Control (%)		Mean Yield Increase (%)	Application Type(s)	Inoculated?	Max. Pest Pressure in UTC (%)	Phyto-tox ?	Publication Status	Notes
								fl oz/ acre	g a.i./ ha	Leaves	Fruit							
CROP GROUP 13: BERRIES AND SMALL FRUITS: STRAWBERRIES																		
Phomopsis Leaf Spot and Fruit Rot	*Phomopsis obscurans*	Strawberries #1	KAK-2016-SBerry-MI	MI	Oso	7	6 - 9	6.5	25	98	NA	4-day post-harvest: 240	Preventative	No	39.5	No	PDMR (Planned fall 2018 publication) (Permission)	New data.
								13	50	100	NA	273						
		Strawberries #2	KAK-2017-SBerry-MI	MI	Oso	5	7 - 14	13	50	83	80	4-day post-harvest: 2350	Preventative	No	35.1	No	PDMR (Planned fall 2018 publication) (Permission)	New data.
							Mean	6.5	25	98	NA	4-day post-harvest: 240						
								13	50	92	80	1312						

1. "Veggieturbo 5SC Suspension Concentrate Fungicide" is Kaken's EPA registered brand name for Polyoxin D Zinc Salt 5SC Fungicide.
"Oso 5%SC Fungicide" and "Tavano 5%SC Fungicide" are Certis USA, L.L.C. supplemental distributor brand names for Polyoxin D Zinc Salt 5SC Fungicide.
"CX-10440" is the Certis USA, L.L.C. formulation code for Polyoxin D Zinc Salt 5SC Fungicide.

NR. Not reported.

Preventative and curative: Treatments include at least one application after disease was observed.
Curative: Disease was confirmed to be present before the first treatment was applied.

The mean control of strawberry Phomopsis leaf spot (blight) for the polyoxin D zinc salt 5SC formulation based upon two trials is 91%. Mean control was 99% and 83% based upon Trial Numbers KAK-2016-SBerry-MI and KAK-2017-SBerry-MI, respectively. Summaries of both of these trials are included in this document. Both trials are not yet published. Trial Numbers KAK-2016-SBerry-MI and KAK-2017-SBerry-MI do *not* included data on any OMRI-listed products that are EPA registered for use on strawberries for treatment of Phomopsis.

Comparison with Cueva (Synthetic)

Cueva provided 94% control of strawberry phomopsis leaf spot in a single published efficacy trial. This is between the 83% and 99% control seen for the polyoxin D zinc salt 5SC formulation.

The polyoxin D zinc salt 5SC formulation is a reduced risk product compared to Cueva. Cueva has a phytotoxicity warning on its label ("may cause some copper toxicity on some plant species"), has higher acute toxicity (harmful if swallowed or absorbed through skin, and has higher environmental toxicity (toxic to fish and aquatic organisms).

CONCLUSION: The polyoxin D zinc salt 5SC formulation offers organic strawberry growers:

- **Competitive efficacy for control of Phomopsis leaf spot;**
- **A treatment option *after* Phomopsis leaf spot is first observed;**
- **Competitive or superior crop, worker, and environmental safety;**
- **A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and**
- **Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.**

OVERALL CONCLUSION

Based upon *disease significance and efficacy data alone*, there is *organic grower need* for the polyoxin D zinc salt 5SC formulation (a.k.a. Oso) for treatment of:

- **Blueberries for control of:**
  - **Alternaria blight (*Alternaria* spp.); and**
  - **Botrytis blight (*Botrytis cinerea*);**
- **Caneberries for control of:**
  - **Botrytis fruit rot (*Botrytis cinerea*); and**
  - **Powdery mildew (*Podosphaera aphanais*);**
- **Cranberries for control of:**
  - **Cottonball (Monilinia oxycocci); and**
  - **Fruit rot complex (*Coleophoma empetri*, *Colletotrichum acutatum*, *Colletotrichum gloeosporioides*, *Phyllosticta vaccinii*, and *Physalospora vaccinii*, etc.);**
- **Grapes for control of:**
  - **Phomopsis fruit rot (*Phomopsis viticola*);**
- **Strawberries for control of:**
  - **Anthracnose fruit rot (*Colletotrichum acutatum*);**
  - **Gray mold (*Botrytis cinerea*);**
  - **Leather rot (*Phytophthora cactorum*; and**
  - **Phomopsis fruit rot (soft rot) (*Phomopsis obscurans*); and**
- **Basil for control of:**
  - **Downy mildew (*Peronospora belbahrii*).**

OMRI-listed alternatives initially identified as having comparable or superior efficacy and therefore identified for more detailed comparisons were:

- **Blueberries/mummyberry (*Monilinia vaccinii-corymbosi*): Optiva;**
- **Grapes black rot (*Guignardia bodwellii*): Badge X2 and Nu-Cop 50 WP;**
- **Grapes/bunch rot (*Botrytis cinerea*): Double Nickel 55 and Double Nickel LC;**
- **Grapes/downy mildew (*Plasmopara viticola*): Badge X2, Cueva, and Oxidate;**
- **Grapes/powdery mildew (*Erysiphe necator*): Micro Sulf, Lifegard WG and Stargus; and**
- **Strawberries/Phomopsis leaf spot (*Phomopsis obscurans*): Cueva.**

Based upon *efficacy data and other considerations*, there is *organic grower need* for the polyoxin D zinc salt 5SC formulation (a.k.a. Oso) for treatment of:

- **Blueberries for control of mummyberry (*Monilinia vaccinii-corymbosi*). Compared to Optiva, the polyoxin D zinc salt 5SC formulation offers organic blueberry growers:**
  - **Competitive efficacy for control of mummyberry;**
  - **Competitive worker and environmental safety;**
  - **A treatment option *after* mummyberry is first observed;**
  - **A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and**
  - **Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.**

- **Grapes for the control of black rot (*Guignardia bodwellii*). Compared to Badge X2 and Nu-Cop 50 WP, the polyoxin D zinc salt 5SC formulation offers organic grape growers:**
  - **Competitive efficacy for control of black rot;**
  - **Greater crop, worker, and environmental safety;**
  - **An opportunity to reduce the amount of copper applied to their vineyards and thereby reduce the negative effects of copper on soil;**
  - **Reduced (EPA's minimum) personal protective equipment requirement;**
  - **Greater flexibility in growing the crop (0-day PHI instead of 1-day; 4-hour worker re-entry interval instead of 48-hours or 24-hours);**
  - **A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and**
  - **Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.**

- **Grapes for the control of bunch rot (*Botrytis cinerea*). Compared to Double Nickel 55 and Double Nickel LC, the polyoxin D zinc salt 5SC formulation offers organic grape growers:**
  - **Competitive or superior efficacy for control of bunch rot;**
  - **A treatment option *after* bunch rot is first observed;**
  - **Competitive worker and environmental safety;**
  - **A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and**
  - **Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.**

- **Grapes for the control of downy mildew (*Plasmopara viticola*). Compared to Badge X2, Cueva, and Oxidate, the polyoxin D zinc salt 5SC formulation offers organic grape growers:**
  - **Competitive or superior efficacy for control of downy mildew;**
  - **Greater to significantly greater crop, worker, and environmental safety;**
  - **Reduced (EPA's minimum) personal protective equipment requirement;**
  - **Greater flexibility in growing the crop [0-day PHI instead of 1-day PHI; 4-hour worker re-entry interval instead of 48 hours (Badge X2)];**
  - **A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and**
  - **Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.**

- **Grapes for control of powdery mildew (*Erysiphe necator*). Compared to Micro Sulf, Lifegard WG, Stargus, and Serifel, the polyoxin D zinc salt 5SC formulation offers organic grape growers:**
  - **Competitive or superior efficacy for control of powdery mildew;**
  - **A treatment option *after* powdery mildew is first observed;**
  - **Competitive or superior crop, worker, and environmental safety;**
  - **Greater flexibility in growing the crop [0-day PHI instead of 1-day PHI; 4-hour worker re-entry interval instead of 48 hours (Badge X2)];**
  - **Increased applicator comfort (no respirator is required as is required for Lifegard WG and Stargus);**
  - **A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and**
  - **Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.**

- **Strawberries for control of Phomopsis leaf spot (*Phomopsis obscurans*). Compared to Cueva, the polyoxin D zinc salt 5SC formulation offers organic strawberry growers:**
  - **Competitive efficacy for control of Phomopsis leaf spot;**
  - **A treatment option *after* Phomopsis leaf spot is first observed;**
  - **Competitive or superior crop, worker, and environmental safety;**
  - **A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and**
  - **Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.**

Please note:

- **For scheduling reasons, this analysis is limited to berries and small fruits and basil. Similar results are anticipated if other crop/disease combinations were analyzed.**
- **There is no EPA registered, OMRI-listed alternative for treatment of cranberries for control of cottonball (*Monilinia oxycocci*).**

COMPATIBILITY WITH OMRI-LISTED FUNGICIDES

ACTINOVATE, REGALIA, AND NOVASOURCE'S LIME-SULFUR

Blueberry/mummyberry trial #5 (Trial No. KAK-2016-Blueberry-WA-Org) is summarized above and is provided again below because it provides examples of how Oso can be an important addition to treatment programs with OMRI-listed products.

a. Design

Blueberry / Mummyberry (*Monilinia vaccinii-corymbosi*) #5: Trial No. KAK-2016-Blueberry-WA-Org: Design				
Title:	Organic Mummy Berry & Botrytis Control in Blueberries of Western Washington 2016			
Author and affiliation:	Alan Schreiber Agricultural Development Group, Inc.			
Publication:	Not published; permission received.			
Location:	Mt. Vernon, Washington			
Crop:	Highbush Blueberry (variety: Reka)			
Disease name:	Mummy berry			
Pathogen:	*Monilinia vaccinii-corymbosi*			
Test plot design:	Randomized complete block			
Number of replicates:	4			
Application equipment:	Rears OverRo			
Spray volume:	100 gallons/acre			
Application type(s):	Preventative			
Number of applications:	7			
Chronology:	Application Dates	Application Interval	Growth Stage	Evaluation Dates
	02/27/2016		Veg Bud	05/03/2016
	03/07/2016	9 days	Veg Tip	06/23/2016
	03/16/2016	9 days	Pre Bud	
	03/25/2016	9 days	Pink Bud	
	03/31/2016	6 days	10% Bloom	
	04/08/2016	9 days	30% Bloom	
	04/15/2016	7 days	50% Bloom	

b. Results

Blueberries / Mummyberry (*Monilinia vaccinii-corymbosi*) #5: Trial No. KAK-2016-Blueberry-WA-Org: Results									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	Appl Code	Incidence Leaf Strikes/Plot) (05/03/2016)		Incidence (Infected Fruit) (06/23/2016)	
						Measured	Percent Control	Measured	Percent Control
Untreated control			Not Applicable			16.0 abc		45.0 a	
Oso 5%SC	6.5 fl oz	25	Polyoxin D zinc salt	19	ABCDEF	26.3 a	-64.4	37.0 a	17.8
Oso 5%SC	13 fl oz	50	Polyoxin D zinc salt	19	ABCDEF	10.8 c	32.5	31.5 a	30.0
Fracture	20 fl oz		Banda de Lupinus albus doce (BLAD)	M12	ABCDEFG	21.0 abc	-31.3	39.8 a	11.6
Zen-O-Spore	4 lb		*Ulocladium oudemansii* (U3 Strain)	NC	ABCDEFG	18.0 abc	-12.5	32.5 a	27.8
Actinovate AG	12 oz		*Streptomyces lydicus* WYEC 108	NC	ABCDEFG	16.8 abc	-5.0	39.0 a	13.3
Double Nickel LC	1 qt		*Bacillus amyloliquefaciens* str. D747	44	ABCDEFG	12.8 bc	20.0	33.5 a	25.6
Regalia	2 qt		*Reynoutria sachalinensis* extract	P5	ABCDEFG	12.0 c	25.0	39.0 a	13.3
NovaSource's Lime-Sulfur	2% v/v		Calcium polysulfide	M2	ABCD	9.8 c	38.8	36.0 a	20.0
Oso 5%SC	13 fl oz		Polyoxin D zinc salt	19	BDF	25.3 ab	-58.1	24.3 a	46.0
Actinovate AG	12 oz		*Streptomyces lydicus* WYEC 108	NC	ACEG				
Oso 5%SC	13 fl oz		Polyoxin D zinc salt	19	BDF	20.8 abc	-30.0	32.8 a	27.1
Regalia	2 qt		*Reynoutria sachalinensis* extract	P5	ACEG				
Actinovate AG	12 oz		*Streptomyces lydicus* WYEC 108	NC	ACEG				
Oso 5%SC	13 fl oz		Polyoxin D zinc salt	19	EFG	15.8 abc	1.3	29.3 a	34.9
NovaSource's Lime-Sulfur	2% v/v		Calcium polysulfide	M2	ABCD				
Oso 5%SC	13 fl oz		Polyoxin D zinc salt	19	ACEG	21.5 abc	-34.4	25.8 a	42.7
Regalia	2 qt		*Reynoutria sachalinensis* extract	P5	BDF				
Actinovate AG	12 oz		*Streptomyces lydicus* WYEC 108	NC	ACEG	22.0 abc	-37.5	39.0 a	13.3
Regalia	2 qt		*Reynoutria sachalinensis* extract	P5	ACEG				
Double Nickel LC	1 qt		*Bacillus amyloliquefaciens* str. D747	44	BDF				
Zen-O-Spore	4 lb		*Ulocladium oudemansii* (U3 Strain)	NC	BDF				
Treatment means followed by the same letter are not statistically different according to Bartlett's X2 test at P = 0.05.									

The first application was made on February 27, 2016. Based upon feedback from Washington State University plant pathologists, this was prior to ascospore release (i.e., prior to crop infection). Therefore, the treatments were applied preventatively.

The researcher described the mummyberry pressure as moderate.

No phytotoxicity was reported.

c. Discussion

Used alone:

- Actinovate (containing *Streptomyces lydicus* WYEC 108; no FRAC Code; biological);
- Regalia (containing *Reynoutria sachalinensis* extract; FRAC Code P5), and
- NovaSource's Lime-Sulfur (containing calcium polysulfide; FRAC Code M2)

each provided control of mummyberry fruit infections (fruit strikes) on blueberries that was better than the untreated control.

Oso enhanced the performance of Actinovate, Regalia, and NovaSource's Lime-Sulfur in the treatment of blueberries for control of mummyberry.

When Oso was used in combination with:

- Actinovate, better control of blueberry/ mummyberry fruit strikes (46.0 % control) was achieved than when Actinovate was used alone (13.3% control).
- Regalia, better control of blueberry/ mummyberry fruit strikes (42.7% control) was achieved than when Regalia was used alone (13.3% control).
- Regalia and Actinovate, better control of blueberry/ mummyberry fruit strikes (27.1% control) was achieved than when Regalia was used alone (13.3% control) and when Actinovate was used alone (also 13.3% control).
- NovaSource's Lime-Sulfur, better control of blueberry/mummyberry fruit strikes (34.9% control) was achieved than when NovaSource's Lime-Sulfur was used alone (20.0% control).

DOUBLE NICKEL LC

a. Design

Powdery Mildew (*Sphaerotheca fuliginea*) / Squash: Trial No. CER-2014-064: Design		
Title:	CER-2014-064	
Author and affiliation:	Gary Cloud	
Publication:	Not published. Certis data. Permission.	
Location:	Quitman, GA	
Crop:	Squash (Yellow crook neck)	
Disease name:	Powdery mildew	
Pathogen:	*Sphaerotheca fuliginea*	
Application codes and dates:	A	06/21/2014
	B	06/28/2014
	C	07/04/2014
	D	07/11/2014
	E	07/18/2014
	F	07/25/2014
	G	08/01/2014
	H	08/08/2014

b. Results

Powdery Mildew (*Sphaerotheca fuliginea*) / Squash: Trial No. CER-2014-064: Results									
Treatment	Rate/ Acre	g a.i./ ha	Active Ingredient	FRAC Code	App. Code	Yield (lb) 08/08/2014		Yield (lb) 08/15/2014	
						Measured	Percent Increase	Measured	Percent Increase
Untreated control			Not Applicable			5.38 b		8.78 a	
Double Nickel [A]	1 qt		*Bacillus amyloliquefaciens* strain 747	44	A-H	5.59 b	3.9	8.18 a	-6.8
Double Nickel [A]	1 qt		*Bacillus amyloliquefaciens* strain 747	44	ACEG	6.99 b	29.9	9.83 a	12.0
Oso	6.5 fl oz	25	Polyoxin D zinc salt	19	BDFH	12.48 a	132.0	12.00 a	36.7
Double Nickel [A]	1 qt		*Bacillus amyloliquefaciens* strain 747	44	ACEG				

Treatment means followed by the same letter are not statistically different according to the Student-Newman-Keuls test at P = 0.05.

A. The formulation (55 vs LC) was not specified. LC (liquid concentrate) is inferred based upon the units (quarts/acre) of the application rates.

c. Discussion

Yellow crook neck squash plants were treated using three different treatment patterns:

- Eight Double Nickel LC applications at 7-day intervals;
- Four Double Nickel LC applications at 14-day intervals; and
- Eight applications total at 7-day intervals, with Double Nickel LC applied first and then alternated with Oso for the balance of the treatment program.

The largest yield increases relative to the untreated control were obtained when Double Nickle LC applications were alternated with Oso applications (132.0% increase for harvest 1 and 36.7% increase for harvest 2).

Therefore, Oso enhanced the performance of Double Nickel LC in the treatment of squash for control of powdery mildew.

NOT RECOMMENDED FOR USE WITH *TRICHODERMA* SPECIES

Polyoxin D zinc salt stops the growth of sensitive fungi. Therefore, Kaken does not recommend the use of polyoxin D zinc salt as a tank-mix partner or as part of the treatment program with products containing *Trichoderma* species:

- Bio-Tam (EPA Reg. No. 80289-9) contains at least:
  - 5 million *Trichoderma asperellem* (ICC 012) colony forming units ; and
  - 5 million *Trichoderma gamsii* (ICC 080) colony forming units

  and is registered for control of *Phytophthora* which is the genus that causes leather rot of strawberries.
- Rootshield Plus WP (EPA Reg. No. 68539-9) contains at least:
  - 10 million *Trichoderma harzianum* Rifai strain T-22 colony forming unit per gram dry weight; and
  - 5.3 million *Trichoderma virens* strain G-41 colony forming unit per gram dry weight

  and is registered for control of *Phytophthora* which is the genus that causes leather rot of strawberries.
- Rootshield Plus Granules (EPA Reg. No. 68539-10) contains at least:
  - 10 million *Trichoderma harzianum* Rifai strain T-22 colony forming unit per gram dry weight; and
  - 5.3 million *Trichoderma virens* strain G-41 colony forming unit per gram dry weight

  and is registered for control of *Phytophthora* which is the genus that causes leather rot of strawberries.

RESISTANCE MANAGEMENT

The following text is from US EPA PR Notice 2017-1 regarding resistance management.

> *"What causes pesticide resistance; how does it happen?*
> *In general, pesticide resistance occurs when genetic or behavioral changes enable pest individuals to tolerate or survive what would otherwise be lethal doses of a pesticide and then spread those changes through the larger pest population. These changes are usually biochemical in nature (e.g., genes allowing metabolic detoxification of a pesticide occur as a result of random mutation, and these in turn allow pest individuals to survive repeated and/or lower dose applications of a given pesticide). If a pesticide is not rotated with other chemicals with different modes of action over several applications, and/or if that pesticide is not used at a dose that is lethal enough to kill almost all of the pest population, then the genes responsible for the resistant trait can spread quickly through the population (i.e., pesticide susceptible individuals are killed off, but resistant ones that are not challenged by pesticides with different modes of action can then mate with one another and make the resistance trait more common over time)."*
>
> *Generally, how common / widespread is pesticide resistance?*
> *Resistance appears to be generally increasing in the U.S. and worldwide. For example, globally the number of unique herbicide-resistant weed species has risen from one in 1957 to over 440 in 2014 (www.weedscience.org). Between 1908 and 2012, the number of insecticide-resistant arthropod species has risen from one to 574 (www.pesticideresistance.org). Interested readers can find a list of resistant plant pathogens (as well as several other documents relevant to fungicide resistance) at http://www.frac.info/publications/downloads. This is a website maintained by the Fungicide Resistance Action Committee (FRAC). For insecticides (both within the U.S. and globally), there is a publicly available, searchable database of refereed publications that report*
> *resistance at http://www.pesticideresistance.org/index.php (maintained by Michigan State University). While the genetics of any individual pest population plays a role, a major human factor that fosters resistance development is a lack of understanding of resistance-management options available to crop producers who use pesticides routinely.*
>
> *What are the concepts that guide resistance-management strategies?*
> *EPA supports broader efforts at developing comprehensive resistance-management strategic plans that may take into account local conditions, soil management, crop rotation, cultural approaches and other factors. Resistance-management labeling will provide pesticide users with easy access to important information regarding target-site resistance, the cornerstone of most resistance-management programs. Development of pesticide resistance is influenced by a number of factors. One important factor that fosters pesticide resistance is the repeated use of pesticides with the same mode of action on the same pest population. Thus, an important proactive pesticide resistance-management strategy is to rotate pesticides with different modes of action to control target pests in any given location. This approach may delay the development of one important type of resistance, target site resistance, without resorting to increased rates and frequency of application, and may prolong the useful life of pesticides.*
>
> *If pesticides are used in a manner that facilitates the development and/or spread of resistance in target pest populations, pesticide users are likely to increase their use of multiple pesticides in attempts to manage pests that are becoming less susceptible to each pesticide application. This in turn would increase loading of pesticides in the environment, with the potential for unintended consequences such as increased impacts on non-target wildlife and increased exposure to humans. Without appropriate actions to manage*

> *resistance evolution, target pests would eventually show widespread resistance that no management tactic could adequately address, thus leading to potentially significant crop losses. Pesticide users look to product labeling as a primary source for their use instructions, and resistance-management guidance on labeling could significantly and immediately assist users to avoid or delay the spread of resistance in pests.*
>
> *The agency has found pesticide resistance to be an adverse effect in that it can increase pesticide use and create unnecessary economic losses. The lack of appropriate resistance-management guidance on labeling may become a factor that could strongly influence EPA's regulatory conclusions on the risks and benefits of a pesticide."*

Polyoxin D zinc salt has a unique, non-toxic mode of action. No other active ingredient registered for use in North America has the same mode of action (FRAC Code 19). Polyoxin D zinc salt can play an important role in resistance management programs. Polyoxin D zinc salt, if accepted by the National Organic Program, will be a new resistance management tool for organic growers.

UPDATED JUSTIFICATION FOR APPROVAL UNDER §205.601

The information below expands upon and clarifies information in the September 12, 2012 NOP Technical Report for polyoxin D zinc salt.

IDENTIFICATION OF THE PETITIONED SUBSTANCE

Active Ingredient

The petitioned substance is ***limited*** to polyoxin D zinc salt which is a 1:1 complex of polyoxin D and zinc. The CAS number for polyoxin D zinc salt is 146659-78-1.

Fourteen polyoxins have been identified and have been designated polyoxin A through polyoxin N. Polyoxin A through polyoxin N each have a ***different*** chemical structure. The petitioned substance does ***not*** include all polyoxins. Specifically, the petitioned substance does ***not*** include:

- Polyoxin A through C;
- Polyoxin E though N;
- Polyoxin A through C in combination with zinc; and/or
- Polyoxin E though N in combination with zinc.

The properties of polyoxins vary with the chemical structures. Kaken Pharmaceutical Co., Ltd. markets Polyoxin Complex in Asia. Polyoxin Complex contains multiple polyoxins and has significantly different efficacy compared to polyoxin D zinc salt.

Formulation

The 5% suspension concentrate formulation of polyoxin D zinc salt is the ***only*** formulation proposed for use in organic agriculture. The inert ingredients have been specifically selected for use in organic formations. The 5% suspension concentrate is registered by Kaken as Veggieturbo 5SC Suspension Concentrate Fungicide (EPA Reg. No. 67183-4) and is marketed in the United States by Certis USA L.L.C. as Oso 5%SC Fungicide (EPA Reg. No. 67183-4-70051).

Please note that the 11.3% water dispersible granular (WDG) formulation is ***not*** proposed for use in organic agriculture. The 11.3% WDG formulation has inert ingredients that are ***not*** compatible with organic agriculture.

CHARACTERIZATION OF THE PETITIONED SUBSTANCE

Polyoxin D zinc salt is used exclusively for the protection of plants against sensitive fungal plant pathogens.

Neither polyoxin D nor polyoxin D zinc salt are antibiotics. Polyoxin D and polyoxin D zinc salt have never been used or proposed for use as pharmaceuticals for use in human or veterinary medicine. Based upon screening data, polyoxin D has ***no commercially viable efficacy*** against tested common human or veterinary pathogens (bacteria, fungi, and yeast).

STATUS

US EPA Label: Use on Growing Crops

The most recent VEGGIETURBO 5SC Suspension Concentrate Fungicide label was stamped "Accepted" by the US EPA on January 3, 2018. Please see Appendix 1. Please note that the directions for use have been restructured so that they are in crop group number order instead of alphabetical order.

US EPA Label: Post-Harvest Use

The US EPA has issued a registration for Polyoxin D Zinc Salt 5-SC Post-Harvest (EPA Reg. No. 68173-5) for post-harvest use on pome fruits, pomegranates, and stone fruits. However, the product launch has been delayed for the development of large scale efficacy trial data to confirm and/or refine the directions for use.

Residue Authorizations

The US EPA has established a tolerance exemption for residues of polyoxin D zinc salt for all crops (pre-harvest and post-harvest) treated according to good agricultural practice (40 CFR §180.1285).

Crops grown in the United States and treated with polyoxin D zinc salt according to the US EPA registered label may be exported to:

- Canada;
- Mexico;
- New Zealand;
- South Korea; and
- Taiwan.

These countries have enacted regulations that are similar to EPA's tolerance exemption. Numerical maximum residue limits (MRLs) have not been established.

Kaken is pursuing additional imported crop authorizations for polyoxin D zinc salt that are similar to the US EPA's tolerance exemption. Applications to permit importation of crop commodities treated with polyoxin D zinc salt are pending or in preparation. The list of pending applications include the European Union.

No CODEX MRL has been proposed or accepted. The CODEX system does *not* have a provision for the concept of an MRL exemption. Only numerical MRLs may be established in the CODEX system.

International Authorizations for Use in Organic Agriculture

No application for international authorization for use in organic agriculture has been approved or is pending.

Polyoxin D zinc salt was first registered for use in Canada during 2017. During 2018, Engage Agro will be launching sales of the polyoxin D zinc salt 5SC formulation in Canada under the Diplomat brand name. Kaken will be investigating opportunities for organic use in Canada.

EVALUATION QUESTIONS FOR SUBSTANCES TO BE USED IN ORGANIC CROP PRODUCTION

1. What category of OFPA does this substance fall under?

Polyoxin D zinc salt is proposed as a substance described in 7 USC 6517 (c)(1)(B)(i) as "a toxin derived from bacteria."

Kaken Pharmaceutical Co., Ltd. (Kaken) proposes to *amend 7 CFR §205.601(i) to add polyoxin D zinc salt* as a synthetic substance allowed for use in organic crop production as plant disease control. ^^

2. Describe the most prevalent process used to manufacture or formulate the petitioned substance.

Active Ingredient Production

Polyoxin D is produced via a fermentation process using a naturally occurring, non-GMO microorganism. Polyoxin D is a naturally occurring substance.

Polyoxin D is highly water soluble. To reduce its water solubility, polyoxin D is converted to polyoxin D zinc salt using a very simple chemical reaction.

Kaken purchases and does not control the production process for the starting material containing zinc that is used to convert polyoxin D to polyoxin D zinc. Therefore, Kaken cannot assert that the zinc source is derived from native mined zinc (or from recycled zinc). Nonetheless, Kaken can confirm that detailed chemical analyses of multiple routine production batches of Polyoxin D Zinc Salt Technical confirm that no toxicologically significant heavy metals are present at or above the level of detection.

Polyoxin D zinc salt has been classified as a synthetic substance. During the spring 2013 public hearing, Dr. Davis, a former chair of the NOSB Crops Subcommittee, described polyoxin D zinc salt as a "naturally derived fermentation product with a twist."

5SC Formulation Production

The polyoxin D zinc salt 5SC formulation is produced via a blending process in which Polyoxin D Zinc Salt Technical is blended with inert ingredients that are each approved for use in organic agriculture. No chemical reactions occur via the formulation process.

3. Is the substance synthetic? Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by a naturally occurring biological process.

During its April 2013 public hearing, the National Organic Standards Board classified polyoxin D zinc salt as a synthetic substance. Please see the answer to question 2 above for addition information.

4. Describe the persistence or concentration of the petitioned substance and/or its by-products in the environment.

As noted in the September 23, 2012 Technical Report, "Data reviewed by the EPA indicate that polyoxin D zinc salt degrades within 2-3 days of application, with a low toxicity profile [73 FR 69559]."

Neither polyoxin D zinc salt nor its by-products will persist or concentrate in the environment.

5. Describe the toxicity and mode of action of the substance and its breakdown products and any contaminants. Describe the persistence and areas of concentration in the environment of the substance and its breakdown products.

Timeline	
1997/08/20	US EPA issued the first registration of Polyoxin D Zinc Salt Technical.
2012/09/12	US EPA issued the tolerance exemption of all crops. Additional mammalian toxicology and environmental degradation data on TGAI were accepted by EPA.
2012/09/23	NOP Technical Evaluation Report for polyoxin D zinc salt is issued.
2012/09/27	US EPA issued the first registration of Veggieturbo 5SC Suspension Concentrate Fungicide.

The Technical Evaluation Report for Polyoxin D zinc salt was issued 4 days *before* Veggieturbo 5SC Suspension Concentrate Fungicide was first registered by the US EPA and did *not* consider data summaries included in the petition regarding Polyoxin D Zinc Salt 5SC Fungicide (EPA Reg. No. 67183-4).

Toxicity of Polyoxin D Zinc Salt Technical

Toxicity data submitted to and accepted by the US EPA and previously summarized for NOP but *not* included in the September 23, 2012 Technical Report for polyoxin D zinc salt are summarized below.

Assay	Polyoxin D Zinc Salt Technical		
	US EPA Comment	Meaning	Ref.
Developmental Toxicity (Teratology) (rabbit)	Maternal NOEL > 800 mg/kg/day. Pup NOEL > 800 mg/kg/day.	Does not cause birth defects in rabbits.	BRAD.
Developmental Toxicity (Teratology) (rat)	NOAEL > 1000 mg/kg/day.	Does not cause birth defects in rats.	EPA Review 05/11/2012.
Mutagenicity (*in vivo* mouse micronucleus test)	No mutagenic effects. No chromosomal mutations. No systemic toxicity. *In vitro* effects seen in earlier studies could *not* be replicated in the *in vivo* (whole animal) test.	Definitive study. Does not cause generic damage.	EPA Review 05/11/2012.
Two-Generation Reproduction	No reproductive effects at the limit dose.	Does not adversely effect reproduction.	EPA Review 05/11/2012.
Immunotoxicity (mouse)	Low immunotoxicity.	Does not adversely effect the immune system.	EPA Review 05/11/2012.
BRAD = US Environmental Protection Agency Office of Pesticide Programs Biopesticide Registration Action Document: Polyoxin D Zinc Salt (1997).			

The US EPA stated on pages 56131-56132 of the September 12, 2012 Federal Register,

> "Relevant data and information submitted for the previous tolerance exemption (73 FR 69560) and for this expansion of the tolerance exemption indicate that polyoxin D zinc salt has negligible acute, subchronic, chronic, and developmental toxicity. Moreover, polyoxin D zinc salt is defined by its fungistatic non-toxic mode of action, and demonstrates no significant mammalian effect. Therefore, the Agency concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of polyoxin D zinc salt. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has arrived at this conclusion because *the data and information available on polyoxin D zinc salt do not demonstrate toxic potential to mammals.* Thus, there are no threshold effects of concern and, as a result, an additional margin of safety is not necessary." (Emphasis added.)

Toxicity of Veggieturbo 5SC Suspension Concentrate Fungicide

Assay	Veggieturbo 5SC Suspension Concentrate Fungicide		
	End-Point	EPA Category/ Description	Ref.
Acute oral (rats)	LD_{50} > 5000 mg/kg (females)	IV: Practically non-toxic.	EPA Review 09/07/2012.
Acute dermal (rats)	LD_{50} > 5050 mg/kg (males, females, and combined)	IV: Practically non-toxic.	EPA Review 09/07/2012.
Acute inhalation (rats; 4 hour)	LC_{50} > 2.20 mg/L (males, females, and combined)	IV: Practically non-toxic.	EPA Review 09/07/2012.
Primary eye irritation (rabbits)	Maximum average score was 4 one hour after test material installation. No irritation in any eyes at 24 hours after treatment.	IV: Practically non-toxic.	EPA Review 09/07/2012.
Primary dermal irritation (rabbits)	The primary index was 0.3 at 72 hours. Product is slightly irritating.	IV: Practically non-toxic.	EPA Review 09/07/2012.
Dermal sensitization (Guinea pigs)	The test substance produced very faint to faint erythema in 15 to 20 test animals, but no reaction in any Naive control animals after treatment.	No applicable EPA toxicity category. Label statement: Mild dermal sensitizer.	EPA Review 09/07/2012.

The acute toxicity of Veggieturbo 5SC Suspension Concentrate Fungicide is so low (all Category IV) that the US EPA does not require a first aid statement for Veggieturbo 5SC Suspension Concentrate Fungicide.

Mode of Action

Worldwide, polyoxin D zinc salt is produced and registered exclusively by Kaken Pharmaceutical Co., Ltd. (Kaken). This does *not* make Polyoxin D zinc salt an antibiotic. Polyoxin D and polyoxin D zinc salt are *not* antibiotics. They have *never* been marketed for use as pharmaceuticals for use in human medicine or in veterinary medicine. Based upon screening data, polyoxin D has *no commercially viable efficacy* against tested common human or veterinary pathogens (bacteria, fungi, and yeast).

6. Describe any environmental contamination that would result from the petitioned substance's manufacture, use, misuse, or disposal.

Veggieturbo 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051) are both registered for terrestrial use only on crops. Intentional misuse involving direct application to water could harm fish and aquatic invertebrates. Risk to fish and aquatic invertebrates from registered uses is low due to the low application rates and rapid environmental degradation.

7. Describe any known chemical interactions between the petitioned substance and other substances used in organic crop production. Describe any environmental or human health effects from these chemical interactions.

Actinovate, Regalia and NovaSource's Lime-Sulfur

In Trial No. KAK-2016-Blueberry-WA-Org, the following products, used alone, each provided control of mummyberry fruit infections (fruit strikes) on blueberries that was better than the untreated control:

- Actinovate (containing *Streptomyces lydicus* WYEC 108; no FRAC Code; biological);
- Regalia (containing *Reynoutria sachalinensis* extract; FRAC Code P5), and
- NovaSource's Lime-Sulfur (containing calcium polysulfide; FRAC Code M2).

Oso enhanced the performance of Actinovate, Regalia, and NovaSource's Lime-Sulfur in the treatment of blueberries for control of mummyberry.

When Oso was used in combination with:

- Actinovate, better control of blueberry/ mummyberry fruit strikes (46.0 % control) was achieved than when Actinovate was used alone (13.3% control).
- Regalia, better control of blueberry/ mummyberry fruit strikes (42.7% control) was achieved than when Regalia was used alone (13.3% control).
- Regalia and Actinovate, better control of blueberry/ mummyberry fruit strikes (27.1% control) was achieved than when Regalia was used alone (13.3% control) and when Actinovate was used alone (also 13.3% control).
- NovaSource's Lime-Sulfur, better control of blueberry/mummyberry fruit strikes (34.9% control) was achieved than when NovaSource's Lime-Sulfur was used alone (20.0% control).

Double Nickel (containing *Bacillus amyloliquefaciens* str 747)
In Trial No. CER-2014-064, yellow crook neck squash plants were treated using three different treatment patterns:

- Eight Double Nickel applications at 7-day intervals;
- Four Double Nickel applications at 14-day intervals; and
- Eight applications total at 7-day intervals, with Double Nickel applied first and then alternated with Oso for the balance of the treatment program.

The largest yield increases relative to the untreated control were obtained when Double Nickle applications were alternated with Oso applications (132.0% increase for harvest 1 and 36.7% increase for harvest 2).

Therefore, Oso enhanced the performance of Double Nickel in the treatment of squash for control of powdery mildew.

Trichoderma (Bio-Tam and RootShield)
Polyoxin D zinc salt stops the growth of sensitive fungi. Therefore, Kaken does not recommend the use of polyoxin D zinc salt as a tank-mix partner or as part of the treatment program with products containing *Trichoderma* species [(Bio-Tam (EPA Reg. No. 80289-9), Rootshield Plus WP (EPA Reg. No. 68539-9) and Rootshield Plus Granules (EPA Reg. No. 68539-10)].

8. Describe any effects of the petitioned substance on biological or chemical interactions in the agro-ecosystem, including physiological effects on soil organisms, and crops.

Veggieturbo 5SC Suspension Concentrate Fungicide and Oso 5%SC Fungicide are each registered for foliar application to treatment of the above ground plant parts. Neither product is registered for application to the soil.

A special study described in the May 31, 2016 petition was conducted specifically for NOP and determined that the polyoxin D zinc salt 5SC formulation does *not* adversely effects beneficial soil organisms, including beneficial soil fungi.

In addition, polyoxin D zinc salt has been determined to not adversely effect earth worms. These data are also summarized in the May 31, 2016 petition.

9. Discuss and summarize findings on whether the petitioned substance may be harmful to the environment.

Please see the Kaken's above responses to items 4, 5, and 6.

- Neither polyoxin D zinc salt nor its by-products will persist or concentrate in the environment.
- The data and information available on polyoxin D zinc salt do not demonstrate toxic potential to mammals.
- The acute toxicity of Veggieturbo 5SC Suspension Concentrate Fungicide is so low (all Category IV) that the US EPA does not require a first aid statement for Veggieturbo 5SC Suspension Concentrate Fungicide.
- Polyoxin D and polyoxin D zinc salt are *not* antibiotics. They have *never* been marketed for use as pharmaceuticals for use in human medicine or in veterinary medicine.
- Veggieturbo 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051) are both registered for terrestrial use only on crops. Intentional misuse involving direct application to water could harm fish and aquatic invertebrates. Risk to fish and aquatic invertebrates from registered uses is low due to the low application rates and rapid environmental degradation.

In addition, polyoxin D zinc salt does *not* adversely effect honey bees, ladybird beetles, or other beneficial insects.

10. Describe and summarize any reported effects on human health from use of the petitioned substance.

Kaken is not aware of any reported adverse effects on human health resulting from the use of polyoxin zinc D zinc salt or any of its formulations.

11. Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance. Provide a list of allowed substances that may be used in place of the petitioned substance.

A list and brief description of the non-synthetic and synthetic products that may be used in place of the petitioned substance for use on Crop Group 13 and Crop Group 19 is provided below. For more detailed descriptions, please see the Evaluation of Organic Grower Needs, Step 2, Identification of OMRI-List Alternative Products, Efficacy Data, Product Hazards, and Restrictions beginning on page 127 of this addendum.

Please note that none on the listed alternatives have the same mode of action as polyoxin D zinc salt. As such, none of the listed alternatives is a true replacement for polyoxin D zinc salt. Instead, the listed products are EPA registered for the same crop/disease combination and are OMRI-listed.

US EPA Registered OMRI-Listed Alternatives [1] to Veggieturbo 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051)				
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.
Crop Group 13: Berries and Small Fruits: Blueberries / Alternaria Fruit Rot (*Alternaria* spp.)				
Non-synthetic	44	*Bacillus amyloliquefaciens* strain MBI 600	Serifel	71840-18
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Optiva	264-1160
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Optimum	264-1160
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3
Non-synthetic	NC; Biological	*Streptomyces lydicus* WYEC 108	Actinovate AG	73314-1
Non-synthetic	NC; Botanical oil	Neem oil	Trilogy	70051-2
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate 2.0	70299-2
Crop Group 13: Berries and Small Fruits: Blueberries / Botrytis Blight (*Botrytis cinerea*)				
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel 55	70051-108
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel LC	70051-114
Non-synthetic	44	*Bacillus amyloliquefaciens* strain F727	Stargus	84059-28
Non-synthetic	44	*Bacillus amyloliquefaciens* strain MBI 600	Serifel	71840-18
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Optiva	264-1160
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Optimum	264-1160
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3
Non-synthetic	NC; Biological	*Aureobasidoium pullulans* strains DSM 14940 and DSM 19941	Botector	86174-3
Non-synthetic	NC; Biological	*Streptomyces lydicus* WYEC 108	Actinovate AG	73314-1
Non-synthetic	NC; Botanical oil	Neem oil	Trilogy	70051-2
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539
Synthetic	NC; Inorganic salt	Potassium silicate	Sil-Matrix	82100-1
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate 2.0	70299-2
Synthetic	NC; Oxidizing agent	Hydrogen peroxide, Hydrogen dioxide	Perpose Plus	86729-1
Crop Group 13: Berries and Small Fruits: Blueberries / Mummyberry (*Monilinia vaccinii-corymbosi*)				
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel 55	70051-108
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel LC	70051-114
Non-synthetic	44	*Bacillus amyloliquefaciens* strain MBI 600	Serifel	71840-18
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata ASO	264-1153
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Optiva	264-1160
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Optimum	264-1160
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3
Non-synthetic	NC; Biological	*Streptomyces lydicus* WYEC 108	Actinovate AG	73314-1
Non-synthetic	NC; Botanical oil	Clove oil, Rosemary oil, Peppermint oil	BacStop	NA; 25(b)
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate 2.0	70299-2

US EPA Registered OMRI-Listed Alternatives [1] to Veggieturbo 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051)				
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.
Crop Group 13: Berries and Small Fruits: Caneberries / Botrytis Fruit Rot (*Botrytis cinerea*)				
Non-synthetic	44	Bacillus amyloliquefaciens strain D747	Double Nickel 55	70051-108
Non-synthetic	44	*Bacillus amyloliquefaciens* strain MBI 600	Serifel	71840-18
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Optimum	264-1160
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3
Non-synthetic	NC; Biochemical	Rhamnolipid biosurfactant	Zonix	72431-1
Non-synthetic	NC; Biological	*Aureobasidium pullulans* strains DSM 14940 and DSM 14941	Botector	86174-3
Non-synthetic	NC; Biological	*Streptomyces lydicus* WYEC 108	Actinovate AG	73314-1
Non-synthetic	NC; Botanical oil	Neem oil	Trilogy	70051-2
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)
Synthetic	M1	Copper octanoate	Cueva	67702-2-70051
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate 2.0	70299-2
Crop Group 13: Berries and Small Fruits: Caneberries / Powdery Mildew (*Podosphaera aphanis*)				
Non-synthetic	44	*Bacillus amyloliquefaciens* strain MBI 600	Serifel	71840-18
Non-synthetic	44	*Bacillus pumilis* strain QST 2808	Sonata ASO	264-1153
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3
Non-synthetic	NC; Biochemical	Rhamnolipid biosurfactant	Zonix	72431-1
Non-synthetic	NC; Biological	*Streptomyces lydicus* WYEC	Actinovate	73314-1
Non-synthetic	NC; Botanical oil	Neem oil	Trilogy	70051-2
Non-synthetic	NC; Botanical oil	Cinnamon oil	Cinnerate	NA; 25(b)
Non-synthetic	NC; Botanical oil	Garlic oil, Cottonseed oil, Corn oil	Mildew Cure	NA; 25(b)
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)
Non-synthetic	NC; Organic acid	Citric acid	Nuke Em	NA; 25(b)
Synthetic	M2	Sulfur	Acoidal	62562-4
Synthetic	M2	Sulfur	Cosavet-DF	70905-1
Synthetic	M2	Sulfur	Defend DF	62562-8
Synthetic	M2	Sulfur	Kumulus DF	51306-352-66330
Synthetic	M2	Sulfur	Micro Sulf	55146-75
Synthetic	M2	Sulfur	Microthiol Disperss	70506-187
Synthetic	M2	Sulfur	Thiolux	34704-1079
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Kaligreen	70231-1
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541
Synthetic	NC; Inorganic salt	Potassium silicate	Sil-Matrix	82100-1
Synthetic	NC; Organic salt	Potassium salts of fatty acids	M-Pede	10163-324
Synthetic	NC; Organic salt	Insecticidal soap	Des-X	67702-22-70051
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate	70299-2
Synthetic	NC; Oxidizing agent	Hydrogen peroxide, Hydrogen dioxide	Perpose Plus	86729-1

US EPA Registered OMRI-Listed Alternatives [1] to Veggieturbo 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051)				
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.
Synthetic	NC; Petroleum oil	Mineral oil	Glacial Spray Liquid	34704-849
Synthetic	NC; Petroleum oil	Mineral oil	JMS Stylet Oil	65564-1
Synthetic	NC; Petroleum oil	Mineral oil	Omni Supreme Spray	5905-368
Synthetic	NC; Petroleum oil	Mineral oil	PureSpray Green	69526-9
Synthetic	NC; Petroleum oil	Mineral oil	TriTek	48813-1
Synthetic	NC; Petroleum oil	Aliphatic petroleum solvent	SuffOil-X	48813-1-68539
Crop Group 13: Berries and Small Fruits: Cranberries / Cottonball (*Monilinia oxycocci*)				
No alternatives				
Crop Group 13: Berries and Small Fruits: Cranberries / Fruit Rot Complex (*Coleophoma empetri*, *Colletotrichum acutatum*, *Colletotrichum gloeosporioides*, *Phyllosticta vaccinii*, and *Physalospora vaccinii*, etc.)				
Synthetic	M1	Copper hydroxide	Nu-Cop 50 WP	42002-7
Synthetic	M1	Copper hydroxide	Champ WG	55146-1
Synthetic	M1	Copper hydroxide, Copper oxychloride	Badge X2	80289-12
Synthetic	M1	Copper sulfate pentahydrate	CS 2005	66675-3
Synthetic	M1	Cupric hydroxide	Nu-Cup HB	42750-132
Synthetic	M1	Cuprous oxide	Nordox 75 WG	48142-4
Crop Group 13: Berries and Small Fruits: Grapes / Black Rot (*Guignardia bidwellii*)				
Non-synthetic	44	*Bacillus amyloliquefaciens* strain F727	Stargus	84059-28
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151
Non-Synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)
Synthetic	M1	Basic copper sulfate	Basic Copper 53	45002-8
Synthetic	M1	Copper oxychloride, Copper hydroxide	Badge X2	50289-12
Synthetic	M1	Copper hydroxide	Champ WG	55146-1
Synthetic	M1	Copper hydroxide	Nu-Cop 50 WP	42002-7
Synthetic	M1	Copper octanoate	Cueva	67702-2-70051
Synthetic	M1	Copper sulfate pentahydrate	CS 2005	66675-3
Synthetic	M1	Cupric hydroxide	NuCop 50 DF	45002-4
Synthetic	M1	Cupric hydroxide	Nu-Cop HB	42750-132
Synthetic	M1	Cuprous oxide	Nordox 75 WG	48142-4
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate 2.0	70299-2
Crop Group 13: Berries and Small Fruits: Grapes / Bunch Rot (*Botrytis cinerea*)				
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel 55	70051-108
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel LC	70051-114
Non-synthetic	44	*Bacillus amyloliquefaciens* strain F727	Stargus	84059-28
Non-synthetic	44	*Bacillus amyloliquefaciens* strain MBI 600	Serifel	71840-18
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Optiva	264-1160
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Optimum	264-1160
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3
Non-synthetic	NC; Biological	*Aureobasidium pullulans* strains DSM 14940 and DSM 14941	Botector	86174-3
Non-synthetic	NC; Biological	*Streptomyces lydicus*	Actinovate AG	73314-1
Non-synthetic	NC; Biological	*Ulacladium ouderansii* strain U3	Zen-O-Spore	75747-2

US EPA Registered OMRI-Listed Alternatives [1] to Veggieturbo 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051)				
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.
Non-synthetic	NC; Botanical oil	Neem oil	Trilogy	70051-2
Non-synthetic	NC; Botanical oil	Clove oil, Rosemary oil, Peppermint oil	BacStop	NA; 25(b)
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate 2.0	70299-2
Synthetic	NC; Oxidizing agent	Hydrogen peroxide, Hydrogen dioxide	Perpose Plus	86729-1
Synthetic	NC; Petroleum oil	Mineral oil	JMS Stylet Oil	65564-1
Synthetic	NC; Petroleum oil	Mineral oil	PureSpray Green	69526-9
Synthetic	NC; Petroleum oil	Aliphatic petroleum solvent	SuffOil-X	48813-1-68539
Synthetic	NC; Petroleum oil	Mineral oil	TriTek	48813-1
Crop Group 13: Berries and Small Fruits: Grapes / Downy Mildew (*Plasmopara viticola*)				
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel 55	70051-108
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel LC	70051-114
Non-synthetic	44	*Bacillus amyloliquefaciens* strain F727	Stargus	84059-28
Non-synthetic	44	*Bacillus amyloliquefaciens* strain MBI 600	Serifel	71840-18
Non-synthetic	44	*Bacillus mycoides*, isolate J	LifeGard WG	70051-119
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3
Non-synthetic	NC; Biological	*Streptomyces lydicus*	Actinovate AG	73314-1
Non-synthetic	NC; Botanical oil	Neem oil	Trilogy	70051-2
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)
Synthetic	M1	Basic copper sulfate	Basic Copper 53	45002-8
Synthetic	M1	Copper oxychloride, Copper hydroxide	Badge X2	80289-12
Synthetic	M1	Copper hydroxide	Champ WG	55146-1
Synthetic	M1	Copper hydroxide	Nu-Cop 50 WP	42002-7
Synthetic	M1	Copper octanoate	Cueva	67702-2-70051
Synthetic	M1	Copper sulfate pentahydrate	CS 2005	66675-3
Synthetic	M1	Copper sulfate pentahydrate	Copper Sulfate Crystals	56576-1
Synthetic	M1	Copper sulfate pentahydrate	Quimag Quimicos Arguila Copper Sulfate Crystals	73385-3
Synthetic	M1	Cupric hydroxide	NuCop 50 DF	45002-4
Synthetic	M1	Cupric hydroxide	Nu-Cop HB	42750-132
Synthetic	M1	Cuprous oxide	Nordox 75 WG	48142-4
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate 2.0	70299-2
Synthetic	NC; Oxidizing agent	Hydrogen peroxide, Hydrogen dioxide	Perpose Plus	86729-1

US EPA Registered OMRI-Listed Alternatives [1] to Veggieturbo 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051)				
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.
Crop Group 13: Berries and Small Fruits: Grapes / Phomopsis (*Phomopsis viticola*)				
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel 55	70051-108
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel LC	70051-114
Non-synthetic	44	*Bacillus amyloliquefaciens* strain F727	Stargus	84059-28
Non-synthetic	44	*Bacillus amyloliquefaciens* strain MBI 600	Serifel	71840-18
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Optiva	264-1160
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3
Non-synthetic	NC; Botanical oil	Clove oil, Rosemary oil, Peppermint oil	BacStop	NA; 25(b)
Synthetic	M1	Copper oxychloride, Copper hydroxide	Badge X2	80289-12
Synthetic	M1	Copper hydroxide	Champ WG	55146-1
Synthetic	M1	Copper octanoate	Cueva	67702-2-70051
Synthetic	M1	Copper sulfate pentahydrate	CS 2005	66675-3
Synthetic	M1	Cupric hydroxide	Nu Cop 50 DF	45002-4
Synthetic	M1	Cupric hydroxide	Nu Cop HB	42750-132
Synthetic	M1	Cuprous oxide	Nordox	48142-4
Synthetic	M2	Sulfur	Acoidal	62562-4
Synthetic	M2	Sulfur	Defend DF	62562-8
Synthetic	M2	Sulfur	Kumulus DF	51306-352-66330
Synthetic	M2	Sulfur	Micro Sulf	55146-75
Synthetic	M2	Sulfur	Microthiol Disperss	70506-187
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539
Crop Group 13: Berries and Small Fruits: Grapes / Powdery Mildew (*Erisyphe necator*)				
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel 55	70051-108
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel LC	70051-114
Non-synthetic	44	*Bacillus amyloliquefaciens* strain F727	Stargus	84059-28
Non-synthetic	44	*Bacillus amyloliquefaciens* strain MBI 600	Serifel	71840-18
Non-synthetic	44	*Bacillus mycoides*, isolate J	LifeGard WG	70051-119
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Optiva	264-1160
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Optimum	264-1160
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3
Non-synthetic	NC; Biological	*Streptomyces lydicus* WYEC	Actinovate	73314-1
Non-synthetic	NC; Botanical oil	Cinnamon oil	Cinnerate	NA; 25(b)
Non-synthetic	NC; Botanical oil	Garlic oil, Cottonseed oil, Corn oil	Mildew Cure	NA; 25(b)
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)
Non-synthetic	NC; Botanical oil	Neem oil	Trilogy	70051-2
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)
Non-synthetic	NC; Organic acid	Citric acid	Nuke Em	NA; 25(b)

US EPA Registered OMRI-Listed Alternatives [1] to Veggieturbo 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051)				
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.
Synthetic	M1	Copper hydroxide	Nu-Cop 50 WP	42002-7
Synthetic	M1	Copper hydroxide	Champ WG	55146-1
Synthetic	M1	Copper hydroxide	Nu-Cop HB	42750-132
Synthetic	M1	Copper hydroxide, Copper oxychloride	Badge X2	80289-12
Synthetic	M1	Copper octanoate	Cueva	67702-2-70051
Synthetic	M1	Copper sulfate pentahydrate	CS 2005	66675-3
Synthetic	M1	Copper sulfate pentahydrate	Copper Sulfate Crystals	56576-1
Synthetic	M1	Cupric hydroxide	Nu-Cop 50 DF	45002-4
Synthetic	M1	Cuprous oxide	Nordox	48142-4
Synthetic	M2	Sulfur	Acoidal	62562-4
Synthetic	M2	Sulfur	Cosavet-DF	70905-1
Synthetic	M2	Sulfur	Defend DF	62562-8
Synthetic	M2	Sulfur	Kumulus DF	51306-352-66330
Synthetic	M2	Sulfur	Micro Sulf	55146-75
Synthetic	M2	Sulfur	Microthiol Disperss	70506-187
Synthetic	M2	Sulfur	Thiolux	34704-1079
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Kaligreen	70231-1
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70871-1-68539
Synthetic	NC; Inorganic salt	Potassium silicate	Sil-Matrix	82100-1
Synthetic	NC; Organic salt	Potassium salts of fatty acids	M-Pede	10163-324
Synthetic	NC; Organic salt	Insecticidal soap	Des-X	67702-22-70051
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate	70299-2
Synthetic	NC; Oxidizing agent	Hydrogen peroxide, Hydrogen dioxide	Perpose Plus	86729-1
Synthetic	NC; Petroleum oil	Mineral oil	Glacial Spray Liquid	34704-849
Synthetic	NC; Petroleum oil	Mineral oil	JMS Stylet Oil	65564-1
Synthetic	NC; Petroleum oil	Mineral oil	Omni Supreme Spray	5905-368
Synthetic	NC; Petroleum oil	Mineral oil	PureSpray Green	69526-9
Synthetic	NC; Petroleum oil	Mineral oil	SuffOil-X	48813-1-68539
Synthetic	NC; Petroleum oil	Mineral oil	TriTek	48813-1
Crop Group 13: Berries and Small Fruits: Strawberries / Anthracnose Fruit Rot (*Colletotrichum acutatum*)				
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel 55	70051-108
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel LC	70051-114
Non-synthetic	44	*Bacillus amyloliquefaciens* strain MBI 600	Serifel	71840-18
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Optimum	264-1160
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3
Non-synthetic	NC; Biological	*Aureobasidoium pullulans* strains DSM 14940 and DSM 19941	Botector	86174-3
Non-synthetic	NC; Biological	*Streptomyces lydicus* WYEC	Actinovate	73314-1
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)

US EPA Registered OMRI-Listed Alternatives [1] to Veggieturbo 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051)				
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.
Synthetic	M1	Copper octanoate	Cueva	67702-25-70051
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539
Synthetic	NC; Oxidizing agent	Hydrogen peroxide, Hydrogen dioxide	Perpose Plus	86729-1
Crop Group 13: Berries and Small Fruits: Strawberries / Gray Mold (*Botrytis cinerea*)				
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel 55	70051-108
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel LC	70051-114
Non-synthetic	44	*Bacillus amyloliquefaciens* strain F727	Stargus	84059-28
Non-synthetic	44	*Bacillus amyloliquefaciens* strain MBI 600	Serifel	71840-18
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Optiva	264-1160
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Optimum	264-1160
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3
Non-synthetic	NC; Biochemical	Rhamnolipid biosurfactant	Zonix	72431-1
Non-synthetic	NC; Biological	*Aureobasidoium pullulans* strains DSM 14940 and DSM 19941	Botector	86174-3
Non-synthetic	NC; Biological	*Gliocladium catenulatum*	Prestop	64137-11
Non-synthetic	NC; Biological	*Streptomyces lydicus* WYEC	Actinovate	73314-1
Non-synthetic	NC; Botanical oil	Cinnamon oil	Cinnerate	NA; 25(b)
Non-Synthetic	NC; Botanical oil	Clove oil, Rosemary oil, Peppermint oil	BacStop	NA; 25(b)
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)
Non-synthetic	NC; Botanical oil	Neem oil	Trilogy	70051-2
Synthetic	M1	Copper octanoate	Cueva	67702-25-70051
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate	70299-2
Synthetic	NC; Oxidizing agent	Hydrogen peroxide, Hydrogen dioxide	Perpose Plus	86729-1
Synthetic	NC; Petroleum oil	Mineral oil	JMS Stylet Oil	65564-1
Synthetic	NC; Petroleum oil	Mineral oil	PureSpray Green	69526-9
Crop Group 13: Berries and Small Fruits: Strawberries / Leather Rot (*Phytophthora cactorum*)				
Non-synthetic	BM2	*Trichoderma asperellum, Trichoderma gamsii*	Bio-Tam	80289-9
Non-synthetic	BM2	*Trichoderma harzianum* strain R-22, *Trichoderma virens* strain G41	Rootshield Plus+ Granules	68539-10
Non-synthetic	BM2	*Trichoderma harzianum* strain R-22, *Trichoderma virens* strain G41	Rootshield Plus+ WP	68539-9
Non-synthetic	NC; Biological	*Aureobasidium pullulans* strains DSM 14940 and DSM 14941	Botector	86174-3
Non-synthetic	NC; Biological	*Gliocladium catenulatum*	Prestop	64137-11

US EPA Registered OMRI-Listed Alternatives [1] to Veggieturbo 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051)				
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.
Crop Group 13: Berries and Small Fruits: Strawberries / Phomopsis Leaf Spot (Blight) (*Phomopsis obscurans*)				
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3
Non-synthetic	NC; Biological	*Aureobasidoium pullulans* strains DSM 14940 and DSM 19941	Botector	86174-3
Synthetic	M1	Copper octanoate	Cueva	67702-2-70051
Synthetic	M1	Cupric hydroxide	Nu-Cop 50 DF	45002-4
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539
Crop Group 13: Berries and Small Fruits: Strawberries / Phomopsis Fruit Rot (*Phomopsis obscurans*)				
Non-synthetic	NC; Biological	*Aureobasidoium pullulans* strains DSM 14940 and DSM 19941	Botector	86174-3
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539
Crop Group 13: Berries and Small Fruits: Strawberries / Powdery Mildew (*Podosphaera aphanis*, *Sphacelotheca* sp.)				
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel 55	70051-108
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel LC	70051-114
Non-synthetic	44	*Bacillus amyloliquefaciens* strain MBI 600	Serifel	71840-18
Non-synthetic	44	*Bacillus pumilus* strain QST 2808	Sonata	264-1153
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade ASO	264-1152
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Max	264-1151
Non-synthetic	44	*Bacillus subtilis* strain QST 713	Serenade Optimum	264-1160
Non-synthetic	NC; Biochemical	Rhamnolipid biosurfactant	Zonix	72431-1
Non-synthetic	NC; Biological	*Streptomyces lydicus* WYEC	Actinovate	73314-1
Non-synthetic	NC; Botanical oil	Neem oil	Trilogy	70051-2
Non-synthetic	NC; Botanical oil	Cinnamon oil	Cinnerate	NA; 25(b)
Non-synthetic	NC; Botanical oil	Garlic oil, Cottonseed oil, Corn oil	Mildew Cure	NA; 25(b)
Non-synthetic	NC; Botanical oil	Clove oil, Rosemary oil, Peppermint oil	BacStop	NA; 25(b)
Non-synthetic	NC; Botanical oil	Rosemary oil, Clove oil, Thyme oil	Sporatec	NA; 25(b)
Non-synthetic	NC; Botanical oil	Soybean oil	Golden Pest Spray	57538-11
Synthetic	M1	Copper octanoate	Cueva	67702-2-70051
Synthetic	M2	Sulfur	Acoidal	62562-4
Synthetic	M2	Sulfur	Cosavet-DF	70905-1
Synthetic	M2	Sulfur	Defend DF	62562-8
Synthetic	M2	Sulfur	Kumulus DF	51306-352-66330
Synthetic	M2	Sulfur	Micro Sulf	55146-75
Synthetic	M2	Sulfur	Microthiol Disperss	70506-187
Synthetic	M2	Sulfur	Thiolux	34704-1079
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1
Synthetic	NC; Inorganic salt	Potassium bicarbonate	EcoMate Armicarb O	5905-541
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Kaligreen	70231-1
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70871-1-68539
Synthetic	NC; Inorganic salt	Potassium silicate	Sil-Matrix	82100-1
Synthetic	NC; Organic salt	Potassium salts of fatty acids	M-Pede	10163-324
Synthetic	NC; Organic salt	Insecticidal soap	Des-X	67702-22-70051
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate	70299-2
Synthetic	NC; Oxidizing agent	Hydrogen peroxide, Hydrogen dioxide	Perpose Plus	86729-1

US EPA Registered OMRI-Listed Alternatives [1] to Veggieturbo 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) and Oso 5%SC Fungicide (EPA Reg. No. 68173-4-70051)				
NOP Status	FRAC [A] Code(s)	Active Ingredient(s)	Product	EPA Reg. No.
Synthetic	NC; Petroleum oil	Mineral oil	Glacial Spray Liquid	34704-849
Synthetic	NC; Petroleum oil	Mineral oil	JMS Stylet Oil	65564-1
Synthetic	NC; Petroleum oil	Mineral oil	Omni Supreme Spray	5905-368
Synthetic	NC; Petroleum oil	Mineral oil	PureSpray Green	69526-9
Synthetic	NC; Petroleum oil	Mineral oil	SuffOil-X	48813-1-68539
Synthetic	NC; Petroleum oil	Mineral oil	TriTek	48813-1
Crop Group 19: Herbs and Spices : Basil / Downy Mildew (*Peronospora belbahrii*)				
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel 55	70051-108
Non-synthetic	44	*Bacillus amyloliquefaciens* strain D747	Double Nickel LC	70051-114
Non-synthetic	P5	*Reynoutria sachalinensis* extract	Regalia	84059-3
Non-synthetic	NC; Biological	*Streptomyces lydicus* WYEC	Actinovate	73314-1
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Agricure	70870-1
Synthetic	NC; Inorganic salt	Potassium bicarbonate	Milstop	70870-1-68539
Synthetic	NC; Oxidizing agent	Hydrogen dioxide, Peroxyacetic acid	Oxidate	70299-2

1. Botector (EPA Reg. No. 86174-3), based upon the January 5, 2018 EPA accepted label, is approved by NOP for use in organic production. No OMRI listing is noted. Nonetheless, Botector is included in the above table. Fracture (EPA Reg. No. 84876-1-279) is a biopesticide but is *not* currently OMRI-listed based upon information on the Internet.

For alternative products for other crop/disease combinations, please see the May 31, 2016 petition Overview of OMRI-Listed Alternatives section beginning on page 50.

Though the list of US EPA registered OMRI-listed alternatives is long, *the list of US EPA registered OMRI-listed alternatives with comparable or superior efficacy is short*.

Based upon *disease significance and efficacy data alone*, there is *organic grower need* for the polyoxin D zinc salt 5SC formulation (a.k.a. Oso) for treatment of:

- Blueberries for control of Alternaria blight (*Alternaria* spp.) and Botrytis blight (*Botrytis cinerea*);
- Caneberries for control of Botrytis fruit rot (*Botrytis cinerea*) and powdery mildew (*Podosphaera aphanais*);
- Cranberries for control of cottonball (Monilinia oxycocci) and fruit rot complex (*Coleophoma empetri*, *Colletotrichum acutatum*, *Colletotrichum gloeosporioides*, *Phyllosticta vaccinii*, and *Physalospora vaccinii*, etc.);
- Grapes for control of Phomopsis fruit rot (*Phomopsis viticola*);
- Strawberries for control of anthracnose fruit rot (*Colletotrichum acutatum*), gray mold (*Botrytis cinerea*), leather rot (*Phytophthora cactorum*), and Phomopsis fruit rot (soft rot) (*Phomopsis obscurans*); and
- Basil for control of downy mildew (*Peronospora belbahrii*).

OMRI-listed alternatives initially identified as having comparable or superior efficacy and therefore identified for more detailed comparisons were:

- Blueberries/mummyberry (*Monilinia vaccinii-corymbosi*): Optiva;
- Grapes black rot (*Guignardia bodwellii*): Badge X2 and Nu-Cop 50 WP;
- Grapes/bunch rot (*Botrytis cinerea*): Double Nickel 55 and Double Nickel LC;
- Grapes/downy mildew (*Plasmopara viticola*): Badge X2, Cueva, and Oxidate;
- Grapes/powdery mildew (*Erysiphe necator*): Micro Sulf, Lifegard WG and Stargus; and
- Strawberries/Phomopsis leaf spot (*Phomopsis obscurans*): Cueva.

Based upon *efficacy data and other considerations*, there is *organic grower need* for the polyoxin D zinc salt 5SC formulation (a.k.a. Oso) for treatment of:

- Blueberries for control of mummyberry (*Monilinia vaccinii-corymbosi*). Compared to Optiva, the polyoxin D zinc salt 5SC formulation offers organic blueberry growers:
  - Competitive efficacy for control of mummyberry;
  - Competitive worker and environmental safety;
  - A treatment option *after* mummyberry is first observed;
  - A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and
  - Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.

- Grapes for the control of black rot (*Guignardia bodwellii*). Compared to Badge X2 and Nu-Cop 50 WP, the polyoxin D zinc salt 5SC formulation offers organic grape growers:
  - Competitive efficacy for control of black rot;
  - Greater crop, worker, and environmental safety;
  - An opportunity to reduce the amount of copper applied to their vineyards and thereby reduce the negative effects of copper on soil;
  - Reduced (EPA's minimum) personal protective equipment requirement;
  - Greater flexibility in growing the crop (0-day PHI instead of 1-day; 4-hour worker re-entry interval instead of 48-hours or 24-hours);
  - A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and
  - Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.

- Grapes for the control of bunch rot (*Botrytis cinerea*). Compared to Double Nickel 55 and Double Nickel LC, the polyoxin D zinc salt 5SC formulation offers organic grape growers:
  - Competitive or superior efficacy for control of bunch rot;
  - A treatment option *after* bunch rot is first observed;
  - Competitive worker and environmental safety;
  - A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and
  - Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.

- Grapes for the control of downy mildew (*Plasmopara viticola*). Compared to Badge X2, Cueva, and Oxidate, the polyoxin D zinc salt 5SC formulation offers organic grape growers:
  - Competitive or superior efficacy for control of downy mildew;
  - An opportunity to reduce the amount of copper applied to their vineyards and thereby reduce the negative effects of copper on soil;
  - Greater to significantly greater crop, worker, and environmental safety;
  - Reduced (EPA's minimum) personal protective equipment requirement;
  - Greater flexibility in growing the crop [0-day PHI instead of 1-day PHI; 4-hour worker re-entry interval instead of 48 hours (Badge X2)];
  - A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and
  - Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.

- Grapes for control of powdery mildew (*Erysiphe necator*). Compared to Micro Sulf, Lifegard WG and Stargus, the polyoxin D zinc salt 5SC formulation offers organic grape growers:
  - Competitive or superior efficacy for control of powdery mildew;
  - A treatment option ***after*** powdery mildew is first observed;
  - An opportunity to reduce the amount of copper applied to their vineyards and thereby reduce the negative effects of copper on soil;
  - Competitive or superior crop, worker, and environmental safety;
  - Greater flexibility in growing the crop [0-day PHI instead of 1-day PHI; 4-hour worker re-entry interval instead of 48 hours (Badge X2)];
  - Increased applicator comfort (no respirator is required as is required for Lifegard WG and Stargus);
  - A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and
  - Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.

- Strawberries for control of Phomopsis leaf spot (*Phomopsis obscurans*). Compared to Cueva, the polyoxin D zinc salt 5SC formulation offers organic strawberry growers:
  - Competitive efficacy for control of Phomopsis leaf spot;
  - A treatment option ***after*** Phomopsis leaf spot is first observed;
  - Competitive or superior crop, worker, and environmental safety;
  - Increased applicator comfort (no respirator is required as for Serifel);
  - A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and
  - Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.

Please note:

- For scheduling reasons, this analysis is limited to berries and small fruits and basil. Similar results are anticipated if other crop/disease combinations were analyzed.
- There is no EPA registered, OMRI-listed alternative for treatment of cranberries for control of cottonball (*Monilinia oxycocci*).

Please also note:

- The polyoxin D zinc salt 5SC formulation has been demonstrated to *improve* the performance of:
  - Double Nickel LC (containing *Bacillus amyloliquefaciens* strain D747; FRAC Code 44).
  - Actinovate (containing *Streptomyces lydicus* WYEC 108; no FRAC Code; biological);
  - Regalia (containing *Reynoutria sachalinensis* extract; FRAC Code P5); and
  - NovaSource's Lime-Sulfur (containing calcium polysulfide; FRAC Code M2).
- Polyoxin D zinc salt stops the growth of sensitive fungi. Therefore, Kaken does not recommend the use of polyoxin D zinc salt as a tank-mix partner or as part of the treatment program with products containing *Trichoderma* species [(Bio-Tam (EPA Reg. No. 80289-9), Rootshield Plus WP (EPA Reg. No. 68539-9) and Rootshield Plus Granules (EPA Reg. No. 68539-10)].

12. Describe any alternative practices that would make the use of the petitioned substance unnecessary.

For all uses of the polyoxin D zinc salt 5SC formulation included in this addendum with at least one OMRI-listed alternative product for the specified crop/disease combination, excluding strawberry/leather rot, there are OMRI-listed *synthetic* alternative products. Therefore, with the exception of strawberry/leather rot, NOP has determined that cultural practices alone are *not* sufficient to address organic grower needs.

CRITERIA

7 USC §6517(c)(1) states:

"Exemption for prohibited substances in organic production and handling operations The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this chapter only if—

(A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that the use of such substances—

(i) would not be harmful to human health or the environment;

(ii) is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products; and

(iii) is consistent with organic farming and handling."

Kaken proposed that polyoxin D zinc salt:

- Would not be harmful to human health or the environment;
- Is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products;
- Is consistent with organic farming and handling; and
- Therefore qualifies for addition to 7 CFR §205.601(i) as a synthetic substance allowed for use in organic crop production as plant disease control.

LEVEL PLAYING FIELD

Kaken proposes that the National Organic Standards Board and the National Organic Program should have a level playing field when considering proposed additions to the list of synthetic substances allowed for use in organic crop production. The criteria used in the evaluation of polyoxin D zinc salt should be no more restrictive than those applied to the synthetic substances currently listed in 7 CFR §205.601(i) as permitted in organic agriculture for use on crops as plant disease control.

APPENDIX 1: VEGGIETURBO 5SC SUSPENSION CONCENTRATE FUNGICIDE EPA ACCEPTED LABEL (JANUARY 3, 2018)

068173-00004.20171218.Changes_IMPLEMENTED.pdf
VEGGIETURBO 5SC (EPA File Symbol 68173-4) • Page 1 of 23
December 18, 2017 Proposed Master Label Fast-Track Amendment
Based upon the May 16, 2017 EPA accepted label. Updated resistance management.
Cucurbit, stone fruit, and grape/berries new disease claims and new/edited application details.
"Not for use in California" statements added (artichoke, banana/plantain, ginseng, sugar beets).

[Front Panel]

Polyoxin D Zinc Salt	GROUP	19	FUNGICIDE

VEGGIETURBO™ 5SC

Suspension Concentrate Fungicide

Optional text:

For Control of Fungal Diseases of Listed Vegetable and Fruit Crops
Biofungicide For Control of Fungal Diseases of Listed Vegetable and Fruit Crops
Biochemical Fungicide For Control of Fungal Diseases of Listed Vegetable and Fruit Crops
Biofungicide
Biochemical Fungicide

Active Ingredient	
Polyoxin D zinc salt	5.0%
Other Ingredients	95.0%
Total	100.0%

Contains 7.03 ounces of active ingredient per gallon.

KEEP OUT OF REACH OF CHILDREN

CAUTION

ACCEPTED
01/03/2018
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 68173-4

See back panel for additional precautionary statements.
[Alternate statements:]
See below for additional precautionary statements.
See inside panel for additional precautionary statements.
See inside panels for additional precautionary statements.
See inside panels for additional precautionary statements and directions for use.
See inside panels for additional Precautionary Statements, First Aid Statements, Directions for Use, and Storage and Disposal Statements.
See inside panels for complete label.
See booklet for additional precautionary statements.
See booklet for additional precautionary statements and directions for use.
See booklet for additional precautionary statements, directions for use, and storage and disposal statement.
See booklet for complete label
See attached booklet for additional Precautionary Statements, First Aid Statements, Directions for Use, and Storage and Disposal Statements.
See accompanying shipping documents for complete label.

[*Containers up to 2.5 gallons:*]
SHAKE WELL BEFORE USE

Produced by:
Kaken Pharmaceutical Co., Ltd.
28-8, Honkomagome 2-chome, Bunkyo-ku,
Tokyo, JAPAN 113-8650

EPA Reg. No. 68173-4
EPA Est. No. 89397-JPN-1 (or 92668-JPN-1)

NET CONTENTS: **1 Quart (32 Fluid Ounces)**
1 Gallon (128 Fluid Ounces)
2.5 Gallons (320 Fluid Ounces)
266 Gallons (1000 Liters)

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December 18, 2017 Proposed Master Label Fast-Track Amendment
Based upon the May 16, 2017 EPA accepted label. Updated resistance management.
Cucurbit, stone fruit, and grape/berries new disease claims and new/edited application details.
"Not for use in California" statements added (artichoke, banana/plantain, ginseng, sugar beets).

[Back Panel]

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

Caution. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with skin and clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse**.**

Optional Statements (EPA Category IV toxicity for acute oral, acute dermal, acute inhalation, eye irritation and dermal irritation)	
FIRST AID	
IF ON SKIN OR CLOTHING:	• *Take off contaminated clothing.* • *Rinse skin immediately with plenty of water for 15-20 minutes.* • *Call a poison control center or doctor for treatment advice.*
IF IN EYES:	• *Hold eye open and rinse slowly and gently with water for 15-20 minutes.* • *Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.* • *Call a poison control center or doctor for further treatment advice.*
IF SWALLOWED:	• *Call a poison control center or doctor immediately for treatment advice.* • *Have person sip a glass of water if able to swallow.* • *Do not induce vomiting unless told to do so by the poison control center or doctor.* • *Do not give anything to an unconscious person.*
IF INHALED:	• *Move person to fresh air.* • *If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.* • *Call a poison control center or doctor for further treatment advice.*
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. *HOTLINE NUMBER: 1-800-255-3924*	

PERSONAL PROTECTIVE EQUIPMENT (PPE)

All mixers, loaders, applicators and other handlers must wear:

- Long-sleeved shirt and long pants;
- Socks;
- Shoes; and
- Chemical-resistant gloves.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.
When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides, the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should:

- Remove clothing/PPE immediately if pesticides get inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

[For 1 liter, 1 gallon and 2.5 gallon containers:]
For terrestrial use. This pesticide is moderately toxic to aquatic invertebrates and fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate. Do not allow runoff into lakes, streams, ponds or public waterways. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Observe the most restrictive labeling limitations and precautions of all products used in mixtures.

[For 1000 liter container:]
For terrestrial use. This pesticide is moderately toxic to aquatic invertebrates and fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate. Do not allow runoff into lakes, streams, ponds or public waterways. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Observe the most restrictive labeling limitations and precautions of all products used in mixtures. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

GENERAL INFORMATION

VEGGIETURBO 5SC can be applied as a preventative or curative treatment in conjunction with good management practices.
VEGGIETURBO 5SC can be used alone or, when diseases not specified on this label are present or expected, in combination and/or rotation with other appropriately labeled fungicides as a tool for integrated disease management in labeled agricultural crops. See "Mixing and Handling Instructions" below for additional information.
Preharvest Interval (PHI) = 0 days. VEGGIETURBO 5SC is exempt from the requirement for residue tolerance and therefore can be applied up to and including the day of harvest.

RESISTANCE MANAGEMENT RECOMMENDATIONS

This product contains a Group 19 fungicide. Any fungal population may contain individuals naturally resistant to this product and other Group 19 fungicides. A gradual or total loss of pest control may occur over time if these fungicides are used repeatedly in the same fields. Appropriate resistance management strategies should be followed. To delay fungicide resistance, take one or more of the following steps:

- Rotate the use of this product or other Group 19 fungicides within a growing season sequence with different groups that control the same pathogens. Avoid application of more than the specified maximum number of applications and 2 consecutive sprays of this product or other fungicides in the same group in a season.
- Use tank mixtures with fungicide from a different group that are equally effective on the target pest when such use is permitted. Use at least the minimum application rate as labeled by the manufacturer.
- Adopt an integrated disease management program for fungicide use that includes scouting, uses historical information related to pesticide use, and crop rotation, and which considers host plant resistance, impact of environmental conditions on disease development, disease thresholds, as well as cultural, biological and other chemical control practices.
- Where possible, make use of predictive disease models to effectively time fungicide applications. Note that using predictive models alone is not sufficient to manage resistance.
- Monitor treated fungal populations for resistance development.
- Contact your local extension specialist or certified crop advisor for any additional pesticide resistance management and/or IPM recommendations for specific crops and pathogens.
- For further information or to report suspected resistance contact your pesticide distributor or university extension specialist.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours unless wearing appropriate PPE.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is: coveralls, socks, shoes, and chemical-resistant gloves.

MIXING AND APPLICATION INSTRUCTIONS

VEGGIETURBO 5SC may be applied by ground or aerial spray equipment, as a soil drench, or by chemigation through sprinklers or drip irrigation. See the table below for information on application methods and timing for specific crops and diseases.

For spray application, mix VEGGIETURBO 5SC in water and apply as a spray to foliage, fruit, or other above-ground plant parts. For optimum control of labeled diseases, apply in sufficient volume of water to provide thorough coverage with minimal run-off.

See "Chemigation Instructions" below for information about applying VEGGIETURBO 5SC through irrigation systems.

[For 1 quart, 1 gallon and 2.5 gallon containers:]
Mixing instructions for VEGGIETURBO 5SC:

- *Shake well before use.*
- *Fill tank with water to ½ of the intended final volume.*
- *Start agitation of the spray tank.*
- *Add the appropriate amount of product to the tank according to the rates in this label.*
- *Agitate to ensure thorough mixing while adding the remaining required water.*
- *Do not allow the mixture to stand without agitation.*
- *Mix only the amount of solution needed to treat the desired area.*

[For 1000 Liter container:]
Thoroughly agitate product when product is in use.

When tank mixing VEGGIETURBO 5SC with other products, observe all precautions and limitations on each separate product label.

When planning to mix this product with others, it advisable to conduct a "jar test" to determine the physical compatibility of this product with the others. Using a quart jar, add the products (with agitation) to approximately one quart of water in the proportions they will appear in the final mixture. Add dry formulations first, followed by flowables, then emulsifiable concentrates like VEGGIETURBO 5SC last. After thorough mixing, allow this mixture to stand for 5 minutes. If the combination remains mixed or can be readily remixed, it is physically compatible. Once compatibility has been proven, use the same sequence for adding required ingredients to the tank.

To assess the potential for phytotoxicity, test tank mixtures on a small number of plants prior to more widespread application.

If more applications or shorter intervals than indicated in the table below are needed to maintain disease control, alternate VEGGIETURBO 5SC with other fungicides having different modes of action to avoid or slow development of pathogen resistance. See "Resistance Management Recommendations" above for more information.

Use of an adjuvant may enhance spray coverage of dense crop canopy, or plants that are difficult to wet due to waxy or hairy surfaces. Use only adjuvants that are labeled for such uses. Refer to "Mixing and Application Instructions" above for information on testing physical compatibility of VEGGIETURBO 5SC with other products.

BANDED (IN-FURROW) APPLICATION

Use the table below to determine the correct application rate in fluid ounces of product per 1,000 row feet based on row spacing and desired rate per acre. Mix the required amount of VEGGIETURBO 5SC in water and apply as banded spray (4" to 6" wide) or seedline drench centered over the planting furrow. Apply to soil immediately before seeding or directly over seeds in the furrow just before they are covered with soil. The volume of water required per acre or per 1,000 row feet will depend on the application equipment used. Consult your local cooperative extension service if you need assistance calibrating band spraying equipment.

Rates for banded (in-furrow) application: Find desired application rate in the left column. Read across the line to the correct row spacing indicated at the top to find the number of fluid ounces per 1000 row feet that will provide the desired application rate per acre.

Fluid oz. per acre	Fluid ounces per 1000 row feet														
	Space between rows (inches)														
	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40
6.50	0.15	0.17	0.20	0.22	0.25	0.27	0.30	0.32	0.35	0.37	0.40	0.42	0.45	0.47	0.50
13.00	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95	0.99

CHEMIGATION INSTRUCTIONS

GENERAL INFORMATION:

- Apply this product only through pressurized irrigation systems such as sprinkler irrigation including center pivot, lateral move, end tow, side (wheel) roll, traveler, big gun, solid set, or hand move; or drip (trickle) irrigation systems. Do not apply this product through any other type of irrigation system.
- Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.
- If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts.
- Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.
- A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.
- Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.
- Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, back flow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

- The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection.
- The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.
- Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
- Do not apply when wind speed favors drift beyond the area intended for treatment.
- Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.
- Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and injector system and flush with clean water before use. Failure to provide a clean tank, free of scale or residues may reduce effectiveness of this product.

DRIP (TRICKLE) AND MICRO-IRRIGATION CHEMIGATION:

- The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from back flow.
- The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
- Systems must use a metering pump such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
- Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer, or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.

SPRINKLER CHEMIGATION:

- The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from back flow.
- The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
- Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

- Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Apply to moderately moist soils. Use volumes that thoroughly wet the soil but that do not cause significant runoff or excessive drip from pots. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.
- Do not apply when wind speed favors drift beyond the area intended for treatment.

CROPS, DISEASES AND APPLICATION RATES

CROP GROUP 1: ROOT AND TUBER VEGETABLES: Carrots and Parsnips		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
Alternaria leaf blight (*Alternaria dauci*) **Cercospora leaf blight** (*Cercospora carotae*) **Powdery mildew** (*Erysiphe polygoni*) **Rhizoctonia crown rot and leaf blight** (*Rhizoctonia solani*)	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	Begin applications soon after plant emergence and repeat on 7-14 day interval as long as conditions favor disease development. Apply as a foliar spray in sufficient water to achieve thorough coverage of all above- ground plant parts. May also be applied through overhead sprinkler irrigation. See "Chemigation Instructions" for additional information.
A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre.		

CROP GROUP 1: ROOT AND TUBER VEGETABLES: Ginseng †		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
Alternaria blight (*Alternaria panax*) **Botrytis blight** (*Botrytis cinerea*)	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	Apply as foliar spray every 7-10 days beginning within 2 weeks after plant emergence, prior to disease development (consult local extension service for advice on timing against these diseases). Continue throughout the season as needed to maintain control.
Cylindrocarpon root rot (*Cylindrocarpon destructans*) **Rhizoctonia root and crown rot** (*Rhizoctonia solani*)		Apply as soil drench every 14-28 days, beginning within 2 weeks after plant emergence.
A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre. † Not for use in California.		

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Cucurbit, stone fruit, and grape/berries new disease claims and new/edited application details.
"Not for use in California" statements added (artichoke, banana/plantain, ginseng, sugar beets).

CROP GROUP 1: ROOT AND TUBER VEGETABLES: Potatoes		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
Black scurf (*Rhizoctonia solani*)	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	Apply as banded spray in-furrow at planting, either just before placement of seed pieces or over seed pieces before covering with soil. See additional instructions under BANDED (IN-FURROW) APPLICATION.
Early blight (*Alternaria solani*) **Late blight** (*Phytophthora infestans*)*		Apply as a foliar spray in sufficient water to provide thorough coverage of all foliage. May also be applied through overhead sprinkler irrigation. See "Chemigation Instructions" for additional information. Begin as a preventative application and continue on a 7-14 day interval as needed to maintain control.
White mold (*Sclerotinia sclerotiorum*)		Apply in 30 - 50 gallons of water per acre as a directed spray toward soil surface, lower leaves, and stems. May also be applied through overhead sprinkler irrigation. See "Chemigation Instructions" for additional information.
* Suppression only. A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre.		

CROP GROUP 1: ROOT AND TUBER VEGETABLES: Sugar Beet †		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
Cercospora leaf spot (*Cercospora beticola*)	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	Begin applications at first sign of disease symptoms and repeat on 7-14 day interval as long as conditions favor disease development. Apply as a foliar spray in sufficient water to achieve thorough coverage of all above- ground plant parts. May also be applied through overhead sprinkler irrigation. See "Chemigation Instructions" for additional information.
Rhizoctonia crown and root rot (*Rhizoctonia solani*)		Apply as banded spray or drench in seed furrow at planting. See additional instructions below for banded application rates. Can also be applied through overhead sprinkler irrigation. See "Chemigation Instructions" for additional information. Make subsequent applications at 7-14 day intervals either through chemigation, or as a spray/drench directed at the base of each plant.
A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre. † Not for use in California.		

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Cucurbit, stone fruit, and grape/berries new disease claims and new/edited application details.
"Not for use in California" statements added (artichoke, banana/plantain, ginseng, sugar beets).

CROP GROUP 3: BULB VEGETABLES: Chive, Daylily, Elegans hosta, Fritillaria, Garlic, Kurrat, Lady's leek, Leek, Lily, Onion, Shallot, Cultivars, varieties, and/or hybrids of these		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
Alternaria blight and Purple blotch (*Alternaria* spp.) **Botrytis leaf blight /Leaf spot/Neck rot** (*Botrytis* spp.) **Downy mildew** (*Peronospora* spp.)* **Rust** (*Puccinia alii* or *Puccinia porri*)	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	Apply as foliar preventative spray (ground, aerial, or through overhead sprinklers) before disease onset and continue at 7-14 day intervals as needed to maintain control. Coverage may be enhanced by use of a spray adjuvant.
* Suppression only. A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre.		

CROP GROUP 4: LEAFY VEGETABLES (EXCEPT BRASSICA VEGETABLES): **Amaranth, Arugula (garden rocket), Asparagus chicory, Beet greens (spinach beet), Borage, Catalogna, Celery, Chard, Chaya, Chicory, Colocasia, Corn salad (mâche), Dandelion, Endive, Escarole, Fenugreek, Garden cress, Ground-elder, Kailan, Lettuce (Head, Leaf, Iceberg, Romaine), Mizuna, Purslane, Radichetta, Radicchio, Sorrel, Spinach, Spinach beet (beet greens), Spring greens (Spring mix), Stinging nettle, Tatsoi, Tropaeolum (*Nasturtium*), Turnip greens, Watercress (*Nasturtium*), Water spinach (ong choy), Yarrow**		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
Alternaria leaf spot (*Alternaria* spp.) **Downy mildew** (*Bremia lactucae* and *Peronospora* spp.)* **Powdery mildew** (*Golovinomyces (Erysiphe) cichoracearum*) **White rust** (*Albugo occidentalis*)	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	Begin applications soon after plant emergence or transplanting and repeat on 7-14 day interval as long as conditions favor disease development. Apply as a foliar spray in sufficient water to achieve thorough coverage of all above- ground plant parts.
Botrytis damping off (*Botrytis* spp.)		Apply as banded spray (4-6" wide) over the seed furrow at planting or transplanting. See additional instructions under BANDED (IN-FURROW) APPLICATION.
Botrytis leaf blight, Botrytis rot (*Botrytis* spp.)		Begin preventative foliar applications when conditions favor disease development and continue at 7-14 day intervals as long as needed to maintain control.
Bottom rot (*Rhizoctonia solani*)		Apply in 30 - 50 gallons of water per acre as a directed spray toward soil surface and lower leaves. Begin applications at head formation, before leaves contact the ground. Repeat every 7-14 days as needed to maintain control.
Lettuce drop (*Sclerotinia* spp.)		Apply in 30 - 50 gallons of water per acre as a directed spray toward soil surface and lower leaves. Make first application to direct-seeded lettuce immediately after emergence. For transplanted lettuce, make first application immediately after transplanting. In both cases, apply prior to disease development. Apply again if soil is disturbed by cultivation or thinning and conditions continue to favor disease development.

* Suppression only.

- May also be applied through overhead sprinkler irrigation. See "Chemigation Instructions" for additional information.
- A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre.

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"Not for use in California" statements added (artichoke, banana/plantain, ginseng, sugar beets).

CROP GROUP 5: BRASSICA (COLE) LEAFY VEGETABLES: Broccoli, Broccoli raab, Brussels Sprouts, Cabbage, Chinese broccoli, Chinese Cabbage (Bok Choi, Napa, Gai choy), Cauliflower, Cavalo broccolo, Collards, Kale, Kohlrabi, Mizuna, Mustard Greens, Mustard spinach, Rape greens		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
Alternaria leaf spot (*Alternaria* spp.) **Anthracnose** (*Colletotrichum* spp.) **Gray mold** (*Botrytis cinerea*) **White spot** (*Cercosporella* spp.)	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	Apply as a foliar spray in sufficient water to attain thorough coverage. Use of an adjuvant may enhance spray coverage, especially of waxy leaves. Begin preventive sprays when conditions favor disease development, and continue on a 7-14 day spray interval as needed.
Bottom rot (*Rhizoctonia solani*) **Sclerotinia rot** (*Sclerotinia sclerotiorum*)		Apply in 30 - 50 gallons of water per acre as a directed spray toward soil surface and lower leaves. Begin applications at head formation, before leaves contact the ground. Repeat every 7-14 days as needed to maintain control.
A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre.		

CROP GROUP 6: LEGUME VEGETABLES (SUCCULENT OR DRIED): Bean (Lupines spp.), Bean (*Phaseolus* spp., including Field bean, Kidney bean, Lima bean, Navy bean, Pinto bean, Runner bean, Snap bean, Tepary bean, Wax bean), Bean (*Vigna* spp., including Adzuki bean, Asparagus bean, Blackeyed pea, Catjang, Chinese longbean, Cowpea, Crowder pea, Moth bean, Mung bean, Southern pea, Urd bean, Yardlong bean) Broad bean (Fava bean), Chickpea (Garbanzo bean), Guar, Jackbean, Lablab bean (hyacinth bean), Lentil, Pea (*Pisum* spp., including Dwarf pea, Edible pod pea, English pea, Field pea, Garden pea, Green pea, Snow pea, Sugar snap pea), Pigeon pea, Soybean, Sward bean.		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
Asian Soybean Rust (*Phakopsora pachyrhizi*) **Gray mold** (*Botrytis cinerea*) **Powdery mildew** (*Erysiphe pisi*)	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	Begin applications at first sign of disease symptoms and repeat on 7-14 day interval as long as conditions favor disease development. Apply as a foliar spray in sufficient water to achieve thorough coverage of all above- ground plant parts. May also be applied through overhead sprinkler irrigation. See "Chemigation Instructions" for additional information.
Stem rot / White mold (*Sclerotinia sclerotiorum*)		Apply in 30 - 50 gallons of water per acre as a directed spray toward soil surface, lower leaves, and stems. May also be applied through overhead sprinkler irrigation. See "Chemigation Instructions" for additional information.
A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre.		

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Cucurbit, stone fruit, and grape/berries new disease claims and new/edited application details.
"Not for use in California" statements added (artichoke, banana/plantain, ginseng, sugar beets).

CROP GROUP 8: FRUITING VEGETABLES: Eggplant, Groundcherry, Peppers (all types), Tomatillo, Tomatoes (all types)		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
Anthracnose (*Colletotrichum* spp.)* **Early blight** (*Alternaria solani*) **Gray mold/Botrytis rot** (*Botrytis* spp.) **Late blight*** (*Phytophthera infestans*) **Leaf mold** (*Fulvia (Cladosporium) fulvum*, also known as *Passalora fulva*) **Powdery mildew** (*Leveillula, Oidiopsis, Erysiphe*, and *Sphaerotheca* spp.) **Target spot** (*Corynespora cossiicola*)*	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	Apply as a preventative foliar spray when conditions favor disease development. Repeat application at 7-14 day intervals as needed during infection periods. Mix in sufficient water to attain thorough coverage of foliage and fruit (if present).
Southern blight (*Sclerotium rolfsii*)* **Verticillium wilt** (*Verticillium dahliae*)*		See additional instructions under BANDED (IN-FURROW) APPLICATION. Can also be applied through surface (not buried) drip or overhead sprinkler irrigation. See "Chemigation Instructions" for additional information. Make subsequent applications at 7-14 day intervals either through surface drip or overhead sprinkler irrigation, or as a spray/drench directed at the base of each plant.

* Suppression only.
A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre.

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"Not for use in California" statements added (artichoke, banana/plantain, ginseng, sugar beets).

CROP GROUP 9: CUCURBIT VEGETABLES: **Chayote (fruit), Chinese waxgourd (Chinese preserving melon), Citron melon, Cucumber, Gherkin, Gourd (edible, including hyotan, cucuzza, hechima, Chinese okra), *Momordica* spp. (includes balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (includes true cantaloupe, cantaloupe, casaba, crenshaw melon, golden pershaw melon, honeydew melon, honey balls, mango melon, Persian melon, pineapple melon, Santa Claus melon, and snake melon), Pumpkin, Squash (including acorn squash, butternut squash, calabaza, crookneck squash, hubbard squash, scallop squash, spaghetti squash, straightneck squash, vegetable marrow, zucchini), Watermelon, Hybrids and varieties of these**		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
Anthracnose (*Colletotrichum orbiculare*) **Downy mildew** (*Pseudoperonospora cubensis*)* **Early blight** (*Alternaria* sp.) **Gray mold** (*Botrytis* sp.) **Gummy stem blight** (*Didymella bryoniae* and *Phoma cucurbitacearum*) **Powdery mildew** (*Erysiphe* and *Sphaerotheca* spp. and *Podosphaera xanthii*) **Scab** (*Cladosporium* sp.) **Target leaf spot/Corynespora leaf spot/ Corynespora blight** (*Corynespora cassiicola*)	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	Mix in sufficient volume of water for good spray coverage (typically 50-100 gallons per acre). Begin preventive sprays when conditions favor disease development, and continue on a 7-14 day spray interval as needed. For *Downy mildew*, begin preventive sprays when conditions favor disease development, and continue on a 5-8 day spray interval as needed.
Southern blight (*Sclerotium rolfsii*)		See additional instructions under BANDED (IN-FURROW) APPLICATION. Can also be applied through surface (not buried) drip or overhead sprinkler irrigation. See "Chemigation Instructions" for additional information. Make subsequent applications at 7-14 day intervals either through surface drip or overhead sprinkler irrigation, or as a spray/drench directed at the base of each plant.
* Suppression only. A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre.		

CROP GROUP 10: CITRUS FRUITS: **Calamondin, Citron, Citrus hybrids (Chironja, Tangelo, Tangor), Clementine, Grapefruit, Kumquat, Lemon, Lime, Mandarin (Tangerine), Orange, Pummelo, Sutsuma mandarin**		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
***Alternaria* brown spot** (*Alternaria alternata*)	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	Apply as preventative foliar spray before disease development, when spring flush is ¼ to ½ expanded. If needed, make second application to fully expanded flush.
Botrytis rot (*Botrytis cinerea*)		Begin preventative applications during bloom when rain or fog is expected. Repeat every 7-14 days as long as conditions favoring disease persist.
Septoria spot (*Septoria citri*)		Apply as a preventative spray in late fall or early winter, just before or after the first rain. Additional applications may be necessary during seasons of heavy rainfall.
A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre.		

CROP GROUP 11: POME FRUITS: Apple, Crabapple, Loquat, Mayhaw, Pear, Quince		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
Alternaria leaf spot (*Alternaria mali*) **Leaf blotch** (*Diplocarpon mali*) **Powdery mildew** (*Podosphaera leucotricha, Phyllactinia mali*) **Scab** (*Venturia* spp.)*	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	Apply as foliar spray in sufficient water to attain thorough coverage of foliage and fruit. For *Powdery mildew* control, begin as preventative and repeat on 7-14 day interval as needed. Use in an alternating program with a sterol inhibitor (DMI) fungicide. For *Scab suppression*, begin sprays at green tip and continue every 7-10 days as needed.
* Suppression only. A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre.		
Alternaria rot (*Alternaria tenuis*) **Bitter rot** (*Glomerella cingulata*) **Cedar apple rust**** (*Gymnosporangium juniperi-virginianae*) **Flyspeck** (*Schizothyrium pomi*, formerly *Microthyriella rubi*) **Sooty blotch** (*Gloeodes pomigena*) **White rot**** (*Botryosphaeria dothidea*)	6.5 fl. oz./acre (0.42 - 0.36 oz. a.i./acre) Do not apply more than 2.16 oz. a.i./acre/season (6 appl. at max. rate).	Begin applications prior to disease development. Repeat at 7-10 day interval as needed. May be applied from green-tip to day of harvest.
** Suppression only.		

CROP GROUP 12: STONE FRUITS: Apricot (including Japanese), Capulin, Cherry (including Black, Nanking, Sweet, Tart), Jujube (Chinese), Nectarine, Peach, Plum (including American, Beach, Canada, Cherry, Chickasaw, Damson, Japanese, Klamath, prune), Plumcot, Sloe, Cultivars, varieties, and/or hybrids of these.		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
Botrytis blossom blight (*Botrytis cinerea*) **Leaf curl** (*Taphrina demormans*)* **Monilinia brown rot blossom blight** Monilinia brown rot fruit rot (*Monilinia* sp.) **Powdery mildew** (*Podosphaera* spp., *Sphaerotheca pannosa*) Scab (*Cladosporium carpophilum*)*	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	Apply as foliar spray in sufficient water to attain thorough coverage of foliage and fruit. For *Botrytis blossom blight* control, apply at full bloom if wet weather occurs during bloom. For *Leaf curl suppression and Scab* suppression, apply preventatively at bud swell. Repeat on 14-28 day intervals as needed. For *Monilinia brown rot blossom blight and fruit rot* control, apply preventatively when conditions favor disease development. Repeat on 7-14 day interval as needed. For preventative control of post-harvest brown rot fruit rot, apply at 6.5 fl. oz./acre up to 3 days pre-harvest. For *Powdery mildew* control, begin as preventative and repeat on 7-14 day interval as needed. Use in an alternating program with a sterol inhibitor (DMI) fungicide.
* Suppression only. A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre.		

CROP GROUP 13-07: BERRIES AND SMALL FRUITS
[Excluding Blueberry (highbush and lowbush), Cranberry, Grape, and Strawberry]:
Amur river grape; Aronia berry; Bayberry; Bearberry; Bilberry; Blackberry (including Andean blackberry, arctic blackberry, bingleberry, black satin berry, boysenberry, brombeere, California blackberry, Chesterberry, Cherokee blackberry, Cheyenne blackberry, common blackberry, coryberry, darrowberry, dewberry, Dirksen thornless berry, evergreen blackberry, Himalayaberry, hullberry, lavacaberry, loganberry, lowberry, Lucretiaberry, mammoth blackberry, marionberry, mora, mures deronce, nectarberry, Northern dewberry, olallieberry, Orgeon evergreen berry, phenomenalberry, rangeberry, ravenberry, rossberry, Shawnee blackberry, Southern dewberry, tayberry, youngberry, zarzamora, and cultivars, varieties and/or hybrids of these); Buffalo currant; Buffaloberry; Che; Chilean guava; Chokecherry; Cloudberry; highbush; Currant, black; Currant, red; Elderberry; European barberry; Gooseberry; Honeysuckle, edible; Huckleberry; Jostaberry; Juneberry (Saskatoon berry); Kiwifruit, fuzzy; Kiwifruit, hardy; Lingonberry; Maypop; Mountain pepper berries; Mulberry; Muntries; Native currant; Partridgeberry; Phalsa; Pincherry; Raspberry, black and red; Riberry; salal; schisandra berry; Sea buckthorn; Serviceberry; Wild raspberry; cultivars, varieties, and/or hybrids of these

SEE SEPARATE TABLES FOR BLUEBERRIES, CRANBERRIES, GRAPES, AND STRAWBERRIES.

DISEASES/PATHOGENS	RATES	ADDITIONAL INFORMATION
***Alternaria* leaf spot and fruit rot** (*Alternaria* spp.) **Anthracnose leaf & fruit rot** (*Colletotrichum* spp.)* **Gray mold/fruit rot/Botrytis blight** (*Botrytis cinerea*) **Powdery mildew** (*Sphaerotheca macularis*, *Erysiphe* spp.) Yellow rust (*Phragmidium rubi-idaei*)	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	Apply as a foliar spray in sufficient water to provide thorough coverage. Can also be applied through overhead sprinkler irrigation. See "Chemigation Instructions" for additional information. Begin as a preventative application and continue on a 7-14 day interval as needed to maintain control. For control of *Botrytis* and other fruit diseases, begin applications at flowering.

* Suppression only.
A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre.

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Cucurbit, stone fruit, and grape/berries new disease claims and new/edited application details.
"Not for use in California" statements added (artichoke, banana/plantain, ginseng, sugar beets).

CROP GROUP 13-07: BERRIES AND SMALL FRUITS: Blueberries, highbush and lowbush		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
***Alternaria* leaf spot and fruit rot** (*Alternaria* spp.) **Anthracnose leaf & fruit rot** (*Colletotrichum* spp.)* **Gray mold/fruit rot/Botrytis blight** (*Botrytis cinerea*) **Mummyberry** (*Monilinia vaccinii-corymbosi*) **Powdery mildew** (*Sphaerotheca macularis*, *Erysiphe* spp.)	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	Apply as a foliar spray in sufficient water to provide thorough coverage. Can also be applied through overhead sprinkler irrigation. See "Chemigation Instructions" for additional information. Begin as a preventative application and continue on a 7-14 day interval as needed to maintain control. For control of *Botrytis and other fruit diseases*, begin applications at flowering. For control of *Mummyberry*, begin applications at early green tip.
* Suppression only. A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre.		

CROP GROUP 13-07: BERRIES AND SMALL FRUITS: Cranberries		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
Cottonball (*Monilinia oxycocci*) **Cranberry Fruit Rot Complex** (*Allantophompsis* sp., *Botrytis cinerea*, *Colletotrichum acutatum*, *Colletotrichum gloeosporioides*, *Coloepnoma empetri*, *Fusicoccum putrefaciens*, *Glomerella cingulata**, *Phomopsis vaccinii*, *Physalospora vaccinii*, *Phyllosticta vaccinii*)	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	Apply as a foliar spray in sufficient water to provide thorough coverage. Can also be applied through overhead sprinkler irrigation. See "Chemigation Instructions" for additional information. For *Cottonball*, begin as a preventative application at 10% bloom. Continue on a 7-14 day interval as needed to maintain control. For *Cranberry fruit rot complex*, begin as a preventative application at 40% bloom. Continue on a 7-14 day interval as needed to maintain control. For best performance, apply in 20 gallons water/acre.
* Suppression only. A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre.		

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Cucurbit, stone fruit, and grape/berries new disease claims and new/edited application details.
"Not for use in California" statements added (artichoke, banana/plantain, ginseng, sugar beets).

CROP GROUP 13-07: BERRIES AND SMALL FRUITS: Grapes: For pre-harvest use on all grapes		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
Black rot (*Guignardia bidwellii*)* **Downy mildew** (*Plasmopara viticola*) **Gray mold/bunch rot** (*Botrytis cinerea*) **Phomopsis fruit rot** (*Phomopsis viticola*) **Powdery mildew** (*Erysiphe* (*Uncinula*) *necator*)	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	For *Black rot* suppression, begin as a preventative spray when shoots are 3-5 inches long. Repeat every 7-14 days as needed to maintain control. For *Downy mildew* and *Phomopsis fruit rot*, begin as a preventative spray when shoots are 3-5 inches long. Repeat every 7-14 days as needed to maintain control. For *Gray mold / Bunch rot*, begin application at early bloom. Apply a maximum of 6 applications per season at a minimum of 7-day intervals. For optimal control, include application at veraison as one of the 6 applications. For *Powdery mildew*, begin as a preventative spray and repeat every 14 days as needed to maintain control.
A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre. * Suppression only.		

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Cucurbit, stone fruit, and grape/berries new disease claims and new/edited application details.
"Not for use in California" statements added (artichoke, banana/plantain, ginseng, sugar beets).

CROP GROUP 13-07: BERRIES AND SMALL FRUITS: Strawberries		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
***Alternaria* leaf spot and fruit rot** (*Alternaria* spp.) **Anthracnose fruit rot** (*Colletotrichum acutatum*, *C. dematium*) **Common leaf spot** (*Mycosphaerella fragariae*) **Gray mold/fruit rot/Botrytis blight** (*Botrytis cinerea*) **Leather rot** (*Phytophthora cactorum*) **Phomopsis leaf spot and fruit rot** (*Phomopsis obscurans*) **Powdery mildew** (*Sphaerotheca macularis*, *Erysiphe* spp.) **Rhizopus soft rot** (*Rhizopus* sp. and *Mucor* sp.) **Tan brown rot** (*Hainesia lythri*)	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	Apply as a foliar spray in sufficient water to provide thorough coverage. Can also be applied through overhead sprinkler irrigation. See "Chemigation Instructions" for additional information. For *Alternaria*, *Anthracnose fruit rot*, *Common leaf spot*, *Gray mold*, *Leather rot*, *Phomopsis leaf spot and fruit rot*, *Powdery mildew*, and *Tan brown rot*, begin as a preventative application and continue on a 7-14 day interval as needed to maintain control. For *Rhizopus soft rot*, begin as a preventative application and continue on a 7-10 day spray interval as needed to maintain control. For control of fruit diseases, begin applications at flowering.
A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre.		

CROP CROUP 19: HERBS AND SPICES †: Allspice, angelica, anise, anise, star, annatto (seed), balm, basil, borage, burnet, camomile, caper buds, caraway, caraway, black, cardamom, cassia bark, cassia buds, catnip, celery seed, chervil (dried), chive, chive, Chinese, cinnamon, clary, clove buds, coriander leaf (cilantro or Chinese parsley), coriander seed (cilantro), costmary, cilantro (leaf), culantro (seed), cumin, curry (leaf), dill (dillweed), dill (seed), fennel (common), fennel, Florence (seed), fenugreek, grains of paradise, horehound, hyssop, juniper berry, lavender, lemongrass, lovage (leaf), lovage (seed), mace, marigold, marjoram, mustard (seed), nasturtium, nutmeg, parsley (dried), pennyroyal, pepper, black, pepper, white, poppy (seed), rosemary, rue, saffron, sage, savory, summer and winter, sweet bay, tansy, tarragon, thyme, vanilla, wintergreen, woodruff, and wormwood.		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
Downy mildew (*Peronospora* spp. and others) **Powdery mildew** (*Oidium* spp. and others)	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 2.2 oz. a.i./acre/season (6 appl. at max. rate).	Begin preventive sprays when conditions favor disease development, and continue on a 7-10 day spray interval as needed.
† Not for use in California. • Product may harm herbs and spices, especially new leaves. Do not apply to herbs and spices without prior testing on a small number of plants. • A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre.		

CROP GROUP 24: TROPICAL AND SUBTROPICAL FRUIT, INEDIBLE PEEL: Bananas and Plantains *		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
Black Sigatoka leaf streak (*Mycosphaerella fijiensis* Morelet) **Yellow Sigatoka leaf spot** (*Mycosphaerella musicola*)	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	Begin applications when leaves first appear and repeat on a 7-21 day interval or as needed. Apply in sufficient water to obtain thorough coverage of foliage. For improved control, product may be tank- mixed with other fungicides registered for control of Sigatoka at label rates. When conditions are conducive to rapid disease development and/or heavy disease pressure, higher application rates and rotational spray programs with other fungicides registered for control of Sigatoka are recommended.
* For use in Hawaii and Puerto Rico only. A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre.		

MISCELLANEOUS COMMODITIES (NO CROP GROUP): Artichokes (Chinese and Jerusalem) †		
DISEASES/PATHOGENS	**RATES**	**ADDITIONAL INFORMATION**
Gray mold/Botrytis rot (*Botrytis cinerea*) **Powdery mildew** (*Leveillula taurica, Erysiphe cichoracearum*)	6.5 - 13.0 fl. oz./acre (0.42 - 0.72 oz. a.i./acre) Do not apply more than 4.2 oz. a.i./acre/season (6 appl. at max. rate).	Begin applications at first sign of disease symptoms and repeat on 7-14 day interval as long as conditions favor disease development. Apply as a foliar spray in sufficient water to achieve thorough coverage of all above- ground plant parts. May also be applied through overhead sprinkler irrigation. See "Chemigation Instructions" for additional information.
A rate of 6.5 fl. oz./acre may be used for preventative applications before onset of visible disease, in periods of low disease pressure, or in a tank mix with other fungicides for resistance management. Otherwise, use a rate of 13.0 fl. oz./acre. † Not for use in California.		

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in dry place away from food or feed.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING:

[*Containers ≤ 5 gallons:*]

Nonrefillable container. Do not reuse or refill this container. Completely empty container into application equipment. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning (if available), or puncture and dispose of in a sanitary landfill or by incineration, if allowed by State and local authorities. If burned, stay out of smoke.

[*Containers > 5 gallons:*]

Nonrefillable container. Do not reuse or refill this container. Completely empty container into application equipment. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. *Triple rinse as follows:* Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two or more times. *Pressure rinse as follows:* Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. Then offer for recycling or reconditioning (if available), or puncture and dispose of in a sanitary landfill or by incineration, if allowed by State and local authorities. If burned, stay out of smoke.

WARRANTY

Kaken Pharmaceutical Co., Ltd. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purpose referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the disease problem, condition of the crop, incompatibility with other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESSED OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

VEGGIETURBO™ is a trademark of Kaken Pharmaceutical Co., Ltd.

Label Version No. _____

Note: Subcommittee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

National Organic Standards Board (NOSB)
Livestock/Aquaculture Subcommittee (LS) Meeting Notes
Tuesday, February 6, 2018 3:00 pm ET

Attending: Ashley Swaffar, (AS), Chair; Sue Baird (SB), Vice Chair; Harriet Behar (HB); Jesse Buie (JB); A-dae Romero-Briones (ARB); Dan Seitz (DS)
Absent: None
Staff: Michelle Arsenault (MA)

Work Agenda

Petitioned Materials						
Substance	**Nat'l List §**	**Contact**	**TR requested**	**Notes**	**Scheduled, Discussed, Voted**	**Meeting**
Glycolic Acid 2016	205.603	AS	Y	Petition sent to LS 06 06 15. Response/request for TR due 08 08 16. TR requested 07 19 16. TR sent to LS 11 07 17. Response/request for TR due 01 08 18. TR found sufficient 12 19 17.	Jul 19, 2016, Dec 19, Feb 20	Spr 2018
Oxalic Acid	205.603	HB	Y	Petition sent to LS 10 27 17. Response/request for TR due 12 26 17. Petition found suff 12 5 17. TR Requested 12 5 17	Dec 5	TBD
Aquaculture Substances (See table below)				On hold until aquaculture rule is published.	TBD	TBD

2020 Sunsets TR Requests: July 2017, Summary: Spr 2018, Review: Fall 2018						
Name	**National List §**	**Con tact**	**TAP/TR**	**Notes**	**Scheduled, Discussed**	**Review Meeting**
Alcohols: Ethanol, Isopropanol	205.603	JB	N	1995 TAP; 2014 TR Ethanol; 2014 TR Isopropanol	Dec 5	Summary: Spr 2018 Review: Fall 2018
Aspirin	205.603	AS	Y	1995 TAP. TR requested 07 28 17. TR in contracting. TR sent to LS 12 20 17. Response due 02 19 18	Dec 19	"
Biologics, Vaccines	205.603	HB	N	2011 TR (Vaccines from Excluded Methods); 2014 TR (Aquaculture)	Dec 19	"
Electrolytes	205.603	HB	N	1995 TAP; 2015 TR	Dec 19	"

Glycerine	205.603	SB	N	2010 TAP (Livestock)	Feb 6	"
Phosphoric acid	205.603	DS	N	2003 TAP (Handling). Low priority	Jan 16	"
Lime, hydrated	205.603	ARB	N	1995 TAP; 2015 TR	Feb 6	"
Mineral oil	205.603	ARB	N	2002 TAP; 2015 TR	Feb 6	"
Sucrose octanoate esters	205.603	SB	N	2005 TR	Feb 6	"

Other projects					
Project	**Contact**	**TR Reqst ?**	**Notes**	**Discussed, Voted**	**Meeting**
Defining emergency treatment for parasiticides	HB	N	Approved for addition to work agenda 07 15 16. Discussion doc. Postponed until Fall 2017	Dec 5, Dec 19, Jan 16, Feb 20	TBD
Research Priorities (RP)	HB/AS/SB	NA	RPs due to MS Aug 2017		Fall 2018
Organic poultry task force	ARB/AS/HB		Discuss formation of Task Force - on hold pending resolution of OLPP final rule.	NA	NA

Commented [AM-A1]: As per NOP

* Yellow highlight indicates committee action needed *Highlight indicates review completion/vote taken

Agenda

- Approve notes from January 16, 2018
- 2020 sunset: Glycerine (SB)
- 2020 sunset: Sucrose octanoate esters (SB)
- 2020 sunset: Lime, hydrated (ARB)
- 2020 sunset: Mineral oil (ARB)
- 2020 sunset: Biologics, vaccines (HB)
- Defining emergency treatment for parasiticides (HB)
- Other items
- Adjourn

Discussion

- **Notes from the** January 16 were approved with no changes
- **2020 sunset: Glycerine (SB).** The lead summarized the uses and previous review history of glycerine, and the group discussed it. It was noted that this is a non-controversial substance.

- **2020 sunset: Sucrose octanoate esters (SOE) (SB).** The lead summarized the uses and past NOSB reviews for SOE. The LS members modified some of the questions that will be included for public comment.
- **2020 sunset: Lime, hydrated (ARB).** The lead described the uses of hydrated lime and summarized previous comments. Hydrated lime is only permitted for use as an external parasiticide. A member clarified the difference between the various forms of lime, noting that hydrated lime is not allowed as a soil amendment.
- **2020 sunset: Mineral oil (ARB).** The lead summarized the use and manufacture of mineral oil, noting that it is derived from crude oil. Previous reviews did not elicit many comments. The group discussed adding some questions regarding its usage and how it is being applied.
- **2020 sunset: Biologics, vaccines (HB).** Based on a conversation on the last call, the lead modified the draft review and the group discussed the changes. A member asked about the presence of Confidential Business Information (CBI) in vaccines, and questioned how the NOSB can fully evaluate a substance without knowing that information. A member also asked about alternative practices. The lead will make some additional edits and will finalize the document for submission to NOP.
- **Defining emergency treatment for parasiticides (HB).** The LS would like to bring this forth as a discussion document and will request this on the upcoming Executive call.
- **Other items.** None
- **The meeting was adjourned.**

Previous LS Notes

Future Call Schedule (1st and 3rd Tuesdays 3:00 ET)

January 2, 2018 - cancelled

January 16, 2018

- 2020 sunset: Glycerine (SB) - discuss
- 2020 sunset: Sucrose octanoate esters (SB) - discuss
- 2020 sunset: Phosphoric acid (DS) - discuss
- 2020 sunset: Lime, hydrated (ARB) - discuss
- 2020 sunset: Mineral oil (ARB) – discuss
- 2020 sunset: Biologics, Vaccines (HB) - discuss
- Defining emergency treatment for parasiticides (HB)

February 6, 2018

- 2020 sunset: Glycerine (SB). Deferred to next call.
- 2020 sunset: Sucrose octanoate esters (SB). Deferred to next call.
- 2020 sunset: Lime, hydrated (ARB). Deferred to next call.
- 2020 sunset: Mineral oil (ARB). Deferred to next call.
- 2020 sunset: Biologics, vaccines (HB)
- Defining emergency treatment for parasiticides (HB)

February 20, 2018

- Glycolic Acid (AS) - Discuss draft proposal
- Defining emergency treatment for parasiticides (HB) - Discuss next steps
- Aspirin (AS) - TR sufficiency (due Feb 19)

March 6, 2018

March 20, 2018

April 3, 2018

April 17, 2018

May 1, 2018

May 15, 2018
June 5, 2018
June 19, 2018
July 3, 2018
July 17, 2018
August 7, 2018
August 21, 2018
September 4, 2018
September 18, 2018
October 2, 2018
October 16, 2018
November 6, 2018
November 20, 2018
December 4, 2018
December 18, 2018

Spring 2018 Milestones	Target dates (tentative)
New NOSB member orientation	TBD
NOSB - Spring 2018 proposals due to NOP	Feb 21, 2018
NOP - Complete Spring 2018 NOSB meeting tentative agenda	Mar 6, 2018
NOP - Post proposals, Open public comment	Mar 6, 2018
Discuss work agendas on ES call	Mar 9, 2018
Public comment closes	Apr 4, 2018
NOP - Send compiled public comments to NOSB	Apr 9, 2018
Work agendas finalized on ES call (last call before fall meeting)	Apr 13, 2018
Public comment webinar(s)	Apr 17 & 19, 2018
Spring 2018 NOSB meeting – Tucson, AZ	Apr 25-27, 2018

Aquaculture petitions						
Substance	**Nat'l List §**	**Contact**	**TR requested**	**Notes**	**Scheduled, Discussed, Voted**	**Meeting**

Aquaculture-CO_2, (for aquatic plants)	205.609	TF/CBo	N	Petition sent to CS 5 30 12. Will rqst modification from petitioner (for use pattern). Updated petition was deemed sufficient. TR deemed unnecessary.	NA	Proposal TBD
Aquaculture-Chlorine (for aquatic plants)	205.609	FT	2011 Crops TR 2006 TR 1995 TAP	Petition sent to CS on 5 30 12. Determine petition sufficiency. CS requested clarification from petitioner 11 20 12. 2011 TR deemed suff for this review 11 20 12. Additional aquaculture TR deemed unnecessary. Sent follow up questions to petitioner. Response deemed sufficient.	NA	Proposal TBD
Aquaculture-Micronutrients (for aquatic plants)	205.609	FT	2010 TR (Nickel) 6/2013 Minerals TR	Petition sent to CS on 06 08 12. Petition sufficiency response due 08 08 12? CS sent request to NL Mgr. 12 04 12 for additional info. Questions clarified by petitioner. Petition found sufficient 06 18 13 and 07 02 13. TR deemed unnecessary.	NA	Proposal TBD
Aquaculture-Lignin sulfonate (chelating agent for aquatic plants) CAS #s 9009-75-0, 8062-15-5, 8061-51-6	205.609	JR	2/2011 Crops TR 7/2013 TR Aquatic Animals TR	Petition sent to CS on 07 03 12. Petition Sufficiency Response due 09 04 12. CS sent request to NL Mgr 12 04 12 for additional info and TR. Questions clarified by petitioner. Petition found sufficient 6 18 13 and 07 02 13.	NA	Proposal TBD
Aquaculture-Vitamins (B1, B12, H) for aquatic plants	205.609	CW	4/2013 Aquatic Animals TR	Petition sent to CS 08 10 12. Petition Sufficiency response due 10 10 12. Petition found sufficient 06 18 13.	NA	Proposal TBD
Aquaculture - Biologics: Vaccines for Aquatic Animals	205.611	JR	2011 TR (Vaccines made from GMOs)	Petition sent to LS 06 14 12. Petition found sufficient and TR requested on 05 21 13. (NOP note: TR sent to LS 01 24 14. TR deemed sufficient 02 03 14	NA	Proposal TBD

Aquaculture - Chlorine (for aquatic animals)	205.611	FT	N Crops 2011 Crops 2006 Crops 1995 Livestock 2006 Handling 2006	Petition sent to LS on 05 30 12. Petition found sufficient 07 03 12. No TR requested	NA	Proposal TBD
Aquaculture – Tocopherols (for aquatic animals)	205.611	TF/CBo	2013 TR 1995 TAP rvw	Petition sent to LS on 05 30 12. Petition found sufficient 08 06 12. TR requested 08 06 12. Draft TR sent to LS on 04 16 13. TR found sufficient 06 04 13	NA	Proposal TBD
Aquaculture – Vitamins (for aquatic animals)	205.611	CW/FT	Yes 2013 TR	Petition sent to LS 05 30 12. Response due ~07 30 12. Petition found suff 08 06 12. Requested joint TR with minerals 08 06 12. TR sent to LS 04 29 13. TR found suff 06 18 13.	NA	Proposal TBD
Aquaculture - Trace Minerals (for aquatic animals)	205.611	CW/FT	2013 TR	Petition sent to LS on 06 08 12. Response due ~08 08 12. Petition found sufficient 08 06 12? Requested joint TR with Vitamins 08 06 12. TR sent to LS 06 25 13. Suff due 08 27 13. TR found sufficient 07 16 13. Fall 2013 meeting cancelled.	NA	Proposal TBD

NOSB Crops Subcommittee
Microcrystalline Cheesewax
TR Sufficiency Review
February 6, 2018

Introduction

Microcrystalline cheesewax is a food-grade product which is composed of a blend of Microcrystalline Wax (CAS # 64742-42-3), Paraffin Wax (CAS # 8002-74-2), and Petrolatum (CAS # 8009-03-8). These ingredients are blended in different amounts to achieve the desired characteristics (i.e., flexibility, melting point, etc.) for a range of applications. All three of the ingredients are derived from the refinement of crude oil, as mixtures of long-chain hydrocarbons with relatively high melting points (>51 °C). Microcrystalline cheesewax is a complex combination of long chain (>12 C) hydrocarbons and is differentiated from paraffin waxes due to their higher average molecular weight, longer hydrocarbon chains, and the increased branching of the alkane chains.

The primary use of microcrystalline cheesewax in organic crop production is in log-based mushroom cultivation as a sealant for inoculation sites. In the cultivation process, a log is inoculated with spawn by drilling into the material and depositing the spawn. The microcrystalline cheesewax is then applied to the inoculation site to both secure the mushroom spawn, as well as to seal in the moisture required for successful cultivation

Background

Microcrystalline cheesewax was petitioned on 05/22/08 to be added to the National List §205.601(o) to be used as a production aid in log grown mushroom culture. On 06/16/008 the NOSB made a final recommendation to include microcrystalline cheesewax (CAS #'s 64742-42-3, 8009-03- 08, and 8002-74-2) on The National List §205.601(o) as a production aid in log grown mushroom culture made without either ethylene-propylene co-polymer or synthetic colors.

Microcrystalline cheesewax is currently listed under the National Organic Program (NOP) regulations at 7 CFR §205.601(o) as a synthetic substance allowed as a "production aid" for "use in log grown mushroom production," with the exception that the wax "must be made without either ethylene-propylene co-polymer or synthetic colors."

Status Updates

- **Organic Foods Production Act, USDA Final Rule:**

Neither microcrystalline cheesewax, nor its components identified in this petition are listed in the Organic Foods Production Act of 1990.

- **Canadian General Standards Board Permitted Substances List**

CAN/CGSB-32.311 "Table 6.5 Processing aids" prohibits the use of microcrystalline wax "either alone or in formulations with paraffin wax."

- **CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)**

Neither microcrystalline cheesewax, nor its components identified in this petition are listed in the CODEX (GL 32-1999).

- **European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008**

Neither microcrystalline cheesewax, nor its components identified in this petition are listed in EC No. 834-2007 nor EC No. 889/2008.

- **Japan Agricultural Standard (JAS) for Organic Production**

Neither microcrystalline cheesewax, nor its components identified in this petition are listed in the JAS for Organic Production.

Evaluation Questions answered by the Technical Evaluation Review

Indicate which category in OFPA that the substance falls under.

Microcrystalline Cheesewax may be considered as a seal; it is used in the cultivation of shitake mushrooms as a sealant to keep the inoculated spawn in place, while also sealing in the required moisture (NOSB, 2008).

Describe the persistence or concentration of the petitioned substance and/or its by-products in the environment (7 U.S.C. § 6518 (m) (2)).

A series of assessments done by Bareco Products, REPSO PETROLEO, S.A., and CONCAWE (Conservation of Clean Air and Water in Europe), found that the substance breaks down into a variety of smaller hydrocarbons (alkanes) in soil (Kimmons, 2006). These processes were found to be carried out by microfauna and microflora, with microflora as the more active means of degradation.

Following the completions of these studies, the respective firms labeled the substance as "readily biodegradable" in soil, indicating no expected persistence of the petroleum waxes, or their by-products in the environment (Kimmons, 2006). A literature search on the bioaccumulation of microcrystalline cheesewax gave no results, other than the studies cited in the initial petition for the substance delivered to the NOSB. Due to the labeling of microcrystalline wax as "readily biodegradable" in the environment, environmental contamination due to use, misuse, or disposal of the substance are not anticipated (SCF, 1995; EFSA, 2013).

Since the substance is isolated from refining crude oil, the manufacture and handling of the crude oil are the most likely means for environmental contamination. However, if good manufacturing practices are followed, incidents of contamination will be minimal.

Is there now an effective natural or approved synthetic replacement for the Microcrystalline Cheesewax that are derived from petroleum by-products?

Beeswax is a natural wax that may be used as a sealant for mushroom cultivation in place of microcrystalline cheesewax. Beeswax is naturally produced by bees for beehive construction. This natural wax is readily available for use in mushroom cultivation, without the potential environmental hazards of the handling and processing of crude oil, as required for microcrystalline cheesewax. However, the seal formed by beeswax is inferior to that which is produced by the application of microcrystalline cheesewax. This is due to several considerations. Beeswax has a relatively low melting point (62 to 64 °C) compared to the substance (>80 °C), resulting in the softening and lower viscosity under environmental conditions (Kimmons, 2006). Furthermore, beeswax has a greater concentration of aromatic molecules, which act to attract insects that remove the sealant from the inoculation site (Kimmons, 2006).

Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

An alternative practice for mushroom cultivation is the use of plastic bags, which are more efficient as a means of sealing in moisture to allow for mushroom cultivation. However, plastic bags are unable to help to secure the mushroom spawn, which may fall out of the inoculation site (Kimmons, 2006). Furthermore, this practice also relies on the use of plastic bags derived from crude oil sources, which may not be biodegradable. These bags are also not FDA approved for use in and around food products and are likewise not approved for use under NOP regulations.
There are no other alternative methods for 'log grown' mushroom cultivation.

Technical Review Sufficiency Determination

- **Is consistent in format, level of detail and tone**

The TR is consistent and provides clear explanation and sufficient detail.

- **Is technically objective and free from opinions or conjecture**

The research is presented objectively and without opinions or presumptions.

- **Is written in a style appropriate for non-technical readers (e.g. free of technical jargon)**

While there is technical jargon and chemical references, it is explained throughout the TR, and can be understood. The nature of the topic requires advanced technical knowledge, but the document is written in a manner to minimize additional research on the reader's part.

• Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance

The information gathering, information synthesis, document preparation and quality assurance is sufficient in this current TR.

• Is based on the best available information that can be obtained within the designated time frame

The TR contains information that is important to the Crops Subcommittee in determining the validity of the petitioner's use of this product.

• Is thoroughly supported using literature citations
The TR is well-referenced and includes 13 citations spanning both recent and earlier research on the subject.

• Addresses all evaluation questions in the TR template
All evaluation questions are adequately addressed.

TR Report received: 01.11.2018. Compiled by Savan Group

- Philip Shivokevich, Assistant Professor of Chemistry, Lander University
- Audrey Nicoleau, Technical Writer, Savan Group

Allyl Isothiocyanate

Crops

Identification of Petitioned Substance

Chemical Names:
Allyl isothiocyanate

Other Name:
2-propenylisothiocyanate
3-isothiocynanato-1-propene
Allyl isosulfocynate

Trade Names:
Oil of mustard
Allyl isothiocynanate (AITC

CAS Numbers:
57-06-07

Other Codes:
200-309-2 (EINECS No.)
24862709 (PubChem ID)

Summary of Petitioned Use

The petition before the National Organic Standards Board (NOSB) is to add allyl isothiocyanate (AITC, oil of mustard) as an allowed synthetic substance in organic crop production (§205.601) as a pre-plant fumigant. This includes the addition of AITC as a synthetic substance for use as an organic option supporting the certification of organic nursery seed and nursery stock plants in organic crop production with specific regard to the "Strawberry Nursery Stock Certification" and the "Nematode Certification". Specifically, AITC produced through chemical synthesis is petitioned for use. There is no related ruling offered by the National Organic Program (NOP) regarding the use of AITC in organic crop or livestock production from which comparisons may be drawn.

Although AITC is naturally generated through the composting and decomposition of mustard greens, the use of synthetic AITC as a pre-plant fumigant for organic crop production necessitates consideration of the chemistry of the concentrated substance in the terrestrial environment at the proposed application rates. Use of synthetic AITC must be evaluated against the criteria in the Organic Foods Production Act (OFPA), with consideration of the potential toxicity to beneficial soil microorganisms and terrestrial animals as well as alternative substances and practices available to organic crop producers.

Characterization of Petitioned Substance

Composition of the Substance:

The compositions of allyl isothiocyanate (AITC) formulations differ depending on the source of AITC and intended purpose of the product. At the molecular level, allyl isothiocyanate, with a molecular formula of C4H5NS, is a volatile organic compound composed of carbon, hydrogen, nitrogen and sulfur atoms (Chemical Book, 2010). Synthetic sources of AITC may contain traces of residual reagents and solvents used during synthesis, extraction, and/or purification of the substance. The synthetic sources being considered for pre-plant fumigation are typically greater than 95 percent pure (Isagro USA, 2013). Natural sources of AITC may contain small amounts of other plant-derived chemicals and solvent residues depending on the plant source and extraction technique employed to isolate AITC.

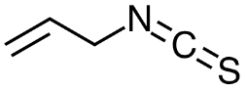

Figure 1. Allyl isothiocyanate (AITC) structural formula

Source or Origin of the Substance:

Both solvent extraction from natural plant sources and chemical synthetic procedures are used in the commercial production of allyl isothiocyanate (AITC). Historically, AITC has been extracted from the dried seeds of Brassica nigra (black mustard) for various industrial and therapeutic applications (Merck, 2006). Before being extracted, AITC is liberated from the glucosinolate sinigrin through reaction with myrosinase, an enzyme released when black mustard seeds are crushed (Romanowski, 2000). Chemical synthetic methods for AITC production from allyl iodide and potassium thiocyanate were published in the 1920s and variants of this process currently remain in use (Fan, 2012).

In addition to mustard seeds and foliage, a number of other plants (e.g., cabbage, kale, horseradish) naturally produce AITC. Likewise, synthetic AITC is added to processed foods as a flavoring agent and/or preservative. Table 1 below provides additional information on the occurrence of AITC in common food items. AITC concentrations observed in processed foods may represent naturally formed AITC released from glucosinolates and/or synthetic AITC intentionally added during food production.

Table 1. Occurrence of AITC in Common Foods

Product	AITC concentration (mg/kg)
Brussels sprouts	0.10
Cabbage	3.00
Cauliflower	0.08
Horseradish	1,350
Mustard	400–15,000
Baked goods	25–100
Condiments	700–5,000
Fats, oils	50
Fish products	0.05–0.07
Gelatins, puddings	1.00–2.00
Meat products	35–60
Seasonings, flavorings	6–30
Snack foods	48–100

Data Sources: Stofberg 1987; Velisek, 1995; Burdock, 2010

mg/kg = milligrams per kilogram (equivalent to parts per million, ppm)

Properties of the Substance:

Allyl isothiocyanate (AITC) is a colorless to light amber oily liquid with pungent odor. A summary of the chemical and physical properties of pure AITC is provided below in Table 2.

Table 2. Chemical and Physical Properties for AITC

Property	Value/Description
Color	Clear, colorless to light amber
Physical State	Oily liquid
Molecular Formula	CH_2=CHCH_2N=C=S (C_4H_5NS)
Molecular Weight, g/mol	99.15
Freezing Point, °C	–80; –102.5
Boiling Point, °C	150–154
Density, g/mL	1.0126
Solubility in water at 20 °C, mg/L	2,000 (soluble)
Solubility in organic solvents	Miscible in many organic solvents, including ethanol, ethyl ether, chloroform and benzene
Soil Organic Carbon-Water Partition Coefficient (K_{oc}), mL/g	260 (Moderately mobile in soils)
Aerobic Soil Half-life (DT_{50})	Literature suggests DT_{50} is 2 days

Hydrolysis	Facile (fully degraded within 80 minutes at pH 8)
Photodegradation	Photolysis not expected due to lack of chromophores; degraded in the atmosphere by photochemically produced hydroxyl radicals (half-life = 2.4 hours at 25 °C).
Octanol/Water Partition Coefficient (K_{ow})	141

Data Sources: HSDB, 2013; US EPA, 2013a; Chemical Book, 2010.

Specific Uses of the Substance:

Synthetic allyl isothiocyanate (AITC) generally is used as an insecticide, bacteriocide, nematicide for certain crop protection applications, while synthetic and natural forms of AITC (i.e., volatile oil of mustard) are commonly used for the flavoring and preservation of foods (EFSA, 2010). The current review is focused on the United States Environmental Protection Agency (US EPA) registered uses of AITC for pre-plant soil fumigation.

According to US EPA, AITC is a biochemical pesticide used as an "insect and animal repellent, feeding suppressant, insecticide, fungicide, herbicide and nematicide" (US EPA, 2013a). AITC is used heavily in the sugar industry due to its potent fungicidal activity. In this context, the substance protects sugar beets from fungi during storage (Romanowski, 2000). AITC has also been used for combatting Hylemya brassicae (the cabbage maggot fly) and other plant pests.

Numerous small-scale uses of AITC have also been reported in the available literature. For example, AITC may be used as a chemical feedstock in the production of war gases (Merck, 2006), a counter-irritant in medicine, a repellent for cats and dogs, a deterrent in some model airplane cements, and externally as a rubefacient (i.e., a substance for topical application that produces redness of the skin) (Gosselin, 1984).

With respect to "Strawberry Nursery Stock Certification" and the "Nematode Certification," AITC has potential to be a readily biodegradable alternative to other eradication treatments that are mandatory for maintaining pest cleanliness of the stock in these programs. Traditional eradication treatments include thermotherapy, fumigation using broad-spectrum fumigants such as methyl bromide or Telon II™, or steam treatments. The biggest issue generally facing nursery stock is nematodes (Meadows 2013). Like methyl bromide and Telon II™, AITC has been demonstrated to have a broad nematicidal activity (Yu 2005, Oliveira 2011, Aissani 2013). Thus, AITC or AITC-containing plant materials possess good potential to serve as alternative nematicides that are safer and more environmentally benign than traditional synthetic fumigants. However, the effectiveness of AITC can be selective. In a 2005 study, the nematicidal activity of AITC was evaluated using seven different species of nematodes, including six of the most important parasitic nematode species in agriculture world-wide (Yu 2005). The study found that the susceptibility or tolerance of nematode species was highly variable. While AITC was found to be toxic and possess anti-hatching activity against all the species in the study, the required concentrations of AITC for effective nematicidal activity was different across the species studied. This is a similar observation found in the fungicidal activity of AITC. However, the study also demonstrated that AITC was safe to a wide range of important agricultural crops (e.g., alfalfa, soybean, tomato, etc.) at concentrations that are toxic to parasitic nematodes (Yu 2005). Thus, phytotoxicity would not be a concern when AITC is used as a nematicide. The variability in effective concentrations for nematicidal activity suggests that careful evaluation of effective dosages and testing is required to ensure pest eradication that meets certification standards.

AITC was also found to be highly effective in eradicating *Rhizoctonia solani*, a plant pathogenic fungus, which causes seedling damping off and seedling blight in nursery stock of perennial and vegetable crops (Dhingra 2004). However, it should be noted that the rate of fungal activity needs to be determined before planting as the wait period between soil treatment and planting has a drastic influence on disease control.

Approved Legal Uses of the Substance:

The United States Food and Drug Administration (FDA) regulations allow the use of allyl isothiocyanate (AITC) as a food additive and active ingredient in certain drugs. According to FDA regulations, AITC may

be added to food as a synthetic flavoring substance or adjuvant if the substance is used in the minimum quantity to produce the intended effects and in accordance with the principles of good manufacturing practice (21 CFR 172.515). FDA acknowledges that some over-the-counter drug products contain AITC as the active ingredient, although inadequate data are available to establish general recognition of safety and effectiveness for these products. Specifically, AITC may be used in nasal decongestant drug products (21 CFR 310.545(a)(6)(ii)) as well as commercially available fever blister and cold sore treatments (21 CFR 310.545(a)(10)(v)).

The US EPA regulates all non-food applications of AITC, including its use as a fungicide, insecticide and animal repellent. Although US EPA first registered oil of mustard for pesticidal use in 1962, AITC is the active ingredient in only six EPA-registered products (EPA, 2013a; US EPA, 2014). Currently registered products include outdoor animal repellants and broad spectrum pre-plant soil biofumigants for control of certain soil-borne fungi, nematodes, weeds and insects (EPA, 2014). According to EPA regulation, AITC is exempt from the requirement of a tolerance for residues when used as a component of food grade oil of mustard, in or on all raw agricultural commodities (40 CFR 180.1167). The petitioned non-food use of AITC as a pre-plant fumigant would not lead to residues on food due to the prescribed use pattern and rapid dissipation of the substance in the environment.

Action of the Substance:

Allyl isothiocyanate (AITC) controls soil-borne pathogens, nematodes and weeds by acting as a general irritant and/or desiccant that may alter respiration in target diseases and pests. Following injection into the soil using a drip irrigation system or tractor for shank application, AITC acts to reduce the populations of soil-borne plant diseases and pests (Isagro USA, 2013).

Research involving exposure of bacterial species to AITC has provided insight into the toxic mode of action of pesticides containing AITC toward microbes. Reduced oxygen uptake and inhibition of some enzymatic activities were observed in gram-positive bacteria exposed to AITC. In the bacterium Escherichia coli, AITC exposure leads to disruption of the cellular membrane with concomitant leakage of intracellular metabolites. In particular, treatment of E. coli with AITC results in significant loss of intracellular adenosine triphosphate (ATP), an energy carrier for numerous metabolic processes. Experiments in another gram- positive bacterium suggest that AITC alters bacterial proteins by oxidative cleavage of disulfide bonds and attack of free amino groups (Hyldgaard, 2012; Faleiro, 2011). In addition to the toxic mode of action described above, AITC also acts as a potent animal repellent owing to its very pungent, irritating odor (US EPA, 2013a).

Combinations of the Substance:

Formulated pesticide products may contain more than one active ingredient, as well as surfactants, carriers and other adjuvants. The Isagro USA products included in the current petition contain synthetic allyl isothiocyanate (AITC) at 99.8% and 96.3% with no other active ingredients listed on the label (Isagro USA, 2013). Alternatively, a related insect control concentrate contains a mixture of AITC (3.7%) and capsicum oleoresin (0.42%) as the active ingredients (Champon, 2012). No other ingredients are listed on the label for this product. Dog and cat repellent products contain a complex mixture of essential oils and synthetic active ingredients, including oil of lemongrass (2.0%), oil of citronella (1.2%), AITC (0.20%), oil of orange (0.02%), methyl salicylate (0.02%), geraniol (0.04%), ionone alpha (0.01%), and oil of bergamot (0.11%). However, the manufacturer does not disclose the identity of other formulation ingredient on the label (Bakers, 2008). Overall, product formulations are considered confidential business information, and companies may reformulate products at any time.

Status

Historic Use:

Mustard oils produced through the pressing of black mustard seeds consist mostly of fatty acids as well as small amounts of allyl isothiocyanate (AITC). In fact, it is the AITC component of mustard oil that imparts its characteristic fragrance. Pressed mustard oil has been used for cooking and other cultural purposes for

centuries, especially in northern India (Shiva, 2000). However, the available literature suggests that it is the fatty acid composition, and not the AITC content, that is responsible for its historical uses in Indian culture.

The process of biofumigation or 'green manuring' utilizes Brassica plants (e.g., the mustard plant) as cover crops. The biofumigation process takes advantage of the naturally occurring volatile compounds (allelochemicals such as AITC) that are specific to the Brassicaceae genus and are released from damaged plant tissues when the cover crop is plowed under before reaching full maturity. It has been found that volatile chemicals like AITC are useful in the control of soil-borne pests and pathogens. In situations where green manuring or plow down crops are not practical, growers may utilize de-oiled mustard seed meals and powders in which the fatty acids have been removed from the seed through extraction. Noticeable differences in the amount of AITC produced from these meals is observed depending on how the mustard was grown, handled and processed (MPT, 2011).

US EPA first registered naturally occurring AITC as a component of oil of mustard in 1962 (US EPA, 2013a). As the key component of Oil of Mustard, EPA determined that AITC was the residue of concern and characterized the hazards to human health and the environment in the Reregistration Eligibility Decision for Flower Oils and Vegetable Oils (US EPA, 1993), the Biopesticides Registration Action Document for Oriental Mustard Seed (US EPA, 2008), and the Vegetable and Flower Oil Summary Document for Registration Review (US EPA, 2010). Products containing synthetic AITC are currently registered as pre-plant soil biofumigants and animal repellents. The biofumigation products included in the current petition are registered for use as insecticides, fungicides, herbicides and nematicides, and are applied by drip or shank injection (US EPA, 2013a; Isagro USA, 2013).

Organic Foods Production Act, USDA Final Rule:

Neither of the terms "allyl isothiocyanate" or "oil of mustard" are mentioned in the Organic Foods Production Act of 1990 (OFPA). However, the OFPA states that handlings operators shall not "use any packaging materials, storage containers or bins that contain synthetic fungicides, preservatives, or fumigants." None of the National List sections for organic crop production (7 CFR 205.601 and 205.602), organic livestock production (7 CFR 205.603 and 205.604), or organic handling (7 CFR 205.605 and 205.606) mention the use of AITC, oil of mustard, or fumigants. The current petition represents the first consideration of synthetic AITC biofumigants in any form of organic production in the United States.

International

Guidelines and regulations from a number of international organizations and regulatory bodies indicate that allyl isothiocyanate (AITC) is not permitted for use in organic production. Below, international standards and regulations regarding the use of chemical fumigants in any form of organic production are summarized.

Canadian General Standards Board

Canadian organic production standards forbid the use of "equipment, packaging materials and store containers, or bins that contain a synthetic preservative or fumigant" (CAN, 2011a). In addition, allyl isothiocyanate and oil of mustard are not listed on the Canadian Organic Production Systems Permitted Substances List (CAN, 2011b).

Codex Alimentarius

Allyl isothiocyanate and oil of mustard are not allowed for use in organic production under the Codex guidelines. Although pre-plant soil fumigation is not specifically mentioned, item six of Annex 1states that steam sterilization may be used for the control of soil diseases and pests when proper rotation of soil renewal cannot take place (Codex, 2013). It is further noted in item seven that "only in cases of imminent or serious threat to the crop and where the measures identified in 6 (above) are, or would not be effective, recourse may be had to products referred to in Annex 2." Synthetic allyl isothiocyanate is not currently included in Annex 2 as a permitted substance for plant pest and disease control (Codex, 2013).

European Economic Community Council

Commission Regulations (EC) No 834/2007 and 889/2008 do not permit the use of allyl isothiocyanate, oil of mustard or any other synthetic substance for pre-plant soil fumigation. As stated in EC 889/2008:

> *Where plants cannot be adequately protected from pests and diseases by measures provided for in Article 12 (1)(a), (b), (c) and (g) of Regulation (EC) No 834/2007, only products referred to in Annex II to this Regulation may be used in organic production. Operators shall keep documentary evidence of the need to use the product.*

Neither "allyl isothiocyanate" nor "oil of mustard" is listed in Annex II of EC 889/2008.

Japan Ministry of Agriculture, Forestry, and Fisheries

According to the Japanese standard, allyl isothiocyanate and oil of mustard are not listed as allowed substances for any purpose in organic plant production. Carbon dioxide is the only synthetic substance allowed for plant pest and disease control, and is limited to use in storage facilities (JMAFF, 2005a). This allowance is also listed in the Japanese standards for organic livestock products (JMAFF, 2005b). No mention of allyl isothiocyanate, oil of mustard, or fumigation was identified in the Japanese standards for organic feeds (JMAFF, 2005c) and organic processed foods (JMAFF, 2005d).

International Federation of Organic Agricultural Movements

Under the IFOAM Norms, fumigation with ethylene oxide, methyl bromide, aluminum phosphide or other substance not contained in Appendix 4 of the Norms is a prohibited pest control practice (IFOAM, 2014). Neither "oil of mustard" nor "allyl isothiocyanate" is listed in Appendix 4, and therefore AITC is not allowed for use in any form of organic production.

United Kingdom Soil Association

According to section 4.13.3 of the UK Soil Association organic crop production guide, growers may not use chemical fumigants in stores or on premises where organic crops are stored (Soil Association, 2014). There is no mention of AITC as a permitted pre-plant soil fumigant under the UK Soil Association standards.

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

Evaluation Question #1: Indicate which category in OFPA that the substance falls under: (A) Does the substance contain an active ingredient in any of the following categories: copper and sulfur compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers? (B) Is the substance a synthetic inert ingredient that is not classified by the EPA as inerts of toxicological concern (i.e., EPA List 4 inerts) (7 U.S.C. § 6517(c)(1)(B)(ii))? Is the synthetic substance an inert ingredient which is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part 180?

(A) As indicated in its chemical name and molecular formula (C4H5NS), allyl isothiocyanate (AITC) contains a single sulfur atom; therefore, AITC may be considered a sulfur compound.

(B) AITC is an active ingredient; it is not considered an inert ingredient when used in pesticide products. According to EPA regulation, AITC is exempt from the requirement of a tolerance for residues when used as a component of food grade oil of mustard, in or on all raw agricultural commodities (40 CFR 180.1167). The petitioned non-food use of AITC as a pre-plant fumigant and rapid dissipation of AITC in the environment precludes the occurrence of AITC residues on food.

Evaluation Question #2: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or

formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

A variety of preparatory techniques are available for allyl isothiocyanate (AITC), ranging from the *in situ* generation of AITC in agricultural fields using Brassica cover crops and mustard seed meal to synthetic production processes such as extraction of AITC from natural plant sources and industrial production techniques. The sections below provide details regarding three general strategies of producing AITC as a soil biofumigant.

Natural Formation from Plant Materials

Growers seeking to reduce the application of chemical inputs commonly utilize specialized cover crops for soil quality improvement and pre-plant pest management. In particular, cover crops consisting of mustard plants and related Brassica species (i.e., cole crops) are capable of naturally producing AITC for soil biofumigation (Haramoto, 2004). Mustards and related plants contain elevated amounts of glucosinolates[1] and the hydrolase enzyme, myrosinase (Borek, 1995). The glucosinolate sinigrin and enzyme myrosinase remain in separate compartments of the plant cell under typical growing conditions (Romanowski, 2000). Once the plant tissue is damaged, however, the enzyme myrosinase is released and liberates AITC from the glucosinolate sinigrin through enzymatic hydrolysis (bond cleavage with water) (Figure 2). Therefore, flailing and plowing under mustard and related cover crops is a natural way of generating AITC in soil for pre-plant soil fumigation.

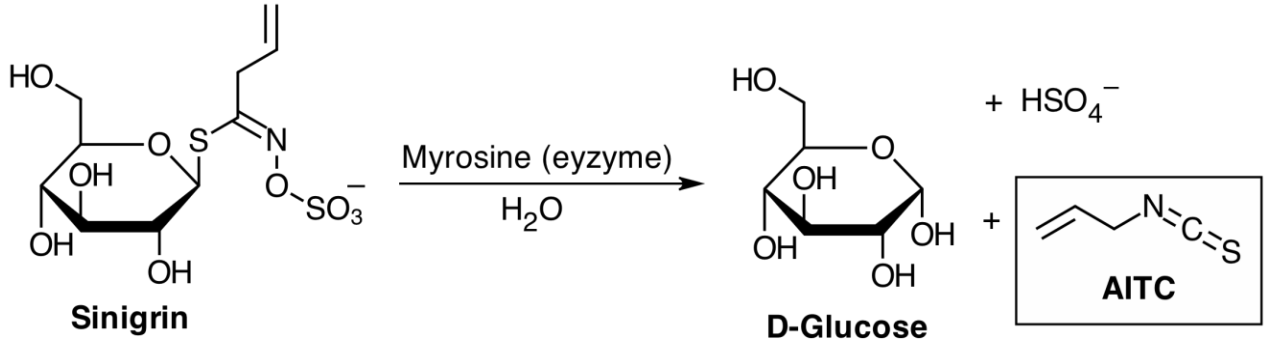

Figure 2. AITC is naturally produced through the enzymatic reaction of myrosinase with the glucosinolate sinigrin under moist conditions.

When living plant tissues containing the glucosinolate sinigrin and the enzyme myrosinase (e.g., mustard plants) are crushed, water within the plant material is available to facilitate AITC formation. Alternatively, crushing dried mustard seed in the absence of water does not lead to an immediate reaction. Commercial mustard meals prepared through the crushing of mustard seeds followed by removal of fatty acids using a hexane wash are marketed as sources of AITC for biofumigation (US EPA, 2008). Mincing mustard seed brings the key reaction components into physical proximity, but the enzymatic reaction resulting in liberation of AITC from the sinigrin precursor is initiated only through the introduction of water. AITC is released when mustard seed meal is wetted, and therefore incorporation of mustard seed meal into moist soil represents a natural approach to generating AITC on-site for soil biofumigation (Johnson, 2011). With the typical application rate of 1 ton/acre (Farm Fuel Inc., 2013b) and AITC content of mustard seed meal ranging from 2–17 g/kg (Dai and Lim, 2014), the equivalent application rate of AITC is 4–33 lb/acre. The available resources indicate that some organic growers, including organic strawberry producers, are adopting mustard seed meal as a natural option for soil pest control.

[1] Glucosinolates are organic anions containing a D-thioglucose moiety, a sulfonated oxime (N-O bonded group) and a unique side chain.

Extraction from Natural Sources

Chemically pure AITC was first produced through the extraction of the appropriate plant materials (e.g., mustard leaves and seeds) followed by distillation of the resulting extract residue. Much like the natural process described above, extraction of AITC involves the initial liberation of AITC from the glucosinolate sinigrin through reaction with myrosinase, an enzyme released when black mustard seeds and plant tissues are crushed (Romanowski, 2000). The original and more recent patent literature describes processes in which mustard seed is cracked and then combined with water to activate the enzyme myrosinase for AITC production (Mustakas, 1963; Sakai, 2005a and 2005b). This "activated mustard slurry" is allowed to react for a specified period of time at slightly elevated temperatures (e.g., 50 °C) before the AITC generated through enzymatic hydrolysis of sinigrin is separated from the bulk mustard seed residue. The ground mustard seed powders used in these processes are commonly defatted (devoid of fatty acids) through washing with hexanes to accelerate the hydrolysis reaction. Isolation of the resulting AITC from mustard slurries typically involves solvent (e.g., hexane, ethanol, diethyl ether) extraction and/or steam distillation (Sharma, 2012; Li, 2010).

Chemical Synthesis

Commercial sources of AITC are primarily produced using chemical synthetic methods. Specifically, AITC is produced on an industrial scale by reaction of allyl chloride, bromide or iodide ($CH_2=CH–CH_2X$, where X = Cl, Br or I) with alkali rhodanides (e.g., potassium thiocyanate) in a two-phase solvent system comprised of water and 1,2-dichloroethane (Figure 3) (Romanowski, 2000). Numerous variants of this basic chemical reaction have been published in the scientific and patent literature. As an example, catalytic amounts of methyl trioctyl ammonium chloride [$(CH_3)(C_8H_{17})_3NCl$] were used in the reaction between allyl bromide ($CH_2=CH–CH_2Br$) and potassium thiocyanate in acetonitrile solvent (Patent CN102452967 A).

Alternatively, a method involving the initial reaction of allyl amine ($CH_2=CH-CH_2-NH_2$) and carbon disulfide (CS_2) followed by oxidation of the reaction intermediate using a peroxide to form AITC recently appeared in the published patent literature (Patent CN101735128 B). This method is not currently employed in the industrial production of AITC.

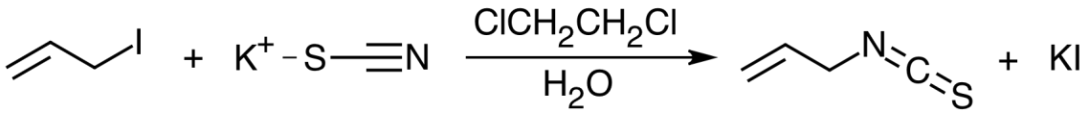

Figure 3. AITC can be industrially produced through treatment of allyl halides such as allyl iodide with alkali rhodanides such as potassium thiocyanate in a mixture of water and 1,2-dichloroethane.

<u>Evaluation Question #3:</u> Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).

Allyl isothiocyanate (AITC) may be considered synthetic or natural (nonsynthetic) depending on the method utilized for its production. Under the USDA organic regulations, the NOP defines synthetic as "a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes" (7 CFR 205.2).

According to this definition, *in situ* production of AITC from mustard and related cover crops or mustard seed meals constitutes a natural (nonsynthetic) process. In contrast, industrial sources of AITC are produced through chemical synthesis, and would therefore be considered synthetic due to the application of synthetic chemicals (reagents and solvents) in both the production as well as the purification/processing of crude AITC. It is unlikely that residues of chemical precursors will persist in the petitioned form of the substance, synthetic AITC.

Evaluation Question #4: Describe the persistence or concentration of the petitioned substance and/or its by-products in the environment (7 U.S.C. § 6518 (m) (2)).

This section summarizes technical information related to the persistence of allyl isothiocyanate (AITC) in soil, water, and the atmosphere. The compiled data indicate that AITC is readily biodegradable in all three environmental compartments. Production and use of AITC as a flavoring agent and ingredient in ointments may result in its release to the environment through waste streams, while its use as a soil fumigant and animal repellent will necessarily result in direct release to the environment. Because AITC is a volatile organic compound and has the potential to cause irritation and systemic toxicity, exposure of and potential adverse effects on non-target receptors (humans and wildlife) is likely considering its proposed use pattern as a pre-plant soil biofumigant at the application rates proposed (85–340 lbs/acre). In addition to synthetic sources, AITC is also present in the seeds and leaves of plants such as mustards, horseradish and broccoli (HSDB, 2013; US EPA, 2013a).

Soil incorporation of AITC is most relevant as the petitioned use involves addition of AITC to soils as a pre-plant biofumigant. AITC released to soil is expected to have moderate mobility based on the calculated Koc of 260 mL/g. Significant volatilization from moist and dry soils is expected for AITC based on its Henry's Law constant and vapor pressure that are on the same order of magnitude as these same parameters for conventional fumigants. Decomposition half-lives for AITC in soil range from 20 to 60 hours. The mean soil half-life of 47 ± 27 hours (approximately two days) was determined based on dissipation studies in six different soil types, with the greatest AITC degradation rates observed in soils that have high organic carbon and total nitrogen contents. Comparison of aerobic (with oxygen) and anaerobic (without oxygen) soil dissipation studies indicates that biodegradation from soil microbial activity is not an important fate process for AITC (HSDB, 2013; US EPA, 2013a, 2013b).

Although AITC is not intended to be applied directly to water, runoff from treated fields may lead to releases of the substance to neighboring water bodies. When released to water, AITC is expected to adsorb to suspended solids and sediment based on its estimated organic carbon partition coefficient (Koc). Half-lives for volatilization of AITC from a model river (6.5 hours) and model lake (5 days) are relatively short; however, adsorption of AITC to suspended solids and sediment in the water column may diminish volatilization from water surfaces. Adsorption may increase the half-life of volatilization from a model pond to an estimated 30 days. With a bioconcentration factor (BCF) of 12, it is unlikely that AITC will bioaccumulate in aquatic organisms. Hydrolysis is expected to be an important environmental fate process since isocyanates readily hydrolyze at environmentally relevant pH levels of five to nine (HSDB, 2013). At environmentally relevant pH ranges (pH between six and eight), AITC will degrade completely. Within this pH range, the primary degradates identified include allyl thiocyanate (ATC), allyl amine (AA) and carbon disulfide (CDS). The profile of decomposition products for AITC in water is largely dependent on the temperature and pH of the aqueous medium (Figure 4). AITC and its isomerization product ATC are typically observed under environmental conditions. Under basic (high pH) conditions, AA, CDS, allyl dithiocarbamate (ADTC) and diallylthiourea (DATU) were the major reaction products identified. AA and CDS were also the primary degradates of AITC in neutral (pH 6) and slightly acidic (pH 4) media. Traces of other minor degradation products have also been observed in published decomposition studies (Pecháček, 1997). AA is expected to biodegrade quickly in the environment, making human and animal exposure to AA unlikely following AITC application to soils (US EPA, 2013a). Background levels of CDS are found naturally in the environment (US EPA, 2013a). However, assuming an AITC application rate of 300 lbs/acre (Isagro USA, 2013) and 25% transformation to CDS (Pecháček, 1997), it is conceivable that approximately 60 lbs/acre of CDS would be released to the environment from a single application of synthetic AITC. This concentration of CDS in the environment is not representative of naturally occurring background levels.

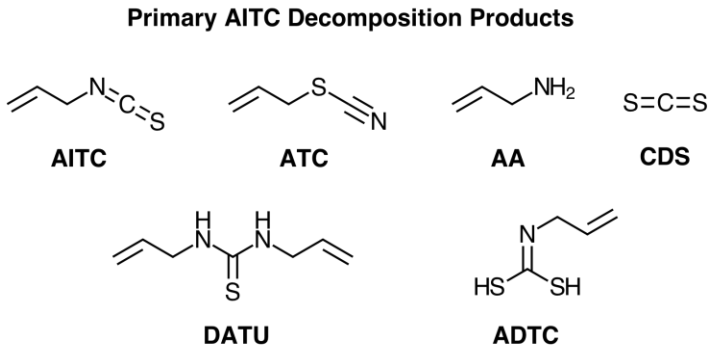

Figure 4. AITC readily isomerizes to ATC and forms a variety of decomposition products in water.

AITC released to the air will exist primarily in the vapor form considering the relatively high vapor pressure of 3.7 mm Hg at 25 ºC. Direct photolysis of AITC by sunlight will not occur due to the absence of chromophores in the AITC chemical structure that would absorb radiation at wavelengths greater than 290 nm. However, vapor-phase AITC undergo facile degradation in the atmosphere through reaction with photochemically produced hydroxyl radicals (half-life = 2.4 hours) (HSDB, 2013).

Evaluation Question #5: Describe the toxicity and mode of action of the substance and of its breakdown products and any contaminants. Describe the persistence and areas of concentration in the environment of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)).

This section summarizes allyl isothiocyanate (AITC) toxicity to four taxa groups, including mammals, fish, aquatic invertebrates and soil microorganisms. Overall, it can be concluded that the toxicity rating of AITC ranges from toxic to practically non-toxic to the few non-target taxa groups evaluated in the literature. The risk of toxicity associated with mammalian exposure to AITC is variable depending on the source and concentration of AITC used in toxicity testing. According to US EPA, oil of mustard containing AITC at a concentration of 4.43% is practically non-toxic (Category IV) via the acute oral and inhalation routes of exposure. In addition, oil of mustard is not an acute dermal irritant (Category IV) or sensitizing agent.

Studies further suggest that AITC is slightly toxic via the dermal route of exposure (Category III) and is a slight eye irritant (Category III) (US EPA, 2010). In contrast, acute oral toxicity testing for a product containing 99.8% AITC using rats as test subjects provided an LD50 value of 425.4 mg/kg (US EPA, 2013b). US EPA classifies pure AITC as moderately toxic for acute oral and inhalation exposure (Category II). Likewise, highly concentrated AITC is categorized as highly toxic (Category I) for primary eye and dermal irritation because the substance is highly corrosive. US EPA classifies pure AITC as a dermal sensitizer based on a dermal sensitization test in guinea pigs (US EPA, 2013b). The European Food Safety Authority (EFSA) concluded that AITC may cause hypersensitivity, based on the occurrence of allergies to mustard and reports of allergic contact dermatitis in humans (EFSA, 2010).

Inhalation toxicity data for AITC and its degradates are not available. US EPA waived data requirements for the 90-day subchronic inhalation toxicity study despite the high volatility of AITC and the fact that the label Personal Protective Equipment requirements for registered AITC products indicates concerns about inhalation exposure (Isagro USA, 2013). The structural similarity of AITC to the conventional fumigant methyl isothiocyanate (MITC) derived from metam-based fumigant pesticides raises additional concerns regarding inhalation toxicity, since respiratory irritation from inhalation exposure is the risk driver for MITC.

The physical properties of AITC are very similar to those of the conventional soil fumigant MITC (vapor pressure = 16 mm Hg at 25 ºC, application rate = 40–300 lbs/acre), for which a great deal of environmental fate and air monitoring data are available (CDPR, 2002a; CDPR, 2002b; US EPA, 2009a). Air monitoring studies for MITC conducted near application sites demonstrate high air concentrations of MITC in the first 24 hours after the application, tapering off over the course of a week. Indeed, MITC has been responsible for a number of poisoning incidents in which hundreds of people were evacuated from their homes in

response to MITC drift from applications up to 0.5 miles distant (CDPR, 2014). Based on the similar physical properties of AITC to MITC, it is thus possible to predict that use of AITC will result in exposure via inhalation for pesticide applicators and residential bystanders due to the proposed use pattern in soil biofumigation. The impact of these exposures is unknown because inhalation toxicology studies are not available; however, products labels for conventional fumigant products containing AITC indicate high inhalation hazards and require applicators to utilize respirators (Isagro USA, 2014).

AITC has been evaluated for developmental and reproductive effects, carcinogenicity and mutagenicity potential in mammals. One study evaluating the developmental toxicity of AITC and related compounds found no difference in the percentage of abnormal fetuses in AITC-treated offspring compared to control groups (US EPA, 2013a). The authors concluded AITC did not demonstrate teratogenic potential at the no observed adverse effect level (NOAEL) of 60 mg/kg, an amounts equivalent to 4.2 grams of AITC for a 150 pound person. AITC was found to cause transitional-cell papillomas of the urinary bladder in male rats, but the evidence of carcinogenicity in female rats was ambiguous and AITC demonstrated no carcinogenic effects in mice (Dunnick, 1982; NTP, 1982). Taken together, the results of several reverse mutation studies, in vitro mammalian gene mutation studies using mouse lymphoma cells, and an in vivo mammalian chromosome aberration study suggest that AITC is not likely to be a mutagen. Increases in mutant frequency were observed even at lower test concentrations (e.g., 0.4 to 0.8 mg/mL); however, these tests were conducted without S9 activation (i.e., no mammalian enzymes for substrate metabolism were present) and the tests were complicated by cytotoxicity at higher doses (US EPA, 2013a). Nevertheless, AITC is included on Columbia University's list of carcinogens, mutagens, and reproductive poisons commonly used in research laboratories (Columbia, 2008).

One of the degradation products of AITC is carbon disulfide, CS2 (CDS). There are concerns regarding exposure to CDS because it is listed by the State of California on the Proposition 65 list as a developmental toxicant (OEHHA, 2014) and is known to induce neuropathological changes and other toxic effects in rodents exposed through inhalation over an intermediate during of less than one year (OEHHA, 2001). As discussed in Evaluation Question #4, AITC biodegrades in the environment to form a variety of breakdown products, including CDS at approximately 20–30% transformation. Because CDS is a major degradate of AITC, the human and environmental toxicity of CDS should be considered as part of the evaluation of AITC for use in organic crop production. Please see Evaluation Question #10 for additional information on the human toxicity potential of CDS.

In reviewing pesticide products containing AITC as the active ingredient, US EPA waived the data requirements for birds, freshwater fish, freshwater invertebrates, non-target plants and non-target insects (US EPA, 2013a). Details regarding the rationale for these data waivers are provided below in Table 3.

Table 3. US EPA Waiver of Non-Target Organism Data Requirements for AITC.

Study Description	**Rationale Statement**
Avian Acute Oral	No acute oral exposure anticipated based on the application method and rapid environmental degradation.
Avian Dietary	No dietary exposure anticipated based on the application method and rapid environmental degradation.
Freshwater Fish LC50	Very Highly Toxic (96-hour LC_{50} = 0.077 ppm), but no aquatic exposure anticipat based on the application method and rapid environmental degradation.
Freshwater Invertebrate	Very Highly Toxic (48-hour EC_{50} = 0.73 ppm), but no aquatic exposure anticipate based on the application method and rapid environmental degradation.
Non-target Plants	No non-target exposure anticipated based on the application method and rapid environmental degradation.
Non-target Insects	No non-target exposure anticipated based on the application method and rapid environmental degradation.

LC_{50} = Concentration of AITC lethal to 50 percent of test organisms

EC_{50} =Effective concentration at which 50 percent of test organisms experience adverse effects, excluding death

Very few peer-reviewed papers on the ecological toxicity of AITC are available. The aquatic toxicity of AITC was evaluated for Japanese rice fish (Oryzais latipes) using a continuous-flow-mini-diluter system and five concentrations of AITC. Significant mortality was observed in O. latipes exposed to AITC on an acute basis (96-hour LC50 = 0.077 mg/L), and the maximum allowable toxicant concentration (MATC) for chronic (28-day) exposure to AITC was 0.013 mg/L (Holcombe, 1995). Another study found that pure AITC and essential oil extracts containing AITC are completely larvicidal in mosquitoes (A. aegypti) even at the lowest concentration tested (0.1 mg/mL); however, this measurement indicates that AITC is significantly less toxic compared to some synthetic pesticides. In addition, AITC was toxic to the freshwater water flea (Daphnia magna) with a 50% effective concentration value of 0.735 mg/L based on combined mortality and immobility measurements (Park, 2011). As expected, AITC is also highly toxic to soil microorganisms and nematodes, such as the non-parasitic free-living soil nematode Caenorhabditis elegans (Donkin, 1995). See Evaluation Question #8 for additional information on the toxicity of AITC to soil organisms.

Evaluation Question #6: Describe any environmental contamination that could result from the petitioned substance's manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)).

Considering its moderately high volatility (3.7 mm Hg at 25°C), high application rates (85–340 lbs/acre), and agricultural use as a soil biofumigant, releases of allyl isothiocyanate (AITC) to the environment are inevitable. AITC is both flammable and potentially toxic to nontarget organisms such as mammals and fish (Sigma Aldrich, 2014a). Aquatic wildlife may be exposed to AITC through spills and/or irrigation runoff. As with conventional fumigants, measures such as the use of plastic tarps on treated fields or application of AITC through a drip system could be taken to further protect humans (bystanders and workers) and nontarget terrestrial organisms from exposure to AITC following soil biofumigation. The rapid breakdown and dissipation of AITC in the environment reduces the probability of contamination of groundwater and surface water due to agricultural applications of the substance.

In the absence of accidental spills, the risk of water contamination from the use of AITC as a soil biofumigant is considered to be minimal. The release of chemical reagents (e.g., allyl iodide and potassium thiocyanate) and highly toxic, flammable and hazardous solvents (e.g., 1,2-dichloroethane) used in the production of AITC due to improper handling/disposal could lead to serious environmental impairments and ecotoxicity in both terrestrial and aquatic environments (Sigma Aldrich, 2014b). No incidents involving the release of these chemical feedstocks from AITC production facilities have been reported to date. Although possible, it is unlikely that large-scale spills and associated environmental contamination will occur when AITC soil biofumigation products are used in accordance with label instructions.

It must be noted that the application rates and the emission rates of AITC are very different between mustard cover crops or seed meals (effective application rate 4–33 lbs/acre) and >95% pure AITC applied at 85–340 lbs/acre. The rate of dissipation of AITC into the environment from mustard cover crops or seed meals is slower than that of AITC applied as a pure substance because the rate of generation is dependent on exposure of the shredded leaves or mustard meal to water, the action of the enzyme, and the rate of escape of AITC from the organic matrix. Thus, while AITC is naturally produced from mustard cover crops or seed meals, as well as other Brassica crop varieties in the agricultural environment without apparent impacts, it is not at all clear that higher application rates of pure AITC will be equally without impact; in fact, the high volatility and high proposed application rates suggest exposure patterns similar to conventional fumigants. The fact that structurally related isothiocyanates such as methyl isothiocyanate (MITC, the active fumigant from application of metam sodium) are strong respiratory sensitizers suggests that AITC may pose similar risks. Because the inhalation toxicity data are not a part of the data package submitted by the registrant, it is difficult to know precisely how toxic AITC is by the inhalation route.

Evaluation Question #7: Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling. Describe any environmental or human health effects from these chemical interactions (7 U.S.C. § 6518 (m) (1)).

Limited technical information is available regarding the potential for chemical interactions between allyl isothiocyanate (AITC) and other substances used in organic livestock production. One possible interaction between the petitioned substance and other materials used in organic crop production involves the reaction of AITC with free amino acids, peptides and proteins contained in organic composts and fertilizers. Specifically, electrophilic (electron deficient) AITC is capable of reacting with the nucleophilic (electron rich) amino groups of the free amino acids alanine and glycine (Cejpek, 2000), as well as cysteine, lysine and arginine residues of intact proteins (Kawakishi, 1987). Diminished enzymatic digestibility was documented for some of the resulting protein-AITC adducts; however, it is uncertain how these chemical transformation products might affect the absorption and metabolism of amino acid building blocks in plants. Related technical information on the effect of AITC on the beneficial soil organisms that facilitate uptake of organic nutrients through plant roots is provided below in Evaluation Question #8.

Evaluation Question #8: Describe any effects of the petitioned substance on biological or chemical interactions in the agro-ecosystem, including physiological effects on soil organisms (including the salt index and solubility of the soil), crops, and livestock (7 U.S.C. § 6518 (m) (5)).

The current technical evaluation report concerns the use of allyl isothiocyanate (AITC) as a pre-plant soil biofumigant for control of soil microorganisms and nematodes, insects and weeds in organic crop production. When used for this purpose, it is understood that AITC will interact with multiple components of the terrestrial agro-ecosystem (i.e., agricultural land). Although limited technical information is available regarding non-target effects of AITC application on livestock and wildlife, the available literature suggests the risk of impairment is minimal when label instructions and precautions are followed. Leakage of AITC, particularly large-scale spills, near the agro-ecosystem will result in the destruction to soil organisms (plants, fungi, etc) and may be hazardous to non-target wildlife in the area.

Toxicity of AITC to soil-dwelling organisms is well documented in the scientific literature due to use of the substance as a pre-plant soil biofumigant. The primary targets of AITC biofumigants are deleterious soil microorganisms, and a significant body of research has been conducted on the efficacy of synthetic AITC in addition to plant materials that naturally infuse AITC into the soil for plant pathogen control (Weerakoon, 2012). One study demonstrated inhibition of the plant pathogenic fungi Pythium ultimum and Rhizoctonia solani using shredded leaves of different Brassica species. It should be noted that AITC comprised greater than 90% of the volatile chemicals measured from these leaves (Charron, 1999). Another study investigated Indian mustard and pure AITC suppression of mycelial growth and sclerotial germination of Atherlia rolfsii, a soil-borne plant pathogen, which causes southern blight in crops. It was shown that intact Indian mustard, as opposed to pure AITC, exhibited the strongest antimicrobial action at a concentration of one gram per liter (Harvey, 2002).

Other studies have demonstrated that AITC released from mustard plants can disrupt mutualistic fungal associations (i.e., arbuscular mycorrhiza) with certain plants species. For example, even low levels of AITC (i.e., approximately 0.001 millimolar) infused in soil by invasive garlic-mustard plants have the ability to significantly suppresses fungal growth and spore germination of the beneficial soil fungus Glomus clarum (Cantor, 2011). In another study, it was also found that AITC emitted from garlic mustard adversely impacts the abundance of entomopathogenic fungi (i.e., fungal parasite of pest insects) in forest soils (Vaicekonyte, 2012). These reports provide direct evidence that AITC does not specifically target soil pests; rather, AITC is a broad-spectrum antimicrobial compound that effectively kills both plant pathogens and beneficial soil microorganisms. Additionally, it is known that certain species of soil fungi enhance the bioavailability of organic soil nutrients and mediate the uptake of these nutrients by their mycorrhiza host plants (Näsholm, 2009). AITC drift would therefore be problematic for both the beneficial soil fungi and associated plants.

In addition to soil microorganisms, plants, insect pests and animals have demonstrated varying responses to AITC soil treatments. Phytotoxicity studies of various seed meals demonstrated that mustard seed meal, which releases AITC in soil, prevented or significantly diminished germination of lettuce seeds within the first week after application (Meyer, 2011). Larvae of the pest Cyclocephala spp. (masked chafer beetle) were well controlled when macerated Brassica tissue was applied as four to eight percent of the soil, giving an

average AITC concentration of 11.4 mg per liter of soil atmosphere (Noble, 2002). AITC extracted from horseradish was tested as a fumigant against four major pest species of stored rice, including Sitophilus zeamais (maize weevil), Rhizopertha dominica (lesser grain borer), Tribolium ferrugineum and Liposcelis entomophila (book louse). Adult mortality of 100% of all four pest species after 72 hour exposure to AITC fumes at an atmospheric concentration of 3 mg/mL showed no significant difference in insecticidal activity compared to insects exposed to phosphine (PH3; a stored commodity fumigant) at 5 mg/mL (Wu, 2009).

Improper use or disposal of chemical reagents (e.g., potassium thiocyanate and allyl iodide) and highly toxic solvents (e.g., 1,2-dichloroethane) during the production of AITC would likely result in adverse effects to soil organisms. However, based on the chemical composition of potential contaminants, spills of AITC and precursors are unlikely to alter pH and chemical composition of the soil. Improper treatment and subsequent release of extraction mixtures containing volatile mustard seed meal and volatile solvents (e.g., hexane) may also impair soil populations. Although possible, these types of spill scenarios are unlikely due to manufacturing safeguards.

Technical information regarding the potential impacts of AITC on endangered species, populations, viability or reproduction of non-target organisms and the potential for measurable reductions in genetic, species or ecosystem biodiversity, is not readily available.

As previously mentioned, AITC can have a short-term deleterious effect on beneficial soil microorganisms and mutualistic fungal interactions, which is observed for other broad-spectrum fumigants, such as methyl bromide and Telone II™. However, long term soil effects for other fumigation agents is relatively non-existent, as they have not been as widely utilized as methyl bromide and have only received considerable attention since the ban on methyl bromide in 2005.

In a short term study (28 days) of the effect of AITC on soil bacterial and fungal communities, the application of AITC significantly decreased soil fungal populations but had negligible impact on soil bacterial numbers (Hu 2015). However, AITC did have an influence on certain microbial community composition changes. The results showed increased proportions in bacterial taxa, which include bacteria associated with fungal disease suppression. The increase in these bacteria and decrease in overall fungal populations following amendment with AITC suggests that the observed efficacy of AITC on fungal suppression was not only due to direct toxicity of AITC against soil fungi but also to biological interactions and competition with the altered microbial community that existed following fumigation. In comparison, a short-term study found that methyl bromide amended soil results in a complete collapse of the microbial community, due to its acute toxicity, after one week following application (Ibekwe 2001). After 12 weeks, the microbial diversity had recovered to a small extent but was still well below the unchanged soil control. While there was no direct comparison to AITC in this study, methyl isothiocyanate, an aliphatic analog of AITC, was used. Microbial communities from soil samples treated with methyl isothiocyanate or 1,3-dichloropropene (i.e., Telone II™) were not as severely effected. Of the three fumigants, 1,3-dichloropropene exerted the least effect on the microbial community structure.

Evaluation Question #9: Discuss and summarize findings on whether the use of the petitioned substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

Allyl isothiocyanate is a naturally occurring essential oil and is not persistent or bioaccumulative in the environment. Both synthetic and natural sources of the substance are readily biodegradable in all three environmental compartments. Similar to other soil fumigants such as MITC, soil decomposition half-lives for AITC range from 20 to 60 hours, with higher rates of AITC degradation in soils with high organic carbon and total nitrogen contents. Although AITC has the potential to adsorb to suspended solids and sediments, it rapidly dissipates in water due to facile hydrolysis and volatilization from the water surface. Photochemically produced hydroxyl radicals degrade atmospheric AITC with a half-life of 2.4 hours. Allyl amine and carbon disulfide, a naturally occurring sulfur compound, are the primary byproducts of AITC under environmentally relevant conditions (HSDB, 2013; US EPA, 2013a; US EPA, 2013b).

Based on the available literature, it can be concluded that pure AITC ranges from highly toxic to practically non-toxic to various taxa groups. AITC is classified as an eye and skin irritant and is moderately acutely toxic (Category II) to mammals via the oral route of exposure. Data are lacking on inhalation toxicity; however, the structural similarity of AITC to methyl isothiocyanate (MITC; CH3N=C=S) and known irritant properties of AITC (see Evaluation Question #10 below) would indicate that inhalation toxicity may be a concern. The bulk of the available literature for extended dosing studies suggests that AITC is not a developmental or reproductive toxicant, and is unclassifiable as to its carcinogenicity (US EPA, 2013a; IARC, 1999). In comparison to moderate acute oral toxicity in mammals, AITC is highly toxic to aquatic organisms, such as fish and aquatic invertebrates (US EPA, 2013a). Exposure of aquatic organisms to AITC may occur from spills and short-term runoff following irrigation or heavy rain. As a potent soil fumigant, AITC is highly toxic to pathogenic soil organisms as well as non-parasitic free-living soil nematodes (Donkin, 1995) and symbiotic soil fungi (Cantor, 2011).

The release of chemical reagents (e.g., allyl iodide and potassium thiocyanate) and highly toxic, flammable and hazardous solvents (e.g., 1,2-dichloroethane) used in the production of AITC due to improper handling/disposal could lead to serious environmental impairments and ecotoxicity in both terrestrial and aquatic environments (Sigma Aldrich, 2014b). No incidents involving the release of these chemical feedstocks from AITC production facilities have been reported. In addition to targeting soil pathogens, insects and weeds, AITC is also toxic to fungi that produce mutualistic relationships with plants and prey on pest insects (Cantor, 2011; Vaicekonyte, 2012). Therefore, non-target plants and beneficial microorganisms would be damaged in treatment plots and neighboring areas due AITC drift.

<u>Evaluation Question #10:</u> Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

Natural sources of allyl isothiocyanate (AITC) contained in natural vegetable oils (e.g., mustard oil) are generally non-toxic to humans via the oral route of exposure. This observation is not surprising considering the high concentrations of AITC (3 mg/kg to 15 g/kg) generally found in popular food items such as kale, broccoli, mustard and horseradish. However, moderate doses of concentrated AITC are considered toxic to mammals based on laboratory studies in animals.

Acute, sub-chronic and even chronic (long-term) exposure to AITC is likely for humans living and working near AITC application sites. Studies investigating the time-course of sensitization and desensitization to AITC nasal stimuli in healthy human subjects found that short-term sensitization occurred but markedly decreased in intensity with increasing time between nasal stimulation with AITC (Brand, 2002). AITC vapor is lacrimatory (causes tears to form), and can causes keratitis in which the front part of the eye becomes inflamed and eyesight is temporary impaired (HSDB, 2013). Allyl isothiocyanate is known to irritate the mucous membranes and induce inflammatory skin conditions (eczema) or skin lesions (vesicles). Indeed, patch tests for irritant contact dermatitis with radishes and AITC produced positive reactions (IARC, 1999). Other studies have concluded that contact dermatitis from AITC occurs in only a limited number of cases, despite frequent exposure to the substance in fresh foods and various condiments (Lerbaek, 2004). There are no reports of acute systemic toxicity in humans related to ingestion of AITC found naturally or artificially in foods. A 90-day (sub-chronic) oral toxicity study conducted by the National Toxicology Program in rats determined a No Observed Adverse Effect Level (NOAEL) of 25 mg AITC/kg-body weight/day, the highest dose tested in the study (US EPA, 2013a).

Inhalation toxicity data for AITC and its degradates are not available. Data requirements for the 90-day subchronic inhalation toxicity study were waived by US EPA, which is unusual, considering the high volatility of AITC and the fact that the label Personal Protective Equipment requirements for registered AITC products indicates concerns about inhalation exposure (Isagro USA, 2013):

> *Where liquid contact is a potential all handlers (including mixers, loaders and applicators) in addition to the above listed PPE must wear an air purifying respirator with an organic-vapor removing cartridge with pre- filter approved for pesticides (MSHA/NIOSH approved number prefix TC-23C), or a canister approved for pesticides*

(MSHA/NIOSH) approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P, or HE pre-filter.

The structural similarity of AITC to the conventional fumigant MITC derived from metam-based fumigant pesticides raises additional concerns regarding inhalation toxicity, since respiratory irritation from inhalation exposure is the risk driver for MITC. Because the inhalation toxicity data were not required by US EPA, this remains as a significant data gap.

When taken together, the bulk of the available literature suggests that AITC is unclassifiable as to carcinogenicity and mutagenicity. The International Agency for Research on Cancer (IARC) categorized AITC in Group 3, "not classifiable as to its carcinogenicity to humans," based on inadequate evidence in humans and limited evidence in experimental animals for carcinogenicity of AITC (IARC, 1999). AITC was initially tested for carcinogenicity as part of a 2-year carcinogenesis bioassay of food grade AITC (greater than 93% pure) administered to one strain of mice and one strain of rats in corn oil five times per week for 103 weeks. No incidence of tumors was observed in mice; however, a statistically significant increased incidence of epithelial hyperplasia (proliferation of skin cells) and transitional-cell papillomas (benign epithelial tumor) of urinary bladder was observed in male rats (US EPA, 2013a; IARC, 1999; NTP 1982).

Subsequent studies confirmed the absence of carcinogenicity in mice treated with AITC via gavage administration (IARC, 1999). Despite the carcinogenic response in male rates exposed to AITC via gavage, a number of studies have demonstrated the potential AITC at lower dietary exposure levels (<1 mg/kg) to protect against and in some cases reverse the development of colorectal (Musk, 1993), bladder (Zhang, 2010), and presumably other cancer cell lines (Wang, 2010).

National Toxicology Program (NTP) studies on AITC show inconsistent results for gene mutation studies in the bacterium Salmonella typhimurium (AMES test) with and without exogenous metabolic activation using extracts containing mammalian enzymes. AITC did not induce gene mutation in several Salmonella strains in the absence of metabolic activation. A negative response was also observed in one trial using mouse lymphoma cells without activation at concentrations ranging from 0.05 to 0.8 mg/mL; however, two other trials without activation demonstrated a significant increase in average mutant frequency and reduction in total growth at concentrations between 0.4 and 1.4 mg/mL. The authors noted that the positive results were observed without metabolic activation, thus leading to considerably different experimental conditions compared to natural biological (in vivo) conditions. The results of these studies are also compromised by the high degree of cytotoxicity observed at moderate to high doses. An in vivo mammalian chromosome aberration study conducted using mice dosed via direct injection of AITC into the body cavity revealed no differences between treatment and control mice (US EPA, 2013a; IARC, 1999). Accordingly,

The [US Environmental Protection] Agency has determined that the weight of evidence demonstrates that AITC is not likely to be a mutagen. In addition, the method of application and rapid degradation rate for the proposed pre-plant soil treatment, together with appropriate PPE, mitigates exposure to humans.

In comparison to AITC, the related chemical MITC has shown limited evidence of carcinogenicity in animal studies. US EPA determined that the current data set is insufficient to characterize the cancer risk of MITC and requested inhalation carcinogenicity studies with MITC in rats and mice (US EPA, 2009). On the contrary, the parent compound (metam-sodium) and breakdown product (methyl isocyanate, MIC) of MITC are considered to be carcinogenic and mutagenic based on the results of tissue cultures (in vitro) and lifetime animal dosing studies (US EPA, 2009; CDPR, 2003). In light of the health concerns for these related chemicals (MITC and MIC), it will be necessary to update the literature review on the carcinogenic potential of AITC as new scientific insights become available.

One of the major degradation products of AITC is carbon disulfide, CS2 (CDS). There are concerns regarding exposure to CDS because it is listed by the State of California on the Proposition 65 list as a developmental toxicant (OEHHA, 2014) and is a known human neurotoxin. In addition to animal studies, CDS has been found to cause reproductive toxicity in males and females through occupational exposure.

Specifically, significant adverse effects on spermatogenesis, sex hormone levels and libido in men, as well as menstrual disturbances in women were observed in workers exposed to CDS levels of 3.1–14.8 mg/m3 (OEHHA, 2001). Studies have also identified alterations in the nerve conduction of workers exposed to lower levels of CDS over an extended period of time (chronic exposure). A NIOSH occupational study in male factory workers exposed to AITC air concentrations of 0.6 to 16 ppm for a mean duration of 12 years resulted in a lowest observed adverse effect level (LOAEL) of 7.6 ppm based on minor neurological effects (OEHHA, 2001). In another study, male workers exposed to CDS for an average of 14 years had higher rates (42%) of 24-hour electrocardiogram abnormalities than non-exposed workers (OEHHA, 2001).

Evaluation Question #11: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

A variety of alternative substances are available to organic producers for controlling insect pests, weeds and other soil-borne pests. These substances include natural materials for biofumigation, microbial biopesticides, and naturally derived chemicals that alter soil pH. The following paragraphs describe how these substances may be used in organic production, as well as their efficacy and the availability of commercial products containing these substances.

Biofumigation using soil amendments or cover crops is a natural alternative to the use of commercially available chemical fumigants (including methyl bromide, chloropicrin, 1,3-dichloropropene, metam-sodium and metam-potassium) for controlling soil-borne pathogens, nematodes, insects and weeds prior to planting. Conventional soil fumigants are not allowed in the production of organic crops. In addition to allyl isothiocyanate (AITC), other naturally occurring isothiocyanates such as methyl isothiocyanate (MITC) and phenyl isothiocyanate exhibit nematocidal, bactericidal, fungicidal and herbicidal properties (Figure 5).These related isothiocyanates are generated by enzymatic degradation of the corresponding glucosinolate contained in cruciferous vegetables much like the formation of AITC. For example, MITC is enzymatically released from glucocapparin (i.e., methyl glucosinolate) naturally contained within the caper plant. MITC is primarily used in conventional agriculture as the active pesticidal substance released from degradation of metam-sodium and metam-potassium, which are highly toxic and widely used chemical fumigants (Johnson, 2009; Romanowski, 2000).

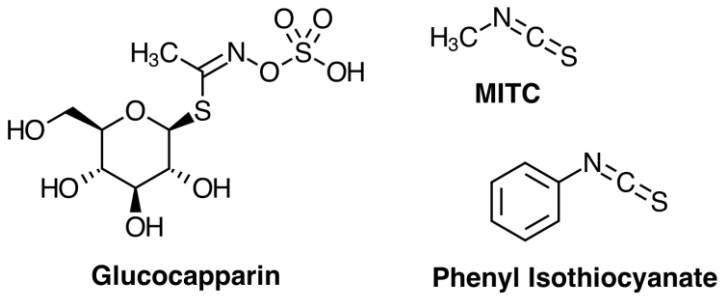

Figure 5. Chemical structures of glucocapparin, methyl isothiocyanate (MITC) and phenyl isothiocyanate.

Meals that are produced when mustard seeds are pressed to extract natural oils have been shown to suppress weeds and soil-borne pathogens. It is recommended that mustard seed meals be applied at a rate of 1,000–4,000 pounds per mulched acre and that the grower observe a waiting period of 20 days before planting (Johnson, 2011; Farm Fuel Inc, 2013). While high application rates are required to generate sufficient amounts of AITC for biofumigation, the excess seed meal fertilizes the soil with nitrogen, carbon and other nutrients that generally accompany organic material additions to soils (Johnson, 2011).

Regarding biofumigation, the compiled data indicate an increased rate of AITC release to soil with increasing relative humidity and temperature (Dai, 2014). Particle size and oil content of the mustard meal powder also affects the release rate. The available literature suggests that mustard seed meal biofumigants can lead to extended protection against deleterious soil pathogens (Weerakoon, 2012). Indeed, the incorporation of AITC using intact mustard products (e.g., mustard seed meals or soil incorporation of

mustard cover crops) may alter the composition of the soil fungal community. For example, seed meal-treated soils exhibited preferential proliferation of Trichoderma spp., a genus of fungi that forms mutualistic relationships with several plant species, which may contribute to long-term control of pathogenic fungi such as Pythium abappressorium (Weerakoon, 2012).

A number of field trials have been conducted using mustard green manures (plowed cover crops) and seed meals for the biofumigation of agricultural fields. For example, one study found that soil incorporation of 2,240 kg/ha to 4,480 kg/ha mustard seed meal can increase yields of plasticulture-grown strawberries when compared to control plots. In addition to the partial control of soil-borne anthracnose, soil incorporation of mustard seed meal can greatly decrease competition from broadleaf weeds for strawberry plants established in the fall (Deyton, 2010). Extension specialists and industry groups have also reported yield improvement for strawberries and other crops grown in soils pre-treated with mustard meals (Farm Fuel, 2013a; Johnson, 2011). Although mustard seed meals have shown potential, specific meals or blends of seed meals must be used at high application rates in combination with other practices since results vary due to field activity (CDPR, 2013; Mazzola, 2010). In addition, some natural substances and practices are not compatible with the use of mustard meals for biofumigation. Green manures and seed meals that naturally produce AITC may be harmful to certain beneficial soil nematodes responsible for biologically controlling deleterious soil pathogens, indicating incompatibility of mustard meals and certain biocontrol agents (Henderson, 2009). See also Evaluation Question #11 for details regarding the use of beneficial nematodes as an alternative to soil fumigation.

Biologically based pesticides are also available for the management of soil-borne pests. These include both microbial biopesticides, including products derived from microbes and their metabolites, and biochemical biopesticides, which are naturally occurring or naturally inspired synthetic chemicals. For example, the OMRI approved Regalia® product is formulated with extract of giant knotweed (Reynoutria sachalinensis, 20%) to induce systemic resistance to certain fungi in strawberry and other treated plants. An insufficient number of large-scale, on-farm demonstrations have been conducted to determine the potential of this and related biopesticides as fumigant alternatives (CDPR, 2013).

Microbial biopesticides are also being investigated as viable fumigant alternatives. These pesticides may include the entire microorganisms and/or chemical products they produce as metabolites. For example, Streptomyces lydicus strain WYEC 108 is a naturally occurring bacterium commonly found in soil and recently formulated in commercial biopesticide products (CDPR, 2013). It is thought that the bacterium exerts its antimicrobial properties by colonizing the growing root tips of plants and parasitizing root decay fungi such as Fusarium, Pythium, and other species (US EPA, 2009b). When used in strawberry production, the Actinovate® (S. lydicus) product showed good yields compared to untreated controls in field trials. No adverse environmental or human health effects are expected from use of this bacterial strain in agriculture. Fungal species belonging to the Muscador genus produce volatile compounds that can kill nematodes, insects and plant pathogens. Other examples of microbial biopesticides include Serenade® (Bacillus subtilis strain 713), Bionematicide Melocon® (Paecilomyces lilacinas and Gliocladium), and fungal biocontrol SoilGard® (Trichoderma virens) for control of soil-borne diseases caused by Pythium, Rhizoctonia and Fusarium (CDPR, 2013; Certis USA, 2014). Some species of nematodes are also effective for pest control. Specifically, the beneficial nematode Heterorhabditis bacteriophora is commercially available and effectively controls pest through production of a toxic bacterial during its development in the host insect (Buglogical, 2014; Arbico Organics, 2014).

Soil pH is an important factor influencing the development of certain soil-borne diseases. The classic example of this phenomenon is clubroot disease of crucifers caused by Plasmodiophora brassicae. Symptoms of clubroot include aboveground stunting, severely swollen and deformed roots, root rot, and plant death. This condition is a major problem in acidic soils (pH of 5.7 or lower); the disease is dramatically reduced when the pH rises from 5.7 to 6.2 and is practically eliminated at soil pH values greater than 7.3 or 7.4 (Koike, 2003). Once posing a major threat in the Salinas Valley of Central California, this disease has been largely managed in recent decades by liming the soil (i.e., adding calcium hydroxide) to raise the pH (Koike, 2003). According to the National List, “hydrated lime,” which is primarily

composed of calcium hydroxide [Ca(OH)2], is only approved for use as a component of foliar sprays for plant disease control in organic crop production (7 CFR 205.601(i)(4)). Organic crop producers may use naturally mined minerals, such as calcium carbonate (CaCO3), as alternatives to raise soil pH.

Evaluation Question #12: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

Organic farmers are generally dependent upon preventative cultural practices and physical controls for suppressing pest insects, weeds and soil-borne pathogens. The "Crop pest, weed, and disease management practice standard" in the NOP rule states that producers must use the following management practices to prevent crop pests, weeds and diseases (7 CFR 205.206(a)):

- Crop rotation and soil and crop nutrient management practices;
- Sanitation measures to remove disease vectors, weed seeds and habitat for pest organisms;
- Cultural practices that enhance crop health, including selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds and diseases.

Pest problems may be controlled through mechanical or physical methods (7 CFR 205.206(b)):

- Augmentation or introduction of predators or parasites of the pest species;
- Development of habitat for natural enemies of pests;
- Nonsynthetic controls such as lures, traps and repellents.

Organic producers may control weed problems using the following activities (7 CFR 205.206(c)):

- Mulching with fully biodegradable materials;
- Mowing;
- Livestock grazing;
- Hand weeding and mechanical cultivation;
- Flame, heat or electrical means;
- Plastic or other synthetic mulches: Provided that, they are removed from the field at the end of the growing or harvest season.

Lastly, the standard allows for the following activities to control plant disease problems (7 CFR 205.206(d)):

- Management practices which suppress the spread of disease organisms;
- Application of nonsynthetic biological, botanical or mineral inputs.

While some conventional farms rely heavily on chemical fumigation of soil, organic producers must develop a diverse tool kit for effective pre-plant pest, weed and plant disease management that ensures acceptable yields. Grower experience and continued research has led to current practices such as soil inversion by deep plowing, the application of Brassica seed meals or other antimicrobial crop residues (Evaluation Question #11), crop rotations and anaerobic soil disinfestation. Crop rotation remains the primary method of combating soil pests. The following paragraphs describe currently developed and experimental practices that may serve as alternatives to chemical fumigants such as AITC in organic crop production.

Over the past several millennia, farmers have developed various crop rotation methods to increase yields by improving soil fertility and better controlling pests, weeds and plant diseases. Organic farmers base their crop rotations on whether various plants in their rotational lineup are considered light or heavy feeders and on the suite of pests that attack similar crops. Soil-depleting crops, including row crops like corn, soybeans, vegetables and potatoes, are typically rotated with crops that incorporate nutrients into the soil, such as the legume sods—alfalfa and clover—and various grasses (Baldwin, 2006). In addition to soil fertility, crop rotations are critical for reducing the adverse impacts of insects, weeds and pathogens. By changing the environmental conditions in the field and removing food sources to prevent pest buildup, crop rotations can enable farmers to effectively reduce pest populations (McGuire, 2003). Crops of the same

family should not follow one another in the field, and should typically be separated by at least two years and as much as five years to minimize the occurrence of pests and pathogens in the soil (Baldwin, 2006). A rotation of crop families might include Brassicaceae (cole crops), followed by Asteraceae (lettuce, cut flowers), followed by Solanaceae (tomatoes, potatoes, peppers, eggplants), followed by Curbitaceae (squashes, cucumbers and melons). Specific plant diseases will require tailored crop rotations; for example, detection of Sclerotium rolfsii (southern blight) in vegetable crops may require a rotation of corn, grass, hay or pasture crop for two or three years (Baldwin, 2006). Crop rotations are most effective when combined with such practices as composting, cover cropping, green manuring and short pasturing cycles.

Planting cover crops for biological fumigation prior to planting has the potential to significantly reduce the need for chemical fumigation in conventional crop production and is a commonly used approach in organic agriculture. Specifically, certain varieties of mustard cover crops (e.g., Ida Gold, Mighty Mustard and Pacific Gold) planted in a resting field are grown for a certain period of time and then plowed under before reaching full maturity in order to maximize the concentration of nutrients and allelochemicals (e.g., AITC and glucosinolates) available from the mustard crop (Johnson, 2009). The damaged plant tissues naturally release AITC for biofumigation, as discussed in previous sections of this report. Cover crops of wheat, barley, oats, rye, sorghum and sudangrass have been shown to suppress weeds and in some cases nematodes and insect pests (Baldwin, 2006). Some cover crops, such as vetches and clovers, encourage populations of beneficial insects like ladybugs that prey on pest insects (Baldwin, 2006). Green manures from various cover crops may also serve as energy sources for beneficial microorganisms that out-compete plant pathogens and potentially confer disease resistance to crops (McGuire, 2003). In the larger context of sustainable agriculture, planting cover crops between production cycles can help minimize soil erosion, naturally enhance soil fertility without the use of synthetic fertilizers, and improve weed, insect and disease management in fields (Baldwin, 2006).

Non-chemical methods including anaerobic soil disinfestation (ASD), steam sterilization and soil solarization are being further developed as alternatives to chemical fumigation. ASD is a method that creates anaerobic (without oxygen) conditions in the soil profile by incorporating readily available carbon sources into topsoil that irrigated to field capacity and covered by a tarp. The tarp is left covering the soil for a certain period of time to maintain the high soil moisture level and oxygen-free conditions. Anaerobic organisms produce byproducts that are toxic to soil pathogens through their metabolisms of the added carbon (UCANR, 2014). The typical procedure involves the following steps: 1) spread carbon source such as rice bran, 2) incorporate in soil, 3) form beds and lay drip tape, 4) cover with plastic tarp, 5) irrigate and keep at field capacity, 6) leave for three weeks, 7) punch holes in plastic, 8) plant fruit or vegetable crop (e.g., strawberries) a few days later (Shennan, 2012). Rice bran is the primary carbon source used to date; other potential sources include molasses, grape pommace and ethanol (used in Japan) (CDPR, 2013). Researchers are currently experimenting with application rates of organic matter and ways of managing nitrogen runoff before the technique is adopted in large-scale agricultural systems.

Steam treatments effectively manage pathogens and weeds in soil directly contacted by the steam. While steam application to static soil may take hours to heat, physically mixing steam and soil results in rapid heating of the soil within approximately 90 seconds. Trials indicate strawberry yields in steamed soils are equal to yields from fumigated soils, and weed and pathogen management using this method is equivalent to fumigation in the soil zone where steam is applied (CDPR, 2013). Because of the labor intensive and expensive nature of steam treatments, questions remain about the economic and environmental practicality of this approach. Steam treatments could be combined with alternative substances such as biopesticides to reduce cost and other limitations, but these combinations must be investigated before implementation in agriculture (CDPR, 2013).

A third non-chemical approach involves the use of plastic sheets to trap solar energy and kill soil-borne organisms with heat. Known as soil solarization, the heat produced using this method kills soil-borne seeds and microorganisms near the surface, but fails to reach organisms deeper in the root zone (CDPR, 2013).

This technique is limited to growing regions where solarization temperatures are high enough to be effective. Although additional trials are needed, the combination of soil solarization with biofumigants such as mustard seed meal may improve control of soil pests (CDPR, 2013).

A significant amount of funding has been made available for research into biofumigation and non-chemical approaches to soil disinfestation in light of the methyl bromide phase-out and environmental impacts of related chemical fumigants. While some of the methods described above are ready for implementation in crop production, research efforts aimed at improving existing techniques and developing new strategies to eliminate the use of fumigants are ongoing. In addition to traditional crop rotation, the available information suggests that the variety of available management techniques preclude the application of synthetic biofumigants such as AITC in organic crop production.

Report Authorship

The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:

October 3, 2014, Technical Evaluation Report:

- Pesticide Research Institute

February 12, 2018, Technical Evaluation Report Update (substantive revisions to October 3, 2014, Technical Evaluation Report are highlighted):

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All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

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Note: Subcommittee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

National Organic Standards Board (NOSB)
Materials/GMO ad hoc Subcommittee Meeting Notes
Tuesday, February 13, 2018 2:00 pm ET

Attending: Harriet Behar (HB), Chair; Emily Oakley (EO); Dave Mortensen (DM); Tom Chapman (TC); Dan Seitz (DS), Vice Chair; Lisa de Lima (LD)
Absent: Tom Chapman (TC)
Staff: Michelle Arsenault (MA)

Work agenda

Materials Projects	Contact	Notes	Discussed, Voted	Meeting
Research Priorities Proposal May 2012 Framework Proposal	EO	Subcommittee reps to MS DS - LS EO - CS LD - HS RPs from Subcomm due to MS in July	NA	Fall 2018
Petition and TR tracking	HB/LB	Ongoing	NA	NA
GMO Projects	**Contact**	**Notes**	**Vote**	**Meeting**
Non-GMO organic seed integrity proposal (formerly Seed Purity from GMOs)	DS, DM, HB	Part of Seed purity doc will be incorporated into "Prevention Strategies for Excluded Methods in Crops and Handling" doc. MS submitted a request to the ES in August 2017 to convene a seed purity task force. Pending NOP approval, for future work agenda.	Jan 30, Feb 13	Spr 2018
Excluded Methods Terminology	HB	Proposal	Jan 9	TBD

Other Projects

Project Idea	Contact	Notes*	Vote	Meeting
Contamination of Farm Inputs Discussion Document	HB	Moved to Materials from Crops for continued work.	Jan 30	TBD
Sanitizers	HB, EO, JM, AB	Pending NOP approval	Jan 9	Fall 2018

Agenda

- Approval of January 30, 2018 notes
- Materials and TR update (MA)
- Genetic integrity of seed used on organic land (DS, DM, HB)
- Excluded methods terminology (HB)
- Contamination of farm inputs (HB)
- Sanitizer work agenda progress (HB)
- Other items
- Adjourn

Discussion

- **The notes of** January 30 were approved with no changes.
- **Materials and TR update (MA).**
    - New materials report was sent Friday, Feb 9. Changes since last month include:
        - CS: Polyoxin D addendum was sent last week.
        - CS: Calcium acetate TR request in development
        - CS: Sodium citrate TR approved
        - CS: AITC TR - in review by NOP
        - HS: TR for sodium chlorite for production of chlorine dioxide gas sent to HS
        - LS: Glycolic acid - TR approved by LS
        - LS: Oxalic acid - TR in contracting
        - LS: Ammonium citrate and glycinate - TR in contracting
        - Petitions - NOP received 3 new petitions
- **Genetic integrity of seed used on organic land (DS, DM, HB).** HB is attending a seed integrity meeting next week and will be discussing thresholds. The three co-leads plan to discuss this topic after the conference. A member noted the community interest and engagement in this topic. He received an organic newsletter with an article about seed integrity, in which the author mentioned that the NOSB will be discussing genetic integrity at the spring meeting, and he also attended a panel in PA recently noting that members of the panel expressed excitement that the NOSB was discussing this issue. The HS Chair will check with the NOP about posting this for the Spring meeting.
- **Excluded methods terminology (HB).** The MS Chair spoke with NOP about the request to pause work on excluded methods until APHIS develops guidance on this, so the NOSB is aligned with APHIS. APHIS is in the midst of building a coordinated framework on GE and GMOs across agencies. The MS expressed a desire to work with APHIS, as and NOP do not have the same mandate with regard to GMOs. A member noted that he has worked with APHIS for the last decade and organic standards are not their focus. The Subcommittee will work on a document, but will not ask to bring it to the Spring NOSB meeting.
- **Contamination of farm inputs (HB).** The MS won't have a document on contamination of farm inputs, which was added to the work agenda by NOP, for the Spring meeting but may have a verbal update as to its status.
- **Sanitizers** (HB). The MS is seeking to undertake a comprehensive review of sanitizers to develop a framework for reviewing sanitizers across the different sections of the national list. The MS submitted a revised request to NOP in support of this and is awaiting feedback.
- **Other items.**
    - Natamycin. A member noted that natamycin, which is used for mold inhibition, was recently petitioned in Crops. It is classified differently by the FDA, and the Crops

Subcommittee is trying to determine classification. It was noted that Natamycin was petitioned before and it was determined to be an antibiotic and was denied for addition to the List. The MS Chair asked for feedback about how to move forward.

- **The meeting was adjourned**

[Previous MS Notes]

Future Call Schedule (2nd Tuesday 2:00 ET)

January 30, 2018 - additional call
Contamination of farm inputs (HB).
Genetic integrity of seed used on organic land (DS, DM, HB).
February 13, 2018
March 13, 2018
April 10, 2018
May 8, 2018
June 12, 2018
July 10, 2018
August 14, 2018
September 11, 2018
October 9, 2018
November 13, 2018
December 11, 2018

Spring 2018 Milestones	Target dates (tentative)
New NOSB member orientation	TBD
NOSB - Spring 2018 proposals due to NOP	Feb 21, 2018
NOP - Complete Spring 2018 NOSB meeting tentative agenda	Mar 6, 2018
NOP - Post proposals, "Open" public comment	Mar 6, 2018
Discuss work agendas on ES call	Mar 9, 2018
Public comment closes	Apr 4, 2018
NOP - Send compiled public comments to NOSB	Apr 9, 2018
Work agendas finalized on ES call (last call before fall meeting)	Apr 13, 2018
Public comment webinar(s)	Apr 17 & 19, 2018
Spring 2018 NOSB meeting – Tucson, AZ	Apr 25-27, 2018

NOSB Crops Subcommittee
Polyoxin D Zinc Salt
TR Sufficiency Review

January 16, 2018; Revised February 17, 2018

Introduction

Polyoxin D Zinc Salt (EPA Reg. No. 68173-1) is a fungicide derived from *Streptomyces cacaoi* var. *asoensis*, a soil borne microorganism, through an aerobic fermentation process. The active portion of Polyoxin D Zinc Salt is Polyoxin D which is produced by a microorganism that is naturally occurring in the soil. Polyoxin D inhibits the growth of phytopathogenic fungal cell wall chitin by competitively inhibiting chitin synthease. Without chitin, susceptible fungi are unable to continue growing and infecting plant cells.

Background

Polyoxin D Zinc Salt was petitioned in 2012 as a synthetic substance to be allowed for use in Organic Crop Production (CFR 205.601). The NOSB noted in its Petitioned Material Proposal that the manufacturer of Polyoxin D Zinc Salt could not confirm the source of the zinc salt as to whether it was "virgin" zinc from a mine or from a recycled zinc source. Furthermore, the manufacturer chose to withhold disclosure of its manufacturing process, citing it as proprietary and confidential business information.

In the petitioner's response to NOP TR dated September 23, 2012, the petitioner stated that the petitioner is not the producer of the zinc source used in the production of Polyoxin D Zinc Salt and does not know if the zinc is "virgin" zinc from a mine or recycled zinc. The NOSB voted unanimously to classify polyoxin D zinc salt as a synthetic substance.

Kaken has stated in its February 2, 2018 petition addendum (pages 7 and 232):

> "Based upon detailed chemical analyses submitted to and reviewed and accepted by the US EPA, Polyoxin D Zinc Salt Technical (EPA Reg. No. 68173-1) does *not* contain any toxicologically significant heavy metal impurities at or above the level of detection."
>
> "Kaken purchases and does not control the production process for the starting material containing zinc that is used to convert polyoxin D to polyoxin D zinc. Therefore, Kaken cannot assert that the zinc source is derived from native mined zinc (or from recycled zinc). Nonetheless, Kaken can confirm that detailed chemical analyses of multiple routine production batches of Polyoxin D Zinc Salt Technical confirm that no toxicologically significant heavy metals are present at or above the level of detection."

Kaken has further stated in its February 2, 2018 petition addendum (pages 7):

> "The US Environmental Protection Agency has determined that the polyoxin D zinc salt has no toxicological end-point to use in a human risk assessment. Polyoxin D zinc salt:
> - Does *not* cause genetic damage (is *not* mutagenic);
> - Does *not* cause birth defects (is *not* teratogenic);

- Does *not* cause infertility (is *not* a reproductive toxin);
- Does *not* cause cancer (is *not* carcinogenic);
- Does *not* cause adverse effects on the nervous system (is *not* neurotoxic);
- Does *not* cause adverse effects on the immune system (is *not* immunotoxic); and
- Does *not* cause adverse effects in any organ system (is *not* chronically toxic)."

On January 29, 2013, the Crops Subcommittee's listing motion was rejected by a vote of 3 yes , 4 no and 1 abstention.

On April 11, 2013, the formal recommendation of the NOSB to add Polyoxin D zinc Salt to 205.601 in the National List failed by a vote of 6 yes and 9 no. The rationale being that the material was deemed non-essential.

A new petition was submitted May 31, 2016 and included responses to questions and concerns raised by members of the NOSB during the April 2013 public hearing. The May 31, 2016 petition summarized new studies on possible adverse effects on non-target organisms and efficacy data for Veggieturbo 5SC Fungicide (EPA Reg. No. 68173-4).

The December 12, 2017 TR was prepared in response to the Crops Subcommittee's request regarding the May 31, 2016 petition.

On February 2, 2018, the petitioner submitted a petition addendum that includes: (1) updates; (2) summaries of new efficacy data, including summaries of efficacy data for the OMRI-listed alternative products; and (3) a detailed analysis of grower needs.

The update in the February 2, 2018 petition addendum specifies that polyoxin D zinc salt has been used commercially in Japan for 45 years and currently is not approved for organic use anywhere in the world.

Below are questions and answers posed by the Subcommittee during the previous review process. These responses are from the firm Conn & Smith, Inc. in a letter dated October 26, 2017.

Q1a: Could Polyoxin D function without the zinc salt added to it to improve surface retention?

A1a: Polyoxin D without the zinc salt is not an EPA registered pesticide. It would be prohibitively costly to pursue EPA registration of polyoxin D (without the zinc) as a new active ingredient. New efficacy studies would be required. Commercially viable efficacy is not anticipated. If commercially viable efficacy could be demonstrated, well over 1 million dollars in new EPA registration studies would be required.

Surface tension is not the issue. Water solubility is the issue. Polyoxin D is very water soluble and would wash off the plant surface. Contact with the plant surface is needed for efficacy.

Q1b: Would there be a possible replacement that would be non-synthetic?

A1b: This will depend upon the *published* efficacy data for each crop/ disease combination of any candidate non-synthetic replacement. This question also misses an important point. Polyoxin D zinc salt provides a new mode of action for organic growers who already have a short list of available modes of action. A new mode of action provides a tool for resistance management. Pathogen resistance to some fungicide active ingredients has been observed. More information of fungicide resistance is available from the Fungicide Resistance Action Committee at http://www.frac.info/home.

Q1c: What is the action and use of Polyoxin D complex by itself compared to with zinc added?

A1c: "Polyoxin D complex" *does not exist*.

- Polyoxin D zinc salt is an EPA registered pesticide.
- Polyoxin complex is not an EPA registered pesticide. Polyoxin complex is produced by Kaken and registered by Kaken for use in Asia. Polyoxin complex is *chemically quite different* than polyoxin D and polyoxin D zinc salt. Polyoxin D zinc salt and polyoxin complex have *very different efficacy*.

World-wide, there is:

- *No* commercial *production* of polyoxin D without the conversion to the zinc salt; and
- *No* commercial *use* of polyoxin D without the conversion to the zinc salt.

The pending petition is limited to polyoxin D zinc salt and its 5SC (5% suspension concentrate) formulation.

Q2: There are numerous studies referenced by the petitioner that the Subcommittee would like verification on to help with the validity of the claims of the petitioner. Some specific examples are studies referenced for: soil studies, beneficial insect impact studies, impact on beneficial soil fungi, mode of action, etc.

A2: Kaken welcomes the comments of the technical reviewer. Kaken notes:

- The studies on soil, beneficial insects, and beneficial soil fungi are applied biology studies, whereas the mode of action studies is physical chemistry (kinetics) studies.
- To provide the requested technical evaluation, the technical reviewer will need technical expertise in *both* biology and physical chemistry (kinetics).

Q3a: Update on global organic use or recognition?

A3a: The polyoxin D zinc salt 5SC formulation is specifically designed for the US organic market. At this time, organic use has been requested for the US only. No applications have been approved or are pending in other parts of the world. Correction of the error-filled September 23, 2012 NOP technical report is effectively a necessary first step before Kaken can realistically consider requesting organic approval in any other part of the world.

Q3b: Any changes?

A3b: Yes, there have been many changes in the United States and internationally. An NOP petition supplement is planned.

Technical Review Sufficiency Determination

• Is consistent in format, level of detail and tone
The TR is consistent and provides clear explanation and sufficient detail.

• Is technically objective and free from opinions or conjecture
The research is presented objectively and without opinions or presumptions.

• Is written in a style appropriate for non-technical readers (e.g. free of technical jargon)
While there is technical jargon and chemical references, it is explained throughout the TR, and can be understood. The nature of the topic requires advanced technical knowledge, but the document is written in a manner to minimize additional research on the reader's part.

• **Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance**
The information gathering, information synthesis, document preparation and quality assurance is sufficient in this current TR.

• **Is based on the best available information that can be obtained within the designated time frame**
The TR contains information that is important to the Crops Subcommittee in determining the validity of the petitioner's use of this product.

• **Is thoroughly supported using literature citations**
The TR is well-referenced and includes approximately 33 citations spanning both recent and earlier research on the subject.

• **Addresses all evaluation questions in the TR template**
All evaluation questions are adequately addressed. Additionally, subsequent questions posed by the Crops Subcommittee were addressed in the Limited Scope Technical Review completed by Conn and Smith in a letter dated October 26, 2017.

Petition sent to CS 06.16.16
Petition sufficiency /TR request due 08 16 16
Petition found sufficient 08.16.16
CS requested Limited Scope TR 10. 04. 16
Limited Scope TR received 10.26.17
Updated Draft TR Report 12.12.17

National Organic Standards Board
Livestock Subcommittee Discussion Document
Clarifying "emergency" for use of synthetic parasiticides in organic livestock production
February 19, 2018

I. INTRODUCTION

The use of parasiticides in organic livestock production under the current regulation is confined to "emergency use". Synthetic parasiticides cannot be used routinely. The organic status of animals must not result in the farmer withholding medical treatment and allow organic livestock to suffer if there is a method to solve the health problem. If there is no organically approved material or activity to solve the problem, the farmer must use a nonapproved material and then remove the products from this animal from sale into the organic marketplace.

Organic farmers rely upon their management skills and knowledge to implement preventative practices such as sourcing disease-free animals into their herds or flocks, monitoring their herds for vigor and selecting breeds which have high resistance to parasites. All organic livestock must have access to the outdoors when appropriate for the region and animal's stage of life. Organic farmers manage their land, especially ruminant pastures, in a manner that reduces the presence of parasites that might infect their animals. If an increased parasite load, for example, is noted in fecal egg counts, farmers have a broad array of alternative treatments available. But when all else fails and animals are not doing well, a farmer, perhaps working with a veterinarian, may need to use one of the synthetic parasiticides on the National List. Use of these synthetic parasiticides in an emergency situation, does not result in the livestock's production to be removed from the organic marketplace.

A discussion document was circulated in Spring 2017 and a proposal circulated in Fall 2017 which sought public comment from a broad cross section of stakeholders to determine if any changes should be made to § 205.238, Livestock Healthcare Practice Standard, as it pertains to parasite prevention plans, use of approved synthetic parasiticides, and if a definition or clarification of the term "emergency" was needed.

II. BACKGROUND

In October 2015 the NOSB recommended continued listing of three parasiticides, ivermectin, moxidectin and fenbenzadole, as part of its sunset review. In April 2016 the NOSB unanimously approved annotations amending the use of fenbenzadole and moxidectin, and in November 2016 the NOSB unanimously (with one absence) approved removal of ivermectin from the National List. On January 19, 2018, a proposed final rule to implement the NOSB recommendations from April 2016 was printed in the Federal Register for public comment.

During the two years these changes to the annotations for these approved synthetic parasiticides were being considered, the NOSB received considerable public comment. In addition to providing factual, technical and scientific information in support of the changes, some stakeholders suggested that the term emergency was not sufficiently well defined and that use of synthetic parasiticides may be abused with the proposed shorter timeframe between use of the parasiticide and the sale of organic livestock products. Some stakeholders supported removal of ivermectin from the National List and the annotation changes to the other two parasiticides but urged clarification of what constitutes an "emergency".

Two documents were presented to the public for comment specifically addressing the term "emergency" when considering the use of approved synthetic parasiticides for organic livestock. Organic producers, organic certifiers and nonprofits that aid transitioning producers commented that there must be a consistently implemented standard across all regions, sizes of farms, and types of farms. The organic standard should not encourage "certifier shopping" to seek out those that interpret the regulations in a looser manner than others, which could be encouraged by gray areas in the rule.

Organic producers consistently ask the National Organic Program for strict standards with clear meanings, so they are confident all organic products in the marketplace meet the same standard. Producers also want to know there is an economic and production "level playing field" between themselves and their competition. Consistent implementation based upon clear and precise definitions within the regulation contribute to both producer and consumer trust in the organic label. Clarification on emergency treatment when using parasiticides for organic livestock will contribute to lessening the gray area on this specific subject.

Providing this clarification also provides a better understanding of what organic certification agencies should look for in an organic system plan and operators should use as preventative management activities. The NOP proposed rule change to greatly lessen the withdrawal time between the use of the parasiticides and sale of organic products, has taken away a strong disincentive for the use of these synthetics. Clarification of when an emergency would allow use of synthetic parasiticides on organic livestock, is a necessity to provide consistency, trust and integrity.

III. RELEVANT AREAS OF THE RULE

Current standard that would be modified once there is a proposal submitted to the NOP

§205.238 Livestock health care practice standard.

(a) The producer must establish and maintain preventive livestock health care practices, including:
(1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;
(2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);
(3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;

(b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, that, such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:
(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
(2) Dairy animals as allowed under §205.603.
(3) Fiber bearing animals, as allowed under §205.603.

§205.603 Synthetic substances allowed for use in organic livestock production.

(a) As disinfectants, sanitizer, and medical treatments as applicable.
(18) Parasiticides—prohibited in slaughter stock. Allowed in emergency treatment for dairy and breeder stock, when organic system plan-approved preventive management does not prevent

infestation. Allowed in fiber bearing animals, when used a minimum of 90 days prior to production of fleece or wool that is to be sold, labeled, or represented as organic. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

(i) Fenbendazole (CAS #43210-67-9)—-Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

(ii) Ivermectin (CAS #70288-86-7)—Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment.

(iii) Moxidectin (CAS #113507-06-5)—-Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

Proposed final rule - January 2018

Changes in bold for ease of identification.

Parasiticides § 205.603(a)(17)

Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. ~~**Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment**~~. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. **Allowed for fiber-bearing animals when used a minimum of 90 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.**

Fenbendazole 205.603 (a)(17)(i)

Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species.

Ivermectin 205.603 (a)(17)(ii)

Removed from the list of approved synthetics

Moxidectin $205.603(a)(17(iii)

Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species.

IV. Public comment

The NOSB asked the following questions in our discussion document for the April 2017 meeting:

1. Does the term "emergency" need to be defined?

2. If so, how should the term "emergency" be defined?

3. Should there be more specific guidelines, such as specific tests for parasite levels as part of the producer's parasite prevention plan, before it is determined that emergency treatment with an approved parasiticide might be needed?

4. What are the challenges for producers, inspectors and certifiers in verifying the documentation and implementation of a parasite management plan in organic operations, and how might these be addressed?

Numerous certifiers and organic stakeholders stated they agreed with the necessity of providing further clarification for the term "emergency" when reviewing the use of the synthetic parasiticides present on the National List of approved substances. Commenters asked for improved transparency of how these synthetics are used, and that use is restricted to times when all other methods have failed and the health of the animal is at risk. Some stated that describing expectations of what constitutes an "emergency" provides a consistent standard for all producers of organic livestock, as well as what the certification agency will review when verifying their operation for compliance to the organic regulation.

Additional language to be added to §205.238(c)(4) [new text *in italics]* **was proposed in our October 2017 proposal document.**

> (4) Administer synthetic parasiticides on a routine basis. *The producer must first use management practices to prevent scientifically identified threshold levels of parasites in their livestock, and secondly use nonsynthetic products to manage parasites. When these two approaches are not effective, this could lead to the emergency treatment and use of National List approved synthetic parasiticides. Examples of materials, management activities and goals used could include:*
>
> *i) Grazing systems and living conditions that prevent livestock parasite infestations by keeping livestock out of paddocks or pens until the parasites are no longer viable in that area.*
> *ii) Maintaining forage diversity, height and grazing frequency to lessen transference of parasites during grazing.*
> *iii) Use of allowed non-synthetic botanicals, biologics and minerals, both internally and externally, to maintain parasite levels in the livestock well below the treatment threshold.*
> *iv) Use various monitoring and documentation methods through the season which inform the operator of the efficacy of their parasite management practices such as fecal sampling and FAMACHA.*
> *v) When the practices provided for in paragraphs (1) through (4) of this section are insufficient to prevent or control parasites within the accepted threshold of that parasite, and for that age of animal and species of animal, a parasiticide included on the National*

List of synthetic substances allowed for use in organic livestock production may be used as an emergency treatment. Provided, That, the conditions for using the substance are documented in the organic system plan, and the organic operator documents proposed improvements to their organic system plan to lessen the need for these National List approved synthetic parasiticides.

Numerous commenters stated this proposal was too prescriptive. While the NOSB was seeking to provide voluntary examples for preventative and monitoring activities similar to the pest management hierarchies found in the crops and handling sections of the rule, there was concern that having them listed in regulatory language resulted in these activities being mandated and not voluntary. There was comment that having these various activities in an NOP guidance document would be better suited to provide these examples for both producers and certifiers in development of an organic system plan's treatment of this issue.

Many commenters preferred a definition of emergency be placed in 205.2, with some suggesting this would be sufficient to address this issue and others suggesting a more general statement be added in the body of the regulation.

Numerous commenters suggested this definition:

A livestock emergency is an urgent, non-routine situation in which the organic system plan's preventive measures and veterinary biologics are proven, by laboratory analysis and visual inspection, to be inadequate to prevent life-threatening illness or to alleviate pain and suffering. In such cases, a producer must administer the emergency treatment (§205.238(c)(7)). Organic certification will be retained provided, that, such treatments are allowed under § 205.603 and the organic system plan is changed to prevent a similar livestock emergency in individual animals or the whole herd/flock in future years as required under §205.238(a).

Many commenters suggested improvements to 205.238 (b)- suggestion in bold

When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, that, such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:
(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and

Parasiticides allowed under §205.603 may be used on

(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
(2) Dairy animals as allowed under §205.603.

(3) Fiber bearing animals, as allowed under §205.603.

Use is approved only in the event of an emergency, and only when management practices include, but are not limited to, grazing systems and living conditions to prevent infestation and reinfestation, forage height diversity, use of allowed nonsynthetic botanicals, biologics

and minerals to maintain parasite levels below treatment thresholds, and including monitoring and documentation of parasites through use of methods such as fecal monitoring and FAMACHA, have proven insufficient to prevent or control parasites within the accepted threshold for specific parasites, age and species of the animal.

V. Discussion

The two items above, improvement to 205.238 (b) and a definition of Emergency treatment of livestock for parasiticide use, when presented together, address both the assessment if there is an emergency and the practices that are may or may not be part of an organic system plan, where appropriate for each site-specific organic livestock operation. The wording in 205.238 (b) is not a mandate, but instead form a strong foundation for operators and certifiers to use when reviewing and verifying their operations are building an organic system that protects the health of their animals and meets the organic regulations.

Each region and operation have their own challenges. New to organic producers who may be accustomed to relying on synthetic parasiticides, could benefit from this language in helping them understand what is required. Having these two descriptions in the rule can also provide the consistency between certifiers in the implementation of the rule, while giving flexibility to allow for operator response to their site-specific needs.

Each age and type of livestock has differing parasite threshold levels that could result in the use of a synthetic parasiticide. These scientifically identified threshold levels can be found within University Extension publications, or by speaking with a veterinarian and other livestock health professionals. The use of monitoring and fecal testing provides both the operator and the certifier tools they can use to judge if the situation is approaching an emergency.

Based upon monitoring, each operation's unique organic system plan should be modified to improve livestock living conditions as well as other practices that might lessen parasite loads before they reach the threshold levels. The use of the synthetic parasiticides is a last resort after other activities have been shown to be ineffective in parasite control.

The short wait time in the NOP proposed final rule, between use of these synthetic parasiticides and the sale of organic livestock products, should only be allowed when there is a documented need for an emergency treatment. This proposal provides a framework to aid operators in understanding what is required for parasite management in their organic system plan as well as what type of documentation needs to be provided to certifiers in their review.

VI. Discussion Questions

1. Does the emergency definition above sufficiently address the issues and clearly describe the situation when a synthetic parasiticide could be used on organic livestock? If not, please provide improved language for NOSB consideration.

2. Does the suggested improved wording for 205.238(b) sufficiently address the management strategies that could be in place, without restricting the operator from other practices that are successful in treating parasites and might not be listed? If not, please provide improved language for NOSB consideration.

3. Are both of these items sufficient to addressing the need for defining and describing an emergency when synthetic parasiticides would be allowed? Are they practical, verifiable and enforceable? Why or why not?

VII. MOTION TO APPROVE THIS DISCUSSION DOCUMENT

Motion by: Harriet Behar
Seconded by:
Yes: No: Abstain: Absent: Recuse:

Approved by Ashley Swaffar, Subcommittee Chair, to transmit to NOSB , 2018

National Organic Standards Board
Livestock Subcommittee Proposal
Clarifying "emergency" for use of synthetic parasiticides in organic livestock production
February 20, 2018

I. INTRODUCTION

Organic farmers rely upon their management skills and knowledge to implement preventative practices such as sourcing disease-free animals into their herds or flocks, monitoring their herds for vigor and selecting breeds which have high resistance to parasites. All organic livestock must have access to the outdoors when appropriate for the region and animal's stage of life. Organic farmers manage their land, especially ruminant pastures, in a manner that reduces the presence of parasites that might infect their animals. If an increased parasite load, for example, is noted in fecal egg counts, farmers have a broad array of alternative treatments available. But when all else fails and animals are not doing well, a farmer, perhaps working with a veterinarian, may need to use one of the synthetic parasiticides on the National List.

The use of approved synthetic parasiticides in organic livestock production under the current regulation is confined to "emergency use". Use of these synthetic parasiticides in an emergency situation does not result in the livestock's products being removed from the organic marketplace. These approved synthetic parasiticides cannot be used routinely. The organic status of animals must not result in the farmer withholding medical treatment. If there is no organically approved material or activity to solve the problem, the farmer must use a nonapproved material and then remove the products from this animal from sale into the organic marketplace (7 CFR 205.238(c)(7)).

A discussion document was circulated in Spring 2017 and a proposal circulated in Fall 2017 which sought public comment from a broad cross section of stakeholders to determine if any changes should be made to §205.238, Livestock Healthcare Practice Standard, as it pertains to parasite prevention plans, use of approved synthetic parasiticides, and if a definition or clarification of the term "emergency" was needed.

II. BACKGROUND

In October 2015 the NOSB recommended continued listing of three parasiticides, ivermectin, moxidectin and fenbenzadole, as part of its sunset review. In April 2016 the NOSB unanimously approved annotations amending the use of fenbenzadole and moxidectin, and in November 2016 the NOSB unanimously (with one absence) approved removal of ivermectin from the National List. On January 19, 2018, a proposed rule to implement the NOSB recommendations from April 2016 was printed in the Federal Register for public comment (83 FR 2498).

During the two year period in which these changes to the annotations for these approved synthetic parasiticides were being considered, the NOSB received considerable public comment. In addition to providing factual, technical and scientific information in support of the changes, some stakeholders suggested that the term emergency was not sufficiently well defined and that use of synthetic parasiticides may be abused with the proposed shorter timeframe between use of the parasiticide and the sale of organic livestock products. Some stakeholders supported removal of ivermectin from the National List and the annotation changes to the other two parasiticides but urged clarification of what constitutes an "emergency".

Two documents were presented to the public for comment specifically addressing the term "emergency" when considering the use of approved synthetic parasiticides for organic livestock. Organic producers, organic certifiers and nonprofits that aid transitioning producers commented that there must be a consistently implemented standard across all regions, sizes of farms, and types of farms. The organic standard should not encourage "certifier shopping" to seek out those that interpret the regulations in a looser manner than others, which could be encouraged by gray areas in the rule.

Organic farmers consistently ask the NOSB for strict standards with clear meanings, so they are confident all organic products in the marketplace meet the same standard. Producers also want to know there is an economic and production "level playing field" between themselves and their competition. Consistent implementation of the National Organic Program regulations, based upon clear and precise definitions contribute to both producer and consumer trust in the organic label. Clarification on emergency treatment when using parasiticides for organic livestock will contribute to lessening the gray area on this specific subject.

Providing this clarification also provides a better understanding of what organic certification agencies should look for in an organic system plan and operators should use as preventative management practices. The NOP proposed rule change to greatly lessen the withdrawal time between the use of the parasiticides and sale of organic products, has taken away a strong disincentive for the use of these synthetics. Clarification of when an emergency would allow use of synthetic parasiticides on organic livestock is a necessity to provide consistency, trust, and integrity.

III. RELEVANT AREAS OF THE RULE

Current regulation addressing livestock health care

§205.238 Livestock health care practice standard.

(a) The producer must establish and maintain preventive livestock health care practices, including:
(1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;
(2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);
(3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;
(b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, that, such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:
(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
(2) Dairy animals as allowed under §205.603.
(3) Fiber bearing animals, as allowed under §205.603.

§205.603 Synthetic substances allowed for use in organic livestock production.

(a) As disinfectants, sanitizer, and medical treatments as applicable.
(18) Parasiticides—prohibited in slaughter stock. Allowed in emergency treatment for dairy and

breeder stock, when organic system plan-approved preventive management does not prevent infestation. Allowed in fiber bearing animals, when used a minimum of 90 days prior to production of fleece or wool that is to be sold, labeled, or represented as organic. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.

(ii) Ivermectin (CAS #70288-86-7)

(iii) Moxidectin (CAS #113507-06-5)—For control of internal parasites only

Proposed rule - January 17, 2018 (83 FR 2498)

Changes in bold for ease of identification.

Parasiticides § 205.603(a)(23)

Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. ~~**Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment**~~. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. **Allowed for fiber-bearing animals when used a minimum of 90 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.**

Fenbendazole § 205.603 (a)(23)(i)

Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species.

~~Ivermectin~~

Removed from the list of approved synthetics

Moxidectin § 205.603(a)(23)(ii)

Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species.

IV. Public comment

The NOSB asked the following questions in the April 2017 discussion document:

1. Does the term “emergency“ need to be defined?

2. If so, how should the term “emergency” be defined?

3. Should there be more specific guidelines, such as specific tests for parasite levels as part of the producer’s parasite prevention plan, before it is determined that emergency treatment with an approved parasiticide might be needed?

4. What are the challenges for producers, inspectors and certifiers in verifying the documentation and implementation of a parasite management plan in organic operations, and how might these be addressed?

Numerous certifiers and organic stakeholders agreed with the necessity of providing further clarification for the term “emergency” when reviewing the use of the synthetic parasiticides present on the National List of approved substances. Commenters asked for improved transparency of how these synthetics are used, and that use is restricted to times when all other methods have failed and the health of the animal is at risk. Some stated that describing expectations of what constitutes an “emergency” provides a consistent standard for all producers of organic livestock, as well as what the certification agency will review when verifying their operation for compliance to the organic regulation.

Additional language to be added to §205.238(c)(4) [new text *in italics]* **was proposed in our October 2017 proposal document.**

> (4) Administer synthetic parasiticides on a routine basis. *The producer must first use management practices to prevent scientifically identified threshold levels of parasites in their livestock, and secondly use nonsynthetic products to manage parasites. When these two approaches are not effective, this could lead to the emergency treatment and use of National List approved synthetic parasiticides. Examples of materials, management activities and goals used could include:*
>
> *i) Grazing systems and living conditions that prevent livestock parasite infestations by keeping livestock out of paddocks or pens until the parasites are no longer viable in that area.*
> *ii) Maintaining forage diversity, height and grazing frequency to lessen transference of parasites during grazing.*
> *iii) Use of allowed non-synthetic botanicals, biologics and minerals, both internally and externally, to maintain parasite levels in the livestock well below the treatment threshold.*
> *iv) Use various monitoring and documentation methods through the season which inform the operator of the efficacy of their parasite management practices such as fecal sampling and FAMACHA.*
> *v) When the practices provided for in paragraphs (1) through (4) of this section are insufficient to prevent or control parasites within the accepted threshold of that parasite, and for that age of animal and species of animal, a parasiticide included on the National List of synthetic substances allowed for use in organic livestock production may be used as an emergency treatment. Provided, That, the conditions for using the substance are*

documented in the organic system plan, and the organic operator documents proposed improvements to their organic system plan to lessen the need for these National List approved synthetic parasiticides.

Numerous commenters stated this proposal was too prescriptive. While the NOSB was seeking to provide voluntary examples for preventative and monitoring activities similar to the pest management hierarchies found in the crops and handling sections of the rule, there was concern that having them listed in regulatory language resulted in these activities being mandated and not voluntary. There was comment that listing various activities in an NOP guidance document would be more useful for both producers and certifiers.

Many commenters preferred that a definition of emergency be placed in 205.2, with some suggesting this would be sufficient to address this issue. Others suggested a more general statement be added to the body of the regulation.

Numerous commenters suggested this definition:

A livestock emergency is an urgent, non-routine situation in which the organic system plan's preventive measures and veterinary biologics are proven, by laboratory analysis or visual inspection, to be inadequate to prevent life-threatening illness or to alleviate pain and suffering. In such cases, a producer must administer the emergency treatment (§205.238(c)(7)). Organic certification will be retained, provided that such treatments are allowed under § 205.603 and the organic system plan is changed to prevent a similar livestock emergency in individual animals or the whole herd/flock in future years as required under §205.238(a).

Many commenters suggested improvements to 205.238 (b)- suggestion in bold

When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, that, such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:
(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and

Parasiticides allowed under §205.603 may be used on

(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
(2) Dairy animals as allowed under §205.603.
(3) Fiber bearing animals, as allowed under §205.603.
(4) ***Organic livestock as provided in §205.238 (b) (1), (2), and (3) and only in the event of an emergency where management strategies have been proven insufficient to prevent or control parasites within the accepted threshold for specific parasites, age and species of the animal. These management strategies include but are not limited to, grazing systems and living conditions that prevent infestation and reinfestation, forage height diversity, use of allowed nonsynthetic botanicals, biologics and minerals to maintain parasite levels below treatment thresholds, and could include monitoring and documentation of parasites through use of methods such as fecal monitoring and FAMACHA.***

V. Discussion

The two items above, improvement to 205.238 (b) and a definition of emergency treatment of livestock for parasiticide use, when presented together, address both emergency assessment, and Organic System Plan practices. The wording in 205.238 (b) is not a mandate, but instead forms a strong foundation for operators and certifiers to use when reviewing and verifying an organic system that protects the health of the animals and meets the organic regulations.

Each region and operation has their own challenges. New-to-organic producers who may be accustomed to relying on synthetic parasiticides, could benefit from this language to help them understand what is required. Having these two descriptions in the rule could also provide the consistency between certifiers in the implementation of the rule, while giving flexibility to allow for operator response to their site-specific needs.

Each age and species of livestock has differing parasite threshold levels that could result in the use of a synthetic parasiticide. Scientifically identified threshold levels can be found within University Extension publications, or by speaking with a veterinarian and other livestock health professionals. The use of monitoring and fecal testing provides both the operator and the certifier tools they can use to judge if the situation is approaching an emergency.

Based upon monitoring, each operation's unique organic system plan should be modified to improve livestock living conditions as well as other practices that might lessen parasite loads before they reach the threshold levels. The use of synthetic parasiticides is a last resort after other activities have been exhausted.

The short wait time as indicated in the January 2018 NOP proposed rule, between use of synthetic parasiticides and the sale of organic livestock products, should only be allowed when there is a documented need for an emergency treatment. This proposal provides a framework to aid operators in understanding what is required for parasite management in their organic system plan as well as what type of documentation needs to be provided to certifiers in their review.

VI. Subcommittee Discussion

The proposed addition to the regulation provides a clear path for operators and certifiers to promote consistency within the certification process. Monitoring, management, and natural products must be used before a synthetic is allowed. The wording above is practical for the operators and provides the verification tools needed by the certifiers, without being too prescriptive or adding excessive paperwork. The wording above meets the concerns of the vast majority of the public commenters, providing both a workable solution and the clarity requested. The definition as presented above, includes many requirements and is better placed within the regulation, rather than in the definition section of the rule.

VII. MOTION TO APPROVE THIS PROPOSAL

Add this to § 205.238 (b)
[assumes adoption of changes in NOP proposed rule (83 FR 2498)]

(4) Organic livestock when meeting the following conditions:

Commented [PD-A1]: This would permit the use of parasiticides on slaughter stock Is that intention?

(b) * * *… Parasiticides allowed under §205 603 may be used on:
(2) Dairy animals, as allowed under § 205 603
(3) Fiber bearing animals, as allowed under § 205 603

(i) A livestock emergency has occurred, defined as an urgent, non-routine situation in which the organic system plan's preventive measures and veterinary biologics are proven, by laboratory analysis or visual inspection, to be inadequate to prevent life-threatening illness or to alleviate pain and suffering.

(ii) Organic livestock has been managed according to 238(b) and 238(c)(2), 238(c)(4), and 603(a)(17) and only in the event of an emergency where management strategies have been proven insufficient to prevent or control parasites within the accepted threshold for specific parasites, age and species of the animal. These management strategies include but are not limited to, forage height and plant diversity to maintain parasite levels below treatment thresholds and monitoring with documentation of parasites through use of methods such as fecal monitoring and FAMACHA (FAffa Malan Chart used for tracking anemia in goats and sheep).

(iii) The organic system plan is changed to prevent a similar livestock emergency in individual animals or the whole herd/flock in future years as required under §205.238(a).

Motion by: Harriet Behar
Seconded by: Jesse Buie
Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Ashley Swaffar, Subcommittee Chair to transmit to NOSB February 2-, 2018

Commented [PD-A2]: Why not keep this part in 205 2?

Commented [PD-A3]: Delete? Sentence structure issue

The meaning of this as written is that the preventive measure are proven to alleviate pain and suffering

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Commented [PD-A4]: Why is this included? 238(a) does not include a requirement to change the OSP so referencing it in this section is unclear Do you want to make a requirement to change the OSP? What in 238 is being referenced?

National Organic Standards Board
Livestock Subcommittee Proposal
Clarifying "emergency" for use of synthetic parasiticides in organic livestock production
February 20, 2018

I. INTRODUCTION

Organic farmers rely upon their management skills and knowledge to implement preventative practices such as sourcing disease-free animals into their herds or flocks, monitoring their herds for vigor and selecting breeds which have high resistance to parasites. All organic livestock must have access to the outdoors when appropriate for the region and animal's stage of life. Organic farmers manage their land, especially ruminant pastures, in a manner that reduces the presence of parasites that might infect their animals. If an increased parasite load, for example, is noted in fecal egg counts, farmers have a broad array of alternative treatments available. But when all else fails and animals are not doing well, a farmer, perhaps working with a veterinarian, may need to use one of the synthetic parasiticides on the National List.

The use of approved synthetic parasiticides in organic livestock production under the current regulation is confined to "emergency use". Use of these synthetic parasiticides in an emergency situation does not result in the livestock's products being removed from the organic marketplace. These approved synthetic parasiticides cannot be used routinely. The organic status of animals must not result in the farmer withholding medical treatment. If there is no organically approved material or activity to solve the problem, the farmer must use a nonapproved material and then remove the products from this animal from sale into the organic marketplace (7 CFR 205.238(c)(7)).

A discussion document was circulated in Spring 2017 and a proposal circulated in Fall 2017 which sought public comment from a broad cross section of stakeholders to determine if any changes should be made to §205.238, Livestock Healthcare Practice Standard, as it pertains to parasite prevention plans, use of approved synthetic parasiticides, and if a definition or clarification of the term "emergency" was needed.

II. BACKGROUND

In October 2015 the NOSB recommended continued listing of three parasiticides, ivermectin, moxidectin and fenbenzadole, as part of its sunset review. In April 2016 the NOSB unanimously approved annotations amending the use of fenbenzadole and moxidectin, and in November 2016 the NOSB unanimously (with one absence) approved removal of ivermectin from the National List. On January 19, 2018, a proposed rule to implement the NOSB recommendations from April 2016 was printed in the Federal Register for public comment (83 FR 2498).

During the two year period in which these changes to the annotations for these approved synthetic parasiticides were being considered, the NOSB received considerable public comment. In addition to providing factual, technical and scientific information in support of the changes, some stakeholders suggested that the term emergency was not sufficiently well defined and that use of synthetic parasiticides may be abused with the proposed shorter timeframe between use of the parasiticide and the sale of organic livestock products. Some stakeholders supported removal of ivermectin from the National List and the annotation changes to the other two parasiticides but urged clarification of what constitutes an "emergency".

Two documents were presented to the public for comment specifically addressing the term "emergency" when considering the use of approved synthetic parasiticides for organic livestock. Organic producers, organic certifiers and nonprofits that aid transitioning producers commented that there must be a consistently implemented standard across all regions, sizes of farms, and types of farms. The organic standard should not encourage "certifier shopping" to seek out those that interpret the regulations in a looser manner than others, which could be encouraged by gray areas in the rule.

Organic farmers consistently ask the NOSB for strict standards with clear meanings, so they are confident all organic products in the marketplace meet the same standard. Producers also want to know there is an economic and production "level playing field" between themselves and their competition. Consistent implementation of the National Organic Program regulations, based upon clear and precise definitions contribute to both producer and consumer trust in the organic label. Clarification on emergency treatment when using parasiticides for organic livestock will contribute to lessening the gray area on this specific subject.

Providing this clarification also provides a better understanding of what organic certification agencies should look for in an organic system plan and operators should use as preventative management practices. The NOP proposed rule change to greatly lessen the withdrawal time between the use of the parasiticides and sale of organic products, has taken away a strong disincentive for the use of these synthetics. Clarification of when an emergency would allow use of synthetic parasiticides on organic livestock is a necessity to provide consistency, trust, and integrity.

III. RELEVANT AREAS OF THE RULE

Current regulation addressing livestock health care

§205.238 Livestock health care practice standard.

(a) The producer must establish and maintain preventive livestock health care practices, including:
(1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;
(2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);
(3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;
(b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, that, such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:
(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
(2) Dairy animals as allowed under §205.603.
(3) Fiber bearing animals, as allowed under §205.603.

§205.603 Synthetic substances allowed for use in organic livestock production.

(a) As disinfectants, sanitizer, and medical treatments as applicable.
(18) Parasiticides—prohibited in slaughter stock. Allowed in emergency treatment for dairy and

breeder stock, when organic system plan-approved preventive management does not prevent infestation. Allowed in fiber bearing animals, when used a minimum of 90 days prior to production of fleece or wool that is to be sold, labeled, or represented as organic. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.

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Proposed rule - January 17, 2018 (83 FR 2498)

Changes in bold for ease of identification.

Parasiticides § 205.603(a)(23)

Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. ~~**Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment**~~. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. **Allowed for fiber-bearing animals when used a minimum of 90 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.**

Fenbendazole § 205.603 (a)(23)(i)

Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species.

~~Ivermectin~~

Removed from the list of approved synthetics

Moxidectin § 205.603(a)(23)(ii)

Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species.

IV. Public comment

The NOSB asked the following questions in the April 2017 discussion document:

1. Does the term “emergency“ need to be defined?

2. If so, how should the term “emergency” be defined?

3. Should there be more specific guidelines, such as specific tests for parasite levels as part of the producer’s parasite prevention plan, before it is determined that emergency treatment with an approved parasiticide might be needed?

4. What are the challenges for producers, inspectors and certifiers in verifying the documentation and implementation of a parasite management plan in organic operations, and how might these be addressed?

Numerous certifiers and organic stakeholders agreed with the necessity of providing further clarification for the term “emergency” when reviewing the use of the synthetic parasiticides present on the National List of approved substances. Commenters asked for improved transparency of how these synthetics are used, and that use is restricted to times when all other methods have failed and the health of the animal is at risk. Some stated that describing expectations of what constitutes an “emergency” provides a consistent standard for all producers of organic livestock, as well as what the certification agency will review when verifying their operation for compliance to the organic regulation.

Additional language to be added to §205.238(c)(4) [new text *in italics]* **was proposed in our October 2017 proposal document.**

> (4) Administer synthetic parasiticides on a routine basis. *The producer must first use management practices to prevent scientifically identified threshold levels of parasites in their livestock, and secondly use nonsynthetic products to manage parasites. When these two approaches are not effective, this could lead to the emergency treatment and use of National List approved synthetic parasiticides. Examples of materials, management activities and goals used could include:*
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> *i) Grazing systems and living conditions that prevent livestock parasite infestations by keeping livestock out of paddocks or pens until the parasites are no longer viable in that area.*
> *ii) Maintaining forage diversity, height and grazing frequency to lessen transference of parasites during grazing.*
> *iii) Use of allowed non-synthetic botanicals, biologics and minerals, both internally and externally, to maintain parasite levels in the livestock well below the treatment threshold.*
> *iv) Use various monitoring and documentation methods through the season which inform the operator of the efficacy of their parasite management practices such as fecal sampling and FAMACHA.*
> *v) When the practices provided for in paragraphs (1) through (4) of this section are insufficient to prevent or control parasites within the accepted threshold of that parasite, and for that age of animal and species of animal, a parasiticide included on the National List of synthetic substances allowed for use in organic livestock production may be used as an emergency treatment. Provided, That, the conditions for using the substance are*

documented in the organic system plan, and the organic operator documents proposed improvements to their organic system plan to lessen the need for these National List approved synthetic parasiticides.

Numerous commenters stated this proposal was too prescriptive. While the NOSB was seeking to provide voluntary examples for preventative and monitoring activities similar to the pest management hierarchies found in the crops and handling sections of the rule, there was concern that having them listed in regulatory language resulted in these activities being mandated and not voluntary. There was comment that listing various activities in an NOP guidance document would be more useful for both producers and certifiers.

Many commenters preferred that a definition of emergency be placed in 205.2, with some suggesting this would be sufficient to address this issue. Others suggested a more general statement be added to the body of the regulation.

Numerous commenters suggested this definition:

A livestock emergency is an urgent, non-routine situation in which the organic system plan's preventive measures and veterinary biologics are proven, by laboratory analysis or visual inspection, to be inadequate to prevent life-threatening illness or to alleviate pain and suffering. In such cases, a producer must administer the emergency treatment (§205.238(c)(7)). Organic certification will be retained, provided that such treatments are allowed under § 205.603 and the organic system plan is changed to prevent a similar livestock emergency in individual animals or the whole herd/flock in future years as required under §205.238(a).

Many commenters suggested improvements to 205.238 (b)- suggestion in bold

When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, that, such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:
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Parasiticides allowed under §205.603 may be used on

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(2) Dairy animals as allowed under §205.603.
(3) Fiber bearing animals, as allowed under §205.603.
(4) ***Organic livestock as provided in §205.238 (b) (1), (2), and (3) and only in the event of an emergency where management strategies have been proven insufficient to prevent or control parasites within the accepted threshold for specific parasites, age and species of the animal. These management strategies include but are not limited to, grazing systems and living conditions that prevent infestation and reinfestation, forage height diversity, use of allowed nonsynthetic botanicals, biologics and minerals to maintain parasite levels below treatment thresholds, and could include monitoring and documentation of parasites through use of methods such as fecal monitoring and FAMACHA.***

V. Discussion

The two items above, improvement to 205.238 (b) and a definition of emergency treatment of livestock for parasiticide use, when presented together, address both emergency assessment, and Organic System Plan practices. The wording in 205.238 (b) is not a mandate, but instead forms a strong foundation for operators and certifiers to use when reviewing and verifying an organic system that protects the health of the animals and meets the organic regulations.

Each region and operation has their own challenges. New-to-organic producers who may be accustomed to relying on synthetic parasiticides, could benefit from this language to help them understand what is required. Having these two descriptions in the rule could also provide the consistency between certifiers in the implementation of the rule, while giving flexibility to allow for operator response to their site-specific needs.

Each age and species of livestock has differing parasite threshold levels that could result in the use of a synthetic parasiticide. Scientifically identified threshold levels can be found within University Extension publications, or by speaking with a veterinarian and other livestock health professionals. The use of monitoring and fecal testing provides both the operator and the certifier tools they can use to judge if the situation is approaching an emergency.

Based upon monitoring, each operation's unique organic system plan should be modified to improve livestock living conditions as well as other practices that might lessen parasite loads before they reach the threshold levels. The use of synthetic parasiticides is a last resort after other activities have been exhausted.

The short wait time as indicated in the January 2018 NOP proposed rule, between use of synthetic parasiticides and the sale of organic livestock products, should only be allowed when there is a documented need for an emergency treatment. This proposal provides a framework to aid operators in understanding what is required for parasite management in their organic system plan as well as what type of documentation needs to be provided to certifiers in their review.

VI. Subcommittee Discussion

The proposed addition to the regulation provides a clear path for operators and certifiers to promote consistency within the certification process. Monitoring, management, and natural products must be used before a synthetic is allowed. The wording above is practical for the operators and provides the verification tools needed by the certifiers, without being too prescriptive or adding excessive paperwork. The wording above meets the concerns of the vast majority of the public commenters, providing both a workable solution and the clarity requested. The definition as presented above, includes many requirements and is better placed within the regulation, rather than in the definition section of the rule.

VII. MOTION TO APPROVE THIS PROPOSAL

Add ~~this~~ to § 205.2 Definitions

Emergency treatment for parasite control in breeding, dairy and fiber bearing animals

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~~Emergency treatment is allowed when~~ An urgent, non-routine situation ~~has occurred~~ in which the organic system plan's preventive measures and veterinary biologics are proven, by laboratory analysis or visual inspection, to be inadequate to prevent life-threatening illness or inadequate to alleviate pain and suffering.

Add this to § 205.238 (b)
[assumes adoption of changes in NOP proposed rule (83 FR 2498)]

(4) Organic breeding, dairy and fiber bearing animals when meeting the following conditions:

(i) Organic livestock has been managed according to 238(b) and 238(c)(2), 238(c)(4), and 603(a)(2317) and only in the event of an emergency where management strategies have been proven insufficient to prevent or control parasites within the accepted threshold for specific parasites, age and species of the animal. These management strategies include but are not limited to, forage height and plant diversity to maintain parasite levels below treatment thresholds and monitoring with documentation of parasites through use of methods such as fecal monitoring and FAMACHA (FAffa Malan Chart—used for tracking anemia in goats and sheep).

(ii) The organic system plan is changed to prevent a similar livestock emergency in individual animals or the whole herd/flock in future years-.

Motion by: Harriet Behar
Seconded by: Jesse Buie
Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Ashley Swaffar, Subcommittee Chair to transmit to NOSB February 2-, 2018

Commented [PD-A1]: This is too long to be a term in the definitions (and does not appear as stated in the regulations or your proposed regulations so would be meaningless from regulatory perspective)

I recommended parentheses to clarify that you are not defining the term emergency everywhere it appears in the regulations (i e , Federal or State emergency pest or disease treatment) but I honestly don't know if this is a common way this is done in regulations However, it may capture your intent at this stage

Commented [PD-A2]: This is regulatory (it specifies the conditions when something can or must be done) and should not be in a definition

You want to define the term (i e , what is

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Commented [PD-A3]: Delete? Sentence structure issue

The meaning of this as written is that the preventive measure are proven to alleviate pain and suffering

Commented [HB4R3]: The veterinary biologics can alleviate pain, is there a better way to word this so the preventative measures are not included in the pain alleviation?

Commented [PD-A5R3]: Suggested adding word "inadequate" to clarify meaning of sentence

Commented [HB6]: No, I will change to breeding, dairy and fiber bearing animals Thanks for catching that!

Commented [HB7]:

National Organic Standards Board
Livestock Subcommittee Proposal
Clarifying "emergency" for use of synthetic parasiticides in organic livestock production
February 20, 2018

I. INTRODUCTION

The use of parasiticides in organic livestock production under the current regulation is confined to "emergency use". Synthetic parasiticides cannot be used routinely. The organic status of animals must not result in the farmer withholding medical treatment and allow organic livestock to suffer if there is a method to solve the health problem. If there is no organically approved material or activity to solve the problem, the farmer must use a nonapproved material and then remove the products from this animal from sale into the organic marketplace (7 CFR 205.238(c)(7)).

Organic farmers rely upon their management skills and knowledge to implement preventative practices such as sourcing disease-free animals into their herds or flocks, monitoring their herds for vigor and selecting breeds which have high resistance to parasites. All organic livestock must have access to the outdoors when appropriate for the region and animal's stage of life. Organic farmers manage their land, especially ruminant pastures, in a manner that reduces the presence of parasites that might infect their animals. If an increased parasite load, for example, is noted in fecal egg counts, farmers have a broad array of alternative treatments available. But when all else fails and animals are not doing well, a farmer, perhaps working with a veterinarian, may need to use one of the synthetic parasiticides on the National List. Use of these synthetic parasiticides in an emergency situation does not result in the livestock's products ~~ion to~~ being removed from the organic marketplace.

A discussion document was circulated in Spring 2017 and a proposal circulated in Fall 2017 which sought public comment from a broad cross section of stakeholders to determine if any changes should be made to §-205.238, Livestock Healthcare Practice Standard, as it pertains to parasite prevention plans, use of approved synthetic parasiticides, and if a definition or clarification of the term "emergency" was needed.

II. BACKGROUND

In October 2015 the NOSB recommended continued listing of three parasiticides, ivermectin, moxidectin and fenbenzadole, as part of its sunset review. In April 2016 the NOSB unanimously approved annotations amending the use of fenbenzadole and moxidectin, and in November 2016 the NOSB unanimously (with one absence) approved removal of ivermectin from the National List. On January 19, 2018, a proposed ~~final~~ rule to implement the NOSB recommendations from April 2016 was printed in the Federal Register for public comment (83 FR 2498).

During the two year period in which~~s~~ these changes to the annotations for these approved synthetic parasiticides were being considered, the NOSB received considerable public comment. In addition to providing factual, technical and scientific information in support of the changes, some stakeholders suggested that the term emergency was not sufficiently well defined and that use of synthetic parasiticides may be abused with the proposed shorter timeframe between use of the parasiticide and the sale of organic livestock products. Some stakeholders supported removal of ivermectin from the National List and the annotation changes to the other two parasiticides but urged clarification of what constitutes an "emergency".

Commented [AM-A1]: Withholding medical treatment and allowing livestock to suffer in order to retain organic status is …not recommended Prohibited Frowned upon?

Commented [PD-A2]: Recommend adding citation to the requirement, to clarify there is an associated regulation

Commented [PD-A3]: Unclear why this is discussed before discussing allowed synthetic parasiticides (is there indication that the parasiticides on National List are not sufficient)?

Commented [AM-A4]: This seems to contradict the sentence above (in the first paragraph)

Commented [PD-A5R4]: I agree, the distinction between allowed synthetic and nonallowed synthetics is confusing in the paragraph above

Two documents were presented to the public for comment specifically addressing the term "emergency" when considering the use of approved synthetic parasiticides for organic livestock. Organic producers, organic certifiers and nonprofits that aid transitioning producers commented that there must be a consistently implemented standard across all regions, sizes of farms, and types of farms. The organic standard should not encourage "certifier shopping" to seek out those that interpret the regulations in a looser manner than others, which could be encouraged by gray areas in the rule.

Organic producers consistently ask the ~~National Organic~~NOSB ~~Program~~ for strict standards with clear meanings, so they are confident all organic products in the marketplace meet the same standard. Producers also want to know there is an economic and production "level playing field" between themselves and their competition. Consistent implementation based upon clear and precise definitions within the regulation contribute to both producer and consumer trust in the organic label. Clarification on emergency treatment when using parasiticides for organic livestock will contribute to lessening the gray area on this specific subject.

Commented [PD-A6]: Producers or consumers? Is this saying same thing as next sentence? Also, please speak from NOSB perspective rather than on behalf of NOP

Commented [PD-A7]: Does NOSB think consumers are aware of varying interpretations of the term "emergency" in § 205 238? Is confusion about parasiticides prevalent and impacting consumer trust?

Providing this clarification also provides a better understanding of what organic certification agencies should look for in an organic system plan and operators should use as preventative management ~~activities~~practices. The NOP proposed rule change to greatly lessen the withdrawal time between the use of the parasiticides and sale of organic products, has taken away a strong disincentive for the use of these synthetics. Clarification of when an emergency would allow use of synthetic parasiticides on organic livestock~~,~~ is a necessity to provide consistency, trust and integrity.

III. RELEVANT AREAS OF THE RULE

Current regulation addressing livestock health care

§205.238 Livestock health care practice standard.

(a) The producer must establish and maintain preventive livestock health care practices, including:
(1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;
(2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);
(3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;
(b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, that, such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:
(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
(2) Dairy animals as allowed under §205.603.
(3) Fiber bearing animals, as allowed under §205.603.

§205.603 Synthetic substances allowed for use in organic livestock production.

(a) As disinfectants, sanitizer, and medical treatments as applicable.
(18) Parasiticides—prohibited in slaughter stock. Allowed in emergency treatment for dairy and breeder stock, when organic system plan-approved preventive management does not prevent

infestation. Allowed in fiber bearing animals, when used a minimum of 90 days prior to production of fleece or wool that is to be sold, labeled, or represented as organic. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.

(ii) Ivermectin (CAS #70288-86-7

(iii) Moxidectin (CAS #113507-06-5)—For control of internal parasites only

Proposed ~~final~~ rule - January 17, 2018 (83 FR 2498 ~~REFERENCE~~)

Changes in bold for ease of identification.

Parasiticides § 205.603(a)(23~~17~~)

Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. **~~Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment~~**. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. **Allowed for fiber-bearing animals when used a minimum of 90 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.**

Fenbendazole § 205.603 (a)(23~~17~~)(i)

Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species.

~~Ivermectin~~ ~~205.603 (a)(17)(ii)~~

Formatted: Strikethrough

Removed from the list of approved synthetics

Moxidectin § ~~§~~205.603(a)(23~~17~~)(~~ii~~i)

Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species.

IV. Public comment

The NOSB asked the following questions in ~~our discussion document for~~ the April 2017 discussion document:~~meeting:~~

1. Does the term "emergency" need to be defined?

2. If so, how should the term "emergency" be defined?

3. Should there be more specific guidelines, such as specific tests for parasite levels as part of the producer's parasite prevention plan, before it is determined that emergency treatment with an approved parasiticide might be needed?

4. What are the challenges for producers, inspectors and certifiers in verifying the documentation and implementation of a parasite management plan in organic operations, and how might these be addressed?

Numerous certifiers and organic stakeholders ~~stated they~~ agreed with the necessity of providing further clarification for the term "emergency" when reviewing the use of the synthetic parasiticides present on the National List of approved substances. Commenters asked for improved transparency of how these synthetics are used, and that use is restricted to times when all other methods have failed and the health of the animal is at risk. Some stated that describing expectations of what constitutes an "emergency" provides a consistent standard for all producers of organic livestock, as well as what the certification agency will review when verifying their operation for compliance to the organic regulation.

Additional language to be added to §205.238(c)(4) [new text *in italics]* **was proposed in our October 2017 proposal document.**

> (4) Administer synthetic parasiticides on a routine basis. *The producer must first use management practices to prevent scientifically identified threshold levels of parasites in their livestock, and secondly use nonsynthetic products to manage parasites. When these two approaches are not effective, this could lead to the emergency treatment and use of National List approved synthetic parasiticides. Examples of materials, management activities and goals used could include:*
>
> *i) Grazing systems and living conditions that prevent livestock parasite infestations by keeping livestock out of paddocks or pens until the parasites are no longer viable in that area.*
> *ii) Maintaining forage diversity, height and grazing frequency to lessen transference of parasites during grazing.*
> *iii) Use of allowed non-synthetic botanicals, biologics and minerals, both internally and externally, to maintain parasite levels in the livestock well below the treatment threshold.*
> *iv) Use various monitoring and documentation methods through the season which inform the operator of the efficacy of their parasite management practices such as fecal sampling and FAMACHA.*
> *v) When the practices provided for in paragraphs (1) through (4) of this section are insufficient to prevent or control parasites within the accepted threshold of that parasite, and for that age of animal and species of animal, a parasiticide included on the National List of synthetic substances allowed for use in organic livestock production may be used*

as an emergency treatment. Provided, That, the conditions for using the substance are documented in the organic system plan, and the organic operator documents proposed improvements to their organic system plan to lessen the need for these National List approved synthetic parasiticides.

Numerous commenters stated this proposal was too prescriptive. While the NOSB was seeking to provide voluntary examples for preventative and monitoring activities similar to the pest management hierarchies found in the crops and handling sections of the rule, there was concern that having them listed in regulatory language resulted in these activities being mandated and not voluntary. There was comment that ~~having these~~listing various activities in an NOP guidance document would be more useful for ~~better suited to provide these examples for~~ both producers and certifiers. ~~in development of an organic system plan's treatment of this issue.~~

Many commenters preferred that a definition of emergency be placed in 205.2, with some suggesting this would be sufficient to address this issue. ~~and o~~Others suggested~~ing~~ a more general statement be added ~~in~~ to the body of the regulation.

Numerous commenters suggested this definition:

A livestock emergency is an urgent, non-routine situation in which the organic system plan's preventive measures and veterinary biologics are proven, by laboratory analysis or visual inspection, to be inadequate to prevent life-threatening illness or to alleviate pain and suffering. In such cases, a producer must administer the emergency treatment (§205.238(c)(7)). Organic certification will be retained, provided that such treatments are allowed under § 205.603 and the organic system plan is changed to prevent a similar livestock emergency in individual animals or the whole herd/flock in future years as required under §205.238(a).

Many commenters suggested improvements to 205.238 (b)- suggestion in bold

When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, that, such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:
(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and

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(2) Dairy animals as allowed under §205.603.
(3) Fiber bearing animals, as allowed under §205.603.
(4) ***Organic livestock as provided in §205.238 (b) (1), (2), and (3) and only in the event of an emergency where management strategies have been proven insufficient to prevent or control parasites within the accepted threshold for specific parasites, age and species of the animal. These management strategies include but are not limited to, grazing systems and living conditions that prevent infestation and reinfestation, forage height diversity, use of allowed nonsynthetic botanicals, biologics and minerals to maintain parasite levels below treatment***

thresholds, and could include monitoring and documentation of parasites through use of methods such as fecal monitoring and FAMACHA.

V. Discussion

The two items above, improvement to 205.238 (b) and a definition of e~~E~~mergency treatment of livestock for parasiticide use, when presented together, address both the assessment if there is an emergency, and the practices that ~~are~~ may or may not be part of an organic system plan, where appropriate for each site-specific organic livestock operation. The wording in 205.238 (b) is not a mandate, but instead forms a strong foundation for operators and certifiers to use when reviewing and verifying ~~their operations are building~~ an organic system that protects the health of the~~ir~~ animals and meets the organic regulations.

Commented [AM-A8]: A little run-on

Each region and operation has~~ve~~ their own challenges. New~~-~~to~~-~~organic producers who may be accustomed to relying on synthetic parasiticides, could benefit from this language ~~in~~ to help~~ing~~ them understand what is required. Having these two descriptions in the rule could~~an~~ also provide the consistency between certifiers in the implementation of the rule, while giving flexibility to allow for operator response to their site-specific needs.

Each age and type of livestock has differing parasite threshold levels that could result in the use of a synthetic parasiticide. ~~These s~~Scientifically identified threshold levels can be found within University Extension publications, or by speaking with a veterinarian and other livestock health professionals. The use of monitoring and fecal testing provides both the operator and the certifier tools they can use to judge if the situation is approaching an emergency.

Commented [AM-A9]: ?

Based upon monitoring, each operation's unique organic system plan should be modified to improve livestock living conditions as well as other practices that might lessen parasite loads before they reach the threshold levels. The use of ~~the~~ synthetic parasiticides is a last resort after other activities have been ~~shown to be ineffective in parasite control.~~exhausted.

The short wait time as indicated in the January 2018 NOP proposed ~~final~~ rule, between use of ~~these~~ synthetic parasiticides and the sale of organic livestock products, should only be allowed when there is a documented need for an emergency treatment. ~~–~~This proposal provides a framework to aid operators in understanding what is required for parasite management in their organic system plan as well as what type of documentation needs to be provided to certifiers in their review.

VI. Subcommittee Discussion

The proposed definition and addition to the regulation ~~proposed~~ provides a clear path for operators and certifiers to promote consistency within the certification process. Monitoring, management, and natural products must be used before a synthetic is allowed. The wording above is practical for the operators and provides the verification tools needed by the certifiers, without being too prescriptive or adding excessive paperwork. The wording above meets the concerns of the vast majority of the public commenters, providing both a workable solution and the clarity requested.

VII. MOTION TO APPROVE THIS PROPOSAL

Add this definition to 205.2

Emergency treatment ~~to allow~~(with allowed synthetic parasiticide~~s use for~~in livestock): A livestock emergency is an urgent, non-routine situation in which the organic system plan's preventive measures and veterinary biologics are proven, by laboratory analysis or visual inspection, to be inadequate to prevent life-threatening illness or to alleviate pain and suffering. In such cases, a producer must administer the emergency treatment (§205.238(c)(7)). Organic certification will be retained, provided that such treatments are allowed under § 205.603 and the organic system plan is changed to prevent a similar livestock emergency in individual animals or the whole herd/flock in future years as required under §205.238(a)

Add this to § 205.238 (b)
[assumes adoption of changes in NOP proposed rule (83 FR 2498)]

(4) Organic livestock as provided in §205.238 (b) (1), (2), and (3) and only in the event of an emergency where management strategies have been proven insufficient to prevent or control parasites within the accepted threshold for specific parasites, age and species of the anima . These management strategies include but are not limited to, grazing systems and living conditions that prevent infestation and reinfestation forage height diversity use of allowed nonsynthetic botanicals, biologics and minerals to maintain parasite levels below treatment thresholds, and could include monitoring and documentation of parasites through use of methods such as fecal monitoring and FAMACHA.

Motion by: Harriet Behar
Seconded by: Jesse Buie
Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Ashley Swaffar, Subcommittee Chair, to transmit to NOSB February 20-, 2018

Commented [PD-A10]: This should mimic exactly the term as it appears in the regulations This may be more cohesive (and require less cross-referencing) if included in regulatory text Consider including in regulatory text rather than in definitions

Commented [PD-A11]: This is not the term that is being defined

Commented [PD-A12]: Best practices for regulatory writing is to not include any requirements within the definition of a term Requirements should appear in outside of the definition (i e , 205 238 or 205 603)

The last two sentences should be removed (they impose requirements) and instead proposed as requirements in 238 below

Commented [PD-A13]: General comment: New requirements here are not obvious when compared to existing regulations, except perhaps the monitoring and documentation that is mentioned (but this is also not included as a requirement)

Commented [PD-A14]: Required at 238(b) and 238(c)(2), 238(c)(4), and 603(a)(17)

Commented [PD-A15]: Required at 238(a)(3)

Commented [PD-A16]: What does this mean? The height of forage or the diversity of pasture species, or both? Forage height diversity does not seem to stand on its own

Commented [PD-A17]: Required at 238(a)(2) and 238(a)(6)

Commented [PD-A18]: Write out in entirety (vs acronym) Reference to a method rather than a description of the actual method is problematic for rule writing as it requires the reader to reference an outside source

Is this method for goats and sheep only? Are there any methods besides fecal monitoring that could be recommended for cattle?

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal
Glycolic Acid
February 20, 2018

Summary of Petition:

The NOSB received a petition to add glycolic acid for use as a component of pre- and post-milking teat dips to control mastitis at §205.603(a) Synthetic substances allowed for use in organic livestock production as disinfectants, sanitizer and medical treatment as applicable).

Summary of Review:

Commented [PD-A1]: You may want to mention the TR if this content is pulled from the TR. People will need to know to look in the TR for the references cited

Specific Uses of the Substance:

Glycolic acid has been shown to be an effective post-milking teat disinfectant for dairy cows (Godden et al., 2016). Specifically, its petitioned use is as a component in a post-milking teat dip to aid in the prevention of bovine mastitis. Teat dips may contain emollients, excipients and other allowed disinfectants. Because glycolic acid conditions the skin by exfoliating cracked skin layers, it removes potential hiding places for mastitis causing bacteria, e.g. ~~*Staphylococcus*~~*Staphylococcus aureus*.

In addition to its uses in skin care, glycolic acid is used in a broad range of applications. For example glycolic acid is used as a descaler for cutting through hard water salts, as a cleaning agent, as a liquid sour in laundry systems, as a copper and aluminum cleaner including boilers and heat exchangers, and as a dairy and CIP cleaner to dissolve casein as well as hard water deposits.

Commented [AM-A2]: Sour?

Glycolic acid is certified by the National Sanitation Foundation (NSF) for use in cleaning potable water wells. It is used widely to rehabilitate the flow efficiency of water wells by enabling water-soluble compounds (chelates) to be easily rinsed away with low corrosion to metal parts. Glycolic acid removes hard water scale (calcium, magnesium, manganese salts), various iron deposits and polysaccharide deposits. Glycolic acid biodegrades rapidly. It is a liquid with low toxicity, low odor, is non-flammable and has negligible fumes.

Approved Legal Uses of the Substance:

The first product containing glycolic acid as an active ingredient was registered by the U.S. Environmental Protection Agency (EPA) in 2001 as a disinfecting cleaner and a disinfectant/sanitizer for non-food contacting, hard non-porous surfaces in residential and public access premises. Since then, additional products have been registered with the EPA. There are no tolerances, exemptions from tolerances, or tolerance petitions for this antimicrobial pesticide. Glycolic acid is approved by FDA as an indirect food additive for use in food packaging adhesives (21 CFR ~~§~~175.105).

Glycolic acid is considered by the FDA to be a human cosmetic that is safe for use by consumers if the concentration is 10 percent or less, the pH is 3.5 or greater and the formulation protects the skin from increased sun sensitivity or the package directions instruct the consumer to use daily protection from the sun (FDA, 2015). Teat dips and udder washes classified as drugs, may currently be marketed without a New Animal Drug Application (NADA) approval. However, the FDA has developed non-binding guidelines for teat antiseptic product development. The guidelines were assembled to inform the drug industry of the types of data that will demonstrate that a teat antiseptic product: 1) is safe for the cow, 2) is effective and 3) fulfills human food safety, manufacturing and environmental requirements. Products to be marketed must be manufactured according the Current Good Manufacturing Practice

(cGMP) regulations (21 CFR Part 211) for pharmaceutical dosage forms under the approved NADA process (FDA, 2016).

The USDA does not regulate glycolic acid for application as a teat dip. However, the USDA regularly reports survey results for the dairy industry including statistics of use and recommendations for pre and post milking teat dips (USDA, 2016).

Action of the Substance:

Glycolic acid is mildly bactericidal. However, its effect on the hyperkeratinization of skin is significant. Hyperkeratinization is a primary event in many skin disorders. It is caused by dying and dead adherent skin cells trapped near a hair follicle in the layers of tightly bound living cells called corneocytes. Normally, the dead cells are sloughed off by the follicles in a process called desquamation, but in the case of hyperkeratinization the dead cells are stuck beneath the tightly bound corneocytes. Dry skin, in wintertime is particularly vulnerable to reduced desquamation and hyperkeratinization. Glycolic acid has a therapeutic effect on hyperkeratinization, and the cohesiveness of corneocytes (Scott and Ruey, 1984). One theory for the mechanism of action of glycolic acid is that it reduces the calcium ion concentration in the epidermis and removes calcium ions from the cell adhesions by chelation. The cell adhesions are thereby disrupted, resulting in desquamation (Wand, 1999).

Glycolic acid reduces cohesiveness in the lower, newly forming layers of corneocytes potentially by inhibition of an enzyme. Glycolic acid does not cause disaggregation of corneocytes of the mature upper layer corneocytes, which would result in damage to the skin. Loosening the corneocytes in the lower layers improves desquamation. Glycolic acid promotes a thinner lower corneocyte layer, which not only improves the skin surface smoothness because the dead cells can migrate to the follicles, but also to improves the flexibility of the lower corneocyte layers (aka corneum stratum). A thin stratum corneum bends more readily without cracking or fissuring than a thick stratum corneum. Glycolic acid improves desquamation even if the skin is dry (Scott and Ruey, 1984). Bacteria take advantage of hyperkeratinization by entering the skin through cracks and fissures and colonizing the dead cells. The action of routine glycolic acid use is to remove both entry and colonization sites for colonizing bacteria that may lead to mastitis.

Manufacture:

Glycolic acid is a widely used industrial chemical with a large synthetic production footprint. It has commonly been produced by the Dupont process (hydratative carbonylation) from formaldehyde, carbon monoxide and water and in the presence of the catalyst sulfuric acid. The reaction is carried out at high pressure (300-700 bar) and temperature (200-250^{o}C).

$$HCHO + CO + H_2O \xrightarrow{\text{catalyst}} HOCH_2COOH$$

Catalysts such as hydrogen fluoride, hydrogen fluoride/boron trifluoride and strongly acidic (perfluorinated) ion exchangers were subsequently introduced in the Chevron and Mitsubishi processes that are effective at low CO pressure (100 bar). Exxon developed another catalytic method to obtain 70% glycolic acid at 150^{o}C on a strongly acidic ion exchanger made from perfluorosulfonic acid resin (Weisserme and Arpe, 2003).

Formaldehyde is a naturally occurring substance. It is the smallest aldehyde. Formaldehyde is produced industrially by the catalytic oxidation of methanol. The most common catalysts are silver metal or a mixture of metal oxides. In the commonly used Formox process, methanol and oxygen react at ca. 250–400°C in presence of iron oxide in combination with molybdenum and/or vanadium to produce formaldehyde according to the chemical equation:

$$2\ CH_3OH + O_2 \xrightarrow{\text{catalyst}} 2\ CH_2O + 2\ H_2O$$

A silver-based catalytic process operates at a higher temperature, about 650 °C. Two chemical reactions on it simultaneously produce formaldehyde: that shown above and the dehydrogenation reaction:

$$CH_3OH \xrightarrow{\text{catalyst}} CH_2O + H_2$$

In principle, formaldehyde could be generated by oxidation of methane, but this route is not industrially viable because the methanol is more easily oxidized than methane (Reuss et al., 2000).

Category 1: Classification

1. Substance is for: X____ **Livestock**

2. For HANDLING and LIVESTOCK use:
   a. Is the substance _____ **Agricultural** or ____X___ **Non-Agricultural?**

   b. If the substance is **Non-agricultural**, is the substance _____ **Non-synthetic** or __X__ **Synthetic?**

All glycolic acid commercially available today is made by one of three processes:

a) High temperature/High pressure continuous flow route practiced by The Chemours Company (formerly DuPont). This is the dominant form of glycolic acid production globally. Formaldehyde and carbon monoxide are the raw materials.
b) Neutralization and reacidification of monochloroacetic acid (MCA). This is small, batch conversions of MCA to glycolic acid with chlorinated organic and salt impurities. MCA is made from chlorine gas and acetic acid. Sodium hydroxide neutralizes the MCA and HCl reacidifies the product to glycolic acid.
c) Enzymatic conversion of glycolonitrile to glycolic acid. Glycolonitrile is made from hydrogen cyanide and formaldehyde and has a similar impurity profile as the high temperature and pressure route of manufacture.

All of these processes would be considered synthetic routes of manufacture. No “natural” source of glycolic acid is viable.

3. For **LIVESTOCK**:

   This product would be listed at §205.6035 Livestock Production-Synthetic. Glycolic Acid is a synthetic substance in that it is manufactured using a chemical process.

Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

Over the counter non-wipe post--milking dairy teat dips containing three percent glycolic acid (e.g. Ocean Blue Barrier®) are also likely to contain 5% glycerol, 5% sorbitol, xanthan gum, povidone k30, c9-11 Pareth-8, FD&C Blue No. 1, sodium hydroxide, water and sodium C14-16 olefin sulfonate. Package instructions do not suggest the use of one post-milking teat dip with another. The glycolic acid used for this formulation may be technical grade. Glycerin, an emollient, does not enhance the absorption of glycolic acid into the skin (Andersen, 1998). Sodium hydroxide is added to raise the pH of the teat dip. Low pH is a potential source of skin irritation when using glycolic acid to treat skin (FDA, 2015). Other ingredients used in teat dips include additional emollients, surfactants, colorants and plasticizers that permit adherence and identification of treated skin. Although there is general acceptance for the use of post milking teat dips, no advantage has been described for the use of multiple teat dip products in the same application (The National Mastitis Council, 2017).

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]

In an early report, undiluted glycolic acid administered to rabbits was shown to cause acid-like burns to their skin and eyes (Carpenter and Smyth, 1946). Fifty and 70% Glycolic Acid applied to the backs of mini pigs for 15 minutes caused epidermal necrosis, inflammatory infiltrate and for 70% Glycolic Acid dermal necrosis after one day (Andersen, 1998). Reproductive, gastrointestinal, developmental and renal toxicity in rats, cats and guinea pigs have also been demonstrated with oral administration of high doses (70-100%) of glycolic acid (NIOSH, 2017). Glycolic acid is known to cause enhanced sensitivity to UV light. Short-term application of 10% glycolic acid sensitizes the skin to UV light. However, this photosensitivity is reversed within a week of terminating treatments (Kaidbey et al., 2003). Glycolic acid is an important metabolite of ethylene glycol. Increased glycolic acid in the blood correlates directly with acute ethylene glycol toxicity and renal failure (Hewlett et al., 1986). Glycolic acid has been widely studied because it is used in health products and cosmetics. However, many of the conclusions of these studies have been equivocal or even contradictory. Varying or unreported conditions, parameters and criteria such as the concentration and grade of glycolic acid used and duration of exposure have made it difficult to assess and compare them. The primary areas of concern for glycolic acid however, are its dermal irritation potential and its potential to increase sensitivity to sunlight. Both of these factors result from glycolic acid's ability to partially remove the stratum corneum layer of skin. Generally, for leave on products, glycolic acid concentrations not greater than 10% at pH no less than 3.0 will not produce unacceptable irritation. Glycolic acid does increase sensitivity to sunlight which should be considered in treatment (Andersen, 1998).

In six studies presented by the US Environmental Protection Agency, glycolic acid was noted to be slightly toxic to bluegill sunfish (Effective Concentration $(EC)_{50}$=93 ppm), and practically non-toxic to bobwhite quail (Lethal Concentration $(LC)_{50}$=>5000 ppm), Mallard duck (LC_{50}=>5000 ppm), fathead minnow (LC_{50}=164 ppm) and daphnia (EC_{50}=141 ppm). In this same review, glycolic acid was noted to be only slightly toxic to mammals with an LC 50 of 1938 ppm (EPA, 2011).

Glycolic acid as glycolate is an important intermediary molecule in plant photorespiration, but in excess it is toxic and can inhibit photosynthesis (Ogren, 2003; Dellero et al., 2016).The degree of inhibition and toxicity both depend on the particular species and variety of affected plant. In maize, for example, the accumulation of glycolate provokes the inhibition of ribulose bisphosphate carboxylase (RUBISCO) and

the subsequent decrease in CO_2 assimilation (Gonzalez-Moro et al., 1997). Because it can inhibit photorespiration glycolic acid may be algistatic for some algal species , e.g. *Selenastrum capricornutum*, but since CO_2 absorption pathways may vary between algal species, e.g. *Chlorella* spp., the appearance of toxicity is likely to be dependent upon glycolic acid concentration (EPA, 2011; Fogg and Nalewajko, 1963; Raven et al., 2012).

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

Most of the glycolic acid is manufactured at a chemical production plant in Belle, West Virginia. This chemical plant is located in the Kanawha Valley which is known for its many chemical manufacturing facilities. There have not been any major spills or accidents at this plant since 2010, when the release of phosgene gas into the atmosphere caused the death of an employee. The State of West Virginia provided the plant operator with a permit to operate and produce glycolic acid in 2015 (West Virginia Department of Environmental Protection, 2015). The permit expires in 2020 and permits respectively maxima of 1.9, 15.5, 15.2 8.14 and 5.85 tons/year of formaldehyde, methanol, formic acid, carbon monoxide and NOx to be released to the atmosphere from the plant's thermal oxidizer.

The US EPA has not received any guideline environmental fate studies on glycolic acid, and has not required studies to be done. Since a toxicological concern has not been identified, the US EPA believes that, based on the currently registered use pattern of glycolic acid for household use as a disinfectant/sanitizer for hard non-porous surfaces in homes, guideline environmental fate or ecological effects studies are not necessary (EPA, 2011).

Various synthetic processes are available for preparing glycolic acid. Contaminants potentially found in downstream products are formaldehyde and monochloroacetic acid which are the starting materials. Residual reagents include sodium chloride, formic acid, methoxyacetic acid which are byproducts from the synthesis process. These impurities must be controlled for safety and the physical and chemical characteristics of the product (Liedtka, 2016). Glycolic Acid is available as a technical grade 70% solution and as higher purity grade solutions of 70% (Glypure 70) and 99% (Glypure 99) (Chemours, 2015). Because of the amount of impurities, technical-grade Glycolic Acid is not used in personal care applications (Andersen, 1998, Table 2). The US FDA found no concerns about the physical and chemical characterization when potential impurities, such as formaldehyde are controlled at acceptable levels. Glycolic acid is a well-characterized small molecule that is likely to be stable under ordinary storage conditions (Liedtka, 2016).

4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].

Labels for products containing 3% glycolic acid for use as a pre- and post--milking teat dip indicate only that the substance can cause eye irritation (MSDS, OceanBlu Barrier, deLaval). Glycolic acid at different concentrations is used for a number of human medical procedures as a keratolytic agent. Glycolic acid at 57-70% is corrosive to the skin and eyes. Ingestion of substantial amounts at this concentration may result in kidney failure (~~Pubchem~~PubChem 2017). Glycolic acid in cosmetic products used by the general public may cause skin and eye irritation when present at high concentrations and low pH values. In addition, manufacturers, importers and suppliers of consumer products should inform consumers that the use of skin exfoliant cosmetic products may result in an enhanced sensitivity to sunburn, and that use of sunscreen protection is advised (NICNAS, 2000).

Occupational exposure to glycolic acid may occur through inhalation and dermal contact with this compound at workplaces where glycolic acid is produced or used. Monitoring and use data indicate that the general population may be exposed to glycolic acid via inhalation of ambient air, ingestion of food and dermal contact with consumer products containing glycolic acid (NCBI, 2017).

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

Commented [AM-A3]: The info here and in #6 seems dense. Is this relevant for livestock and agrosystems or to humans?

The chemomechanic action of alphahydroxy acids (AHAs) in exfoliation is to reduce calcium ion concentration in the epidermis and remove calcium ions from the cell adhesions by chelation causing disruption in cell adhesions and desquamation. Glycolic acid can also suppress melanin formation by inhibition of tyrosinase activity. Intraperitoneal administration of 1000 mg/kg glycolic acid inhibits oxygen consumption and glucose metabolism in rat liver and myocardium *in vivo*, but does not affect brain oxygen consumption. Glycolic acid in high concentrations (70% solution and pure) causes local effects typical of a strong acid, such as dermal and eye irritation. In a 3-week dermal toxicity study in hairless guinea pigs, erythema and/or flaking of the skin were noted at 5% and 10% concentrations of glycolic acid. Glycolic acid induced calculi formation in rats in a 4- to 12-week repeat dose oral toxicity which also disclosed increased renal oxalate and nephrotoxic effects have been observed. In a 2 week study in rats, respiratory tract irritation, hepatocellular degeneration and thymus atrophy were observed. Glycolic acid was negative for mutagenicity in the Ames test and the mouse lymphoma assay and not considered genotoxic. Glycolic acid was negative for clastogenicity in an *in vitro* chromosome aberration assay and an *in vivo* micronucleus assay in mice.

Carcinogenicity from glycolic acid exposure has not been demonstrated. Oral (gavage) doses of glycolic acid up to 600 mg/kg/day were administered to female rats during gestation days 7-21 – Maternal toxicity was seen at doses ≥ 300 mg/kg/day – Developmental toxicity was also noted at doses ≥ 300 mg/kg/day, including fetal weight reduction and increases in skeletal malformation (FDA, 2005). Glycolic acid post milking treatment can affect keratin dynamics (The National Mastitis Council, 2017). Glycolic acid is non-toxic in dogs up to 100 milligrams/kilogram, but nephrotoxic effects result from doses of 250 mg/kg, and fatality occurs if greater than 500 mg/kg is ingested. Glycolic acid is also nephrotoxic to cats (Krop and Gold, 1944).

Glycolic acid is found in the fruit, leaf, stem and root portions of all plants. Glycolic acid is found naturally in extractable amounts in sugar cane and sugar beets (Thangaevelu, 2010; Stark et al., 1950). It is also excreted naturally by several algal species (Tolbert and Zill, 1956). Commonly consumed fruits and vegetables are reported to contain from 0.45-7.4 milligrams glycolic acid per 100 grams fresh wet weight. Tea, coffee, fruit juice and other beverages derived from plant sources may contain 5-7 mg glycolic acid per 100 mL. Foods of animal origin are generally low in glycolic acid, with milk and beef reported to contain 0.06-0.12 mg per 100 g (NICNAS, 2000). It is readily biodegradable in soil and water.

6. Are there any adverse impacts on biodiversity? (§205.200)

Glycolic acid is found in ruminant blood. Studies have shown that it is incorporated into casein, fat and lactose of milk (Peters et al., 1971).

There have not been any reports of adverse environmental events related to glycolic acid release. Approximately 0.15 ml of glycolic acid (3%) is used per udder quarter in a post milking test dip (Matti and Tinnis, 2015). Glycolic acid at a concentration of 70% is approved for use as an acid non-food cleaning agent for removal of rust, corrosion, scale or other deposits that are not readily removed by alkaline cleaners in dairies.

Glycolic acid is a significant industrial chemical (EPA, 2011). If released to air at an extrapolated vapor pressure of 0.02 mm Hg at 25 ^{o}C, glycolic acid will exist solely as a vapor. Vapor-phase glycolic acid will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 3.4 days. Glycolic acid does not contain chromophores that absorb at wavelengths >290 nm and, therefore, is not expected to be susceptible to direct photolysis by sunlight. If released into soil, glycolic acid is expected to have very high mobility based upon an estimated Koc of 0.14. Koc is a measure of the tendency of a chemical to bind to soils, corrected for soil organic carbon content. The pKa of glycolic acid is 3.6, indicating that this compound will exist almost entirely in anion form in the environment and anions generally do not adsorb more strongly to soils containing organic carbon and clay than their neutral counterparts. Volatilization of glycolic acid from moist soil surfaces is not expected to be an important fate process because the compound exists as an anion and ions do not volatilize. Glycolic acid is not expected to volatilize from dry soil surfaces based upon its vapor pressure. Tests for inherent biodegradability showed 86% of the theoretical BOD was reached in 2 weeks. This indicates that biodegradation is an important environmental fate process in soil and water. If released into water, glycolic acid is not expected to adsorb to suspended solids and sediment based upon the estimated low Koc. A pKa of 3.6 indicates glycolic acid will exist almost entirely in the anion form at pH values of 5 to 9 and, therefore, volatilization from water surfaces is not expected to be an important fate process. An estimated BCF of 3 suggests the potential for bioconcentration in aquatic organisms is low. Hydrolysis is not expected to be an important environmental fate process since this compound lacks functional groups that hydrolyze under environmental conditions.

Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

The pathogens that cause mastitis inhabit many locations throughout the dairy cow environment and infect multiple tissues in the udder. As a result, effective prevention and treatments for mastitis in the organic dairy a can range from surface sanitation to parenteral administration of homeopathic medicines, but each alone may not be 100% effective. Thus, there are many possible substances that may serve in place of glycolic acid. Glycolic acid represents a unique approach to bovine teat health, inasmuch as the net effect is to prevent hyperkeratosis, although there is additionally some microbiocidal activity associated with its application.

Vitamin A is similar to glycolic acid in its action, however; the subset of skin cells that are affected are not the same (Scott and Ruey, 1984). Thus, vitamins and minerals to supplement nutrition such as vitamin, selenium, copper, zinc, vitamin A and β-carotene are important to both bolster both cellular and humoral immune response and to maintain skin and udder health (Heinrichs et al., 2009). Low blood plasma concentrations of vitamin A and β-carotene are directly associated with the severity of mastitis in cows (Chew et al., 1982).

Homeopathic pharmacies can provide pre-prepared remedies for mastitis in dairy cows. Udder liniments, containing mint or anti-inflammatory agents are often used as support therapy with

homeopathy (Hovi and Roderick, 1998). More examples include Belladonna for acute postpartum mastitis; Aconitum for routine treatment for all acute cases, particularly those that develop rapidly after exposure to cold dry wind; Apis Mellifica is indicated for first calving, heifers with edema of and around the udder; Bryonia Alba is indicated for swollen and very hard udders; Arnica Montana for mastitis resulting from udder injuries; Belia Perennis for deeper injuries (e.g., neglected milkers); Phytolacca for clinical and chronic cases with sour, coagulated milk, small clots at mid-lactation; Urtica Ulens for clinical cases where edema forms plaques sometimes up to perineum; mixtures of Sulphur, Silica and Carbo Vegetabilis for clinical and subclinical cases; Hepar Sulphuris to aid suppuration and cleaning of udder in summer mastitis cases; Silicea for summer mastitis cases with purulent abscess and Ipeca for treating internal bleeding that produces pink or bloody milk (MacLeod, 1981). Homeopathic remedies used to treat mastitis also include: Belladonna, Lachesis, Vipera Reddi, Conium maculatum + Plumbum iodanum, Phytolacca, Bryon and Silicea (Quiquandon, 1982). Homeopathic remedies are not regulated for efficacy and quality as are veterinary drugs, therapies and medications. Furthermore, some research indicates that homeopathic approaches are not effective therapies for bovine mastitis (Ebert et al., 2017).

Currently only iodine (§205.603(a)(13) and §205.603(b)(3)), chlorhexidine §205.603(a)(6), glycerin §205.603(a)(11), and hydrogen peroxide §205.603(a)(12), are allowed to be used in organic dairy production for mastitis prevention and therapy. Teat dips containing the disinfectants iodine and chlorhexidine are effective in reducing intra-mammary infections (Enger et al., 2016). Iodine is effective as a pre- and post-milking teat dip or spray, however, small increases in milk iodide concentration can be expected with its use. Where sprays usually produce a larger increase than dip cup preparations (French et al., 2016). Chlorine materials (§205.603(a)(7)) and phosphoric acid (§205.603(a)(19)) are allowed for sanitizing equipment and facilities. Vaccines, anti-inflammatory drugs (e.g., aspirin and flunixin), electrolytes, and furosemide (with double the milk withholding period) can also be used for the treatment of clinical mastitis (Ruegg, 2014).

Post-milking teat disinfectants need to be persistent and effective in killing bacteria. They must also leave teats in good condition. Preservation of healthy teat skin is essential for maintaining its natural defense against infection because sore, dry, cracked teats may harbor mastitis-causing pathogens (Hogan et al., 1990; National Mastitis Council, 2017). Barrier type teat disinfectants have been developed to extend the germicidal properties of the disinfectant after the cow leaves the milking parlor. These products contain components that can provide a protective film and seal the teat from mastitis-causing bacteria (Lago et al., 2016). Glycerin is a humectant that is allowed for use as a skin conditioner in teat dips. Aloe is a naturally derived products with skin healing properties that may also be included in teat dips (Fox et al., 2006).

Teat irritation can be caused by interaction between teat dip and management or environmental factors in a herd. Teat dips may promote chapping during extremely cold weather especially with windy conditions. Emollients are incorporated such as glycerin or lanolin to minimize irritation and condition skin, however, the germicidal effectiveness of the teat dip may be diminished with too much emollient (Pankey, 1984). Emollients and humectants do not affect bacterial colonization of the skin (Rasmussen and Larsen, 1998).

2. **For Livestock substances, and Nonsynthetic substances used in Handling**: In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

Yes, - but it is unclear if this substance is needed in organic agriculture as alternatives exist. Therefore, t~~T~~he S~~s~~ubcommittee would like to pose the following questions:

1. Are there alternatives available for pre- and post-milking teat dips?
2. Is this product used in rotation with currently allowed pre- and post-milking teat dips?
3. Do alternatives work ~~in the area of~~ to control~~ling~~ mastitis?

Classification Motion:

Motion to classify glycolic acid as synthetic
Motion by: Ashley Swaffar
Seconded by: Harriet Behar
Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

National List Motion:

Motion to add glycolic acid as petitioned at 205.601
Motion by: Ashley Swaffar
Seconded by: Jesse Buie
Yes: 3 No: 2 Abstain: 0 Absent: 1 Recuse: 0

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Note: Subcommittee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

National Organic Standards Board (NOSB)
Livestock/Aquaculture Subcommittee (LS) Meeting Notes draft
Tuesday, February 20, 2018 3:00 pm ET

Attending: Ashley Swaffar, (AS), Chair; Sue Baird (SB), Vice Chair; Harriet Behar (HB); Jesse Buie (JB); A-dae Romero-Briones (ARB); Tom Chapman (TC) - observer
Absent: Dan Seitz (DS)
Staff: Michelle Arsenault (MA); Devon Pattillo (DM)

Work Agenda

Petitioned Materials						
Substance	**Nat'l List §**	**Contact**	**TR requested**	**Notes**	**Scheduled, Discussed, Voted**	**Meeting**
Glycolic Acid, 2016	205.603	AS	Y	Petition sent to LS 06 06 15. Response/request for TR due 08 08 16. TR requested 07 19 16. TR sent to LS 11 07 17. Response/request for TR due 01 08 18. TR found sufficient 12 19 17.	Jul 19, 2016, Dec 19, Feb 20	Spr 2018
Oxalic Acid	205.603	HB	Y	Petition sent to LS 10 27 17. Response/request for TR due 12 26 17. Petition found suff 12 5 17. TR Requested 12 5 17	Dec 5	TBD
Aquaculture Substances (See table below)				On hold until aquaculture rule is published.	TBD	TBD

2020 Sunsets TR Requests: July 2017, Summary: Spr 2018, Review: Fall 2018						
Name	**National List §**	**Contact**	**TAP/TR**	**Notes**	**Scheduled, Discussed**	**Review Meeting**
Alcohols: Ethanol, Isopropanol	205.603	JB	N	1995 TAP; 2014 TR Ethanol; 2014 TR Isopropanol	Dec 5	Summary: Spr 2018 Review: Fall 2018
Aspirin	205.603	AS	Y	1995 TAP. TR requested 07 28 17. TR in contracting. TR sent to LS 12 20 17. Response due 02 19 18. TR found sufficient 02 20 18	Dec 19, Feb 20	"
Biologics, Vaccines	205.603	HB	N	2011 TR (Vaccines from Excluded Methods); 2014 TR (Aquaculture)	Dec 19	"
Electrolytes	205.603	HB	N	1995 TAP; 2015 TR	Dec 19	"

Glycerine	205.603	SB	N	2010 TAP (Livestock)	Feb 6	"
Phosphoric acid	205.603	DS	N	2003 TAP (Handling). Low priority	Jan 16	"
Lime, hydrated	205.603	ARB	N	1995 TAP; 2015 TR	Feb 6	"
Mineral oil	205.603	ARB	N	2002 TAP; 2015 TR	Feb 6	"
Sucrose octanoate esters	205.603	SB	N	2005 TR	Feb 6	"

Other projects					
Project	**Contact**	**TR Reqst ?**	**Notes**	**Discussed, Voted**	**Meeting**
Clarifying emergency treatment for parasiticides	HB	N	Approved for addition to work agenda 07 15 16. Discussion doc. Postponed until Fall 2017	Dec 5, Dec 19, Jan 16, Feb 20	Spr 2018
Research Priorities (RP)	HB/AS/SB	NA	RPs due to MS Aug 2017	NA	Fall 2018
Organic poultry task force	ARB/AS/HB		Discuss formation of Task Force - on hold pending resolution of OLPP final rule.	NA	NA

* Yellow highlight indicates committee action needed *Highlight indicates review completion/vote taken

Agenda

- Approve notes from February 6, 2018
- Glycolic Acid (AS) - Discuss draft proposal
- Defining emergency treatment for parasiticides (HB) - Discuss next steps
- Aspirin (AS) - TR sufficiency (due Feb 19)
- Other items
- Adjourn

Discussion

- **Notes from the** February 6, 2018 were approved with the removal of thymol, which was a petition that was rejected by the LS.
- **Work agenda.** The NOSB Chair relayed updates from the NOP regarding the NOSB work agenda. For now, work agenda items will remain. The leads will continue work on the proposal on "emergency use of parasiticides" for the spring NOSB meeting. IF it is not ready for spring, it will be brought forth this fall.
- **Defining emergency treatment for parasiticides (HB).** The LS discussed the current iteration of the draft proposal, and voted to bring it to the spring 2017 NOSB meeting for consideration by

the full board.

Motion to accept defining emergency treatment for parasiticides as amended on the call
Motion by: HB
Seconded by: JB
Additional discussion: none
Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

- **Glycolic Acid (AS).** The lead summarized the petitioned uses of glycolic acid. Members discussed efficacy, need, and alternatives. The LS is seeking public comment.

  Motion to classify glycolic acid as synthetic
  Motion by: AS
  Seconded by: HB
  Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

  Motion to add glycolic acid as petitioned at 205.601
  Motion by: AS
  Seconded by: JB
  Additional discussion: none
  Yes: 3 No: 2 Abstain: 0 Absent: 1 Recuse: 0

- **Aspirin (AS).** The lead found the TR sufficient, and will revise the sunset review accordingly before submitting it to the NOP for posting.
- **Other items.** LS cancelled March 6 call.
- **The meeting was adjourned.**

Previous LS Notes

Future Call Schedule (1st and 3rd Tuesdays 3:00 ET)

February 6, 2018
- 2020 sunset: Glycerine (SB). Deferred to next call.
- 2020 sunset: Sucrose octanoate esters (SB). Deferred to next call.
- 2020 sunset: Lime, hydrated (ARB). Deferred to next call.
- 2020 sunset: Mineral oil (ARB). Deferred to next call.
- 2020 sunset: Biologics, vaccines (HB)
- Defining emergency treatment for parasiticides (HB)

February 20, 2018
- Glycolic Acid (AS) - Discuss draft proposal
- Defining emergency treatment for parasiticides (HB) - Discuss next steps
- Aspirin (AS) - TR sufficiency (due Feb 19)

March 6, 2018 - cancelled
March 20, 2018
April 3, 2018

April 17, 2018
May 1, 2018
May 15, 2018
June 5, 2018
June 19, 2018
July 3, 2018
July 17, 2018
August 7, 2018
August 21, 2018
September 4, 2018
September 18, 2018
October 2, 2018
October 16, 2018
November 6, 2018
November 20, 2018
December 4, 2018
December 18, 2018

Spring 2018 Milestones	Target dates (tentative)
New NOSB member orientation	TBD
NOSB - Spring 2018 proposals due to NOP	Feb 21, 2018
NOP - Complete Spring 2018 NOSB meeting tentative agenda	Mar 6, 2018
NOP - Post proposals, Open public comment	Mar 6, 2018
Discuss work agendas on ES call	Mar 9, 2018
Public comment closes	Apr 4, 2018
NOP - Send compiled public comments to NOSB	Apr 9, 2018
Work agendas finalized on ES call (last call before fall meeting)	Apr 13, 2018
Public comment webinar(s)	Apr 17 & 19, 2018
Spring 2018 NOSB meeting – Tucson, AZ	Apr 25-27, 2018

2021 Sunsets TR Requests: July 2018, Summary: Spr 2019, Review: Fall 2019						
Substance	**National List §**	**Con-tact**	**TR re-quest ?**	**Notes**	**Scheduled, Discussed**	**Meeting**
Atropine	205.603(a)			2002 TAP 2017 NOSB Recommendation		Summary: Spr 2019 Review: Fall 2019
(Parasiticide) Fenbendazole	205.603(a)			2015 TR 2017 NOSB Recommendation		"
Hydrogen peroxide	205.603(a)			None. 2015 Crops TR 2017 NOSB Recommendation		"
Iodine	205.603(a)14, and 205.603(b)2			2015 TR 2017 NOSB Recommendation		"
~~Ivermectin~~	~~205.603(a)~~			Nov 2016 NOSB Rec – Removal Included in proposed rule NOP 14-05 (83 FR 2498). 2015 TR		"
Magnesium sulfate	205.603(a)			2011 TR 2017 NOSB Recommendation		"
(Parasiticide) Moxidectin	205.603(a)			2015 TR 2017 NOSB Recommendation		"
Peracetic acid	205.603(a)			2016 TR 2017 NOSB Recommendation		"
Xylazine	205.603(a)			2002 TR Xylazine/Tolazoline 2017 NOSB Recommendation Xylazine/Tolazoline 2019 NOSB Recommendation - Tolazoline		"
Methionine	205.603(d)			2011 TR 2015 NOSB Recommendation		"
Trace minerals	205.603(d)			None 2017 NOSB Recommendation		"
Vitamins	205.603(d)			2015 TR 2017 NOSB Recommendation		"

Aquaculture petitions						
Substance	**Nat'l List §**	**Contact**	**TR requested**	**Notes**	**Scheduled, Discussed, Voted**	**Meeting**
Aquaculture-CO_2, (for aquatic plants)	205.609	TF/CBo	N	Petition sent to CS 5 30 12. Will rqst modification from petitioner (for use pattern). Updated petition was deemed sufficient. TR deemed unnecessary.	NA	Proposal TBD
Aquaculture-Chlorine (for aquatic plants)	205.609	FT	2011 Crops TR 2006 TR 1995 TAP	Petition sent to CS on 5 30 12. Determine petition sufficiency. CS requested clarification from petitioner 11 20 12. 2011 TR deemed suff for this review 11 20 12. Additional aquaculture TR deemed unnecessary. Sent follow up questions to petitioner. Response deemed sufficient.	NA	Proposal TBD
Aquaculture-Micronutrients (for aquatic plants)	205.609	FT	2010 TR (Nickel) 6/2013 Minerals TR	Petition sent to CS on 06 08 12. Petition sufficiency response due 08 08 12? CS sent request to NL Mgr. 12 04 12 for additional info. Questions clarified by petitioner. Petition found sufficient 06 18 13 and 07 02 13. TR deemed unnecessary.	NA	Proposal TBD
Aquaculture-Lignin sulfonate (chelating agent for aquatic plants) CAS #s 9009-75-0, 8062-15-5, 8061-51-6	205.609	JR	2/2011 Crops TR 7/2013 TR Aquatic Animals TR	Petition sent to CS on 07 03 12. Petition Sufficiency Response due 09 04 12. CS sent request to NL Mgr 12 04 12 for additional info and TR. Questions clarified by petitioner. Petition found sufficient 6 18 13 and 07 02 13.	NA	Proposal TBD

Aquaculture-Vitamins (B1, B12, H) for aquatic plants	205.609	CW	4/2013 Aquatic Animals TR	Petition sent to CS 08 10 12. Petition Sufficiency response due 10 10 12. Petition found sufficient 06 18 13.	NA	Proposal TBD
Aquaculture - Biologics: Vaccines for Aquatic Animals	205.611	JR	2011 TR (Vaccines made from GMOs)	Petition sent to LS 06 14 12. Petition found sufficient and TR requested on 05 21 13. (NOP note: TR sent to LS 01 24 14. TR deemed sufficient 02 03 14	NA	Proposal TBD
Aquaculture - Chlorine (for aquatic animals)	205.611	FT	N Crops 2011 Crops 2006 Crops 1995 Livestock 2006 Handling 2006	Petition sent to LS on 05 30 12. Petition found sufficient 07 03 12. No TR requested	NA	Proposal TBD
Aquaculture – Tocopherols (for aquatic animals)	205.611	TF/CBo	2013 TR 1995 TAP rvw	Petition sent to LS on 05 30 12. Petition found sufficient 08 06 12. TR requested 08 06 12. Draft TR sent to LS on 04 16 13. TR found sufficient 06 04 13	NA	Proposal TBD
Aquaculture – Vitamins (for aquatic animals)	205.611	CW/FT	Yes 2013 TR	Petition sent to LS 05 30 12. Response due ~07 30 12. Petition found suff 08 06 12. Requested joint TR with minerals 08 06 12. TR sent to LS 04 29 13. TR found suff 06 18 13.	NA	Proposal TBD
Aquaculture - Trace Minerals (for aquatic animals)	205.611	CW/FT	2013 TR	Petition sent to LS on 06 08 12. Response due ~08 08 12. Petition found sufficient 08 06 12? Requested joint TR with Vitamins 08 06 12. TR sent to LS 06 25 13. Suff due 08 27 13. TR found sufficient 07 16 13. Fall 2013 meeting cancelled.	NA	Proposal TBD

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal:
Polyoxin D Zinc Salt

Summary of Petition:

Two petitions for polyoxin D zinc salt have been submitted to the National Organic Program. Both propose to amend 7 CFR §205.601 to add polyoxin D zinc salt as a synthetic substance allowed for use in organic crop production. The February 2, 2018 petition addendum more precisely specifies that the requested amendment is of 7 CFR §205.601(i).

First Petition (2012)
The first petition is dated March 13, 2012. The Technical Evaluation Report (TR) was dated December 23, 2012. There were three petition updates/ addendums dated (1) October 2, 2012; (2) January 18, 2013; and (3) January 23, 2013 and included Kaken's rebuttals to comments in the TR.

On January 29, 2013, the Crops Subcommittee recommended to:

- Classify polyoxin D zinc salt as a synthetic substance (unanimous); and
- Deny the petition to add Polyoxin D Zinc Salt to the National List at § 205.601 as a Synthetic Substance Allowed for Use in Organic Crop (3 supported listing; 4 opposed listing; 1 abstention).

At the April 11, 2013 public hearing, the National Organic Standards Board voted to:

- Classify polyoxin D zinc salt as a synthetic substance (unanimous); and
- Deny the petition to add Polyoxin D Zinc Salt to the National List at § 205.601 as a Synthetic Substance Allowed for Use in Organic Crop (6 supported listing; 9 opposed listing).

The stated reasons for the April 11, 2013 denial were:

- Polyoxin D zinc salt was deemed non-essential; and
- Polyoxin D zinc salt presented environmental concerns for soil bacteria and fungi health because it was a broad spectrum fungicide.

Second Petition (2016)
The second petition was submitted May 31, 2016 and included summaries of new data developed to respond to questions raised at the April 11, 2013 public hearing. Key new data were:

- A study to evaluate the effects on beneficial soil organisms;
- Studies to evaluate short-term and long-term effects on ladybird beetles; and
- Efficacy data for VEGGIETURBO 5SC Suspension Concentrate Formulation (EPA Reg. No.68173-4) (a.k.a. Oso 5%SC Fungicide, EPA Reg. No. 68173-4-70051).

A US EPA and international regulatory update was submitted October 26, 2017.

The petition addendum submitted February 2, 2018:

- Superseded the October 26, 2017 US EPA and international regulatory update;
- Included the January 3, 2018 EPA stamped accepted label; and
- Included detailed analysis of grower need, including efficacy data for the OMRI-listed alternative products.

The updated list of petitioned crop uses based upon the May 31, 2017 petition, the February 2, 2018 addendum, and the January 3, 2018 EPA stamped accepted label is as follows:

- Crop Group 1: Potatoes;
- Crop Group 4: Leafy vegetables (excluding Brassica vegetables);
- Crop Group 8: Fruiting vegetables;
- Crop Group 9: Cucurbit vegetables;
- Crop Group 11: Pome fruits;
- Crop Group 12: Stone Fruits;
- Crop Group 13-07: Berries and small fruits; and
- Crop Group 19: Herbs and Spices.

Summary of Review:

Polyoxin D zinc salt:

1. Offers product performance ***and*** safety. (Ref. 1, 2)
2. Is well supported by efficacy data, including data for treatments applied ***curatively*** (after disease is first observed). (Ref. 1, 2, 3)
3. Has comparable or superior efficacy (and in some cases, significantly superior efficacy) compared to OMRI-listed alternatives. (Ref. 1, 2, 4)
4. Fills an organic market void for treatment of cranberries for cottonball disease. No organic product is currently available. (Ref. 5)
5. Addresses grower needs submitted to IR-4 for prioritization of limited research funds.
6. Is a reduced risk product with a non-toxic mode of action. (Ref. 6)
7. Is safer for crops, workers, and/or the environment than the OMRI-listed alternative products. (Ref. 7)
8. Does not contain any heavy metal impurities at or above the level of detection. (Ref. 8)
9. Readily degrades under normal environmental conditions. (Ref. 9)
10. Is applied at low rate and much lower rates than, *e.g.*, copper and sulfur products. (Ref. 10)
11. Provides zinc at a micronutrient level that is beneficial to plants. (Ref. 11)
12. Provides a much needed new mode of action for resistance management. (Ref. 12)
13. Has low risk for the environment (soil, water, bees, ladybird beetles, birds, aquatic organisms, mammals, treated crop, non-target plants). (Ref. 13)
14. Will be an important addition to organic growers integrated pest management programs. (Ref. 14)
15. Is compatible with organic products (with the exception of *Trichoderma* spp. products) and ***improves*** the performance of some biological OMRI-listed alternative products. (Ref. 15)
16. Is ***not*** an antibiotic. (Ref. 16)
17. Gives growers needed flexibility (0-day pre-harvest interval, 4-hour worker reentry interval, minimum personal protective equipment requirement, no refrigerated storage requirements, no limits on air or soil temperature at the time of application). (Ref. 3)
18. Gives growers access to key export markets, *e.g.*, United States, Mexico, New Zealand, South Korea. (Kaken is actively working on expanding export opportunities, *e.g.*, to the European Union.) (Ref. 17)

References:

1. May 31, 2016 petition.
2. February 2, 2018 petition addendum.
3. February 2, 2018 petition addendum, Step 1, pages 110-123.
4. February 2, 2018 petition addendum, Step 2, pages 124-191.
5. February 2, 2018 petition addendum, page 144.
6. May 31, 2016 petition, pages 104, 109, 135, 157, 170, 214, 227, 254, 259, 271, 288, 302, 313, 322, 327, 367, 397, 402, 411,and 417; and February 2, 2018 petition addendum, pages 16, 19, 21, and 27.
7. February 2, 2018 petition addendum, Steps 2, 3 and 4, pages 124-220.
8. February 2, 2018 petition addendum, pages 7 and 232.
9. May 31, 2016 petition, page 36. December 12, 2107 TR, page 8, Table 3.
10. May 31, 2016 petition, pages 41-42. February 2, 2018 petition addendum, page 8.
11. May 31, 2016 petition, page 42. February 2, 2018 petition addendum, page 9.
12. May 31, 2016 petition, page 420. February 2, 2018 petition addendum, pages 227-228.
13. May 31, 2016 petition, pages 37-49. February 2, 2018 petition addendum, pages 8-9 and 234. December 12, 2107 TR, page 8, Table 3 and lines 264-267.
14. May 31, 2016 petition, page 9. February 2, 2018 petition addendum, page 30.
15. February 2, 2018 petition addendum, pages 221-226.
16. May 31, 2016 petition, page 32-34. February 2, 2018 petition addendum, pages 7 and 229.
17. February 2, 2018 petition addendum, page 12.

Category 1: Classification

1. The substance is **SYNTHETIC**. Please note the unanimous classification as synthetic during the April 2013 public hearing. No new information has been submitted to suggest changing this classification.

   The February 2, 2018 petition addendum states:

   > **"Polyoxin D is highly water soluble. To reduce its water solubility and thereby increase resident time on plant surfaces, polyoxin D is converted to polyoxin D zinc salt via a simple chemical reaction. This simple chemical reaction is the rationale for the National Organic Standards Board's April 2013 recommended classification of polyoxin D zinc salt as a synthetic substance. Kaken purchases the starting material containing zinc and does *not* control the origin of the zinc (mined vs recycled)."**
   >
   > **"Based upon detailed chemical analyses submitted to and reviewed and accepted by the US EPA, Polyoxin D Zinc Salt Technical (EPA Reg. No. 68173-1) does *not* contain any toxicologically significant heavy metal impurities at or above the level of detection."**

2. Reference to appropriate OFPA category:
   Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(I)]; copper and sulfur compounds; **toxins derived from bacteria**; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

   Polyoxin D zinc salt is a "**toxin derived from a naturally bacteria**." Polyoxin D is produced via fermentation of a naturally occurring (non-GMO) bacteria, *Streptomyces cacaoi* var. aroensis, isolated from a soil sample collected in Japan. (December 12, 2017 TR, lines 179 and 187-188.)

Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

As noted in the February 2, 2018 petition addendum (page 226):

> **"Kaken does *not* recommend the use of polyoxin D zinc salt as a tank-mix partner or as part of a treatment program with products containing *Trichoderma* fungi (Bio-Tam and RootShield)."**

Please note:

- *Trichoderma* is a fungal active ingredient that requires reproduction in the environment to increase its population to achieve desired efficacy.
- Polyoxin D zinc salt stops the growth of fungi and is therefore anticipated to interfere with the efficacy of Bio-Tam and RootShield.
- Based upon product labels, Bio-Tam and RootShield are used primarily for soil-borne diseases, whereas polyoxin D zinc salt is used to control foliar disease of crops. Therefore, it is *unlikely* that an organic grower would have a need to apply polyoxin D zinc salt at the same time Bio-Tam or RootShield is applied.

As also noted in the February 2, 2017 petition addendum (page 11),

"The polyoxin D zinc salt 5SC formulation, when added to a treatment program, provides *superior control* of blueberry mummyberry fruit infections (fruit strikes) than when the following products are used alone:

- **Actinovate (containing *Streptomyces lydicus* WYEC 108; no FRAC Code; biological);**
- **Double Nickle LC (containing *Bacillus amyloliquefaciens* strain 747; FRAC Code 44);**
- **Regalia (containing *Reynoutria sachalinensis* extract; FRAC Code P5), and**
- **NovaSource's Lime-Sulfur (containing calcium polysulfide; FRAC Code M2)."**

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]

Toxicity/Risk

As discussed in the December 12, 2017 TR:

- Metabolites are identified in Figure 2 (page 7);
- The results of environmental studies pf polyoxin D zinc salt are summarized in Table 3 (page 8); and
- **"Based upon the results of Table 3, Polyoxin D Zinc salt is presumed to carry very low environmental risk and because Polyoxin D is formed through a fermentation, it is considered to be less toxic to the environment than a fungicide that was chemically manufactured such as copper, sulfur or petroleum distillates."** (lines 264-267)

Mode of Action

Polyoxin D zinc salt has a unique, non-toxic mode of action. No other active ingredient registered for use in North America has the same mode of action (FRAC Code 19).

As described in the 2012 petition (page 18),

> **"The active portion of polyoxin D zinc salt is polyoxin D which is produced by a microorganism that is naturally occurring in the soil. Polyoxin D inhibits the growth of phytopathogenic fungal cell wall chitin by competitively inhibiting chitin synthetase. Without chitin, susceptible fungi are unable to continue growing and infecting plant cells. Polyoxin D zinc salt does not kill the fungi; it simply stops the fungal growth. The action of Polyoxin D is highly specific; it does not affect bacteria, viruses, or mammals."**

Per comments from the members of the NOSB during the 2013public hearing, further information regarding the elucidation of the mode of action is included in the May 31, 2016 petition.

Environmental Degradation

The December 12, 2017 TR states (lines 206-210),

> **"Soil half-life from aerobic microbial metabolism is reported to be 15.9 days (Esteem Report). Polyoxin D Zinc Salt was shown to undergo aqueous abiotic hydrolysis at pH = 7 and pH= 9 (Esteem Report). Photolytic degradation was observed, DT_{50} = 1.6 d in spring conditions (Esteem Report). Data reviewed by EPA indicated that polyoxin D Zinc Salt biodegrades within 2-3 days of application, with a low toxicity profile [73 FR 69559]."**

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

Manufacture
As noted on the EPA registered labels, Polyoxin D Zinc Salt Technical (EPA Reg. No. 67173-1) and VEGGIETURBO 5SC Suspension Concentrate Fungicide (EPA Reg. No. 67173-4) are produced in Japan. https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1
US environmental contamination via manufacturing is not a concern.

Use and Disposal
As noted on the EPA registered label, VEGGIETURBO 5SC Suspension Concentrate Fungicide (EPA Reg. No. 67173-4) is used at low application rates. The maximum application rate is 13 fl oz/acre (0.72 oz AI/acre = 0.045 lb AI/acre). No environmental contamination is anticipated via use or disposal.

Misuse
No intentional misuse is anticipated. The Environmental Hazards Statement of the VEGGIETURBO 5SC Suspension Concentrate Fungicide label states,

> **"For terrestrial use. This pesticide is moderately toxic to aquatic invertebrates and fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate. Do not allow runoff into lakes, streams, ponds or public waterways. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Observe the most restrictive labeling limitations and precautions of all products used in mixtures."**

4. Discuss the effect of the substance on human health. [§6517(c)(1)(A)(I); §6517(c)(2)(A)(I); §6518(m)(4)]

Polyoxin D Zinc Salt Technical
The December 12, 2017 TR states (lines 218-230):

> **"In animal models, Polyoxin D Zinc Salt was shown to have very low acute toxicity by oral, dermal, and inhalation routes. Only very minor skin irritation was observed for Polyoxin D Zinc Salt, which was not sufficient to warrant classification. Polyoxin D Zinc Salt was shown to cause mild eye irritation. Polyoxin D Zinc Salt was shown not to be a contact sensitizer. Polyoxin D did not demonstrate a mutagenic potential though it did reveal some clastogenic potential with and without metabolic activation. In general, low toxicity was observed for Polyoxin D Zinc Salt in all investigations. During toxicity studies, Polyoxin D Zinc Salt is poorly absorbed with the vast majority of the product (>90%) being excreted unchanged directly in the feces. Polyoxin D Zinc Salt has been used for many years without any notable, consistent adverse human reactions being recorded. Polyoxin D Zinc Salt has been in use as an antifungal agent for over 40 years in Japan on rice, and approved in the USA and Mexico on food crops for over 5 and 3 years respectively and for non-food crops in the USA for over 16 years. The product is derived naturally in Japan from *Streptomyces cacaoi* var *asoensis* and has a unique mode of activity by inhibiting fungal cell wall synthesis. The risk to humans is considered to be extremely low."**

VEGGIETURBO 5SC Suspension Concentrate Fungicide
Please see the February 2, 2017 petition addendum (page 234) for a summary of the acute mammalian toxicology of VEGGIETURBO 5SC Suspension Concentrate Fungicide. Acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, eye irritation, and dermal irritation were each assigned EPA category 4 (practically non-toxic). This is EPA's lowest toxicity category. (EPA Label Review Manual, Chapter 7.)

Please see the Appendix 1 of the February 2, 2017 petition addendum for a copy of the current EPA stamped accepted label. The acute toxicity of VEGGIETURBO 5SC Suspension Concentrate Fungicide is so low that the US EPA label specifies that a ***first aid statement is optional***.

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

Soil Organisms: Nitrogen and Carbon Transformation
As noted in the May 31, 2016 petition (page 37), Kaken commissioned a study entitled, "Effects of VEGGIETURBO 5 SC Suspension Concentrate Fungicide on the Activity of Soil Microflora (Nitrogen and Carbon Transformation Test)." No adverse effects were observed on nitrogen fixation in soil (measured as NO_3-N production) and carbon transformation in soil (measured as O_2 consumption).

Effects on Beneficial Soil Fungi
As noted in the May 31, 2016 petition (page 43), a special study entitled, "Polyoxin D Zinc Salt 5SC Fungicide: Evaluation of Potential Impacts on Soil Fungi" was conducted to address the NOSB's concerns regarding possible effects of polyoxin D zinc salt on beneficial soil fungi.

Field treated soil samples were analyzed in a laboratory.

The soil samples were cultured using malt yeast extract agar which is selective for the growth of fungi. The resulting fungal colonies had normal appearance. The test substance did not adversely effect the morphology of the fungal colonies.

The test substance did not adversely effect the viability of the soil fungi. There was no statistically significant difference in the number of fungal colonies in the control vs treated soil samples for samples collected on Days 0, 1, 7,14, 21, and 28. Interestingly, treatment with the test substance resulted in a statistically significant ***increase*** in the number of viable soil fungi on Day 3 at both the Washington and Wisconsin sites. The reduction of viability of soil fungi that might be anticipated following exposure to most fungicides was ***not*** observed following exposure to the test substance. Instead, a brief and reversible statistically significant increase in soil fungal viability was observed. This is consistent with the non-toxic mode of action of polyoxin D zinc salt, *i.e.*, it reversibly stops the growth of susceptible fungi without killing the fungus.

The evaluation of the appearance and number of cultured fungal colonies did ***not*** differentiate between beneficial and pathogenic soil fungi. Polymerase chain reaction analysis was used to qualitatively confirm that the soil fungi included beneficial soil fungi. The intergenic spacer region gene which is unique to ***beneficial*** fungi was determined to be present in the fungi from both the control and treated soil samples.

This study therefore demonstrated that VEGGIETURBO 5SC Suspension Concentrate Fungicide (EPA Reg. No. 68173-4) containing nominally 5.0% polyoxin D zinc salt, when applied to soil at the maximum application rate (0.72 oz. a.i./acre), did ***not*** adversely effect ***beneficial*** soil fungi.

Honeybees: Acute Oral Toxicity
As noted in the May 31, 2016 petition (page 44), an acute ***oral*** toxicity study was conducted to examine the toxicity of polyoxin D zinc salt to the honeybee *(Apis mellifera).*

The LD_{50} values and 95% confidence limits for Polyoxin D Zinc Salt Technical are as follows:

Time After Dosing (Hours)	Polyoxin D Zinc Salt Technical	
	LD_{50} (µg/Bee)	95% Confidence Limit (µg/Bee)
24	88.105	54.371 to 107.591
48	32.885	28.519 to 37.643
72	33.037	28.610 to 37.824
96	28.774	24.818 to 33.083

The very high acute oral LD_{50} values for Polyoxin D Zinc Salt Technical determined in this study demonstrate the very low acute oral toxicity of Polyoxin D Zinc Salt Technical to honeybees. Using US EPA's hazard classification system for acute LD_{50} data for honeybees (above), Polyoxin D Zinc Salt Technical is *practically non-toxic* to honeybees when honeybees are exposed *orally* to polyoxin D zinc salt.

Honeybees: Acute Contract Toxicity

As noted in the May 31,2016 petition (page 44), an acute *contact* toxicity study in honeybees was conducted. No adverse effects were observed. The report summary is provided below. The study concludes that the acute contact LD_{50} of Polyoxin D Zinc Salt Technical is > 100 µg a.i./bee. Using EPA's classification system for acute honeybee toxicity studies (above), polyoxin D zinc salt is *practically non-toxic* to honeybees when honeybees are exposed via *contact* with residues of polyoxin D zinc salt on plant surfaces.

Ladybird Beetles

During the April 10, 2013 public hearing, a member of the NOSB expressed concern regarding the possible adverse effects on ladybird beetles. Kaken commissioned two studies of the effects of polyoxin D zinc salt on lady bird beetles:

1. Polyoxin D Zinc Salt Technical: A Laboratory Study to Evaluate the 3-Day Acute Toxicity and Developmental Effects on Adult and Third Instar Larvae Ladybird Beetles, Family *Coccinellidae*
2. Polyoxin D Zinc Salt 5SC Fungicide: Life-Cycle Toxicity Study in Multicolored Asian Ladybird Beetle Larvae, *Harmonia axyridis*

No adverse effects on ladybird beetles were observed in either study.

6. Are there any adverse impacts on biodiversity? (§205.200)

No adverse impacts on biodiversity are anticipated based upon the available:

- Efficacy data showing no phytotoxicity data (May 31, 2016 petition and February 2, 2018 addendum);
- Rapid environmental degradation data (December 12, 2017 TR, lines 206-211);
- Toxicity data regarding honeybees and other non-target organisms (December 12, 2017 TR, Table 3);
- Special studies conducted to address the NOSB's concerns about possible effects on beneficial soil organisms and ladybird beetles (May 31, 2016 petition, pages 40-41 and 46-47);
- Estimated low environmental risk (December 12, 2017 TR, lines 264-267).

Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as nonsynthetic and synthetic available materials. [§6518(m)(6)]

Cultural Practices

Cultural practices alone are not sufficient to meet organic growers needs. Please see:

- May 31, 2016 petition, pages 76, 84, 96, 105, 111, 119, 136, 151, 159, 171, 186, 201, 206, 211, 216, 229, 256, 260, 269, 274, 291, 297, 304, 315, 323, 328, 334, 346, 357, 370, 388, 399, 405, and 412; and
- February 2, 2018 petition addendum, pages 15, 18, 21, 23, 24, 25, and 26.

OMRI-Listed Alternatives

The February 2, 2018 petition addendum includes a detailed analysis of OMRI-listed alternatives to VEGGIETURBO 5SC Suspension Concentrate Fungicide (summarized on pages 10-12).

Based upon *disease economic significance and efficacy data alone*, there is organic grower need for the polyoxin D zinc salt 5SC formulation for treatment of:

- **Blueberries for control of:**
  - **Alternaria blight (*Alternaria* spp.); and**
  - **Botrytis blight (*Botrytis cinerea*);**
- **Caneberries for control of:**
  - **Botrytis fruit rot (*Botrytis cinerea*); and**
  - **Powdery mildew (*Podosphaera aphanais*);**
- **Cranberries for control of:**
  - **Cottonball (*Monilinia oxycocci*); and**
  - **Fruit rot complex (*Coleophoma empetri*, *Colletotrichum acutatum*, *Colletotrichum gloeosporioides*, *Phyllosticta vaccinii*, and *Physalospora vaccinii*, etc.);**
- **Grapes for control of:**
  - **Phomopsis fruit rot (*Phomopsis viticola*);**
- **Strawberries for control of:**
  - **Anthracnose fruit rot (*Colletotrichum acutatum*);**
  - **Gray mold (*Botrytis cinerea*);**
  - **Leather rot (*Phytophthora cactorum*); and**
  - **Phomopsis fruit rot (soft rot) (*Phomopsis obscurans*); and**
- **Basil for control of:**
  - **Downy mildew (*Peronospora belbahrii*).**

OMRI-listed alternatives initially identified as having comparable or superior efficacy and therefore identified for more detailed comparisons were:

- **Blueberries/mummyberry (*Monilinia vaccinii-corymbosi*): Optiva;**
- **Grapes black rot (*Guignardia bodwellii*): Badge X2 and Nu-Cop 50 WP;**
- **Grapes/bunch rot (*Botrytis cinerea*): Double Nickel 55 and Double Nickel LC;**
- **Grapes/downy mildew (*Plasmopara viticola*): Badge X2, Cueva, and Oxidate;**
- **Grapes/powdery mildew (*Erysiphe necator*): Micro Sulf, Lifegard WG and Stargus; and**
- **Strawberries/Phomopsis leaf spot (*Phomopsis obscurans*): Cueva.**

Based upon more detailed analysis for other crop/disease combinations for berries and small fruits, there is organic grower need for:

- **Blueberry/mummyberry control. Compared to Optiva, the polyoxin D zinc salt 5SC formulation offers organic blueberry growers:**
  - **Competitive efficacy for control of mummyberry;**
  - **A treatment option *after* mummyberry is first observed;**
  - **Competitive worker and environmental safety;**
  - **A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and**
  - **Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.**

- **Grape/black rot control. Compared to Badge X2 and Nu-Cop 50 WP, the polyoxin D zinc salt 5SC formulation offers organic grape growers:**
  - **Competitive efficacy for control of black rot;**
  - **Greater crop, worker, and environmental safety;**
  - **An opportunity to reduce the amount of copper applied to their vineyards and thereby reduce the negative effects of copper on soil;**
  - **Reduced (EPA's minimum) personal protective equipment requirement;**
  - **Greater flexibility in growing the crop (0-day PHI instead of 1-day; 4-hour worker re-entry interval instead of 48-hours or 24-hours);**
  - **A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and**
  - **Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.**

- **Grape/bunch rot control. Compared to Double Nickel 55 and Double Nickel LC, the polyoxin D zinc salt 5SC formulation offers organic grape growers:**
  - **Competitive or superior efficacy for control of bunch rot;**
  - **A treatment option *after* bunch rot is first observed;**
  - **Competitive worker and environmental safety;**
  - **A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and**
  - **Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.**

- **Grape/downy mildew control. Compared to Badge X2, Cueva, and Oxidate, the polyoxin D zinc salt 5SC formulation offers organic grape growers:**
  - **Competitive or superior efficacy for control of downy mildew;**
  - **An opportunity to reduce the amount of copper applied to their vineyards and thereby reduce the negative effects of copper on soil;**
  - **Greater to significantly greater crop, worker, and environmental safety;**
  - **Reduced (EPA's minimum) personal protective equipment requirement;**

- **Greater flexibility in growing the crop [0-day PHI instead of 1-day PHI; 4-hour worker re-entry interval instead of 48 hours (Badge X2)];**
- **A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and**
- **Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.**

- **Grape/powdery mildew control. Compared to Micro Sulf, Lifegard WG and Stargus, the polyoxin D zinc salt 5SC formulation offers organic grape growers:**
  - **Competitive or superior efficacy for control of powdery mildew;**
  - **A treatment option *after* powdery mildew is first observed;**
  - **An opportunity to reduce the amount of copper applied to their vineyards and thereby reduce the negative effects of copper on soil;**
  - **Competitive or superior crop, worker, and environmental safety;**
  - **Greater flexibility in growing the crop [0-day PHI instead of 1-day PHI; 4-hour worker re-entry interval instead of 48 hours (Badge X2)];**
  - **Increased applicator comfort (no respirator is required as is required for Lifegard WG and Stargus);**
  - **A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM); and**
  - **Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.**

- **Strawberry/Phomopsis leaf spot (blight). Compared to Cueva, the polyoxin D zinc salt 5SC formulation offers organic strawberry growers:**
  - **Competitive efficacy for control of Phomopsis leaf spot;**
  - **A treatment option *after* Phomopsis leaf spot is first observed;**
  - **Competitive or superior crop, worker, and environmental safety;**
  - **A reduced risk product with a new non-toxic mode of action for use in resistance management and integrated pest management (IPM);**
  - **Opportunities for export of the treated crop to Canada, Mexico, New Zealand, South Korea, Taiwan, and a growing list of additional countries.**

Please note:

- **For scheduling reasons, the grower needs analysis is limited to berries and small fruits and basil. Similar results are anticipated if other crop/disease combinations were analyzed.**
- **There is no EPA registered, OMRI-listed alternative for treatment of cranberries for control of cottonball (*Monilinia oxycocci*).**

2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

Yes, in balancing the responses to the criteria above, polyoxin D zinc salt *is compatible* with a system of sustainable agriculture.

Classification Motion:

Motion to classify polyoxin D zinc salt as a ***synthetic*** substance.
Motion by:
Seconded by:
Yes: 0 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National List Motion:

Motion to add polyoxin D zinc salt ***as petitioned at 205.601(i)***
Motion by:
Seconded by:
Yes: 0 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Tamarind Seed Gum

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
Tamarind Seed Polysaccharide (TSP); Tamarind Seed Gum

Other Names:
Tamarind Seed Xyloglucan; Tamarind Seed Galactoxyloglucan; Tamarind Gum; Tamarind Extract; Tamarind Xyloglucan

Trade Names:
GLYLOID®; GLYATE; Tamarind Gum

CAS Numbers:
39386-78-2

Other Codes:
EC/List no. 254-442-6

Summary of Petitioned Use

Tamarind seed gum has been petitioned for addition to the National List at § 205.606 as a non-organic agricultural ingredient permitted in processed products labeled as "organic" when organic forms are not commercially available. This full technical report also addresses additional focus areas requested by the National Organic Standards Board (NOSB) Handling Subcommittee:

- The petitioner states that there are very small amounts of residuals from the processing chemicals utilized to separate the gum from the seed. Are there any health issues from these residuals, including, but not limited to methyl alcohol? *See Evaluation Question #10.*
- How do the properties of this gum vary from other gums on the National List (e.g., gellan gum, xanthan gum, Arabic gum, guar gum, locust bean gum, carob bean gum, tragacanth gum, etc.)? *See Evaluation Question #12.*

Characterization of Petitioned Substance

Composition of the Substance:

Tamarind seed gum is a high molecular weight plant storage polysaccharide (Nishinari, Takemasa, et al. 2007). More specifically, it is a galactoxyloglucan, meaning it is principally comprised of three sugars: glucose, xylose and galactose (Manchanda, 2014; Health Canada, 2017). The linear backbone is a β (1→4)-D-glucan chain, with α-D-xylose units attached to approximately 75 percent of the glucan units. All xyloglucans share this common structure, but additional molecular side chains differentiate tamarind seed gum from other xyloglucan sources (Nishinari et al., 2007). In tamarind seed gum, the xylose units may also have a galactose unit attached by a β 1,2 linkage. The side chains in the structure can alternatively be described as partial substitution at position 6 of the glucopyranosyl unit mainly by a single α-D-xylopyranosyl residue as well as by disaccharide side chains composed of β- D-galactopyran-osyl-(1→2)-α-D-xylopyranosyl residues (Patel et al., 2008) (Gidley et al., 1991). The ratio of glucose, xylose, and galactose is 2.8:2.25:1 (or 43–45% glucose, 35–38% xylose, and 15–17% galactose) (Gidley et al., 1991; Patel, et al., 2008; Khounvilay and Sittikijyothin, 2012; Nishinari et al., 2007). Another minor polysaccharide in tamarind seed gum (2–3 percent) contains unbranched 1,4-β-D-galactopyranan and branched 1,5-α-L-arabinofuranan features (Gidley et al., 1991). The gel form arises when the xyloglucan is in the aqueous phase under certain conditions, and is considered to be a two-phase substance with a three-dimensional macromolecular structure that retains liquid (Salazar-Montoya, Ramos-Ramirez, and Delgado-Reyes 2002). The structure of tamarind seed gum's xyloglucan polysaccharide is shown in Figure 1.

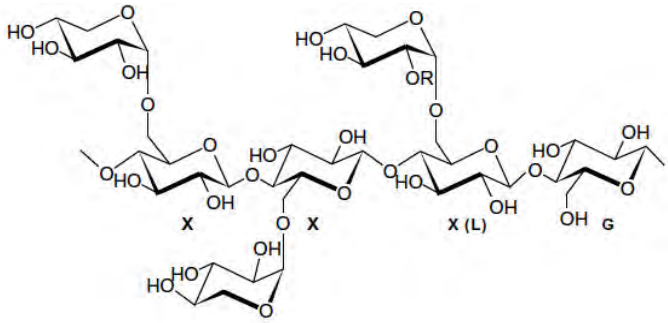

Figure 1. Tamarind seed gum's xyloglucan polysaccharide structure (Patel, et al. 2008). X indicates xylosylated glucopyranose units; G indicates an unsubstituted glucopyranose unit; and L indicates a galactopyranose unit attached to the xylose unit.

The petition for tamarind seed gum submitted to the National Organic Program (NOP) specifically references a brand name, GLYLOID. The composition information above describes GLYLOID. However, although GLYLOID is the only brand name product identified in the petition, an alternative, partially acid-hydrolyzed tamarind seed gum is made by the same manufacturer and marketed under the brand name GLYATE (JHeimbach LLC, 2014). The GRAS notification for tamarind seed polysaccharide (TSP) identifies both GLYLOID and GLYATE as brand/trade names of the substance (JHeimbach LLC, 2014).

Acid hydrolysis is used to separate monosaccharides from polysaccharides (Gidley et al., 1991; Hoebler et al., 1989) and is a processing step used in the production of GLYATE. Information regarding the specific chemical composition of GLYATE was not found in the literature, however it is expected that acid hydrolysis affects its chemical composition and function since it removes certain monosaccharides. The GRAS notification for TSP states that in the production of GLYATE, acid hydrolysis of tamarind kernel powder (TKP) is carried out until the desired viscosity is obtained (JHeimbach LLC, 2014). As will be described under *Action of the Substance*, viscosity is largely determined by a substance's chemical composition.

Source or Origin of the Substance:

Tamarind seed gum comes from the kernel, or endosperm, of seeds of the tamarind tree (*Tamarindus indica L).* Its native range includes the tropical dry savannah of Africa to India and Southeast Asia (CAMEO, 2016), with India being the predominant producer, followed by Thailand, Bangladesh, Sri Lanka, and Indonesia. Thirty-six other countries including Costa Rica, Mexico, and Brazil cultivate the tamarind tree (Bagul, Sonawane, and Arya, 2015). Tamarind trees are leguminous (in the Family Leguminosae, or Fabacae) and produce long pods that contain fruit in the form of a tart, fleshy pulp surrounding glossy, flat seeds. Tamarind pulp is high in tartaric acid and sugars, and is a widely-used food product. The seeds, which are composed of 65–75 percent carbohydrates, are considered a by-product of the pulp industry. Once dehulled and crushed, the seeds make tamarind kernel powder (TKP), a crude preparation of non-starch polysaccharide that functions as an energy reserve for the seed. The purified, soluble polysaccharide fraction of TKP is what is referred to as tamarind seed gum, tamarind seed polysaccharide (TSP), or tamarind seed xyloglucan. For more details on the manufacturing process, see *Evaluation Question #1*.

Properties of the Substance:

Tamarind seed gum is a free-flowing, tasteless powder that is white or light beige in color, and may be odorless or have a slight grease odor. It is insoluble but dispersible in cold water and insoluble in most organic solvents including ethanol, methanol, acetone, and ether (Manchanda, 2014) (Sidley Chemical Co., Ltd. 2013) (Joseph et al., 2012). Tamarind seed gum is soluble in hot water and at least one manufacturer, DSP Gokyo, markets a tamarind seed gum product, GLYLOID 3S, as being cold-water soluble (DSP GOKYO, 2017). A cold, aqueous solution of tamarind seed gum heated to 85˚C results in its dissolution and the formation of a uniform solution (Whistler and Barkalow, 1993). The following subsections detail the viscosity and gelling properties of the substance, which can also be found in Table 1.

Table 1. Properties of tamarind seed gum (Mohamed, Mohamed and Ahmed 2015) (Khounvilay and Sittikijyothin, 2012) (Joseph, et al., 2012) (Nishinari, Takemasa, et al., 2007) (Salazar-Montoya, Ramos-Ramirez and Delgado-Reyes 2002).

Property	Value
Molecular weight*	Reported variously from 650,000–2,100,000 g/mol; most commonly 880,000 g/mol
Viscosity average molecular mass	980,000 g/mol
Linear viscoelasticity	0.637–6.37 Pa of oscillary sheer stress
Viscosity	400-800 mPa·s
Bulk density	0.24–0.651 g/mL
Compressibility index	15.33–16.64%
pH (1% w/v TSP)	6–6.81
Swelling index (in water)	12–17%
Surface tension	61.3–83.26 dynes/cm
Water retention	20.00 ± 1.34%
Moisture content	3.8–8.1%
Melting point	240–260˚C

**While molecular weight plays an important role in determining the viscosity of tamarind seed gum, there is wide variation for this property reported in the literature. Several sources suggest that this is due to the self-association of the polysaccharide chains and the related difficulty in isolating molecular solutions that have been fully solubilized (Picout et al., 2003) (Nishinari et al., 2007). There are also differences based on the method of measurement, for example by gel permeation chromatography or light scattering.*

Viscosity

Similar to other gums, tamarind seed gum is a hydrocolloid. Hydrocolloids are a heterogeneous group of long chain polymers (polysaccharides and proteins) characterized by their property of forming viscous dispersions and/or gels when dispersed in water. Thus, gums are substances that disperse in water and provide a thickening and/or gelling effect by increasing the viscosity of a solution. This effect is common to all hydrocolloids, serving as gums' primary function (Saha and Battacharya, 2010; Edwards, 2003). The viscosity of gum solutions/hydrocolloids depends on how the hydrocolloid behaves in various concentrations or environments, such as temperature, pH, amount of physical agitation, or addition of sugars or other gums. Viscosity at low concentrations only depends on temperature, but at higher concentrations gum viscosity depends on shear rate thinning or thickening. *Shear rate* is a term used to describe the flow characteristics of materials that exhibit a combination of fluid, elastic, viscous, and plastic properties and behaviors (Saha and Battacharya, 2010; Chenlo, 2010). *Shear stress* is the force acting in the plane of the fluid (CP Kelco, 2007).

As with other gums, the viscosity of tamarind seed gum depends largely on its concentration in solution. At low concentrations, the viscosity of a tamarind seed gum solution is dependent only on temperature (Sidley Chemical Co. Ltd., 2013). At higher concentrations of tamarind seed gum, however, the viscosity of a solution decreases as shear rate increases (Khounvilay and Sittikijyothin, 2012; Whistler and Barkalow, 1993), a phenomenon known as shear thinning. *Shear thinning* is the behavior of a fluid becoming runnier and less viscous as it flows in response to an applied force (TACC, 2004). This phenomenon occurs due to the structural reorganization of the polysaccharide molecules in high-concentration TSP solutions during flow (Nishinari and Takahashi, 2003). A similar decrease in viscosity is not observed at lower shear rates, where the solution maintains its viscosity (Khounvilay and Sittikijyothin, 2012).

Temperature also affects the viscosity of tamarind seed gum solutions, over a range of concentrations. Tamarind seed polysaccharide in solution at 25°C is in a substantially disaggregated state of single chains (Gidley et al., 1991). However, when boiled for 20 to 30 minutes, the viscosity peaks (Whistler and Barkalow, 1993) and then decreases, but is still somewhat stable, only decreasing to half of what it was at the peak after 5 hours of boiling (Sidley Chemical Co. Ltd., 2013). Tamarind seed gum has been cited as being relatively heat resistant, though research does indicate that as temperature increases, viscosity decreases (JHeimbach, 2014; Buckley, 2017a).

Tamarind seed gum is also salt resistant, stable at neutral pH, and only minimally affected by the presence of organic acids in the pH range from 2 to 7. In fact, maximum gel strength for a solution with 1 percent tamarind seed gum and 50 percent sugar has been reported to be at pH 2 (Wüstenberg, 2015). Acidification with strong inorganic acids, on the other hand, does cause dramatic decrease in tamarind seed gum's viscosity (Sidley Chemical Co. Ltd., 2013). The acid-hydrolyzed tamarind seed gum product, GLYATE, has a much lower viscosity, ranging from 1 to10 mPa·s, compared to over 400 mPa·s for non-hydrolyzed tamarind seed gum.

Gelling Properties

While all hydrocolloids thicken aqueous dispersions, comparatively few gums form gels. Tamarind seed gum does not form a gel in isolation, but does gel in the presence of alcohol and sugars, and exhibits sol to gel transition at certain temperatures (Chemical Book, 2017). In the aqueous phase, tamarind seed gum combined with 40-70 percent sugar gels over a wide range of pH levels (Nishinari and Takahashi, 2003) (Wüstenberg, 2015). These gels show low syneresis, meaning they do not tend to separate or weep liquid (Wüstenberg, 2015). Tamarind seed gum also forms a gel in the presence of alcohol (Gidley et al., 1991) (Nitta and Nishinari, 2005) (Salazar-Montoya, Ramos-Ramirez, and Delgado-Reyes, 2002) or by removing some of its galactopyranosyl side chains (Nitta, Kim, et al., 2003). One study evaluated gels made from tamarind seed gum and saccharose and found that gel stability and shear resistance was dependent on both the saccharose and polysaccharide concentrations (Salazar-Montoya, Ramos-Ramirez, and Delgado-Reyes, 2002).

Tamarind seed gum has also been reported to have more pronounced shear thinning than xyloglucans from other plants such as apple pomace and *Nicotiana plumbaginifolia* (Sims, et al. 1998).

Specific Uses of the Substance:

Tamarind seed gum is used in numerous applications as a food additive. Because it has rheological functions that affect foods in the liquid phase, tamarind seed gum can be used as a thickening and gelling agent to improve the viscosity of certain foods. It can also modify the texture of foods (Khounvilay and Sittikijyothin, 2012). As an emulsifier, tamarind seed gum stabilizes foods such as ice cream, mayonnaise and cheese (Bagul, Sonawane, and Arya, 2015). Tamarind seed gum forms gel at low water activity, such as in solutions with sugar content greater than 60 percent, and is thus used in jams, jellies, and fruit preserves in place of pectin. It can also function as a starch modifier (Nishinari, Takemasa, et al., 2007). Added to starch, tamarind seed gum produces high viscosity paste with increased pseudo-plasticity. It can improve the gelatinization and retrogradation of tapioca starch pastes during storage at 5˚C (Pongsawatmanit et al., 2006). It can also be used to replace gluten as a dough-binding agent in gluten-free food products (Bagul, Sonawane and Arya, 2015). Added to foods, tamarind seed gum can enhance characteristics such as maintenance of viscosity over a wide range of shear rates, water-holding, and a food's resistance to heat, salt, and pH treatments used during processing (Nishinari, Takemasa, et al., 2007).

Tamarind seed gum is used in textile and jute industries as a textile thickener and for textile sizing during dyeing. It is also used in industries such as printing, paper, plywood, cosmetics, and oil drilling; as a soil stabilizer in mining operations, in the manufacturing of paints (Nagajothi et al., 2017), art preservation (CAMEO, 2016) and other industries. A recent area of interest is its use as an excipient for pharmaceuticals due to its high drug-holding capacity, high swelling index, thermal stability, and non-toxicity (Joseph et al., 2012; Manchanda 2014). Other medicinal uses of tamarind seed gum include eyebaths and for the treatment of ulcers (Mishra and Malhotra, 2009). It has also been suggested as an immunity booster (Bagul, Sonawane, and Arya, 2015).

Approved Legal Uses of the Substance:

Tamarind seed gum, under the chemical name Tamarind Seed Polysaccharide, is Generally Recognized as Safe (GRAS) under GRAS Notice No. 503 (JHeimbach LLC, 2014). The GRAS notice covers the use of tamarind seed polysaccharide as a thickener, stabilizer, emulsifier and gelling agent in 12 food categories: ice cream, sauces and condiments, dressings and mayonnaise, fruit preserves, desserts, beverages, pickles, tsukudani, spreads and fillings, flour products, soup and all other food categories at levels ranging from

0.2–1.5 percent of product composition. Use levels are identified for each food category. The stated intended effect of the addition of tamarind seed gum to food is as a stabilizer and thickener as defined in 21 CFR § 170.3(o)(28). The FDA had no questions in its Agency Response Letter of August 12, 2014 to the industry's determination of GRAS status for tamarind seed gum (FDA 2014).

The GRAS Notice No. 503 for Tamarind Seed Polysaccharide covers three brand name products manufactured by DSP Gokyo: GLYLOID 2A (hot-water soluble), GLYLOID 3S (cold-water soluble), and GLYATE (acid-hydrolyzed, low viscosity).

Tamarind seed gum is on the EPA's 2016 Chemical Data Reporting (CDR) Full Exempt List, which lists chemicals that are fully exempt from reporting requirements under the Toxic Substances Control Act.

Action of the Substance:

The actions of thickening and stabilizing of tamarind seed gum are due to its self-association in solution. Hydrocolloids thicken solutions through the nonspecific entanglement of their long molecular chains. When hydrocolloids are present in a suspension in very dilute concentrations, their individual molecules can move freely and may not cause thickening. As the concentration increases, molecule movement is restricted as they begin to come into contact with one another. The disordered molecule chains become entangled and thickening takes place (Saha and Battachyra, 2010). Gidley et al. (1991) also described "hyperentaglements" which resist shear more than non-specific entanglements, and may occur when stiff chains in a non-ionized environment align with neutral segments in solution.

The specific physiochemical properties of a xyloglucan are a function of the number and position of the side chains attached to its molecular backbone (Nishinari, Takemasa, et al., 2007). In tamarind seed gum, the molecular chain is very stiff and has restricted movement due to the extensive glycosylation (approx. 80 percent) of its cellulose-like backbone (Gidley et al., 1991) (Nishinari and Takahashi, 2003). The polymers show both hydrophobic and hydrophilic properties, leading the individual macromolecules to not fully hydrate and thus to aggregate even in dilute solutions (Picout et al., 2003). Tamarind seed gum xyloglucans also tend to self-associates to a higher degree than do xyloglucans from other sources, even though the solution properties for isolated chains of all xyloglucans are very similar. This has been attributed to the ratio of repeating units that make up tamarind seed xyloglucan enabling more interaction with other molecules including other xyloglucans (Nishinari, Takemasa, et al., 2007). Tamarind seed gum contains a high ratio of heptasaccharides (XXXG; See Figure 1), which self-associate to a larger degree than do other oligosaccharides (Nishinari, Takemasa, et al., 2007). It has also been suggested that the extensive substitution on the molecular backbone helps to shield the polysaccharide from hydrolyzing agents, thus imparting tamarind seed gum's resistance to heat, mild acids, and bases (Mishra and Malhotra, 2009).

The molecular weight (or size of molecules) of a polysaccharide affects its functional properties because viscosity and flow are governed by the interaction of the molecules in solution (Patel et al., 2008; Sims et al., 1998; Gidley et al., 1991). One study sought to modify tamarind seed gum's properties by breaking its polysaccharide units into smaller molecular weight materials via pressure and temperature treatment, enzymatic treatment, irradiation and other methods. The result was that the intrinsic viscosity was decreased with increasing irradiation treatment (Patel et al., 2008). This underscores the mechanism by which tamarind seed gum functions to impart viscosity and thickening to solutions: through interactions which are determined by its physical size and chemical makeup on a molecular level.

Combinations of the Substance:

The petition did not suggest that any formulants are included in tamarind seed gum (Buckley, 2017a). Tamarind seed gum is available as a pure tamarind seed polysaccharide, although some minimal solvent residues may remain in the final product from processing aids used in the purification process. More information on these processing aids is provided in *Evaluation Question #1*.

In application, additional substances such as alcohol, sugar, or oil can be mixed with tamarind seed gum in order to aid in dispersion, although the petitioner states that water alone is sufficient. Tamarind seed gum

forms a gel in combination with alcohol or sugar (Chemical Book, 2017) (Nishinari, Takemasa, et al., 2007). Tamarind seed gum is also commonly mixed with other gelling agents and food additives, including xanthan gum, guar gum, pullulan, dextran, and pectin, among others (Kumar and Bhattacharya, 2008). The gelling of mixtures of various polysaccharides has been widely investigated. One study found that a mixture of tamarind seed gum and gellan gum formed a gel under conditions that would not produce gelling with either individual polysaccharide, indicating synergistic gelation (Nitta, Kim, et al., 2003; Nitta and Nishinari, 2005). Another study examined the relative concentrations of tamarind seed gum polysaccharide and saccharose in solutions for their effects on gelation properties. Gelation increased with the increase of both components and the authors suggested that the polysaccharide and saccharose likely have synergistic effects on the viscoelastic properties of the resultant gel (Salazar-Montoya, Ramos-Ramirez, and Delgado-Reyes, 2002). Similarly, in a study on the effects of mixing tamarind seed gum with tapioca starch, it was found that the gum contributed increased viscosity and heat stability to the gelatinized mixtures as compared to tapioca starch alone (R. Pongsawatmanit et al., 2006).

Status

Historic Use:

Records from the eastern Mediterranean show tamarind trees under cultivation in the fourth century BCE. It is apparently native to tropical Africa and Madagascar, but now found throughout the tropics and introduced to tropical central and South America. It is widely cultivated and has naturalized in many areas. All parts of the tree are used for medicinal purposes, from the bark and leaves to the fruit, and the fruit is widely used as a food (Kew Science, 2017; Ranaivoson, 2015; JECFA, 2017; Williams, 2006; Kuru, 2014).

The seeds have had much more limited use and were mostly discarded until the mid to late 1900s. In 1942, two Indian scientists—T.P. Ghose and S. Krishna—identified the gel-forming substance found in the seeds (Morton, 1987). Its first applications were in the paper and textile industries. Difficulty of protein removal, bitter taste and odor prevented its adoption in food applications (Whistler and Barkalow, 1993) until a process for its purification was patented calling the substance "jellose," "polyose," or "pectin" (Morton, 1987). Tamarind seed gum has been commercially available as a food additive in Japan since 1964 (DSP Gokyo Food & Chemical, 2017).

Organic Foods Production Act, USDA Final Rule:

Tamarind seed gum is not specifically listed in the Organic Foods Production Act of 1990 or in the USDA organic regulations at 7 CFR Part 205. As an agricultural substance, it may only be used as an ingredient or processing aid in or on foods labeled as "organic" if the substance itself is certified organic.

International:

Canadian General Standards Board Permitted Substances List
http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/normes-standards/internet/bio-org/lsp-psl-eng.html
Tamarind seed gum is not permitted as an ingredient on Table 6.3 of the Permitted Substances List. The listing for Gums on this table states that "[t]he following gums are permitted: arabic gum, carob bean gum (locust bean gum), gellan gum, guar gum, karaya gum, tragacanth gum, and xanthan gum."

However, non-organic agricultural ingredients are permitted as a processing aid if organic forms are not commercially available (see CAN/CGSB 32.310 section 9.2.1(d) and 9.2.2(d)).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
http://www.codexalimentarius.org/standards/list-standards/en/?no_cache=1
http://www.codexalimentarius.org/download/standards/360/cxg_032e.pdf
Under the CODEX Alimentarius Guidelines, carob bean gum, guar gum, tragacanth gum, gum arabic, xanthan gum and karaya gum are all permitted with certain restrictions at GL 32-1999 Table 3 "Ingredients

of non-agricultural origin referred to in section 3 of these guidelines." Tamarind seed gum, however, does not appear on this table.

Section 3.4 of the guidelines states: "Certain ingredients of agricultural origin not satisfying the requirement in paragraph [3.3b, which requires agricultural ingredients to be produced organically] may be used, within the limit of maximum level of 5 percent (m/m) of the total ingredients excluding salt and water in the final product, in the preparation of products as referred to in paragraph 1.1(b); where such ingredients of agricultural origin are not available, or in sufficient quantity, in accordance with the requirements of Section 4 [organic production practices] of these guidelines." As such, agricultural forms of tamarind seed gum could be permitted under this section.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:250:0001:0084:EN:PDF
Article 28 states that non-organic agricultural ingredients listed in Annex IX to this Regulation can be used in the processing of organic food, however, tamarind seed gum is not included in on this list. Tamarind seed gum is also not listed under "Food Additives, Including Carriers" in Annex VIII, Section A of EC No. 889/2008. Other gums including carob bean gum, guar gum, Arabic gum, and xanthan gum are listed in this section.

Article 29 describes the authorization of non-organic food ingredients of agricultural origin by member states for agricultural ingredients not appearing in Annex IX. Such non-organic agricultural ingredients may be used according to the conditions laid out in Article 29, which include requirements for evidence of lack of commercial organic supply and notification, among others. Tamarind seed gum could be approved under this provision.

Japan Agricultural Standard (JAS) for Organic Production
http://www.maff.go.jp/e/policies/standard/jas/specific/criteria_o.html
Tamarind seed gum is not listed in Table 1 "Additives" of the Japanese Agricultural Standard for Organic Processed Foods Notification No. 1606, partially revised March 27, 2017. Other gums—including carob bean gum, guar gum, tragacanth gum, Arabian gum, xanthan gum and karaya gum—do appear in Table 1.

Article 4 describes provisions for lack of commercial organic supply: "In case of difficulty to obtain organic plants, organic livestock products or organic processed foods with the same categories of those used for ingredients, those prescribed in items 2 or 4 may be used." Items 2 and 4 describe plants and livestock products that are not in the same categories as organic ingredients, and have not undergone ionizing radiation or recombinant DNA technology. Tamarind seed gum, if not considered in the same category as other listed gums, could be allowed under this provision.

IFOAM – Organic International
http://www.ifoam.bio/en/ifoam-norms
Appendix 4 Table 1, "List of Approved Additives and Processing/Post-Harvest Handling Aids," lists locust bean gum, guar gum, tragacanth gum, Arabic gum, and xanthan gum. Tamarind seed gum is not included.

Section 7.2.1 states: "All ingredients used in an organic processed product shall be organically produced except for those additives and processing aids that appear in Appendix 4. In cases where an ingredient of organic origin is commercially unavailable in sufficient quality or quantity, operators may use non-organic raw materials, provided that:

a. they are not genetically engineered or contain nanomaterials, and

b. the current lack of availability in that region is officially recognized[1] or prior permission from the control body is obtained.
c. the requirements in section 8.1.3 [requirements for percentages of organic ingredients] shall be met."

Tamarind seed gum could be permitted under the above provision.

Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

The petition specifically references tamarind seed gum manufactured under the brand name GLYLOID by DSP Gokyo, sold in the U.S. by Socius Ingredients. On the manufacturer's website, there are two forms of this particular brand name product: GLYLOID 2A (hot water-soluble) and GLYLOID 3S (cold water-soluble) (DSP Gokyo, 2017). Another brand name tamarind seed gum product, GLYATE, was not identified in the petition but is addressed in this report in a following sub-section.

Tamarind kernel powder (TKP) is the pre-purified starting material from which pure tamarind seed gum is extracted. The petitioner (Buckley, 2017a) describes its manufacturing process, beginning with the seeds of the tamarind tree. The black seeds are sieved, roasted, cooled and then put through a rotary mixer to remove the testa, or seed coat. Whistler and Barkalow (1993) noted that the temperature and duration of roasting must be controlled so as to minimize discoloration and decreased molecular weight, which can in turn lower the viscosity of the resulting gum. The light brown to creamy white endosperm is visually sorted to remove any off-color endosperm, then polished in a rotary mixer and cut. The cut endosperm is pulverized in a hammer mill and sifted with a 200-mesh filter to produce pre-purified TKP, consisting primarily of polysaccharide with residual protein, lipid, minerals and no more than 10 percent moisture.

GLYLOID

Extraction of the GLYLOID 2A includes use of methyl alcohol (hereafter referred to as methanol) and sodium hydroxide. In order to purify and remove water from the polysaccharide, the TKP is stirred into a solution of food-grade methanol (Buckley, 2017b). After stirring, food-grade sodium hydroxide is added and the mixture is again stirred at a controlled temperature. Sodium hydroxide solubilizes proteins into the methanol solution to facilitate their separation from the polysaccharide (Buckley, 2017b). The polysaccharide is then separated from the protein, lipid, and minerals by centrifugation. Food-grade citric acid is added to adjust the pH by neutralizing the sodium hydroxide. In this process, hydrogen ions from the citric acid combine with hydroxide ions from the sodium hydroxide to form water, leaving sodium and citrate ions in the methanol solution (Buckley, 2017b).

Extraction of GLYLOID 3S involves heating and then rinsing in methanol to remove the colored material prior to pH adjustment with citric acid. Citric acid is a weak acid and has no effect on the structure or composition of the gum (Buckley, 2017b).

After extraction/purification, the polysaccharide is then dewatered, dried, pulverized, and sieved through a screen (Buckley 2017a). The petitioner states that the dewatering process before drying separates the methanol solution containing sodium citrate from the polysaccharides. The residual levels of methanol in the tamarind seed gum product as reported by the petitioner are less than 50 ppm (Buckley, 2017b). More information on safety is provided in *Evaluation Question #10*.

[1] This may be by inclusion on a government or certification body list of permitted non-organic agricultural ingredients.

GLYATE

Extraction of the GLYATE form of tamarind seed gum (polysaccharide) is done by treating the TKP with food-grade sulfuric acid until hydrolysis results in the desired viscosity. The solution is then neutralized using sodium hydroxide, after which it is sieved and rinsed in methanol (JHeimbach, 2014).

Other Manufacturing Processes

There are other manufacturing processes for tamarind seed gum described in the scientific literature that were not referenced in the petition. These other methods indicate a similar process to obtain the powdered kernel, but indicate a range of organic solvents that can be used to extract the polysaccharide.

In one process, tamarind seeds are roasted and the endosperm is pulverized, after which acetone is added to the TKP to remove oil and fat. The solution is stirred for 12 hours, after which it is filtered through filter paper and the filtrate is retained and dried. Distilled water is then added to the filtrate and the solution is boiled for 20 min at 80˚C, stirred for 2 hours, and centrifuged for 60 minutes at 5000-8000 rpm to remove fiber and other residues. Finally, the supernatant is freeze dried (Nagajothi et al., 2017). A similar method was described in 2012 by Joseph et al., where the TKP is soaked in water and boiled, then filtered and added to an equal amount of acetone to precipitate the polysaccharide, followed by concentration and drying.

In another process hexane extraction is used for defatting TKP, after which the TKP is boiled in water with 0.2 percent citric acid or tartaric acid for 30-40 minutes and allowed to settle overnight. Following, the supernatant is separated from the solution by decanting or siphoning off, and concentrated to 50 percent of its volume by evaporation or vacuum. It may then be added to twice its volume of alcohol in order to obtain a fibrous precipitate which is then filtered and dried (Marathe et al., 2002). The resultant product may also be pulverized in a ball mill (Kumar and Bhattacharya, 2008).

In another method, tamarind kernel powder in cold, distilled water was poured into boiling distilled water and boiled for 20 minutes with stirring in a water bath and then left to settle overnight. The solution was then centrifuged and the supernatant washed with absolute ethanol, diethyl ether and petroleum ether, after which it was dried under vacuum, ground and sieved (Mohamed, Mohamed, and Ahmed, 2015).

Joseph et al. (2012) described an enzymatic method in which the TKP is mixed with ethanol and treated with the enzyme protease. Subsequently, it is centrifuged and the supernatant is again added to ethanol to precipitate the gum, which is then separated and dried (Joseph et al., 2012). The authors note that the purity of the tamarind seed gum is determined by the absence of the protein, which in the described process can denature, forming insoluble precipitates, thus making the separation of the gum more difficult (Joseph et al., 2012).

A U.S. Patent granted in 1990 (Teraoka, 1990) for Shikibo Limited describes the organic solvent extraction process for obtaining tamarind seed polysaccharides utilizing alcohols such as methanol, ethyl alcohol, propyl alcohol, especially isopropyl alcohol, and ketones such as acetone. This patent includes comparative results of various extraction processes including not using any organic solvents. The patent provides research findings on varying levels of extractant use in order to determine minimal level of extractant needed to obtain the polysaccharide.

The JECFA report on tamarind seed polysaccharide (TSP) references the use of methanol, with additional use of acid or alkali treatment (JECFA, 2017). Manchanda (2014) describes the use of either acetone or absolute ethanol and absolute alcohol.

The first patents in the U.S. for extraction of polysaccharides from tamarind seeds were issued in the late 1960s. A patent from 1968 (Gordon, 1968) on behalf of Natural Dairy Product Corporation describes tamarind seed gum purification using a series of extractions, the first of which is with an organic solvent such as an alcohol, ketone, aldehyde or ether to dissolve and remove undesirable proteins and fats. Isopropanol was identified as the preferred extractant. The resulting filtrate still contains some protein fat

and fiber of from the crude TKP, along with the polysaccharides. This filtrate is dried to prevent degradation of the polysaccharides, after which it undergoes a water extraction with 25-35 times its weight of water, heated to 205˚F. The polysaccharides are separated by filtration and recovered by roll drying or alcohol precipitation. Use of roll drying requires the addition of a parting agent such as lecithin. However, due to off flavors attributed to the added lecithin, the author recommended adding glycerol monostearate or polysorbitans as additional parting agents (Gordon, 1968). This process does not appear to be used in current commercial manufacturing of tamarind seed gum.

Differing Perspectives on the Use of Ethanol vs. Methanol as an Extractant

Although Whistler and Burkalow (1993) suggest using ethanol or isopropanol to precipitate the soluble polysaccharide from TKP, the petitioner states that the use of ethanol or isopropanol in place of methanol results in a darker color tamarind seed gum with higher levels of residual protein and fat, which impacts its functionality and lowers its dispersability in water (Buckley, 2017b). One study compared extraction methods using ethanol and an "Accelerated Solvent Extraction" in which methanol extraction was followed by an ethanol extraction. The results showed that methanol extraction yielded pure tamarind seed gum, while the ethanol extraction contained additional components as measured by nuclear magnetic resonance (NMR). Thus, the authors concluded that methanol should be the solvent used to extract TSP (Chawananorasest, Saengtongdee, and Kaemchantuek, 2016).

Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.

Chemicals are used in the extraction of TSP; specific chemicals and processes used in various manufacturing methods are described in *Evaluation Question 1*. Some of the chemical processes described may be classified as non-synthetic or synthetic based on NOP Guidance 5033.

In the process described by the petitioner for the GLYLOID brand name product, the polysaccharide is not chemically modified during the purification processes described in *Evaluation Question 1*. In the addendum to the petition, the petitioner explains that the purpose for the use of methanol as a solvent is to remove water from the polysaccharide, which results in the polysaccharides self-associating into insoluble clumps (Buckley, 2017b), or precipitating. This claim is supported by the literature, where alcohol is widely cited for use in precipitating the polysaccharide (Marathe et al., 2002; (Joseph, et al. 2012; Gordon , 1968; Whistler and Barkalow 1993). Tamarind seed gum is insoluble in most organic solvents, including in methanol, ethanol and acetone (Sidley Chemical Co., Ltd., 2013). Thus, processes employing these solvents, where the filtrate is then filtered and/or dried, are expected to contain unmodified pure TSP with minimal solvent residues. The solvents are removed such that they do not have a technical functional effect in the final product.

The processes described for the GLYATE uses a strong mineral acid (sulfuric acid). Acid hydrolysis chemically modifies the polysaccharide; therefore, this form would be considered synthetic under NOP Guidance 5033.

TSP is a naturally occurring storage polysaccharide in the endosperm of the tamarind tree seed, which is an agricultural source.

Evaluation Question #3: If the substance is a synthetic substance, provide a list of non-synthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

Non-acid-hydrolyzed tamarind seed gum may be classified as a non-synthetic agricultural material based on NOP Guidance 5033. However, acid-hydrolyzed forms (such as GLYATE) and/or forms that include synthetic additives (such as the patent process from 1968) would render the final product synthetic.

Evaluation Question #4: Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.

TSP is Generally Recognized As Safe. GRAS Notice Inventory No. 503 addresses the use of TSP as a thickener, stabilizer, emulsifier and gelling agent in the following food categories: ice cream, sauces and condiments, dressings and mayonnaise, fruit preserves, desserts, beverages, pickles, tsukudani, spreads and fillings, flour products, soup, and all other food categories (JHeimbach LLC 2014). The FDA confirmed having no questions on this Industry GRAS determination on August 12, 2014 (FDA 2014).

Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b)(4)).

The purpose of tamarind seed gum in food is to act as a stabilizer and thickener as defined in 21 CFR 170.3(o)(28). According to the regulations, these are "[s]ubstances used to produce viscous solutions or dispersions, to impart body, improve consistency, or stabilize emulsions, including suspending and bodying agents, setting agents, jellying agents, and bulking agents, etc." This definition does not include the functional effects of a preservative.

One of the notable uses of tamarind seed gum is in fruit jams, jellies, and preserves in place of pectin. Processing fruit into these products is a form of fruit preservation. The degree of preservation, however, is related to the water activity of the product, which is determined by the sugar content. As sugar binds to water in food it is made unavailable for microbial growth (ACS, 2017). Thus, it is not the gelling—or stiffness—of the gum or pectin that preserves the food, but the sugar. Jams and jellies can be made without the use of pectin or any other gelling agent.

Many of the functions of gums as food additives can result in extending shelf life of the products in which they are used (Williams and Phillips, 2003). For example, tamarind seed gum used as a stabilizing agent of ice crystals in frozen pastry products aids in shape preservation (Sidley Chemical Co., Ltd. 2013).

Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).

Tamarind seed gum is not added to food primarily to recreate flavors, colors, textures or nutritive values lost in processing, although one of its functions as a food additive is to improve texture. The actions of stabilizing, thickening, or gelling can all contribute to improving texture. However, none of the literature reviewed for this report suggest that tamarind seed gum recreates texture quality that has been lost due to processing.

Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).

The physiological and nutritional effects of ingesting tamarind seed gum occur during transit through the stomach, small intestine, and colon where there is interaction among nutrients, enzymes, and mucosal cells, and finally fermentation by the colonic microflora. Digestion of sugars and fats may change when foods containing gums as food additives are ingested (Edwards, 2003).

Tamarind seed gum's xyloglucan polysaccharide has the same molecular skeleton as cellulose, and like cellulose, is not readily digested by enzymes found in the human digestive tract. It therefore serves as dietary fiber (Picout et al., 2003). Intake of dietary fiber has numerous health benefits, including lowering the risk for development of coronary heart disease, hypertension, stroke, diabetes, obesity, and certain gastrointestinal diseases. It can also lower blood pressure and cholesterol levels (Koraym, Waters, and

Williams, 2009). Literature has also suggested that xyloglucan oligosaccharides obtained via enzyme hydrolysis may be used as a prebiotic food ingredient to foster intestinal bacteria fermentation (Mishra and Malhotra, 2009).

Existing literature about gums' effect on mineral availability differs depending on whether the assessment was done inside or outside of the organism. One reference noted that gums can decrease mineral availability in the intestines, but that the effect of dietary fibers on mineral absorption in humans is still unclear (Baye, Guyot, and Mouquet-River, 2015). This potential was suggested based on laboratory studies that have shown how various fibers have mineral-binding properties *in vitro*. By contrast, animal and human *in vivo* studies of various soluble dietary fibers fail to demonstrate negative effects on mineral absorption, and some *in vivo* studies with fibers (e.g., pectin, fructooligosacccharides) have shown positive effects on mineral absorption. One possible reason for the difference observed between laboratory and *in vivo* studies is that fermentation of the fibers in the colon may free bound minerals and offset the negative mineral-binding effects of the fibers (Baye, Guyot, and Mouquet-River, 2015).

Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600 (b)(5)).

No reports of residues of heavy metals or contaminants in excess of FDA's tolerances have been identified for tamarind seed gum, and no substances listed on FDA's *Action Levels for Poisonous or Deleterious Substances in Human Food* have been reported as contaminants of concern for tamarind seed gum (FDA, 2017).

The FDA response to the industry GRAS determination acknowledged the specifications for TSP, which limit lead content to less than 2 mg/kg and arsenic to less than 1 mg/kg (FDA, 2014).

The GRAS notice states that the specifications set for GLYLOID 2A and 3S do not include limits for mercury and cadmium. Nevertheless, the levels of these heavy metals were assessed and found to be consistently below the detection level of 0.01 mg/kg. Methanol residues are also tested regularly and consistently found to be under 50 mg/kg (ppm) (JHeimbach, 2014).

Information provided by petitioner, in response to questions from the NOSB, indicates non-detect levels of a wide array of agricultural pesticides in samples of GLYLOID 2A (Buckley, 2017 b).

Health Canada has proposed adding tamarind [seed] gum to its *List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents*. In its rationale, the agency stated that "data was provided demonstrating that tamarind gum can be manufactured, following good manufacturing practices, such that it consistently meets the manufacturer's in-house specifications, including specifications for lead, arsenic, and microbial pathogens. These specifications are generally consistent with internationally-established specifications for many other food additives, including other plant-based gums" (Health Canada, 2017).

Tamarind seed gum is not presently listed in the Food Chemicals Codex (FCC).

Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

The utilization and cultivation of tamarind trees has been cited as having beneficial environmental impacts. As a leguminous tree, tamarind can grow in poor soils due to its nitrogen-fixing ability and it also being drought tolerant (Kumar and Bhattacharya, 2008). The trees are long-lived evergreens, providing a year-round soil cover. They store and recycle nutrients and help stabilize the soil. A mature tree may produce 330 to 500 pounds (150 to 225 kg) of fruit annually, of which seeds make up 33–40 percent. The fruit is generally harvested during the dry season, giving farmers supplemental income in the off-season, which

can discourage timber harvesting (Mahapatra and Tewari, 2005) or other land conversion such as slash and burn for agriculture. The trees are widely cultivated throughout the tropics, and they readily spread and naturalize beyond their native range of Africa. They are not considered a species of concern for conservation (Kew Science, 2017; Ranaivoson, 2014). In sub-Saharan Africa, tamarind trees reportedly contribute to ecosystem stability and food security; however, planting rates are not high in that area. It has been suggested that the development of value-added tamarind products could help maximize the benefits of tamarind trees and enhance their conservation in this area (Ebifa-Othieno et al., 2017). The economic value obtained from the harvest of non-timber forest products such as tamarind has been noted for its potential in sustainable forest management (Mahapatra and Tewari, 2005). In contrast, one research article attributes overexploitation of this species to causing a decline in the number and distribution of tamarind trees within its native range of south western Madagascar (Ranaivoson, 2015).

The production of tamarind seed gum involves the use of processing aids including methanol, isopropanol, sodium hydroxide and citric acid. The petitioner states that the production line is sealed, and the methanol used in the process is recovered through distillation and is then reused. The remaining solvent solution containing sodium citrate is burned, producing water, CO_2, and ash. The petitioner maintains that incinerator emissions are minimal and meet local standards for emissions (Buckleym 2017b). No sources reviewed for this report discuss any environmental pollution resulting from the processing of tamarind seeds into the purified polysaccharide.

In the environment, tamarind seed gum can be broken down via hydrolysis by enzymes of the *Aspergillus oryzae-niger* group, as well as the cellulose decomposer *Myrothecium verrucaria* (Whistler and Barkalow, 1993). The by-products of this hydrolysis/degradation are smaller oligosaccharides, which can be further metabolized by organisms present in the environment and do not pose ecological hazards.

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

Tamarind seed polysaccharides (TSPs), like other xyloglucans, are not digested by human digestive enzymes and may be regarded as part of the dietary fiber portion of the diet (Yamatoya, 2000). Tamarind seed gum is fermented by the intestinal microbiota, notably by clostridia bacteria (Hartmink, 1996). One report indicated that TSPs have a protective effect on liver functioning (Samal, 2014).

The possibility of allergic reaction to tamarind seed gum is negligible. The Health Canada proposal to allow tamarind gum as a food additive (Health Canada, 2017) notes that research data indicate that tamarind gum is not absorbed into the general circulation and there is no systemic exposure to it. The gum is broken and fermented by bacteria in the colon into individual sugars and short chain fatty acids, which are normal constituents of the diet (Health Canada, 2017).

Tamarind seed polysaccharide (gum) was considered by the Joint FAO/WHO Expert Committee Food Additives at its June 2017 meeting. The Committee noted the absence of toxicity in long-term rodent studies and lack of concern regarding genotoxicity, reproductive toxicity and developmental toxicity. They therefore established the allowed daily intake as "not specified" for TSP. The Committee concluded that the estimated dietary exposure of 75 mg/kg body weight per day based on proposed uses and use levels does not present a health concern (JECFA, 2017).

The material safety data sheet for Tamarind Gum (tamarind seed Polysaccharide) published by TCI America does not indicate any carcinogenic or mutagenic concerns, but notes that information on toxicity to humans has not been determined (TCI America, 2005).

Several toxicity studies of tamarind seed gum have been carried out on rodents. In one, rats were fed diets containing different levels of tamarind seed gum ranging from 0-120,000 ppm for 28 days. There were no mortalities, no clinical or ophthalmological signs, no findings related to body weight gain, food consumption, food efficiency, functional behavior or motor activity. There were initial decreases in body

weight gain and food consumption during the first week, but these recovered by the second week of tamarind seed gum administration and were considered to be likely due to reduced palatability. The No Observed Adverse Effect Level (NOAEL) was determined to be the highest level administered: 120,000 ppm, which is equivalent to 10,597 mg/kg body weight for male rats and 10,691 mg/kg body weight for female rats (Heimbach et al., 2013).

In a carcinogenicity study, mice were given tamarind seed gum at levels ranging from 0 to 5 percent of their diet for 78 weeks. Body weight declined in female mice given 1.25 percent or 5 percent gum after 34 weeks. However, there were no treatment-related clinical signs or adverse effects on food consumption, hematology measures, organ weights or survival rate. There were also no treatment-related increases in non-neoplastic or neoplastic lesions, leading the authors to conclude that tamarind seed gum is not carcinogenic in mice for either sex (Sano et al., 1996).

Potential Health Issues from Residual Chemicals Used in Processing of Tamarind Seed Gum

Methanol is one of several solvents that may be used in the extraction of tamarind seed gum. Methanol occurs naturally in plants and animals, and is also a toxic alcohol that is, among other uses, an industrial solvent. Methanol poisoning occurs primarily as a result of ingesting contaminated food or beverages (NIOSH, 2017). Inhalation and dermal or eye contact are other routes of exposure that can have adverse health effects. Methanol toxicity results from its being metabolized via alcohol dehydrogenase to formaldehyde and formic acid. Acute methanol poisoning can produce marked metabolic acidosis, hyperglycemia, cyanosis, respiratory failure, electrolyte imbalance, delayed onset of coma, impaired vision, and blindness (WHO, 2017). The prognosis in cases of methanol poisoning correlates with the amount of methanol ingested and resulting degree of metabolic acidosis. The minimum lethal dose of methanol in adults is believed to be 1 mg/kg of body weight (Korabathina, 2017). Based on the estimated dietary exposure of 75 mg tamarind seed gum per kg of body weight an assumed maximum residual 50 mg methanol per kg of the gum would result in an estimated daily exposure of 0.00375 mg methanol per kg of body weight from the consumption of tamarind seed gum. At this concentration methanol is considered non-toxic (WHO, 2014).

The EPA Oral Reference Dose (RfD) for methanol is 0.5 milligrams per kilogram of body weight per day. This number is an estimate (with uncertainty spanning perhaps an order of magnitude) of daily oral exposure of a chemical to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime. It is a reference point above which the potential risk for adverse health effects increases. However, the EPA notes a lack of data on reproductive or developmental toxicity, leading it to assign only medium confidence to the RfD (EPA, 2000).

21 CFR 173.250 establishes limits on methanol as an extraction residue in spice oleoresins: not to exceed 50 parts per million. It is also limited as an extraction residue in hops to a level not exceeding 2.2 percent by weight, provided that the hops extract is added to the wort before or during cooking in the manufacture of beer, and the label of the hops extract specifies the presence of methanol. Health Canada similarly limits residues of methanol when used as an extraction solvent to 50 ppm in spice extracts and to 2.2 percent for hops extract. In steviol glycosides, the maximum residual level permitted is 200 ppm, and for meat and egg marking inks, processors are to adhere to good manufacturing practices (Health Canada 2016). In Europe, methanol may be used as an extraction solvent during the processing of raw materials, of foodstuffs, of food components or of food ingredients. Its residue is limited to 10 mg/kg for all uses and to 1.5 mg/kg when used as an extractant of natural flavoring materials according to Directive 2009/32/EC, Annex 1, Parts II and III. Methanol is a Class 2 Solvent according to USP-NF 467/ICH Q3C(R6) guidelines, meaning, it is a solvent that should be limited in pharmaceutical applications due to its inherent toxicities. Its permissible daily exposure in pharmaceuticals is 30 mg per day, and its concentration limit is 3000 ppm (ICH, 2016).

Although FDA regulations do not include a legal limit on the maximum amount of methanol residue that can remain in tamarind seed gum, the GRAS Notice for tamarind seed gum reported that methanol

residues are tested regularly and are consistently found to be under 50 mg/kg (ppm) (JHeimbach, 2014), which was accepted by the FDA.

Research indicates that TSPs are not soluble in organic solvents and that processing methods, as described in numerous references, indicate separation of polysaccharides from the organic solvents used during the purification process. If any residues remain they are not expected to exceed acceptable FDA levels.

Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

A review of the literature did not provide any information describing alternative practices that would render the use of gums such as tamarind seed gum unnecessary as a food additive for the purposes for which it is presently approved in processed foods. Like other hydrocolloids, alone or in combination, it functions as a thickener, stabilizer, emulsifier, and under certain conditions a gelling agent as described elsewhere in this report.

An alternative practice could be to make the product without the additive, resulting in products with different consistencies and textures. Producers of processed organic foods could, in some instances, use alternative substances, as discussed below in response to *Evaluation Question 12* and *Evaluation Question 13*.

Evaluation Question #12: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

As discussed previously, tamarind seed gum is derived from non-synthetic, natural sources and is also classified as agricultural. It has numerous potential alternatives, some of which are non-synthetic and many are also agricultural. The availability of agricultural alternatives in certified organic form will be discussed in *Evaluation Question 13*.

The National List includes the following allowed substances which, separately or in combination, may be alternatives or substitutes to tamarind seed gum:

§205.605(a) Nonagricultural, non-synthetic
- Agar-agar
- Carrageenan
- Gellan gum – high acyl form only

§205.605(b) Nonagricultural, synthetic
- Xanthan gum

§205.606 Nonorganic, agricultural
- Gelatin
- Gums – water extracted only (Arabic; guar; locust bean; and carob bean)
- Konjac flour
- Lecithin (de-oiled)
- Pectin (non-amidated forms only)
- Cornstarch (native)
- Sweet potato starch-for bean thread production only
- Tragacanth gum

Tamarind seed gum is the only xyloglucan available for commercial use (Wüstenberg, 2015; Cui, 2005), however there are numerous other natural hydrocolloids that could potentially be substituted for tamarind seed gum. These include both agricultural and non-agricultural substances. Traditional substances which are not hydrocolloids, such as starches and gelatin, can be used. The choice of gum for a particular food

application is dictated by the functionalities required, but strongly influence by price and security of supply. Therefore, starches, which are very economic, are the most commonly used thickening agents, and corn starch, tapioca, wheat arrowroot and rice starches are all available in organic forms. However, starches do not provide the same function as the hydrocolloid gums. For example, tamarind seed gum imparts a viscosity similar to that of starch, however, its viscosity does not deteriorate in the presence of acids, bases, salts and heat like starch does (Sidley Chemical Co. Ltd., 2013). One study evaluated the influence of TSP on the rheological properties and thermal stability of tapioca starch. It found through different mixing ratios of the two substances, peak and final viscosities were greater for mixes with higher TSP proportions. Heat stability was improved over that of pure tapioca starch and water separation was lower than for pure TSP (R. Pongsawatmanit et al., 2006).

Gelatin is derived from partial hydrolysis of collagen fibers extracted from the bones and other body parts of domesticated animals, such as beef cattle. It is by far the most common gelling agent, but, with increasing demand for non-animal products, in particular due to the bovine spongiform encephalopathy outbreak and expansion of the vegan consumer group, processors are actively seeking to replace gelatin in both organic and non-organic food processing. Gelatin could be used as an alternative to tamarind seed gum in combination with gellan gum, but the latter can withstand higher temperatures (Williams and Phillips, 2003).

Other gums may serve as alternatives to tamarind seed gum. Tamarind seed gum has similar solution properties to those of galactomannans (Nitta 2005) such as locust bean gum and guar gum. However, guar gum is superior to tamarind seed gum in dispersion and suspension: it is readily soluble in cold water, whereas tamarind seed gum takes longer to achieve full viscosity. On the other hand, tamarind seed gum has better thermal stability than guar gum and also tolerates higher pH conditions (Chemtotal Pty Ltd., 2017).

Tamarind gum was compared with guar gum and xanthan gum and found to be at least as effective in maintaining viscosity. Data for some of the tests measuring acid resistance and freeze-thaw resistance showed that tamarind gum could be more effective (Health Canada, 2017).

Tara gum is another potential alternative. Tara gum is derived from the endosperm of the seeds of *Caesalpinia spinosa (leguminosae*), a shrub/small tree growing wild in Peru. Tara is a high molecular galactomannan, with similar cold water solubility to guar gum and similar thickening characteristics. It is odorless and tasteless compared with guar gum, improves shelf life of products, and has a smoother, less slimy texture (Silvateam, 2017).

Konjac mannan is a soluble extract of konjac flour made from a dried tuber (*Amorphophallus konjac)* used in Japan to make noodles and konnyaku for use in traditional dishes and desert jelly. It is a glucomannan. It can be combined with xanthan gum to increase gel strength in kappa-carrageenan gels (Williams and Phillips, 2003).

Xanthan gum is of microbial origin and, as another glycosyl-branched cellulosic polysaccharide, has been shown to have an extremely stiff molecular structure and is considered a weak gel. (Gidley et al., 1991). Although the length of tamarind seed xyloglucans is relatively high for polysaccharides, it is much lower than that of xanthan gum's polysaccharide length (Nishinari, Takemasa, et al., 2007) and thus it is relatively flexible as compared to xanthan gum's chains (Picout, et al. 2003) (Nishinari, Takemasa, et al., 2007).

Pectin is another alternative to tamarind seed gum; tamarind seed gum has been widely suggested as an alternative to pectin in making fruit jams, jellies and preserves. Differences between tamarind seed gum and pectin have been widely described. Fruit pectins degrade with boiling, falling to one-third of their original gelling value after one hour of boiling (Kumar and Bhattacharya, 2008). Tamarind polysaccharides, however, do not lose their gelling ability due to boiling in neutral aqueous solutions, even for long periods (Kumar and Bhattacharya, 2008). Unlike fruit pectin, tamarind seed gum can gel at a neutral pH (Marathe,

et al., 2002). Tamarind seed gum is also said to show less syneresis, or weeping, than fruit pectins (R. Whistler, 1973).

Mohamed, Mohamed and Ahmed (2015) compared two tamarind seed gum extracts, from light brown and dark brown seeds, to pectin. They found the former to have higher intrinsic viscosity and molecular weight than that of pectin. They reported that the TSPs form gels over a wide range of pH in the presence of sucrose without acid and base, while commercial pectin forms gels over a narrow (acidic) range of pH in the presence of sucrose. The protein levels in polysaccharide were higher than those in pectin but did not inhibit gel formation (Mohamed, Mohamed, and Ahmed, 2015).

Viscosity

The GRAS Notice (JHeimbach, 2014) compares the viscosity of TSP with xanthan gum, guar gum, locust bean gum, and gum arabic. The comparison indicates that TSP exhibits moderate viscosity with a linear dependence on concentration, and its viscosity is negatively correlated with temperature and is independent of the intensity of shear or stirring force (JHeimbach, 2014). Graphs showing comparisons with other gums for properties such as viscosity are also provided in the petition (Buckley, 2017).

The viscosity of tamarind seed gum xyloglucan is relatively high compared to that of gums with the same contour length due to its self-aggregation (Nishinari, Takemasa, et al., 2007). Xyloglucans have been reported to have a molecular chain persistence length of 6-8 nm, which is slightly larger than that of cellulose and its derivatives. The stiffness of its chains is greater than that of galactomannan chains as found in locust bean and guar gums, but, as noted above, is relatively flexible compared xanthan gum. It's relatively higher viscosity is also due to the polysaccharide's molecular side chains, which makes it more rigid than that of other neutral polysaccharides. Its rigidity is comparable to that of alginates that have a ribbon-like structure stiffened by mutual electrostatic repulsion between adjacent residues (Gidley et al., 1991). Guar gum, another branched polysaccharide has a moderately stiff backbone and is described as having rheological properties of a simple entanglement solution (Gidley et al., 1991). Tamarind xyloglucans behave as linear flexible to semiflexible random coil polysaccharides (Picout et al., 2003) (Nishiniari et al., 2007).

Flow

Tamarind seed gum is similar to the galactomannans locust bean and guar gum in exhibiting consistent flow behavior at low concentrations and shear thinning flow behavior at higher concentrations (ca. >0.5% w/w). Their dynamic rheological properties are similar to those of random coil polysaccharides (Cui, 2005).

Stabilizer

Tamarind seed gum has been found to be comparable to tragacanth, arabic, and karaya gums in stabilizing oil emulsions (R. Whistler, 1973). Comparative stability studies have been undertaken using gum acacia as a standard emulsifying agent. TSP was found to be more effective as a stable emulsifying agent in comparison to gum acacia (Manchanda, 2014).

Other Properties

The sugar-induced gels of tamarind seed gum xyloglucan have high elasticity and display good water holding properties (Cui, 2005). These and its stability to heat, acids and shear have all been noted as unique to this polysaccharide (Mishra and Malhotra, 2009). Another defining characteristic of tamarind seed gum as compared to other gums is its non-threading (Sidley Chemical Co. Ltd., 2013).

Table 2. Comparison of properties between tamarind seed gum and other gums on §205.605-606.

Property	Tamarind seed gum	Gum arabic	Tragacanth gum	Guar gum	Locust (Carob) bean gum	Gellan gum	Xanthan gum
Low Viscosity (only becomes viscous at concentrations greater than 50%)	Moderate viscosity	X					
High Viscosity at 1 % concentration			X				
High Viscosity at low concentrations (but above 1%)						X	X
Viscosity remains unchanged over time at low shear rates	X		X				
Viscosity decreases over time at low shear rates				X			
Forms thermo-reversible gels						X	
Thermally reversible						X	X
Thermally irreversible			X		X		
Insoluble in ethanol	X	X	X	X	X	X	X
Stable under acid conditions	X		X	X	X		X
Controls syneresis (weeping)	X			X	X		X

The relationship between polysaccharides and their rheological behavior is becoming better understood (Mishra and Malhotra, 2009), opening the door to optimization of their functional properties through different combinations, proportions and conditions. As Williams and Phillips (2003) noted, mixtures of gums are commonly used to impart novel textural characteristics to food products. Thus, tamarind seed gum either alone or in combination with other gums can impart novel characteristics to processed food.

Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b) (1)).

Agricultural substances that can be used as alternatives to tamarind seed gum in food processing applications include gums on the National List, and, in certain applications, pectin, starch and konjac flour, which are also on the National List at § 205.606. Water-extracted gum arabic, guar gum, locust bean/carob bean gum are permitted in non-organic form as ingredients in or on processed products labeled as "organic" when not commercially available in organic form, per § 205.606(g). The discussion in *Evaluation Question 12*, comparing tamarind seed gum to these alternatives also applies to the same substances in organic form. At the time of this report, the NOP Organic Integrity Database lists sources of organic locust bean gum, gum arabic/acacia gum, karaya gum, guar gum, tara gum, and konjac gum (NOP, 2017). However, little information was found as to whether the commercially available quantities would meet market demand.

No sources of organic tamarind seed gum or organic TSP are identified in the NOP Organic Integrity Database. Tamarind trees are widely cultivated in the tropics worldwide and can be certified organic. At the time of this report, there are nine sources of organic tamarind (fruit) and one source of tamarind powder listed in the NOP Organic Integrity Database (NOP 2017). However, the processing aid methanol used in the manufacture of tamarind seed gum does not appear on the National List at § 205.605, thus it may not be possible under current regulations to process TKP from certified organic tamarind tree seeds into certified organic tamarind seed gum.

Report Authorship

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All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

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Silver Dihydrogen Citrate

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
Silver Dihydrogen Citrate
Monosilver dihydrogen citrate
Monosilver citrate
Silver; 2-(carboxymethyl)-2, 4-dihydroxy-4-oxobutanoate

Other Name:
Citric acid and silver citrate
2-Hydroxy-1,2,3-propane tricarboxylic acid monohydrate and 2-hydroxy-1,2,3-propane tricarboxylic acid silver (1+) salt monohydrate

Trade Names:
SDC 2400
Silverion 2400

TINOSAN® SDC Active
TINOSAN® SDC lyophilisate
TINOSAN® SDC
FAT 81'034
FAT 81'033
Axenohl
C-1390

CAS Numbers:
No CAS Number available for SDC
77-92-9 (Citric Acid)
206986-90-5 (Silver Citrate hydrate)
14701-21-4 (Silver Ions; electrochemically generated)

Other Codes:
ELINCS number: 460-890-5

Summary of Petitioned Use

The petitioned substance, silver dihydrogen citrate, is intended for use as an antimicrobial processing aid for the processing of poultry (carcasses, parts, and organs) and fruits and vegetables (except for citrus fruit and grapes intended for winemaking). Silver dihydrogen citrate is also intended to be used as a disinfectant and sanitizer for food processing equipment and food contact surfaces.

Characterization of Petitioned Substance

Composition of the Substance:

Silver dihydrogen citrate (SDC) is a stable mixture of citric acid monohydrate and silver dihydrogen citrate monohydrate. Silver dihydrogen citrate (citric acid and silver citrate) is a simple salt, wherein the silver ion is the positively charged ion and the dihydrogen citrate moiety is the negatively charged ion, possessing a negatively charged carboxylate group. This compound is present in a dissociated state in the solution, with the positively charged and negatively charged ions surrounded by water molecules. Typical solution composition of SDC is as follows in Table 1 (Biocience 2015).

Table 1: Silver Dihydrogen Citrate - Typical Solution Composition

Components	Wt %
Water (CAS No. 7732-18-5)	> 76
Citric Acid (CAS No. 77-92-9)	< 22
Silver Ions (CAS No. 14701-21-4; electrochemically generated)	0.24

Anhydrous silver dihydrogen citrate compositions are comprised of silver dihydrogen citrate and citric acid (Arata 2006). The anhydrous composition is prepared by freeze drying a frozen stock solution of silver dihydrogen citrate to yield a translucent, gray crystalline material that can be further ground into a fine powder.

Citric acid ($C_6H_8O_7$, CAS No. 77-92-9) is the compound 2-hydroxy-1,2,3-propanetricarboxylic acid. Citric acid is authorized by the Food and Drug Administration (FDA) for use as a direct food substance (21 CFR 184.1033). It is

described as occurring as colorless, translucent crystals or as a white, granular to fine, crystalline powder. It is anhydrous or contains one molecule of water. The hydrous composition spontaneously loses water in dry air, resulting in their surface assuming a powdery appearance. It is odorless and has a strongly acidic taste. The Food Chemicals Codex (FCC) requires that the material assays at 99.5% to 100.5% (Pharmacopeia 2010). It is a naturally occurring constituent of plant and animal tissues (Pharmacopeia 2010).

Source or Origin of the Substance:

Silver dihydrogen citrate is a synthetic compound that can be produced by two general pathways: electrolytically or chemically. The production of silver dihydrogen citrate by electrolyzing silver metal results in the formation of silver dihydrogen citrate without any byproducts (Arata 2003, Arata 2006). Generally, silver dihydrogen citrate can be made by immersing silver electrodes in an aqueous electrolyte solution that contains citric acid. The aqueous electrolyte solution contains at least 5% citric acid, but usually approximately 10% citric acid (% wt./vol.). An electrolytic potential (12 V to 50 V) is then applied to the electrodes to provide a flow of silver ions. The silver ions then combine with citric acid to form silver dihydrogen citrate.

The chemical production methods use silver citrate (i.e., citric acid trisilver salt hydrate; $Ag_3C_6H_5O_7 \cdot X H_2O$; CAS No. 206986-90-5) as an intermediate substance. First, silver citrate can be produced in analytically pure form by three different processes outlined below (Djokić 2008).

(a) Sodium citrate ($Na_3C_6H_5O_7$; CAS No. 6132-04-3) in aqueous media:
$3\ AgNO_3 + Na_3C_6H_5O_7 \rightarrow Ag_3C_6H_5O_{7\,(s)} + 3\ NaNO_{3\,(aq)}$

(b) Sodium Hydroxide (NaOH; CAS No. 1310-73-2) in aqueous media:
$2\ AgNO_3 + 2\ NaOH \rightarrow Ag_2O_{\,(s)} + 2\ NaNO_{3\,(aq)} + H_2O_{\,(aq)}$
$3\ Ag_2O_{\,(s)} + 3\ H_3C_6H_5O_7 \rightarrow 2\ Ag_3C_6H_5O_{7\,(s)} + 3\ H_2O_{\,(aq)}$

(c) Ammonium Hydroxide (NH_4OH; CAS No. 1336-21-6) in aqueous media:
$AgNO_3 + 3\ NH_4OH \rightarrow [Ag(NH_3)_2]OH_{\,(aq)} + NH_4NO_{3\,(aq)} + 2\ H_2O_{\,(aq)}$
$3\ [Ag(NH_3)_2]OH_{\,(aq)} + 2\ H_3C_6H_5O_7 \rightarrow Ag_3C_6H_5O_{7\,(s)} + (NH_4)_3C_6H_5O_{7\,(aq)} + 3\ NH_4OH_{\,(aq)}$

Then, silver citrate is dissolved in concentrated aqueous solutions of citric acid forming silver dihydrogen citrate according to the following reaction (Djokić 2008):

(d) $Ag_3C_6H_5O_{7\,(s)} + n\ H_3C_6H_5O_{7\,(aq)} \rightarrow [Ag_3(C_6H_5O_7)_{n+1}]^{3n-}{}_{(aq)} + 3n\ H^+{}_{(aq)}$; where $n = 2$ or 1

The reaction is reversible, and the solution composition is dependent on the molar ratio of silver citrate and citric acid.

Properties of the Substance:

Physical and chemical properties of the substances are summarized in Table 2 and Table 3.

Table 2: Physical and Chemical Properties of Silver Dihydrogen Citrate (SCCP 2009).

Property	Value
CAS Reg. Number	N/A
ELINCS	460-890-5
Chemical formula	$AgH_2C_6H_5O_7 \cdot H_2O + H_3C_6H_5O_7 \cdot H_2O$
Molar mass	210 g/mol ($H_3C_6H_5O_7 \cdot H_2O$) and 317 g/mol ($AgH_2C_6H_5O_7 \cdot H_2O$)
Appearance	Translucent gray crystalline material (anhydrous)
Solubility, water	1 g in 1.1 mL (~ 88 g/100 mL)

Table 3: Physical and Chemical Properties of Citric Acid (Pharmacopeia 2010).

Property	Value
CAS Reg. Number	77-92-9
Chemical formula	$H_3C_6H_5O_7$
Molar mass	192.12 g/mol
Appearance	Colorless, translucent crystals/white crystalline powder
Solubility, water	1 g in 0.5 mL (~ 200 g/100 mL)
Solubility, alcohol	1 g in 2.0 mL (~ 50 g/100 mL)

Silver dihydrogen citrate is incompatible with aluminum sulfate, aluminum ammonium chloride, aluminum orthophosphate, chlorides, sequestering agents designed to remove transition metals from solution, ethylenediaminetetraacetic acid (EDTA, above 1.5%), and calcium hardness above 300 ppm. These substances are not on the National List for organic handling.

The petitioned substance is compatible with most metals including stainless steels. Ionic silver rapidly reacts with chlorides and other negatively charged ions that result in low solubility silver salts. This reaction would potentially affect stability of the product.

The petitioned substance is compatible with most metals including stainless steels. Ionic silver rapidly reacts with chlorides and other negatively charged ions that result in low solubility silver salts. This reaction would potentially affect stability of the product.

In addition to the petition substance, silver nanoparticles (Ag-NPs) are well-documented to possess high antimicrobial, antifungal, and antiviral properties and are frequently present in air/water filters, food containers, textiles, and other consumer products (Dubas 2006, Tankhiwale 2009, Duncan 2011). Several explanations have been posited to explain the antimicrobial properties of Ag-NPs (Sondi 2004, Banerjee 2010); however, the most likely explanation is the release of silver ions (Ag^+) which inhibit cell functions and can generate reactive oxygen species (Pal 2007, Hsueh 2015). The rate and extent of Ag^+ ion release from Ag-NPs is highly dependent on the physical properties of the colloidal nanoparticles, including size, shape, and capping agent (Dobias 2013). Thus, the addition of Ag-NPs to the petitioned substance could be added to augment the antimicrobial properties of SDC by increasing the concentration of Ag^+ ions. Studies would be required to determine the concentration and physical properties of Ag-NPs to be added to solutions of SDC for optimal antimicrobial efficiency. Conversely, the concentration of Ag^+ ions in solutions of the petitioned substance can be easily modulated in the synthesis and formulation steps of SDC.

Specific Uses of the Substance:

According to Food Contact Substance Notifications (FCN) 1569, 1600, and 1768, the primary uses of silver dihydrogen citrate in food processing are as a disinfectant and sanitizer for food processing equipment and food contact surfaces and as an antimicrobial agent in the processing of poultry (carcasses, parts, and organs) and fruits and vegetables. The petitioned substance is not permitted for the treatment of citrus fruit or grapes intended for winemaking.

Approved Legal Uses of the Substance:

The United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) has identified aqueous solutions of silver dihydrogen citrate as a food grade substance, approved in 21 Code of Federal Regulations (CFR) for use as an antimicrobial solution applied by spray or dip on poultry carcasses, parts, and organs [FSIS Directive 7120.1 Rev. 42; (USDA 2017)]. According to FCN 1768, aqueous solutions of silver dihydrogen citrate are permitted for use at levels up to 160 parts per million (ppm) silver dihydrogen citrate in the spray or dip applied to poultry carcasses, parts, and organs but are not permitted to be used in combination with any other silver containing antimicrobial or used in chiller baths (FDA

2017). Aqueous solutions of silver dihydrogen citrate stabilized with sodium lauryl sulfate and citric acid (FCN 1569) are permitted for use at levels up to 30 ppm silver dihydrogen citrate in the spray or dip applied to poultry carcasses, parts, and organs but are not permitted for use in combination with any other silver containing antimicrobial or used in chiller baths (FDA 2015).

Aqueous solutions of silver dihydrogen citrate stabilized with sodium lauryl sulfate and citric acid (FCN 1600) are permitted for use as an antimicrobial solution applied by spray or dip on fruits and vegetables intended for processing. Aqueous solutions of silver dihydrogen citrate are permitted for use at levels up to 30 ppm silver dihydrogen citrate in the spray or dip applied to fruits and vegetables intended for processing (FDA 2015). As a food contact surface sanitizer, aqueous solutions of SDC are not intended for use on any citrus fruit nor is it for use on grapes intended for winemaking nor for use in combination with any other silver containing antimicrobial.

The Environmental Protection Agency (EPA) has approved the petitioned substance for use as an antimicrobial, disinfectant, fungicide, and virucide, and food contact surface sanitizer (see EPA Registration Nos. 72977-1, 72977-3, 72977-4, 72977-5, and 72977-6). The substance is the subject of an exemption from tolerance for residues of silver in foods from food contact surface and processing equipment sanitizing applications (40 CFR 180.950).

Silver dihydrogen citrate has been reviewed and certified by NSF International for use as a food contact surface sanitizer and is listed on the Non-Food Compounds White Book, Category D2, "Sanitizers that do not always require a rinse."

Action of the Substance:

The silver ion is well known to be effective against a broad range of microorganisms. The antimicrobial action of silver ions is multifaceted due to strong interactions with the purine and pyrimidine DNA bases and thiol groups (i.e., -SH or sulfhydryl groups) present in enzymes and proteins within the microorganism (Izatt 1971, Bragg 1974). These interactions markedly inhibit bacterial growth (Richards 1984). Silver ions inhibit cell division, damage the cellular envelope, and create structural abnormalities that ultimately result in microbial death (Jung 2008).

The citrate counter ion also significantly contributes to the efficacy of the silver ions antimicrobial properties. Citrate ions stabilize the ionic form and antimicrobial properties of silver(+1), as they do not show a tendency to be oxidized by silver ions (Ag^{+}) which results in Ag^{o} (Djokić 2008). Citric acid is a major constituent of the Kreb's cycle, providing many precursors required for energy metabolism. It is readily recognized by bacteria as either a sole source of carbon and energy or as a co-metabolite in the presence of a food source, such as glucose. Thus, bacteria have both passive diffusional and active transport mechanisms for incorporation of citrate, which increases the permeability of the antimicrobial silver ion when it serves as a citrate cofactor (MacDonald 1958, Korithoski 2005, Pudlik 2011, Mortera 2013).

Combinations of the Substance:

Silver dihydrogen citrate is a formulation consisting of typically electrochemically generated silver ions, which form a complex with a citrate counterion and citric acid. Citric acid is used primarily as a stabilizer and pH control agent. Citric acid is also affirmed by the FDA (21 CFR 184.1033) as generally recognized as safe (GRAS) and may be used with no limitations other than good manufacturing practice. Sodium lauryl sulfate can be introduced intentionally during manufacturing to act as a solution stabilizer and is permitted for direct addition to food for human consumption by the FDA (21 CFR 172.822).

Status

Historic Use:

There are no historic uses of the petitioned substance in organic agricultural production or conventional agricultural production.

Organic Foods Production Act, USDA Final Rule:

Silver dihydrogen citrate is not listed in the Organic Foods Production Act of 1990 (OFPA) or the USDA organic regulations, 7 CFR Part 205.

International

Silver dihydrogen citrate has not been permitted or reviewed by international organizations with regards to organic standards for agricultural production.

Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

A process of making silver dihydrogen citrate is an electrolytic process (Arata 2003, Arata 2006). The process begins with preparation of an electrolyte solution, which is an aqueous solution comprised of citric acid. Water is purified by introducing it into a reverse osmosis unit and passing it through a semi-permeable membrane to remove impurities. Citric acid (anhydrous, 99% pure) is then mixed with the water. Citric acid solutions having citric acid concentrations in the range of about 1% (wt./vol.) to about the solubility limit of citric acid in water (about 60% wt./vol.) are suitable for preparing silver dihydrogen citrate solutions. A pair of silver electrodes (200 troy ounces of 999 fine silver) is immersed into the electrolyte solution at a suitable spacing to allow an ionic current to flow between them. An electrolytic potential is applied across the electrodes to create an ionic current flow between the electrodes. A suitable voltage is about 12 to about 50 volts. The resulting flow of ions through the electrolyte solution results in the production of an aqueous solution of silver dihydrogen citrate and citric acid. It is possible to recirculate the silver dihydrogen citrate solution through the electrolytic cell to increase the final concentration of silver dihydrogen citrate in the solution. The solution may then be used as prepared or stored.

Citric acid may be produced by recovery from sources such as lemon or pineapple juice. Most prevalently, citric acid is produced by mycological fermentation using *Candida spp.* (21 CFR 173.160 and 21 CFR 173.165) and recovery from *Aspergillus niger* fermentation liquor by a solvent extraction process (21 CFR 173.280).

The aforementioned chemical routes using silver citrate (i.e., citric acid trisilver salt hydrate; $Ag_3C_6H_5O_7 \bullet X H_2O$; CAS No. 206986-90-5) as an intermediate can be used to produce aqueous solutions of the petitioned substance (Djokić 2008). However, this route is not used in commercial processes to manufacture or formulate silver dihydrogen citrate.

Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.

Silver dihydrogen citrate is a synthetic material solely manufactured by a chemical process, not extracted from naturally occurring plant, animal, or mineral sources. Silver dihydrogen citrate is produced electrolytically, through the immersion of silver electrodes in an aqueous solution of citric acid. The ionic current flow between the electrodes reacts with the aqueous citric acid to produce an aqueous solution of silver dihydrogen citrate and citric acid. The petitioner does not describe how the citric acid used in manufacturing was made.

Evaluation Question #3: If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

There are no known non-synthetic or natural sources of silver dihydrogen citrate (i.e., citric acid + silver citrate). The petitioned substance is created by a chemical process. Ionic current flow between silver electrodes in a solution of citric acid results in the formation of silver dihydrogen citrate.

Evaluation Question #4: Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.

Silver dihydrogen citrate is not categorized as generally recognized as safe (GRAS). The USDA Food Safety Inspection Service has reviewed and approved silver dihydrogen citrate for use as a food contact substance in applications for treating poultry (FCN 1569 and FCN 1768) and fruits and vegetables (FCN 1600). The substance has been reviewed and approved by the EPA for use as an antimicrobial, disinfectant, fungicide, and virucide, and food contact surface sanitizer (EPA Registration Nos. 72977-1, 72977-3, 72977-4, 72977-5, and 72977-6). The substance is the subject of an exemption from tolerance for residues of silver in foods from food contact surface and processing equipment sanitizing applications (40 CFR 180.950).

Silver dihydrogen citrate has been certified by NSF International, an independent public health and safety organization, for use as a sanitizer on all surfaces and as not always requiring a rinse in and around food processing areas (NSF Registration No. 144518).

The petitioned substance has been added to the list of Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products by the USDA (FSIS Directive 7120.1 Rev. 42).

Citric acid is affirmed by the FDA (21 CFR 184.1033) as generally recognized as safe (GRAS) and may be used with no limitations other than good manufacturing practice. Sodium lauryl sulfate can be introduced intentionally during manufacturing to act as a solution stabilizer and is permitted for direct addition to food for human consumption by the FDA (21 CFR 172.822).

Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b)(4)).

The primary technical function or purpose of silver dihydrogen citrate is for use as an antimicrobial for pathogen control in organic handling. Its intended uses are for (a) direct food contact (secondary direct food additive) in food production related to poultry carcass, organs and parts and fruits and vegetables (except for citrus fruit and grapes intended for winemaking); and for (b) indirect food contact surface sanitization. There is no published information to suggest that the petitioned substance is being used primarily as a preservative.

Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).

There is no information to suggest that silver dihydrogen citrate is used to recreate or improve flavors, colors, textures, or nutritive values lost in the processing of agricultural products. The petition's request is to permit the use of SDC solutions as a processing aid in the wash and/or rinse water for direct and indirect food contact.

Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).

There is no evidence to suggest that aqueous solutions of silver dihydrogen citrate will affect the nutritional quality of the food or feed when it is used as intended. The major component, citric acid, is generally recognized as safe by the FDA (21 CFR 184.1033) and possesses no propensity for positive or adverse effects on the nutritional quality of food or feed when used as intended with the petitioned substance.

Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600 (b)(5)).

In the process for the manufacturing of the petitioned substance, no heavy metals or other contaminants in excess of FDA tolerances have been reported in the petitioned substance.

Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

The environmental impacts of the product from its intended uses have been evaluated by both FDA and EPA. FDA reviewed the environmental impacts resulting from use in poultry and produce processing, while EPA reviewed the impacts as part of the pesticide registration process. During the treatment of the process water at on-site wastewater treatment facilities, the silver component is expected to partition to sludge (94 %) and waste water (6 %) with environmental introduction concentrations of 238 nanograms (ng)per liter (L) and 1.5 ng/L, respectively. The concentration of silver in the sludge is 20,000 times lower than the level requiring disposal as toxic waste. Furthermore, the concentration of silver in waste water is approximately 200 times less than naturally occurring levels of silver in the environment in surface waters (0.2-0.3 µg/L) and is not predicted to impact the natural variation of background silver. These environmental assessments, with the FDA's Findings of No Significant Impact (FONSI) concluded that silver dihydrogen citrate, when used as intended, does not present any significant environmental impacts.

Silver is classified by the EPA as a toxic hazardous waste if detected at 5 mg/L by Toxicity Characteristic Leaching Procedure-EPA method 1311 (EPA HW No. D011; 40 CFR 261.24). According to the 1992 Reregistration Eligibility Decision for silver (EPA-738-F-93-005), the EPA determined that the available acute toxicity data indicate that silver, which persists in the aquatic environment, is highly toxic to fish, aquatic invertebrates, and estuarine organisms. The active disinfectant ingredient, silver dihydrogen citrate (SDC), has an acute LC_{50} for freshwater fish that ranges from 3.9 to 280 µg/L (ppb).

According to classification provided to the European Chemicals Agency (ECHA), silver dihydrogen citrate (i.e., citric acid and silver citrate EC List No. 460-890-5) is classified as Aquatic Chronic 1 and very toxic to aquatic life with long lasting effects (ECHA 2017).

The environmental assessments also concluded that the remaining components, citric acid (21 CFR 184.1033) and sodium lauryl sulfate (21 CFR 172.822), are of a low order of environmental toxicity and the potential impacts from use of the product in the intended applications are well within safe thresholds.

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

Antimicrobial agents are used in the production and processing of agricultural products due to their effectiveness to kill or inhibit growth of microorganisms in and on foods. This is done in an effort to

increase food safety for the consumer, as well as to increase the shelf life of food products. As part of process control activities in the food manufacturing plant, antimicrobial agents have been successfully applied, both in the product formulation stage as direct food additives designed to reduce or eliminate pathogens or spoilage organisms and as processing aids or secondary food additives during the food production process. There are no known reported positive or adverse effects on human health from use of silver dihydrogen citrate. The high-grade silver and citric acid (used electrolytically to prepare silver dihydrogen citrate) have some potential adverse effects on human health. Citric acid is an irritant of the skin, eyes, and respiratory tract; and chronic exposure to silver and silver salts is most commonly associated with a permanent grey or blue discoloration of the skin (i.e., argyria) and other organs (ATSDR 1990, White 2003, Drake 2005), but the EPA considers the effect to be a cosmetic and not a toxicologic effect and has approved pesticide registrations on the basis that using the product within safe regulatory levels prevents this effect.

In general, silver has low acute human toxicity. It has been placed in the EPA Toxicity Category III for acute oral and dermal toxicity, but it is not an eye or skin irritant (Toxicity Category IV). Silver is also not a skin sensitizer. Although repeated contact may cause argyria, this is highly unlikely to be a concern at the highly diluted levels used in food facilities. The EPA has summarized its review of the toxicity data for silver and silver compounds as part of a recent re-registration process evaluating the effects on human health from pesticidal use (EPA 1993). The EPA concluded that no new toxicity studies were required for non-zeolite silver compounds other than a repeat dose inhalation study for silver aerosols. There are also some reports that suggest exposure to high levels of silver salts and other soluble forms of silver may produce other toxic effects, including liver and kidney damage, irritation of the eyes, skin, respiratory, and intestinal tract, and changes in blood cells (Drake 2005).

The safety of the petitioned substance for use in processing of poultry and produce for human consumption has been evaluated by FDA through FCNs 1768, 1569, and 1600. The product's use in food contact surface sanitization has been evaluated by EPA through the pesticide registration process and through evaluation for the exemption from the requirement of a tolerance of silver in the form of silver dihydrogen citrate. Exposures to silver from the intended use of SDC presents no concern for the safety of human health or the environment, as established by FDA through its review of FCNs 1768, 1569, and 1600. The effective FCNs represent FDA's conclusion that the intended uses of SDC are safe for human health, while FDA's environmental reviews concluded that allowing these FCNs to become effective does not significantly affect the quality of the human environment. A safety assessment for citric acid is not included because FDA has affirmed the substance as generally recognized as safe for direct use in human food under 21 CFR 184.1033.

Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

When processing agricultural products, biocides like SDC are paramount in ensuring the safety of consumer. There is no reported literature describing other antimicrobial practices that are available for direct and indirect food contact sanitization in the processing of agricultural products other than the application of biocide solutions. There are other antimicrobial products available for use in organic agricultural processing and sanitization of food contact surfaces: acidified sodium chlorite ($NaClO_2$), chlorine, ozone, and peroxy derivatives (7 CFR 205.605). (See response to Evaluation Question #12.)

Evaluation Question #12: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

Despite information available and government programs efforts to reduce the incidence of *Salmonella*, it continues to be a concern for the meat and poultry industries. Organic acids are excellent antimicrobials against bacteria including *Salmonella* (Mani-López 2012). Organic acids offer several advantages as

antimicrobials because they are GRAS, have no limited acceptable daily intake, are low-cost, easy to manipulate, and effect minor sensory changes on the product. For example, an application of 2% acetic acid reduced the incidence of *Salmonella* on pork cheek meat in addition to significantly reducing aerobic plate and coliform counts (Frederick 1994) More than one treatment was found to sometimes help on the bacterial reduction and produces lesser effects on food quality. Also, poultry scald water containing 0.1% acetic acid at 52 C decreased levels of *S.* Typhimurium and *Campylobacter jejuni* (Okrend 1986). However, it is important to use these acids according to good manufacture practices to avoid the development of *Salmonella* strains resistant to acidic conditions.

The effectiveness of natural organic acids in controlling *L. monocytogenes* has been investigated (Campos 2011). The results of these studies were promising; however, in many instances, combinations of additives or preservative treatments worked best because the efficacy of the antimicrobials can be influenced by the chemical composition and the physical conditions of the various foods. The organic acids include acetic, lactic, malic and citric acid. The antimicrobial action of organic acids is based mainly on their ability to reduce the pH of the aqueous phase of the food. Inthe cases of weak lipophilic organic acids such as acetic or sorbic acid, the undissociated form is also able to penetrate the cell membrane. The latter exerts its inhibitory action by dissociating and acidifying the cytoplasm. Additionally, other mechanisms take place such as inhibition of enzymes, nutrient transport and overall reduction of metabolic activity. Due to their higher solubility, salts (such as sodium or potassium lactates) are more commonly used than the organic acids. The studies showed that a combination of different acids or salts at various stages of processing worked best. Therefore, while the study did look at the use of some acids that are already on the National List of Allowed and Prohibited Materials (7 CFR 205.605), many combinations included acids or salts not on the National List, such as sodium diacetate, acetic acid, benzoic acid, propionic acid, and lauricarginate (Campos 2011).

Lactic acid, produced from fermentation, is currently listed on the National List (7 CFR 205.605(a)) as a non-synthetic material with no restrictions on use and is established as GRAS for using lactic acid as an antimicrobial agent as defined in 21 CFR 170.3(o)(2). The use of lactic acid as an antimicrobial agent is limited to meat products. Lactic acid has been found to be more effective than chlorine treatments of raw meat in poultry processing facilities (Killinger 2010). The acidic nature imparts a mellow and lasting sourness to many products including confectionery.

However, on the NOP National List, there are some synthetic substances allowed, as disinfectants and sanitizers for using on food contact surfaces. These are listed under the 7 CFR 205.605 which delineates the nonagricultural (nonorganic) substances that may be used as ingredients or on processed products that are listed as “organic” or as “made with organic [ingredients or food groups].”

For example, peracetic acid can be substituted for SDC (7 CFR 205.605(b)). Peracetic acid is a mixture of acetic acid and hydrogen peroxide. It is a very strong oxidizing agent and has a strong pungent acetic acid odor. The primary mode of action is oxidation, which differs from SDC. In addition, peracetic acid is considered environmentally safe. Acidified sodium chlorite (using citric acid) and chlorine dioxide, which have the same mode of action as peracetic acid, can also substitute for SDC. (See the NOP petitioned substances database.)

However, bacterial resistance to traditional agricultural biocides is of growing concern (SCENIHR 2010). A number of gram-positive, vegetative bacteria have been isolated from equipment that used chlorine dioxide for high-level disinfection, and several strains, *Bacillus subtilis* and *Micrococcus luteus*, showed stable high-level resistance to the standard use concentration of chlorine dioxide (Martin 2008). The *Bacillus* isolate was also cross-resistant to hydrogen peroxide (7.5%) (Martin 2008). Such reports of bacterial resistance have not been reported for the petitioned substance.

The United States Food and Drug Administration (FDA) regulations allow a number of uses for ethanol in food preparation/storage for humans and animals. For humans, FDA considers ethanol to be "Generally Recognized As Safe" (GRAS) when added directly to human food (21 CFR 184.1293). Ethanol is an approved synthetic substance on the National List for organic livestock production as a disinfectant and sanitizer only (7 CFR 205.603). In addition, ethanol is an approved synthetic substance on the National List for organic crop production when used as an algicide, disinfectant, and sanitizer, including the cleaning of irrigation systems (7 CFR 205.601). Alcohols, including ethanol and isopropanol, are capable of providing rapid broad-spectrum antimicrobial activity against vegetative bacteria, viruses and fungi, but lack activity against bacterial spores (McDonnell 1999). The antimicrobial action of ethanol is due to rapid denaturation of proteins. A study found that a 7% ethanol solution prevented the growth of four common foodborne microorganisms: Listeria monocytogenes, Salmonella typhimurium, Staphylococcus aureus and Escherichia coli O157:H7 (Ahn 1999), however, the CDC recommends against the use of ethanol or isopropanol as the principal sterilizing agent because these alcohols are insufficiently sporicidal (i.e., spore killing) and cannot penetrate protein-rich materials (CDC 2008). Other shortcomings of ethanol are that it can damage rubber and plastic tubing after prolonged use, is highly flammable and must be stored in cool, well-ventilated areas, and evaporates quickly due to its high volatility, which makes extended exposure time difficult to achieve (CDC 2008)

There are no literature reports to our knowledge that directly compare the efficacy of SDC to that of other organically allowed synthetic substances (e.g., chlorine dioxide, acidified sodium chlorite, ozone, etc.). One important distinction of SDC from these common synthetic substances for disinfection of food and food contact surfaces is the action of the substance. Most of the common synthetic substances are strong oxidizers; thus their antimicrobial efficacy generally increase with oxidation potential (i.e., chlorine dioxide < acidified sodium chlorite < ozone). The efficacy of SDC arises from it proceeding from a different mechanism of action, interference with cellular processes. In a closely related study, the antimicrobial effects of chlorine (Cl_2), an oxidizer, and Ag^+ ions on bacterial biofilms were compared (Kim 2008). The antimicrobial activities on biofilm cells were investigated by three methods, each of which used a different analytical principle for the determination of antimicrobial activity. The study found that the resistance of the biofilm cells to the oxidant, chlorine, was increased almost 250 times compared with the resistance to the Ag^+ ion. Thus, due to the different mode of action, Ag^+ ions and SDC, in particular, represent a viable alternative for eliminating pathogenic bacteria that demonstrate resistance to common oxidizing antibacterial agents.

<u>Evaluation Information #13:</u> Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b) (1)).

While agricultural and/or natural antimicrobials may be effective in one way, they may be ineffective in another and do not possess broad spectrum antimicrobial properties (Sebranek 2007). This stresses the necessity of further research in order to ensure that the food safety of these materials is properly assessed. While current research suggests that natural plant extracts can be effective in controlling pathogens in meat products, the most favorable results tend to result from multiple-barrier food preservation systems, which use combinations of agricultural and/or natural antimicrobials and sodium or potassium lactate (or other synthetic antimicrobial ingredients). However, decreasing the shelf life of a product to accommodate the strict use of natural antimicrobials is another option. A survey of organic agricultural antimicrobials is discussed below.

The USDA Organic Regulations do not permit the addition of nitrite to organic processed meat. Alternative methods like the use of celery powder, which is listed on at 7 CFR Part 205.606 and allowed for use in products labeled as "Organic" only when an organic form is not commercially available, are commonly used in meat products. Trials studying natural antimicrobials for the inhibition of *Listeria monocytogenes* on naturally cured frankfurters have been conducted (Xi 2013). Using celery powder containing 12,000 ppm of nitrite, the concentration of nitrite (when the celery powder was used at 0.4% of the frankfurter formulation) resulted in 48 ppm of nitrite added to the frankfurter mixture. In a

conventional curing process, 156 ppm of nitrite is added. The research found that the celery powder achieved the expected color, flavor and other properties of cured meats, but it resulted in lower nitrite levels than occurred with the use of synthetic preservatives.

In the same study by Iowa State University in 2013, powdered concentrates from cranberries, cherries, limes and a blend of cherry, lime and vinegar were evaluated alone and in various combinations for antimicrobial impact on the growth of *L. monocytogenes* in naturally cured frankfurters (Xi 2013). The results showed that cranberry powder at 3% of the formulation, combined with celery powder, achieved inhibition of *L. monocytogenes* following the inoculation of naturally cured frankfurters that was equivalent to that of conventionally cured frankfurters during 49 days of refrigerated storage. Cranberry powder at 1% and 2% in combination with other natural antimicrobials inhibited growth for up to 35 days, while the naturally cured frankfurters without additional antimicrobial ingredients showed growth after 28 days. However, quality assessment of the products showed that 3% cranberry powder was detrimental to the color and sensory and textural attributes of the frankfurters, possibly due to the acidic nature of the cranberry concentrate. It was concluded that, while cranberry concentrate has potential as a natural antimicrobial, it is necessary to develop a means of compensating for the acidic nature of this ingredient to achieve practical applications in organic cured meat products. In addition, for the meat to maintain its organic status, the cranberry powder would also need to be a certified organic ingredient and, per the requirements of 7 CFR 205.606, attempts would need to be made to source organic celery powder.

The effectiveness of essential oils in controlling L. monocytogenes has also been investigated (Campos 2011). The results of the study were promising; however, in many instances, combinations of additives or preservative treatments worked best because the efficacy of the antimicrobials can be influenced by the chemical composition and the physical conditions of various foods. Essential oils (EOs) are oily liquid mixes of volatile and complex compounds that are extracted from different parts of aromatic plants. They are synthesized by plants as secondary metabolites and can be obtained mainly by steam distillation or super critical fluid extraction. Essential oils can contain 20-60 components, depending on the material they come from and the extraction method used. Terpenes and terpenoids make up the constitute majority of the components with the remainder consisting of aromatic and aliphatic compounds of low molecular weight.

Their activity against *Listeria* growth in laboratory media was highly variable (Campos 2011). EOs of bay, coriander, cinnamon, clove, licorice, nutmeg, pepper, oregano, winter savory, spruce and thyme showed the highest inhibitory activity. The effectiveness of oils of basil, lemon balm, marjoram, mastic tree, rosemary and sage were lower than those mentioned above, whereas Listeria showed high resistance to EOs of aniseed, caraway, fennel, garlic, ginger, onion and parsley.

According to the research, the antimicrobial activity of EOs is largely dependent on their composition; however, the mechanism of antimicrobial action of EOs is not well understood. Inhibitory actions are mostly related to the identity of the majority terpenes and terpenoid components, but the minor components have a strong influence on the effectiveness of their antimicrobial action. The main components often consist of: carvacrol, thymol, linalool, eugenol, trans-cinnamaldehyde, p-cymene, 1,8-cineole (eucalyptol) and γ-terpinene, and the research suggests that several components of EOs are involved in the fixation on cell walls and cellular distribution. It's reported that EO components may degrade the cell wall, damage the cytoplasmic membrane and proteins of the membrane, leak vital intracellular compounds, coagulate cytoplasm and deplete the proton motive force, and that EOs also interact with one another, potentially leading to synergistic antimicrobial effects between various oils (Campos 2011). For example, the growth of *L. monocytogenes* was suppressed in laboratory media more when a combination of oils was used (oils of oregano and rosemary; oils of basil, rosemary or sage; and oils of rosemary and licorice) than when these oils were used alone.

Further results in various samples suggested that EOs have lower activity in foods with high fat content. This may be due to: (i) EO dissolution in the lipid fraction of the food, decreasing the concentration in the aqueous phase, together with antimicrobial action; (ii) the reduced water content in foods, particularly in fatty foods, in relation to culture media, which may slow down the movement of the preservative to the active site in the microbial cell; and (iii) the presence of fat in the food which may produce a protective layer around the bacteria (Campos 2011).

Storage temperature, pH, physical structure of food, fat, protein, sugar content, and sensory properties all need to be considered when deciding whether EOs will be affective for controlling pathogens. It was reported that chicken frankfurters treated with 2%v/w of clove oil were unacceptable to the consumer, whereas samples with 1% were accepted. The latter level had effective antilisterial activity in the food. It was found that combining EOs would allow the use of lower levels to reduce *Listeria* growth, minimizing the unacceptable sensory changes in the food. Indirect uses of EOs, for example in water to wash vegetables similar to the use of chlorine, or in the impregnation of porous surface of wood in cheese ripening to improve sanitary safety, are also being considered.

Report Authorship

The following individuals were involved in research, data collection, writing, and editing of this report:

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All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

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665

Overview: The National Organic Program (NOP) and National Organic Standards Board (NOSB) colllaborate to develop and maintain a work agenda, or project list, in support of NOP's mission. To inform the public of the NOSB's work agenda and upcoming plans, this document provides:
- List of projects to be discussed/voted on at the next NOSB meeting
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- Projects on hold (projects the NOSB is not currently actively working on)

NOSB: Next Meeting Work Agenda

Next Meeting:	Spring 2018				
Location:	Tucson, AZ				
Public comment:	4/17/18, 4/19/18, 4/25/18-4/26/18				
Blue - Anticipated to be discussed at next board meeting but not voted on					
Green - Anticipated to be voted on and decided at next board meeting					
Project	**Type**	**Origin**	**Priority**	**Subcommittee**	**Next Meeting Action**
Polyoxin D zinc salt	Material	Petition	1	Crops	Spring 2018
Sulfur (as a molluscicide)	Material	Petition	1	Crops	Spring 2018
Alcohols: ethanol, isopropanol	Material	Sunset	1	Crops	Spring 2018
Sodium carbonate peroxyhydrate	Material	Sunset	1	Crops	Spring 2018
Newspaper or other recycled paper	Material	Sunset	1	Crops	Spring 2018
Plastic mulch and covers	Material	Sunset	1	Crops	Spring 2018
Aqueous potassium silicate	Material	Sunset	1	Crops	Spring 2018
Elemental sulfur	Material	Sunset	1	Crops	Spring 2018
Lime sulfur	Material	Sunset	1	Crops	Spring 2018
Sucrose octanoate esters	Material	Sunset	1	Crops	Spring 2018
Hydrated lime	Material	Sunset	1	Crops	Spring 2018
Liquid fish products	Material	Sunset	1	Crops	Spring 2018
Sulfurous acid	Material	Sunset	1	Crops	Spring 2018
Ethylene	Material	Sunset	1	Crops	Spring 2018

Blue - Anticipated to be discussed at next board meeting but not voted on					
Green - Anticipated to be voted on and decided at next board meeting					
Project	**Type**	**Origin**	**Priority**	**Subcommittee**	**Next Meeting Action**
Microcrystalline cheesewax	Material	Sunset	1	Crops	Spring 2018
Potassium chloride	Material	Sunset	1	Crops	Spring 2018
Sodium dodecylbenzene sulfonate (SDBS)	Material	Petition	1	Handling	Spring 2018
Japones pepper	Material	Petition	1	Handling	Spring 2018
Ethiopian pepper	Material	Petition	1	Handling	Spring 2018
Calcium carbonate	Material	Sunset	1	Handling	Spring 2018
Flavors	Material	Sunset	1	Handling	Spring 2018
Gellan gum	Material	Sunset	1	Handling	Spring 2018
Oxygen	Material	Sunset	1	Handling	Spring 2018
Potassium chloride	Material	Sunset	1	Handling	Spring 2018
Alginates	Material	Sunset	1	Handling	Spring 2018
Calcium hydroxide	Material	Sunset	1	Handling	Spring 2018
Ethylene	Material	Sunset	1	Handling	Spring 2018
Glycerides: mono and di	Material	Sunset	1	Handling	Spring 2018
Magnesium stearate	Material	Sunset	1	Handling	Spring 2018
Phosphoric acid	Material	Sunset	1	Handling	Spring 2018
Potassium carbonate	Material	Sunset	1	Handling	Spring 2018
Sulfur dioxide	Material	Sunset	1	Handling	Spring 2018
Xanthan gum	Material	Sunset	1	Handling	Spring 2018
Fructooligosaccharides (FOS)	Material	Sunset	1	Handling	Spring 2018
Gums: Arabic, Carob bean, Guar, Locust bean	Material	Sunset	1	Handling	Spring 2018
Lecithin - de-oiled	Material	Sunset	1	Handling	Spring 2018
Tragacanth gum	Material	Sunset	1	Handling	Spring 2018
Glycolic acid	Material	Petition	1	Livestock	Spring 2018
Alcohols: ethanol, isopropanol	Material	Sunset	1	Livestock	Spring 2018
Aspirin	Material	Sunset	1	Livestock	Spring 2018
Biologics, vaccines	Material	Sunset	1	Livestock	Spring 2018
Electrolytes	Material	Sunset	1	Livestock	Spring 2018
Glycerine	Material	Sunset	1	Livestock	Spring 2018

Blue - Anticipated to be discussed at next board meeting but not voted on					
Green - Anticipated to be voted on and decided at next board meeting					
Project	**Type**	**Origin**	**Priority**	**Subcommittee**	**Next Meeting Action**
Phosphoric acid	Material	Sunset	1	Livestock	Spring 2018
Lime, hydrated	Material	Sunset	1	Livestock	Spring 2018
Mineral oil	Material	Sunset	1	Livestock	Spring 2018
Sucrose octanoate esters	Material	Sunset	1	Livestock	Spring 2018
Organic Imports Integrity	Practice	NOP	2	Certification, Accreditation, and Compliance	Spring 2018
Inspector qualifications	Practice	NOSB	3	Certification, Accreditation, and Compliance	Spring 2018
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production	Practice	NOSB	3	Certification, Accreditation, and Compliance	Spring 2018
Magnesium chloride reclassification	Material	NOSB	3	Handling	Spring 2018
Defining emergency treatment for parasiticides	Material	NOSB	3	Livestock	Spring 2018
Protecting the Genetic Integrity of Seed Grown on Organic Land	Material	NOSB	3	Materials	Spring 2018
Priority (As defined by the PPM)*					
1 - Sunset items are required to be reviewed at least every 5 years					
1 - Petition for a material that has been found sufficient					
2 - Request to the NOSB from the NOP					
3 - Approved work agenda request (NOSB-Initiated)					
4 - Other work Items					

Overview: The National Organic Program (NOP) and National Organic Standards Board (NOSB) colllaborate to develop and maintain a work agenda, or project list, in support of NOP's mission. To inform the public of the NOSB's work agenda and upcoming plans, this document provides:
- List of projects to be discussed/voted on at the next NOSB meeting
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Also see:	Next Meeting Work Agenda tab for anticipated items at Next work Agenda	Yellow - Waiting on further information, timing of next steps maybe unclear
	Work Agenda Request tab for work agenda items under review	Blue - Anticipated to be discussed at next board meeting but not decided
	HOLD pending Action tab for work agenda items on hold	Green - Anticipated to be voted on and decided at next board meeting
	Definitions tab explanation of terms	White - In process

Started	Status	Item	NL Section	Type	Requestor	Priority	Subcommittee	Last Action	Last Action Date	Next Action	Next Action Date	Expected Full NOSB Consideration	Next Meeting Action	Notes
6/16/2016	Active	Polyoxin D zinc salt	§205.601	Material	Petition	1	Crops	Subcommittee voted on Proposal	12/19/2017	Public Input/Full NOSB Vote	2/20/2018	Spring 2018	Vote	
7/6/2016	Active	Allyl isothiocyanate (AITC)	§205.601	Material	Petition	1	Crops	WAITING - waiting on Technical Review	10/4/2016	Technical Review Sufficiency Determination	4/1/2018	Fall 2018	Not on Agenda	TR expected in March
9/9/2016	Active	Sodium citrate	§205.601	Material	Petition	1	Crops	Draft Proposal	2/6/2018	Subcommittee vote on Proposal	TBD	Fall 2018	Not on Agenda	
7/27/2016	Active	Natamycin	§205.601	Material	Petition	1	Crops	Draft Proposal	12/5/2017	Subcommittee vote on Proposal	TBD	Fall 2018	Not on Agenda	
6/8/2017	Active	Sulfur (as a molluscicide)	§205.601	Material	Petition	1	Crops	Subcommittee voted on Proposal	1/16/2018	Public Input/Full NOSB Vote	4/27/2018	Spring 2018	Vote	
10/25/2017	Active	Ammonium Citrate	§205.601	Material	Petition	1	Crops	WAITING - waiting on Technical Review	11/21/2017	Technical Review Sufficiency Determination	TBD	TBD	Not on Agenda	TR Requested of NOP
10/25/2017	Active	Ammonium Glycinate	§205.601	Material	Petition	1	Crops	WAITING - waiting on Technical Review	11/21/2017	Technical Review Sufficiency Determination	TBD	TBD	Not on Agenda	TR Requested of NOP
1/20/2017	Active	Calcium Acetate	§205.601	Material	Petition	1	Crops	WAITING - waiting on Technical Review	2/6/2018	Technical Review Sufficiency Determination	TBD	TBD	Not on Agenda	TR Requested of NOP
11/2/2017	Active	Alcohols: ethanol, isopropanol	§205.601(a)(1)(i), §205.601(a)(1)(ii)	Material	Sunset	1	Crops	Subcommittee Finalize Preliminary Sunset Review	2/6/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Sodium carbonate peroxyhydrate	§205.601(a)	Material	Sunset	1	Crops	Subcommittee Finalize Preliminary Sunset Review	12/5/2017	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	

Started	Status	Item	NL Section	Type	Requestor	Priority	Subcommittee	Last Action	Last Action Date	Next Action	Next Action Date	Expected Full NOSB Consideration	Next Meeting Action	Notes
11/2/2017	Active	Newspaper or other recycled paper	§205.601(b) and (c)	Material	Sunset	1	Crops	Subcommittee Finalize Preliminary Sunset Review	12/5/2017	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Plastic mulch and covers	§205.601(b)	Material	Sunset	1	Crops	Subcommittee Finalize Preliminary Sunset Review	1/2/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Aqueous potassium silicate	§205.601(e), §205.601(i)	Material	Sunset	1	Crops	Subcommittee Finalize Preliminary Sunset Review	2/6/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Elemental sulfur	§205.601(e)(5), §205.601(i)(10), 205.601(j)(2)	Material	Sunset	1	Crops	Subcommittee Finalize Preliminary Sunset Review	2/20/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Lime sulfur	§205.601(e)(6), §205.601(i)(6)	Material	Sunset	1	Crops	Subcommittee Finalize Preliminary Sunset Review	12/19/2017	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Sucrose octanoate esters	§205.601(e)(10)	Material	Sunset	1	Crops	Subcommittee Finalize Preliminary Sunset Review	12/19/2017	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Hydrated lime	§205.601(i)(4)	Material	Sunset	1	Crops	Subcommittee Finalize Preliminary Sunset Review	1/2/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Liquid fish products	§205.601(j)	Material	Sunset	1	Crops	Subcommittee Finalize Preliminary Sunset Review	1/16/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Sulfurous acid	§205.601(j)	Material	Sunset	1	Crops	Subcommittee Finalize Preliminary Sunset Review	12/19/2017	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Ethylene	§205.601(k)	Material	Sunset	1	Crops	Subcommittee Finalize Preliminary Sunset Review	12/19/2017	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Microcrystalline cheesewax	§205.601(o)	Material	Sunset	1	Crops	Subcommittee Finalize Preliminary Sunset Review	2/20/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Potassium chloride	§205.602(e)	Material	Sunset	1	Crops	Subcommittee Finalize Preliminary Sunset Review	1/16/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
1/2/2015	Active	Sodium dodecylbenzene sulfonate (SDBS)	§205.605(b)	Material	Petition	1	Handling	Subcommittee voted on Proposal	1/16/2018	Public Input/Full NOSB Vote	4/27/2018	Spring 2018	Vote	

Started	Status	Item	NL Section	Type	Requestor	Priority	Subcommittee	Last Action	Last Action Date	Next Action	Next Action Date	Expected Full NOSB Consideration	Next Meeting Action	Notes
12/2/2015	Active	Sodium chlorite for the generation of chlorine dioxide gas	§205.605(b)	Material	Petition	1	Handling	Subcommittee discussion	1/9/2018	Technical Review Sufficiency Determination	3/6/2018	Fall 2018	Not on Agenda	
1/24/2017	Active	Silver dihydrogen citrate	§205.605(b)	Material	Petition	1	Handling	WAITING - waiting on Technical Review	12/5/2017	Technical Review Sufficiency Determination	TBD	TBD	Not on Agenda	
2/9/2017	Active	Japones pepper	§205.606	Material	Petition	1	Handling	Draft Proposal	11/7/2017	Subcommittee vote on Proposal	2/20/2018	Fall 2018	Vote	
2/9/2017	Active	Ethiopian pepper	§205.606	Material	Petition	1	Handling	Draft Proposal	11/7/2017	Subcommittee vote on Proposal	2/20/2018	Fall 2018	Vote	
2/15/2017	Active	Tamarind seed gum	§205.606	Material	Petition	1	Handling	WAITING - waiting on Technical Review	10/3/2017	Technical Review Sufficiency Determination	4/1/2018	Fall 2018	Not on Agenda	TR expected in March
11/2/2017	Active	Calcium carbonate	§205.605(a)	Material	Sunset	1	Handling	Subcommittee Finalize Preliminary Sunset Review	2/20/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Flavors	§205.605(a)	Material	Sunset	1	Handling	Subcommittee Finalize Preliminary Sunset Review	1/2/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Gellan gum	§205.605(a)	Material	Sunset	1	Handling	Subcommittee Finalize Preliminary Sunset Review	2/20/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Oxygen	§205.605(a)	Material	Sunset	1	Handling	Subcommittee Finalize Preliminary Sunset Review	12/5/2017	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Potassium chloride	§205.605(a)	Material	Sunset	1	Handling	Subcommittee Finalize Preliminary Sunset Review	12/5/2017	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Alginates	205.605(b)	Material	Sunset	1	Handling	Subcommittee Finalize Preliminary Sunset Review	12/19/2017	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Calcium hydroxide	205.605(b)	Material	Sunset	1	Handling	Subcommittee Finalize Preliminary Sunset Review	12/5/2017	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Ethylene	205.605(b)	Material	Sunset	1	Handling	Subcommittee Finalize Preliminary Sunset Review	1/2/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Glycerides: mono and di	205.605(b)	Material	Sunset	1	Handling	Subcommittee Finalize Preliminary Sunset Review	2/5/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	

Started	Status	Item	NL Section	Type	Requestor	Priority	Subcommittee	Last Action	Last Action Date	Next Action	Next Action Date	Expected Full NOSB Consideration	Next Meeting Action	Notes
11/2/2017	Active	Magnesium stearate	205.605(b)	Material	Sunset	1	Handling	Subcommittee Finalize Preliminary Sunset Review	2/20/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Phosphoric acid	205.605(b)	Material	Sunset	1	Handling	Subcommittee Finalize Preliminary Sunset Review	12/5/2017	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Potassium carbonate	205.605(b)	Material	Sunset	1	Handling	Subcommittee Finalize Preliminary Sunset Review	2/20/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Sulfur dioxide	205.605(b)	Material	Sunset	1	Handling	Subcommittee Finalize Preliminary Sunset Review	12/19/2017	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Xanthan gum	205.605(b)	Material	Sunset	1	Handling	Subcommittee Finalize Preliminary Sunset Review	2/20/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Fructooligosaccharides (FOS)	§205.606	Material	Sunset	1	Handling	Subcommittee Finalize Preliminary Sunset Review	1/2/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Gums: Arabic, Carob bean, Guar, Locust bean	§205.606	Material	Sunset	1	Handling	Subcommittee Finalize Preliminary Sunset Review	2/20/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Lecithin - de-oiled	§205.606	Material	Sunset	1	Handling	Subcommittee Finalize Preliminary Sunset Review	1/16/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Tragacanth gum	§205.606	Material	Sunset	1	Handling	Subcommittee Finalize Preliminary Sunset Review	2/20/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
6/6/2015	Active	Glycolic acid	§205.603	Material	Petition	1	Livestock	Subcommittee vote on Proposal	12/19/2017	Public Input/Full NOSB Vote	2/20/2018	Spring 2018	Vote	
11/2/2017	Active	Alcohols: ethanol, isopropanol	§205.603	Material	Sunset	1	Livestock	Subcommittee Finalize Preliminary Sunset Review	12/5/2017	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Aspirin	§205.603	Material	Sunset	1	Livestock	Subcommittee Finalize Preliminary Sunset Review	12/19/2017	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Biologics, vaccines	§205.603	Material	Sunset	1	Livestock	Subcommittee Finalize Preliminary Sunset Review	12/19/2017	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	

Started	Status	Item	NL Section	Type	Requestor	Priority	Subcommittee	Last Action	Last Action Date	Next Action	Next Action Date	Expected Full NOSB Consideration	Next Meeting Action	Notes
11/2/2017	Active	Electrolytes	§205.603	Material	Sunset	1	Livestock	Subcommittee Finalize Preliminary Sunset Review	12/19/2017	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Glycerine	§205.603	Material	Sunset	1	Livestock	Subcommittee Finalize Preliminary Sunset Review	2/6/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Phosphoric acid	§205.603	Material	Sunset	1	Livestock	Subcommittee Finalize Preliminary Sunset Review	1/16/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Lime, hydrated	§205.603	Material	Sunset	1	Livestock	Subcommittee Finalize Preliminary Sunset Review	2/6/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Mineral oil	§205.603	Material	Sunset	1	Livestock	Subcommittee Finalize Preliminary Sunset Review	2/6/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
11/2/2017	Active	Sucrose octanoate esters	§205.603	Material	Sunset	1	Livestock	Subcommittee Finalize Preliminary Sunset Review	2/6/2018	Public Input/Full NOSB Discusssion	4/27/2018	Spring 2018	Discussion	
8/10/2017	Active	Imports		Practice	NOP	2	Certification, Accreditation, and Compliance	Draft discussion document	2/13/2018	Subcommittee finalize discussion document	2/27/2018	Spring 2018	Discussion	
1/12/2014	Active	Packaging substances used in organic food handling - including BPA		Material	NOP	2	Handling	Technical Review Sufficiency Determination	8/1/2017	Subcommittee finalize discussion document	TBD	Fall 2018	Not on Agenda	
4/21/2016	Active	Inspector qualifications		Practice	NOSB	3	Certification, Accreditation, and Compliance	Subcommittee voted on Proposal	2/13/2018	Public Input/Full NOSB Vote	4/27/2018	Spring 2018	Vote	
7/15/2016	Active	Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production proposal		Practice	NOSB	3	Certification, Accreditation, and Compliance	Draft Proposal	1/23/2018	Subcommittee finalize proposal	2/27/2018	Spring 2018	Vote	
8/2/2016	Active	Biodegradable biobased mulch	205.601	Material	NOSB	3	Crops	Public Input/Full NOSB Review	8/2/2016	Subcommittee Discussion	TBD	TBD	Not on Agenda	
1/12/2016	Active	Marine materials (marine algae and extracts) on the National List- Crops	205.601	Material	NOSB	3	Crops	Subcommittee discussion	12/5/2017	Draft Proposal	2/20/2018	Fall 2018	Not on Agenda	
1/12/2016	Active	Nutrient Vitamins and Minerals - annotation change	205.605(b)	Material	NOSB	3	Handling	Subcommittee Discussion	Fall 2015	None	TBD	TBD	Not on Agenda	

Started	Status	Item	NL Section	Type	Requestor	Priority	Subcommittee	Last Action	Last Action Date	Next Action	Next Action Date	Expected Full NOSB Consideration	Next Meeting Action	Notes
1/12/2016	Active	Marine materials (marine algae and extracts) on the National List - Handling	205.605a, 205.605b, and 205.606	Material	NOSB	3	Handling	Subcommittee Discussion	11/2/2017	Draft Proposal	TBD	Fall 2018	Not on Agenda	
1/12/2016	Active	Magnesium chloride reclassification	205.605(b)	Material	NOSB	3	Handling	Subcommittee voted on Proposal	2/6/2018	Public Input/Full NOSB Vote	4/27/2018	Spring 2018	Vote	
7/15/2016	Active	Defining emergency treatment for parasiticides		Material	NOSB	3	Livestock	Subcommittee voted on Proposal	1/16/2018	Public Input/Full NOSB Vote	2/20/2018	Spring 2018	Vote	
12/10/2013	Active	Protecting the Genetic Integrity of Seed Grown on Organic Land		Material	NOSB	3	Materials	Subcommittee Discussion	1/30/2018	Draft discussion document	2/27/2018	Spring 2018	Discussion	
11/19/2013	Active	Contamination issues of farm inputs		Material	NOSB	3	Materials	Subcommittee Discussion	2/15/2018	Draft discussion document	TBD	TBD	Not on Agenda	
12/10/2013	Active	Excluded Methods Terminology		Material	NOSB	3	Materials	Subcommittee Discussion	2/15/2018	Draft discussion document	TBD	TBD	Not on Agenda	
Ongoing	Ongoing	Current Research Priorities		Other	Other	4	Materials	Subcommittee Discussion	TBD	Draft Proposal	TBD	Fall 2018	Not on Agenda	
Ongoing	Ongoing	Review of policy & procedure manual (PPM)		Other	Other	4	Policy Development	None	TBD	WAITING - accumulating parking lot changes	TBD	TBD	Not on Agenda	

Priority (As defined by the PPM)*

1 - Sunset items are required to be reviewed at least every 5 years
1 - Petition for a material that has been found sufficient
2 - Request to the NOSB from the NOP
3 - Approved work agenda request (NOSB-Initiated)
4 - Other work Items

Overview: The National Organic Program (NOP) and National Organic Standards Board (NOSB) colllaborate to develop and maintain a work agenda, or project list, in support of NOP's mission. To inform the public of the NOSB's work agenda and

Work agendas under review by NOP or petitions under review by NOSB - no work should be done other than suffiency or requesting/scoping

Status	Item	NL Section	Type	Requestor	Priority	Request/Referred Subcommittee	Requested by Executive Subcommittee	Last Action	Last Action Date	Next Action	Next Action Date	Next Meeting Action	Notes
Requested	Sanitizers		Material	NOSB	3	Materials	yes	Approved by Executive, forwarded to NOP	10/13/2017	HOLD - Pending NOP review for scoping	TBD	Not on Agenda	
Closed	Thymol	§205.603	Material	Petition	1	Livestock	N/A	CLOSED - Petition determined insufficient	12/8/2017	None	Closed	Not on Agenda	

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- Projects on hold (projects the NOSB is not currently actively working on)

Action being taken by USDA or another agency; NOSB and Subcommittee work should hold pending action by agency.

Started	Status	Item	Type	Requestor	Priority	Subcommittee	Last Action	Last Action Date	Next Action	Next Action Date	Expected Full NOSB Consideration	Next Meeting Action	Notes
5/9/2016	Hold Pending Action	Manure treatments	Material	NOP	2	Crops	Public Input/Full NOSB Review	11/2/2017	HOLD	TBD	TBD	Not on Agenda	Hold pending FDA action
7/1/2014	Hold Pending Action	Prohibition of NPEs in inerts - annotation change/ EPA List 4 Inerts annotation change	Material	NOSB	3	Crops	HOLD - pending IWG/EPA/Safer Choice program	Fall 2015	HOLD	TBD	TBD	Not on Agenda	Hold pending USDA/EPA Action
9/6/2016	Hold Pending Action	Field and greenhouse container production	Practice	NOSB	3	Crops	Subcommittee discussion	2/6/2016	HOLD	TBD	TBD	Not on Agenda	On hold pending NOP review of Fall 2017 production systems recommendation

Priority (As defined by the PPM)*

1 - Sunset items are required to be reviewed at least every 5 years
1 - Petition for a material that has been found sufficient
2 - Request to the NOSB from the NOP
3 - Approved work agenda request (NOSB-Initiated)
4 - Other work Items

Overview: The National Organic Program (NOP) and National Organic Standards Board (NOSB) colllaborate to develop and maintain a work agenda, or project list, in support of NOP's mission. To inform the public of the NOSB's work agenda and upcoming plans, this document provides:
- List of projects to be discussed/voted on at the next NOSB meeting
- Full list of active/ongoing NOSB projects

Status	
Active	Active work agenda item being worked on
Requested	Request for work agenda item sent to NOP by NOSB, under review and not yet approved
Waiting for further information	Item on hold pending information USDA agreed to obtain (i.e. Technical Report, TAP, panel, task force, etc.)
Hold Pending Action	Action being taken by USDA or another agency, work should hold pending action
Closed	Complete - to be removed from Work Agenda
Ongoing	Ongoing NOSB work agenda item with periodic or annual updates/actions
Type	
Material	Work agenda item is related to a material (i.e. petition, sunset, annotation, reclassification, discussion document about input issue, etc.)
Practice	Work agenda item about standards non-material related
Other	Work agenda item about neither standards or materials
Requestor	**Priority (As defined by the PPM)***
Sunset	1 - Sunset items are required to be reviewed at least every 5 years
Petition	1 - Petition for a material that has been found sufficient
NOP	2 - Request to the NOSB from the NOP
NOSB	3 - Approved work agenda request (NOSB-Initiated)
Other	4 - Other work Items
*Priority is determined by PPM	
Subcommittee	Subcommittee assigned work agenda item

Last Action/Next Action	
Public Input/Full NOSB Vote	Item is with the NOP for public posting and addition to next full NOSB Agenda. NOSB action at next meeting will be to discuss and review public input and ultimately vote
Public Input/Full NOSB Review	Item is with the NOP for public posting and addition to next full NOSB Agenda. NOSB action at next meeting will be to discuss and review public input, not vote
Subcommittee finalize on Discussion Document	Subcommittee has finalized a document and forwarded to the NOP for public input and full NOSB review.
Subcommittee Finalize Preliminary Sunset Review	Subcommittee has finalized preliminary review of sunset material and forwarded a document to the NOP for public input and full NOSB review
Subcommittee voted on Proposal	Subcommittee has finalized a proposal and forwarded the proposal to the NOP for public input and full NOSB review and vote
Subcommittee Finalize Final Sunset Review	Subcommittee has finalized the sunset review proposal and forwarded the proposal to the NOP for public input and full NOSB review and vote.
Draft…	Subcommittee is in the process of drafting a document, review or proposal
Technical Review Sufficiency Determination	Subcommittee is reviewing a Technical Review for sufficiency
Hold - waiting on Technical Review	Subcommittee is taking no action pending receipt of technical review request to program
Technical Review Request	Subcommittee requests technical review
WAITNG…	Item on hold pending information USDA agreed to obtain (i.e. Technical Report, TAP, panel, task force, etc.)
HOLD…	Subcommittee work is on Hold pending action by gov't agency
Petition determined insufficient	Petition was determined insufficient, reasons provided to NOP, work agenda item closed
Closed	Subcommittee closes work agenda item with no document or proposal
None	No current action but not pending work - normally used for ongoing items with no current work.

Type	Count
Material	66
Practice	3
Other	2

Priority	Next Meeting Action	Count
1	Discussion	41
1	Vote	6
1	Not on Agenda	9
2	Discussion	1
2	Vote	0
2	Not on Agenda	1
3	Discussion	1
3	Vote	4
3	Not on Agenda	6
4	Discussion	0
4	Vote	0
4	Not on Agenda	2

Requestor	Total Count	Next Meeting Count		
Sunset	41	41	100%	x
Petition	15	6	40%	
-HOLD	8	6	75%	
NOP	2	1	50%	
NOSB	11	5	45%	
Other	2	0	0%	

Next Meeting Count		%
#REF!	4	#REF!

National Organic Standards Board
Materials Subcommittee Discussion Document
Protecting the Genetic Integrity of Seed Grown on Organic Land
February 22, 2018

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I INTRODUCTION

The USDA National Organic Program regulations do not allow the use of "excluded methods" in certified organic production. The term "excluded methods" refers specifically to genetically modified organisms (GMO). In the U.S., 94% of ~~the~~ soybeans, 92% of ~~the~~ corn, 94% of ~~the~~ cotton (cottonseed oil is a foodstuff derived from cotton), 75% of ~~the~~ Hawaiian papaya ~~crop~~, 90% of ~~the~~ sugar beets and 90% of ~~the~~ canola crops are genetically engineered. By contrast, less than 1% of crops grown in Europe are genetically modified and that production is limited to a handful of countries in southern Europe. Planting stock can also be genetically engineered, with a GMO non-browning apple poised to be in the marketplace in a few years, as well as fish, pigs, and a wide variety of vegetables and fruits. Various traits are engineered into these patented crops, with herbicide resistance being the main trait, and insecticides incorporated into the DNA of those plants the second main trait.

II BACKGROUND

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Currently, in the U.S., ~~to meet the requirements of the federal organic label~~ no testing is required for presence of foreign genetically engineered materials to meet the requirements of the federal organic label. While so-called process-based standards are in place (buffer distances from GMO crops, temporal separation of when crops are planted etc.) farmers and consumers have no verified Genetically Engineered (GE) free quantitative tests in place even when it's clear~~,~~ such contamination is increasingly likely. For many years farmers who purchase and plant non-organic seed due to the commercial unavailability of organic seed have needed to obtain non-GE affidavits if their seed is a type that has a genetically engineered equivalent in the marketplace~~,~~ that is a cultivar with and without the transformed GMO trait. These affidavits have been accepted as proof by their organic certifiers that the seed is non-GMO. Even if a seed or crop has been found to be "contaminated" with the genome of traceable GMO traits, technically it does not lose its organic certification status. Depending on the requirements of the end buyer, and the integrity of the seller, some of these known contaminated seeds and crops are likely to make it into the organic production stream and ultimately the organic market.

In the raw crop marketplace, buyers respond differently to the risk of genetic contamination: some buyers are performing extensive and expensive testing to determine if there is contamination, while others perform more inexpensive tests only periodically, or perform none at all. Some buyers do testing of grower supplied samples, of deliveries unloaded at the facility, and/or of cleaned product before it is shipped out to the next customer, while others do not. This inconsistency both for seed and for the final crop, leaves organic growers vulnerable to the

varied demands of buyers as well as to genetic contamination that occurred from no fault of their own in the field, during transport, or at the cleaning facility. The European Union, as well as other international and domestic buyers, have set a tolerance limit, allowing some GE contamination (0.9%), while still accepting the product as organic. There are no prescribed or consistent GE tolerance levels for U.S. domestic organic production.

Most organic seed producers take protection of genetic integrity quite seriously. They monitor their custom growers, or their own facilities, when planning location, planting dates, pollination times for their crops, and carefully monitor the integrity of their handling and transport chain. We have heard from a number of organic seed breeder/producers that they elect to drop promising cultivars after investing much in their selection and germplasm evaluation when those cultivars inadvertently become contaminated with GMO genetic material. This has become increasingly problematic with outcrossing crops like maize and canola. Even with this careful oversight, some corn seed breeders report almost 20% contamination of their organic corn seed with foreign GMO germplasm. These seed breeders destroy specific lots of contaminated seed, a loss which they need to compensate for by raising the price of the remaining organic corn seed, resulting in higher prices to organic farmers and ultimately consumers.

III RELEVANT AREAS OF THE STATUTE, RULE and RELATED DOCUMENTS

NOP standards adopted by USDA in a final rule published in December 2000 and fully implemented in October 2002 prohibit~~ed~~ the use of GMOs in the production and handling of organic products certified to national organic standards. The terminology used for GMOs in the NOP Regulation, "excluded methods," is specified under section 205.2 (Terms Defined) as:

> ***Excluded methods***. *A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Excluded methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.*

At ~~the~~ its October 2016 ~~NOSB~~ meeting, the NOSB passed a recommendation ~~a~~to update and clarify the definition of~~n~~ Excluded Methods ~~Terminology proposal was passed to update and clarify the above definition~~. The~~is~~ proposal (dated August 30, 2016) allows the NOP to be more flexible in addressing new technologies as they are developed. Numerous specific methods have been reviewed under this terminology, using transparent criteria, principles and

descriptions. The NOSB has determined some new technologies should be excluded from organic production, and others are still under review.

Detection and Testing Requirements: Under the residue testing requirements of NOP, products from certified organic operations may require testing when there is reason to believe that certified products have come into contact with prohibited substances or have been produced using excluded methods. This requirement is specified in Subpart G (Administrative) of the regulations:

> **§ 205.670 Inspection and testing of agricultural product to be sold or labeled "organic."**
> (b) The Administrator, applicable State organic program's governing State official, or the certifying agent may require pre-harvest or post-harvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods. Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense.

NOP Policy: The NOP finalized a Policy Memo on July 22, 2011 (Policy Memo 11-13) on GMOs. This policy memo reiterates that the use of GMOs is prohibited under NOP regulations, and answers questions that have been raised concerning GMOs, organic production, and handling. The clarification provided is consistent with the explanations provided in the preamble, thus emphasizing that organic certification is a process-based standard and the presence of detectable GMO residue alone does not necessarily constitute a violation of the regulation.

IV DISCUSSION and PUBLIC COMMENT

The NOSB put forth discussion documents on this subject ~~were put forth~~ in 2013, 2014, 2015, 2016 and 2017. Public comment has clearly shown this to be an important issue for organic producers, food processors and consumers. Organic stakeholders would like to see consistency in the organic certification process as it relates to excluded methods and to protect organic integrity overall in order to maintain consumer trust. The genetic integrity of seed used on organic land continues to be at risk, and the risk appears to grow each year. The questions at the end of this document are intended to continue this conversation and ~~bring some clarity to~~inform possible next steps.

Since there is an allowance for the use of non-organic seed when organic seed ~~cannot be found~~ of an equivalent variety in the quality and quantity desired cannot be found, this increases the ~~offers another~~ risk of~~to~~ GMO contamination of organic crops. If a farmer starts out with GMO

contaminated seed, then many of their defensive management tactics are entirely ineffective. The very contaminated seed they plant will freely cross fertilize other cultivars of that crop on their farm greatly compounding the contamination problem. In most cases, non-organic seed producers do not perform the same due diligence in testing and oversight to protect against GMO contamination as organic seed breeders. Some may state in their non-GMO affidavits that their assessment of non-GMO presence is "to the best of their ability", since they are not actually testing to prove this statement as true.

The issue of maintaining the genetic integrity of organic and non-organic seed and planting stock grown on organic land and sold in the organic marketplace is complex, but not an insurmountable task. The respective interests of organic seed and planting stock growers and the farmers who buy their products can be at odds, even though they are both seeking the same ultimate outcome of avoidance of GMO contamination whenever possible. Non-GMO labeling such as the Non-GMO Project does not guarantee 100% GMO free products, with a 0.9% tolerance level allowed in foods for human consumption and a 5% allowance of GMO contamination in livestock feeds whose final product would then be labeled as non-GMO or non-GMO. The Non-GMO Project has a tolerance of 0.25% for seed.

Commented [AM-A1]: ?

Tolerance levels can also present problems. How are these seeds and products to be tested, and by whom, and where in the supply chain? Would a 100% GMO free standard in organic result in large regions of the United States not being able to grow organic crops, preventing the growth of organic acreage and commercial activity in the US? Could those businesses that sell or buy the GMO crops that are causing the contamination be assessed a fee to cover the losses caused by GMO contamination? If so, how could this be implemented in an efficient and fair way?

The~~is~~ question of solving GMO contamination in organic seed and crops does not have clear answers ~~solutions~~, and might result in the unintended consequence of causing damage to the growth and integrity of organic agriculture, as well as negatively impacting organic growers and seed breeders. ~~On the other hand~~However, ~~,~~ both growers and consumers feel contamination of organic seed and crops by GMOs negatively affects the integrity of organic foods.

V DISCUSSION QUESTIONS

The following list of questions is by no means comprehensive, but is a starting point for discussion on possible options to address GMO contamination. -This is a big topic, and we welcome all types of ideas and proposed solutions.

a. Should we move to quantify the extent of GMO contamination in order to better understand the scope of the problem? How could this be accomplished?
b. Should a requirement be in place establishing a seed purity threshold for purchased seed (either organic or nonorganic, or both) planted on organic land? If so, what should the threshold be? How will that threshold vary with crop?

c. Should there be an approved list of tests, and/or testing laboratories, for tracking the presence of GMO in seed and/or crops?
d. Should there be an approved method of sampling for GMO traits? How much of a seed or crop should be tested to provide confidence that the entire lot is likely to be GMO free?
e. Would a seed label statement ~~stating~~ indicating the percentage of GMO traits detected by an approved testing regime, be sufficient in providing the information needed by the purchaser of the seed? No detectable level of GMO traits, .1% or other levels are examples that could be provided.

VI Motion to approve the discussion document on Protecting the Genetic Integrity of Seed Grown on Organic Land~~is discussion document for posting.~~

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Motion by: Dan Seitz

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Seconded by: Dave Mortensen

Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Harriet Behar, Subcommittee Chair to transmit to NOSB, February 27, 2018

NOSB Materials Report: Petition & Technical Report Status

Updated: 3/1/2018

Aquaculture

Overdue items in red

Changes since last report in yellow

Petitioned Inerts - on hold

NL Section	Substance	Type	Technical Report	Next Step	Due Date	NOSB Meeting	Notes
Crops	Natamycin (PDF)	Petition to classify as nonsynthetic	Technical Report (2017)	Subcommittee proposal		TBD	Petition sent to CS on 9/9/2016. TR requested on 11/17/16. TR sent to CS on 11/13/2017; TR approved on 12/5/2017 (posted 1/25)
Crops	Calcium acetate (PDF)	Add to 205.601		TR Development		TBD	Sent to CS on 11/20/17. Petition determined sufficient 2/7/18. TR requested w/additional questions from CS; TR request in development
Crops	Sodium Citrate	Petition, Add to 205.601	Technical Evaluation Report, Crops (2017) (PDF)	Subcommittee proposal		TBD	Petition sent to CS on 7/28/16; Full TR requested 10/04/16; TR sent to CS on 8/7/2017; TR determined insufficient on 9/9/17; add'l Q sent to contractor on 12/12/2017; revised TR sent to CS on 12/20/2017; TR approved on 2/7/18
Crops	Sulfur	Petition, Add to 205.601, molluscicide	Livestock report available	Subcommittee proposal		Spring 2018	Petition sent to CS on 6/08/2017; Petition determined sufficient 9/19/17; no TR requested
Crops	Allyl Isothiocyanate (AITC)	Crops, Add to 205.601		TR sufficiency review	4/18/18	TBD	Sent to CS on 7/6/2016; Ltd TR request 10/04/16; TR assigned 11/18/16; TR sent to CS 2/16
Crops	Polyoxin D Zinc Salt (PDF).	Add to 205.601	2012 (PDF) 2018 TR	Subcommittee proposal		Spring 2018	Sent to CS on 6/16/2016; Ltd TR request 10/04/16; TR assigned 11/18/16; 2nd addendum sent to CS on 10/27/2017; TR sent to CS on 12/19/2017. Petition addendum (#3) sent to CS 02/07/18; TR found sufficient 2/20/18
Crops	Ammonium Citrate (PDF)	Add to 205.601		Petition sufficiency review, including TR request, if applicable	12/26/17	TBD	TR request in development
Crops	Ammonium Glycinate (PDF)	Add to 205.601		Petition sufficiency review, including TR request, if applicable	12/26/17	TBD	TR request in development
Handling	Ethiopian pepper	Petition, add to 205.606		Petition sufficiency review, including TR request, if applicable		TBD	Sent to HS on 2/9/2017; Pet determined sufficient on 4/4/2017; no TR requested additional Qs sent to petitioner on 7/24/17; additional Qs sent to petitioner on 11/8/17
Handling	Japones pepper	Petition, add to 205.606		Petition sufficiency review, including TR request, if applicable		TBD	Sent to HS on 2/9/2017; Pet determined sufficient on 4/4/2017; no TR requested additional Qs sent to petitioner on 7/24/17; additional Qs sent to petitioner on 11/8/17

NOSB Materials Report: Petition & Technical Report Status

Updated: 3/1/2018

Aquaculture

Overdue items in red

Changes since last report in yellow

Petitioned Inerts - on hold

NL Section	Substance	Type	Technical Report	Next Step	Due Date	NOSB Meeting	Notes
Handling	Bisphenol A (BPA)	See Notes	Technical Report (PDF)	Subcommittee Proposal or Discussion Document		TBD	NOP memo on Packaging, Nov 2014; initial TR inadequate - sent for external contracting; new TR sent to HS on 7/10/2017; TR found sufficient on 8/1/2017
Handling	Sodium dodecylbenzene sulfonate (SDBS)	Add to 205.605(b)	Technical Report (PDF)	Subcommittee Proposal		Spring 2016; Spring 2018	Petition sent to HS on 11/2/15; petition determined sufficient on 12/1/2015; no TR needed; referred back to SC at April 2016 NOSB Mtg; TR requested on 5/17/16; TR sent to HS on 5/30/2017; Addendum posted and sent to HS on 7/12/17; TR found sufficient on 8/1/2017
Handling	Silver Dihydrogen Citrate			TR sufficiency review	4/23/18	Spring 2018	Petition determined sufficient on 3/7/17; TR requested; add'l Q for contractor received on 12/5/2017; updated TR sent to HS 2/21/2018, TR suff due 4/23/18
Handling	Tamarind seed gum	Petition, add to 205.606		Under NOP Review		Fall 2018	Sent to HS on 2/15/2017; Additional questions for the petitioner provided on 4/5/2017; Petition addendum sent to HS on 8/10/2017; TR Requested on 10/3/2017; under NOP review
Handling	Sodium Chlorite for production of chlorine dioxide gas	Add to 205.605		TR Review	3/15/18	Fall 2016; TBD	Petition sent to HS on 12/02/2015; Pet determined incomplete on 4/13/2016; add'l info sent to HS on 5/5/2016; Petition determined sufficient on 6/7/16; Proposal vote 8/16/16; taken back to subcommittee for further work; TR requested on 6/6/2017; TR sent to HS on 1/9/2018
Livestock	Oxalic acid (PDF)	Add to 205.603		TR Development		TBD	Sent to LS on 10/27/17; TR Requested on 12/8/2017; TR request in development
Livestock	Glycolic acid (PDF)	Add to 205.603	Technical Report (2017)	NOSB Subcommittee Proposal		Spring 2018	Sent to LS on 6/6/2016; TR requested 7/19/2016; TR assigned 11/18/16; Draft TR sent to LS 11/7/17; TR determined sufficient on 1/12/2018
Handling	Pullulan	Add to 205.605		Petition sufficiency review, including TR request, if applicable	4/30/2018	TBD	Sent to HS 2/27; sufficiency due 4/30/2018

NOSB Materials Report: Petition & Technical Report Status

Tab 2

Updated: 3/1/2018

Overdue items in red

Changes since last report in yellow

NL Section	Substance	Type	Technical Report	Next Step	Due Date	NOSB Mtg 1	NOSB Mtg 2	Sunset Date	Notes
205.605(b)	Alginates	Sunset 2020	2015 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(e)	Aqueous potassium silicate	Sunset 2020	2014 TR	NOSB Meeting #1		Spring 2018	Fall 2018	6/22/2020	
205.601(i)	Aqueous potassium silicate	Sunset 2020	2014 TR	NOSB Meeting #1		Spring 2018	Fall 2018	6/22/2020	
205.606	Arabic gum	Sunset 2020	2018 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.603(a)	Aspirin	Sunset 2020	2017 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.605(a)	Calcium carbonate	Sunset 2020	2018 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.605(b)	Calcium hydroxide	Sunset 2020	1995 TAP	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.606	Carob bean gum	Sunset 2020	2018 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.605(b)	Diglycerides	Sunset 2020	2015 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.603(a)	Electrolytes	Sunset 2020	2015 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(e)	Elemental sulfur	Sunset 2020	1995 TAP	TR Review	TBD	Spring 2018	Fall 2018	3/15/2022	TR sent back to contractor
205.601(i)	Elemental sulfur	Sunset 2020	1995 TAP	TR Review	TBD	Spring 2018	Fall 2018	3/15/2022	TR sent back to contractor
205.601(j)	Elemental sulfur	Sunset 2020	1995 TAP	TR Review	TBD	Spring 2018	Fall 2018	3/15/2022	TR sent back to contractor
205.601(a)	Ethanol	Sunset 2020	2014 TR - Ethanol	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.603(a)	Ethanol	Sunset 2020	2014 TR Ethanol	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(k)	Ethylene	Sunset 2020	2011 Supplemental TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.605(b)	Ethylene	Sunset 2020	1999 TAP - Processing	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	TR Requested - Low Priority
205.605(a)	Flavors	Sunset 2020	2005 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.606	Fructooligosaccharides	Sunset 2020	2015 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.605(a)	Gellan gum	Sunset 2020	2018 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.603(a)	Glycerin	Sunset 2020	2010 TAP (Livestock)	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	TR Requested - Low Priority
205.606	Guar gum	Sunset 2020	2018 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(i)	Hydrated lime	Sunset 2020	2001 TAP	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.603(b)	Hydrated lime	Sunset 2020	2015 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(a)	Isopropanol	Sunset 2020	2014 TR - Isopropanol	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.603(a)	Isopropanol	Sunset 2020	2014 TR Isopropanol	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.606	Lecithin—de-oiled	Sunset 2020	2009 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(e)	Lime sulfur	Sunset 2020	2014 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(i)	Lime sulfur	Sunset 2020	2014 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(j)	Liquid fish products	Sunset 2020	2006 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.606	Locust bean gum	Sunset 2020	2018 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.605(b)	Magnesium stearate	Sunset 2020	2018 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(o)	Microcrystalline cheesewax	Sunset 2020	2018 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	

NOSB Materials Report: Petition & Technical Report Status

Updated: 3/1/2018

Overdue items in red

Changes since last report in yellow

NL Section	Substance	Type	Technical Report	Next Step	Due Date	NOSB Mtg 1	NOSB Mtg 2	Sunset Date	Notes
205.603(b)	Mineral oil	Sunset 2020	2015 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.605(b)	Monoglycerides	Sunset 2020	2015 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(b)	Newspaper or other recycled paper	Sunset 2020	2017 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(c)	Newspaper or other recycled paper	Sunset 2020	2017 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.605(a)	Oxygen	Sunset 2020	1995 TAP	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	TR Requested - Low Priority
205.603(a)	Phosphoric acid	Sunset 2020	2003 TAP (Handling)	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	TR Requested - Low Priority
205.605(b)	Phosphoric acid	Sunset 2020	2003 TAP	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	TR Requested - Low Priority
205.601(b)	Plastic mulch and covers (petroleum-based other than polyvinylchloride (PVC))	Sunset 2020	1995 TAP	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	TR Requested - Low Priority
205.605(b)	Potassium carbonate	Sunset 2020	1995 TAP	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	TR Requested - Low Priority
205.602(e)	Potassium chloride	Sunset 2020	1995 TAP	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	TR Requested - Low Priority; no TR
205.605(a)	Potassium chloride	Sunset 2020	1995 TAP	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(a)	Sodium carbonate peroxyhydrate	Sunset 2020	2014 TR	NOSB Meeting #1		Spring 2018	Fall 2018	6/22/2020	
205.601(e)	Sucrose octanoate esters	Sunset 2020	2005 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.603(b)	Sucrose octanoate esters	Sunset 2020	2005 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.605(b)	Sulfur dioxide	Sunset 2020	2011 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.601(j)	Sulfurous acid	Sunset 2020	2014 TR	NOSB Meeting #1		Spring 2018	Fall 2018	6/22/2020	
205.606	Tragacanth gum	Sunset 2020	2018 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.603(a)	Vaccines	Sunset 2020	2011 TR (Vaccines from Ex	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	
205.605(b)	Xanthan gum	Sunset 2020	2018 TR	NOSB Meeting #1		Spring 2018	Fall 2018	3/15/2022	

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Sunset 2022 48

Sunset 2020 4

Note: Subcommittee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

National Organic Standards Board (NOSB)
Materials/GMO ad hoc Subcommittee Meeting Notes
Tuesday, March 13, 2018 2:00 pm ET draft

Attending: Harriet Behar (HB), Chair; Emily Oakley (EO); Dave Mortensen (DM); Dan Seitz (DS), Vice Chair
Absent: Lisa de Lima (LD); Tom Chapman (TC)
Staff: Michelle Arsenault (MA); Paul Lewis (PL)

Work agenda

Materials Projects	Contact	Notes	Discussed, Voted	Meeting
Research Priorities Proposal May 2012 Framework Proposal	EO	Subcommittee reps to MS DS - LS EO - CS LD - HS RPs from Subcomm due to MS in July	NA	Fall 2018
Petition and TR tracking	HB/LB	Ongoing	NA	NA
GMO Projects	**Contact**	**Notes**	**Vote**	**Meeting**
Non-GMO organic seed integrity proposal (formerly Seed Purity from GMOs)	DS, DM, HB	Part of Seed purity doc will be incorporated into "Prevention Strategies for Excluded Methods in Crops and Handling" doc. MS submitted a request to the ES in August 2017 to convene a seed purity task force. Pending NOP approval, for future work agenda.	Jan 30, Feb 13	Spr 2018
Excluded Methods Terminology	HB	Proposal	Jan 9	TBD

Other Projects

Project Idea	Contact	Notes*	Vote	Meeting
Contamination of Farm Inputs Discussion Document	HB	Moved to Materials from Crops for continued work.	Jan 30	TBD
Sanitizers	HB, EO, JM, AB	Pending NOP approval	Jan 9	Fall 2018

Agenda

- Approval of February 13, 2018 notes
- Update about guest speaker.
- Materials and TR update (MA)
- Sanitizer work agenda progress (HB).
- Other items
- Adjourn

Discussion

- **The notes of February 13** were approved with no changes.
- **Update about guest speaker.** Dr. Chou, who will be a guest speaker on the April 10 MS call, is new to the role of USDA biotech coordinator. Her role is to coordinate across ARS, APHIS, and Foreign Ag, and the NOSB would like to be able to provide her perspective from the organic space. Members asked if she had access to the public comments that were submitted as part of the USDA proposal to coordinate the framework for biotech across USDA. A member shared with the group a 2016 National Academies Press report entitled *Genetically Engineered Crops: Experiences and Prospects.* He noted that this could be very useful to the NOSB as it develops its proposal on Excluded Methods, as the terms have already been defined.
- Materials and TR update (MA). The NOP will eliminate the monthly Materials report as most of the information is captured in the new work agenda report, and is redundant. The NOP will continue to summarize the status of materials during the MS calls.
- Sanitizer work agenda progress (HB). The request to add sanitizers to the work agenda was revised, and the request was approved by the NOP. The MS Chair will update the Executive team on Friday, March 16.
- **Other items:**
    - The MS Chair discussed ways in which the NOSB can encourage petitioners to seek organic alternatives. Suggestions included adding questions to the sunset reviews, and/or to the petition template, specifically items for 205.606.
    - EO will discuss the proposal on marine materials with Handling and Crops, as the intention is to merge the two documents for the Fall meeting, and move it to the Materials Subcommittee.
- **The meeting was adjourned**

Previous MS Notes

Future Call Schedule (2nd Tuesday 2:00 ET)

February 13, 2018
March 13, 2018
April 10, 2018
May 8, 2018
June 12, 2018
July 10, 2018
August 14, 2018
September 11, 2018
October 9, 2018

November 13, 2018
December 11, 2018

Spring 2018 Milestones	Target dates (tentative)
New NOSB member orientation	TBD
NOSB - Spring 2018 proposals due to NOP	Feb 21, 2018
NOP - Complete Spring 2018 NOSB meeting tentative agenda	Mar 6, 2018
NOP - Post proposals, "Open" public comment	Mar 6, 2018
Discuss work agendas on ES call	Mar 9, 2018
Public comment closes	Apr 4, 2018
NOP - Send compiled public comments to NOSB	Apr 9, 2018
Work agendas finalized on ES call (last call before fall meeting)	Apr 13, 2018
Public comment webinar(s)	Apr 17 & 19, 2018
Spring 2018 NOSB meeting – Tucson, AZ	Apr 25-27, 2018

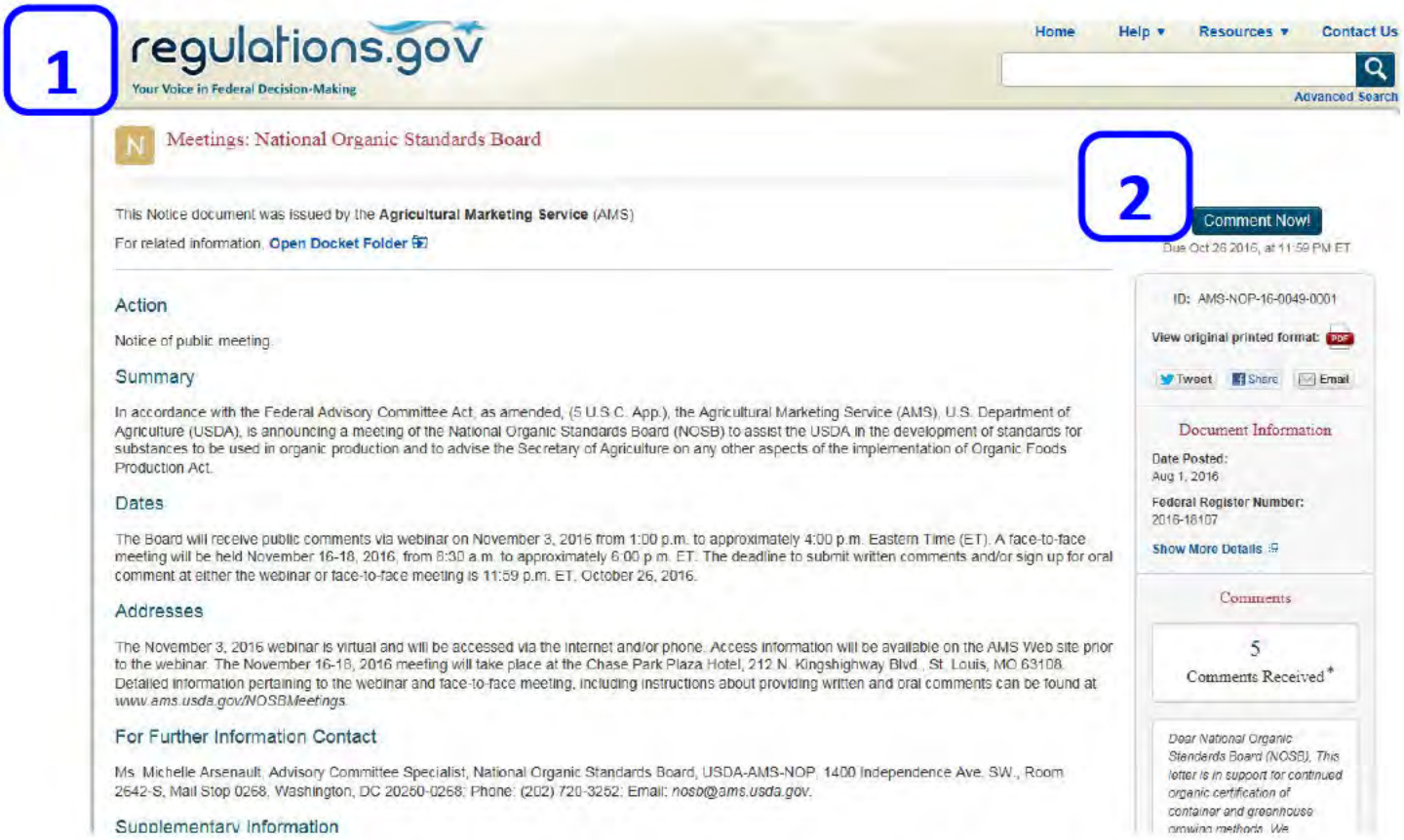
SUBMITTING COMMENTS TO THE NOSB VIA REGULATIONS.GOV

To view the NOSB proposals and discussion documents please visit the NOSB meeting page: https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-tucson-az

1. To submit comments on any of the meeting documents go to Regulations.gov http://www.regulations.gov. You can search by relevant key words like NOP, NOSB, Tucson, the FR notice number (FR AMS-NOP-17-0057), etc. Or click the direct link below.

Comment direct link: https://www.regulations.gov/document?D=AMS-NOP-17-0057-0001

2. Choose the blue button on the top right "Comment now"



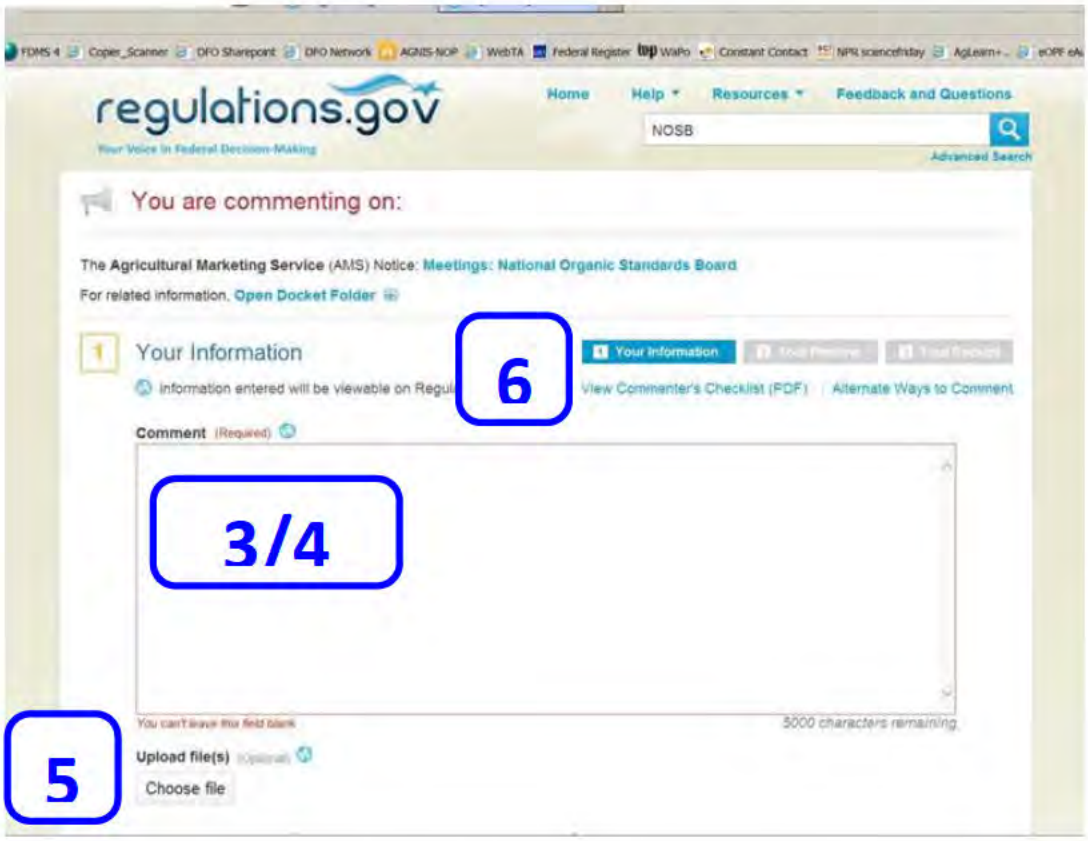
3. Enter your comment in the comment box (see below) and fill in all required fields (name, city, zip code). It's helpful if you indicate at the top of the comment which proposal you are commenting on, but it's not necessary.

4. If you are commenting on multiple topics, you can submit all of them in the comment field, but it's easier for the NOSB to review them if they are submitted separately by topic.

5. If your comments do not fit in this box, you can add an attachment instead (see "choose file" button – circled below).

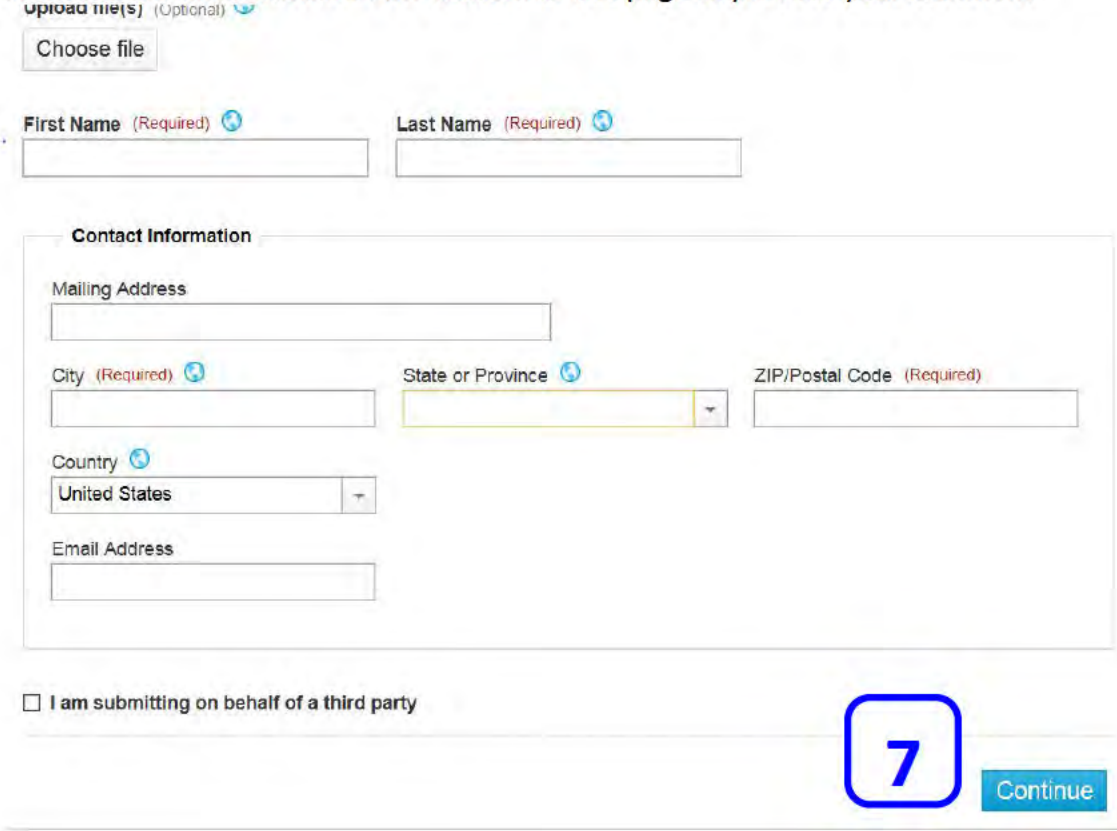
6. To upload a file (a word doc or pdf), click the "choose file" button which will open a box to search your computer. Choose the file and click open and it will upload it to the comment page.

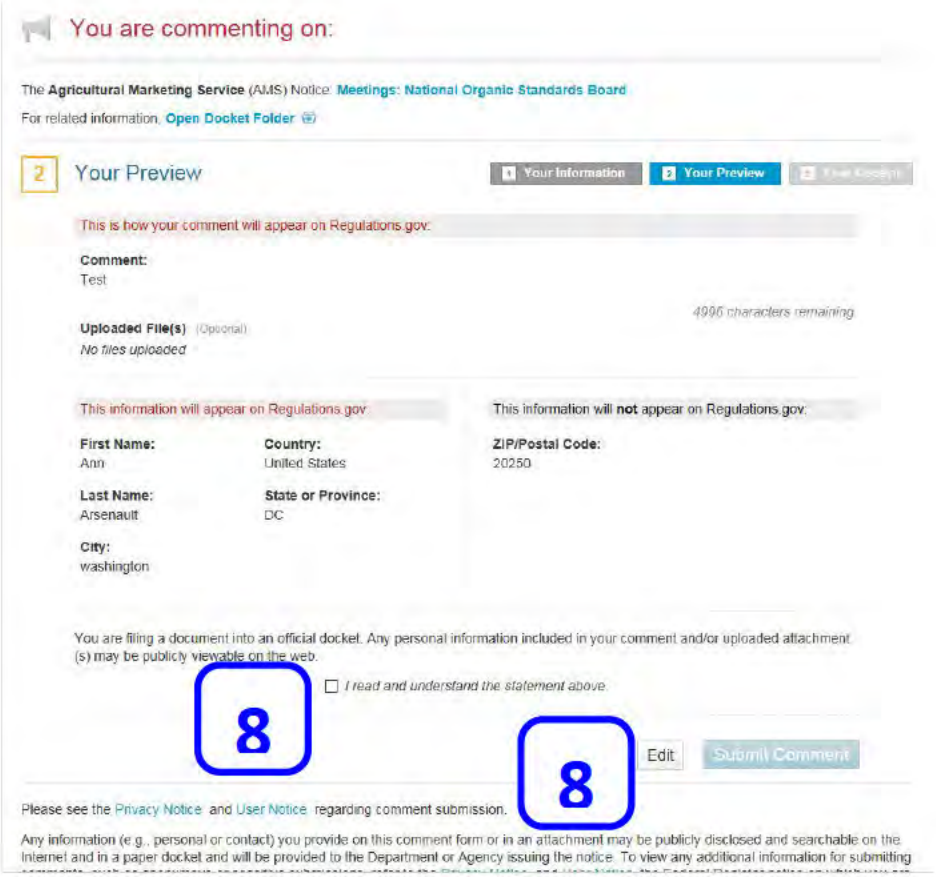
Rev. 3/15/18



6. View Commenters checklist - Helpful Hints about commenting

7. Hit the continue button at the bottom of this page to preview your comment





8. If everything looks good on this page, check the box to agree to the terms, and hit the blue button at the bottom that says Submit Comment. If not, edit first, then submit.

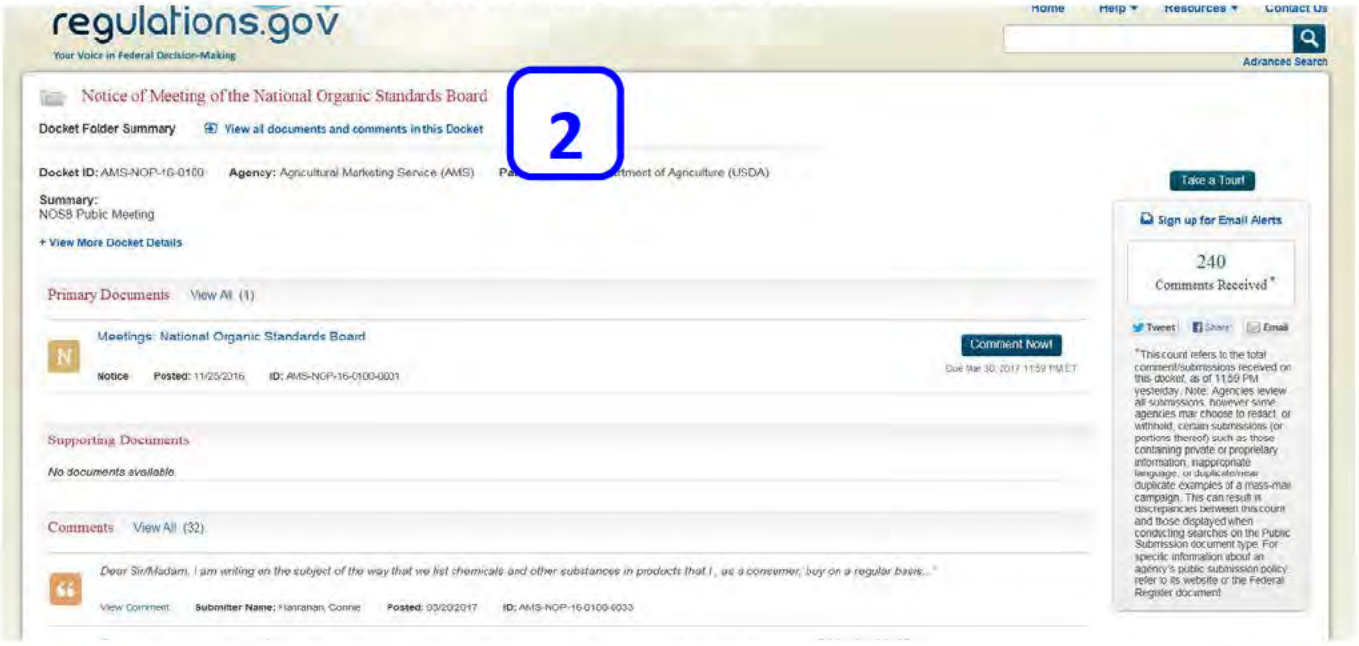
9. You should see a reference number indicating that your comment was submitted successfully!

To view the NOSB proposals and discussion documents please visit the NOSB meeting page:
https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-tucson-az

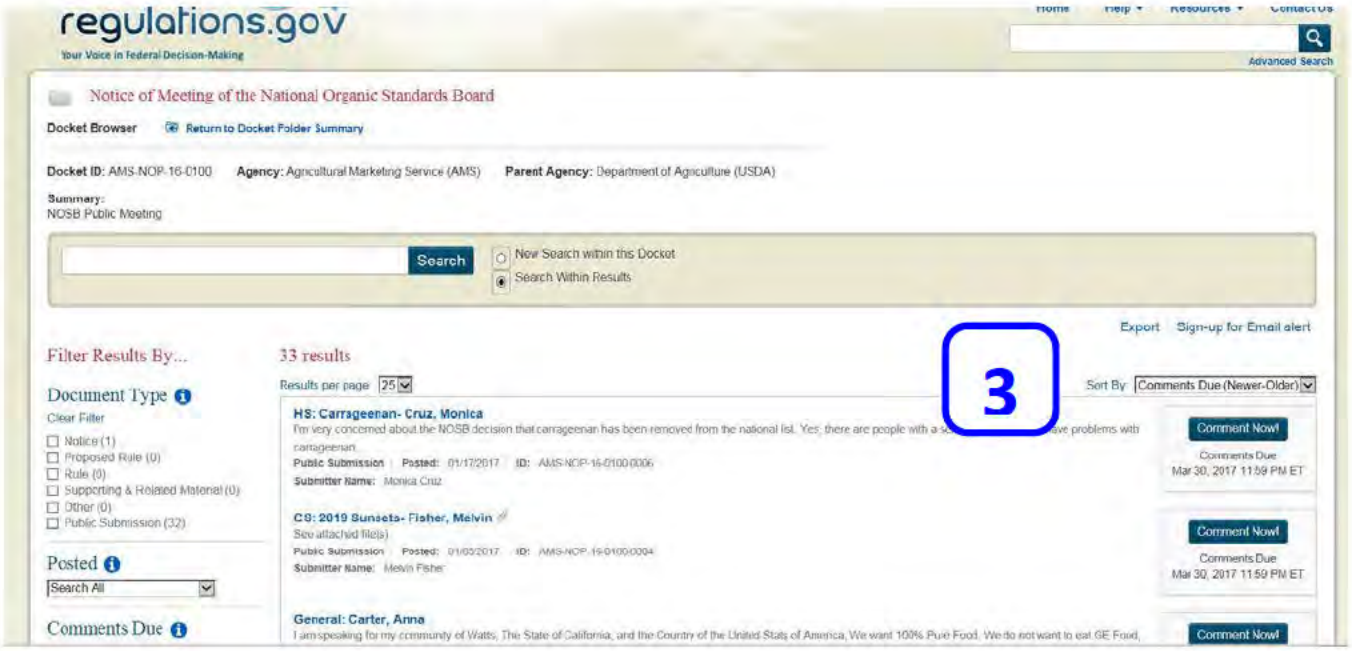
TO READ COMMENTS:

1. **OPEN DOCKET FOLDER: HTTPS://WWW.REGULATIONS.GOV/DOCUMENT?D=AMS-NOP-17-0057-0001**

2. **CLICK VIEW ALL DOCUMENTS AND COMMENTS IN THIS DOCKET**



3. SORT COMMENTS BY TITLE, DATE RECEIVED, SUBMITTER NAME, ETC.



Note: Subcommittee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

National Organic Standards Board (NOSB)
Livestock/Aquaculture Subcommittee (LS) Meeting Notes draft
Tuesday, March 20, 2018 3:00 pm ET

Attending: Ashley Swaffar, (AS), Chair; Sue Baird (SB), Vice Chair; Harriet Behar (HB); Jesse Buie (JB); A-dae Romero-Briones (ARB); Dan Seitz (DS); Tom Chapman (TC) - observer
Absent:
Staff: Michelle Arsenault (MA); Devon Pattillo (DM)

Work Agenda

Petitioned Materials

Substance	Nat'l List §	Contact	TR requested	Notes	Scheduled, Discussed, Voted	Meeting
Glycolic Acid, 2016	205.603	AS	Y	Petition sent to LS 06 06 15. Response/request for TR due 08 08 16. TR requested 07 19 16. TR sent to LS 11 07 17. Response/request for TR due 01 08 18. TR found sufficient 12 19 17.	Jul 19, 2016, Dec 19, Feb 20	Spr 2018
Oxalic Acid	205.603	HB	Y	Petition sent to LS 10 27 17. Response/request for TR due 12 26 17. Petition found suff 12 5 17. TR Requested 12 5 17	Dec 5	TBD
Aquaculture Substances (See table below)				On hold until aquaculture rule is published.	TBD	TBD

2020 Sunsets
TR Requests: July 2017, Summary: Spr 2018, Review: Fall 2018

Name	National List §	Contact	TAP/TR	Notes	Scheduled, Discussed	Review Meeting
Alcohols: Ethanol, Isopropanol	205.603	JB	N	1995 TAP; 2014 TR Ethanol; 2014 TR Isopropanol	Dec 5	Summary: Spr 2018 Review: Fall 2018
Aspirin	205.603	AS	Y	1995 TAP. TR requested 07 28 17. TR in contracting. TR sent to LS 12 20 17. Response due 02 19 18. TR found sufficient 02 20 18	Dec 19, Feb 20	"
Biologics, Vaccines	205.603	HB	N	2011 TR (Vaccines from Excluded Methods); 2014 TR (Aquaculture)	Dec 19	"
Electrolytes	205.603	HB	N	1995 TAP; 2015 TR	Dec 19	"

Glycerine	205.603	SB	N	2010 TAP (Livestock)	Feb 6	"
Phosphoric acid	205.603	DS	N	2003 TAP (Handling). Low priority	Jan 16	"
Lime, hydrated	205.603	ARB	N	1995 TAP; 2015 TR	Feb 6	"
Mineral oil	205.603	ARB	N	2002 TAP; 2015 TR	Feb 6	"
Sucrose octanoate esters	205.603	SB	N	2005 TR	Feb 6	"

Other projects					
Project	**Contact**	**TR Reqst ?**	**Notes**	**Discussed, Voted**	**Meeting**
Defining emergency treatment for parasiticides	HB	N	Approved for addition to work agenda 07 15 16. Discussion doc. Postponed until Fall 2017	Dec 5, Dec 19, Jan 16, Feb 20	Spr 2018
Research Priorities (RP)	HB/AS/SB	NA	RPs due to MS Aug 2017	NA	Fall 2018
Organic poultry task force	ARB/AS/HB		Discuss formation of Task Force - on hold pending resolution of OLPP final rule.	NA	NA

* Yellow highlight indicates committee action needed *Highlight indicates review completion/vote taken

Agenda

- Approve notes from February 20, 2018
- Other items
- Adjourn

Discussion

- **Notes from the** February 20, 2018 were
- **Other items.**
- **The meeting was adjourned.**

Previous LS Notes

Future Call Schedule (1st and 3rd Tuesdays 3:00 ET)

February 20, 2018

Glycolic Acid (AS) - Discuss draft proposal

Defining emergency treatment for parasiticides (HB) - Discuss next steps

Aspirin (AS) - TR sufficiency (due Feb 19)
March 6, 2018 - cancelled
March 20, 2018
April 3, 2018
April 17, 2018
May 1, 2018
May 15, 2018
June 5, 2018
June 19, 2018
July 3, 2018
July 17, 2018
August 7, 2018
August 21, 2018
September 4, 2018
September 18, 2018
October 2, 2018
October 16, 2018
November 6, 2018
November 20, 2018
December 4, 2018
December 18, 2018

Spring 2018 Milestones	Target dates (tentative)
New NOSB member orientation	TBD
NOSB - Spring 2018 proposals due to NOP	Feb 21, 2018
NOP - Complete Spring 2018 NOSB meeting tentative agenda	Mar 6, 2018
NOP - Post proposals, Open public comment	Mar 6, 2018
Discuss work agendas on ES call	Mar 9, 2018
Public comment closes	Apr 4, 2018
NOP - Send compiled public comments to NOSB	Apr 9, 2018
Work agendas finalized on ES call (last call before fall meeting)	Apr 13, 2018
Public comment webinar(s)	Apr 17 & 19, 2018
Spring 2018 NOSB meeting – Tucson, AZ	Apr 25-27, 2018

2021 Sunsets TR Requests: July 2018, Summary: Spr 2019, Review: Fall 2019						
Substance	**National List §**	**Con-tact**	**TR re-quest ?**	**Notes**	**Scheduled, Discussed**	**Meeting**
Atropine	205.603(a)			2002 TAP 2017 NOSB Recommendation		Summary: Spr 2019 Review: Fall 2019
(Parasiticide) Fenbendazole	205.603(a)			2015 TR 2017 NOSB Recommendation		"
Hydrogen peroxide	205.603(a)			None. 2015 Crops TR 2017 NOSB Recommendation		"
Iodine	205.603(a)14, and 205.603(b)2			2015 TR 2017 NOSB Recommendation		"
~~Ivermectin~~	~~205.603(a)~~			Nov 2016 NOSB Rec – Removal Included in proposed rule NOP 14-05 (83 FR 2498). 2015 TR		"
Magnesium sulfate	205.603(a)			2011 TR 2017 NOSB Recommendation		"
(Parasiticide) Moxidectin	205.603(a)			2015 TR 2017 NOSB Recommendation		"
Peracetic acid	205.603(a)			2016 TR 2017 NOSB Recommendation		"
Xylazine	205.603(a)			2002 TR Xylazine/Tolazoline 2017 NOSB Recommendation Xylazine/Tolazoline 2019 NOSB Recommendation - Tolazoline		"
Methionine	205.603(d)			2011 TR 2015 NOSB Recommendation		"
Trace minerals	205.603(d)			None 2017 NOSB Recommendation		"
Vitamins	205.603(d)			2015 TR 2017 NOSB Recommendation		"

Aquaculture petitions						
Substance	**Nat'l List §**	**Contact**	**TR requested**	**Notes**	**Scheduled, Discussed, Voted**	**Meeting**
Aquaculture-CO_2, (for aquatic plants)	205.609	TF/CBo	N	Petition sent to CS 5 30 12. Will rqst modification from petitioner (for use pattern). Updated petition was deemed sufficient. TR deemed unnecessary.	NA	Proposal TBD
Aquaculture-Chlorine (for aquatic plants)	205.609	FT	2011 Crops TR 2006 TR 1995 TAP	Petition sent to CS on 5 30 12. Determine petition sufficiency. CS requested clarification from petitioner 11 20 12. 2011 TR deemed suff for this review 11 20 12. Additional aquaculture TR deemed unnecessary. Sent follow up questions to petitioner. Response deemed sufficient.	NA	Proposal TBD
Aquaculture-Micronutrients (for aquatic plants)	205.609	FT	2010 TR (Nickel) 6/2013 Minerals TR	Petition sent to CS on 06 08 12. Petition sufficiency response due 08 08 12? CS sent request to NL Mgr. 12 04 12 for additional info. Questions clarified by petitioner. Petition found sufficient 06 18 13 and 07 02 13. TR deemed unnecessary.	NA	Proposal TBD
Aquaculture-Lignin sulfonate (chelating agent for aquatic plants) CAS #s 9009-75-0, 8062-15-5, 8061-51-6	205.609	JR	2/2011 Crops TR 7/2013 TR Aquatic Animals TR	Petition sent to CS on 07 03 12. Petition Sufficiency Response due 09 04 12. CS sent request to NL Mgr 12 04 12 for additional info and TR. Questions clarified by petitioner. Petition found sufficient 6 18 13 and 07 02 13.	NA	Proposal TBD

Aquaculture-Vitamins (B1, B12, H) for aquatic plants	205.609	CW	4/2013 Aquatic Animals TR	Petition sent to CS 08 10 12. Petition Sufficiency response due 10 10 12. Petition found sufficient 06 18 13.	NA	Proposal TBD
Aquaculture - Biologics: Vaccines for Aquatic Animals	205.611	JR	2011 TR (Vaccines made from GMOs)	Petition sent to LS 06 14 12. Petition found sufficient and TR requested on 05 21 13. (NOP note: TR sent to LS 01 24 14. TR deemed sufficient 02 03 14	NA	Proposal TBD
Aquaculture - Chlorine (for aquatic animals)	205.611	FT	N Crops 2011 Crops 2006 Crops 1995 Livestock 2006 Handling 2006	Petition sent to LS on 05 30 12. Petition found sufficient 07 03 12. No TR requested	NA	Proposal TBD
Aquaculture – Tocopherols (for aquatic animals)	205.611	TF/CBo	2013 TR 1995 TAP rvw	Petition sent to LS on 05 30 12. Petition found sufficient 08 06 12. TR requested 08 06 12. Draft TR sent to LS on 04 16 13. TR found sufficient 06 04 13	NA	Proposal TBD
Aquaculture – Vitamins (for aquatic animals)	205.611	CW/FT	Yes 2013 TR	Petition sent to LS 05 30 12. Response due ~07 30 12. Petition found suff 08 06 12. Requested joint TR with minerals 08 06 12. TR sent to LS 04 29 13. TR found suff 06 18 13.	NA	Proposal TBD
Aquaculture - Trace Minerals (for aquatic animals)	205.611	CW/FT	2013 TR	Petition sent to LS on 06 08 12. Response due ~08 08 12. Petition found sufficient 08 06 12? Requested joint TR with Vitamins 08 06 12. TR sent to LS 06 25 13. Suff due 08 27 13. TR found sufficient 07 16 13. Fall 2013 meeting cancelled.	NA	Proposal TBD

Nominations for Organic Imports Panel (13 Nominees)
National Organic Standards Board (NOSB) Spring Meeting

Panel Parameters:

- Tentatively scheduled 2 1.5 hour sessions
- If 4 people per session, total of 8
- Do not HAVE to have 8, could have fewer to allow more time
- Option – Invite participation by a non-nominee (e.g., foreign certifier – ECOCERT?)

Clear Agreement – YES

1. Jake Lewin - California Certified Organic Farmers (CCOF) – 4 Yes, 1 Maybe
2. John Bobbe - Organic Farmers' Agency for Relationship Marketing (OFARM) – 5 Yes
3. Silke Fuchshofen - International Organic Inspectors Association (IOIA) – 5 Yes
4. Monique Marez - Organic Trade Association (OTA) – 5 Yes
5. Peter Carlson - US Commodities LLC dba AgMotion – 5 Yes

Maybes - to Discuss

- Mike Dill - Organically Grown C//ompany – 3 Yes; 2 Maybe
- Sam Welsch - One Cert; Mix of Yes/Maybe, One No (Split Votes)
- Erin Heitkamp - Pipeline Foods; Mix of Yes/Maybe, One No (Split Votes)

Overall Votes Suggest NO (Criteria: 1 or fewer (0) people Yes)

1. Christine Halbot Canadian Organic Seed Company Ltd – 5 No
2. Bill Barkley Barkley's Agriculture Consulting – 1 Yes, 1 Maybe, 3 No
3. Pedro A. Landa - Organización Internacional Agropecuaria S.A. – 1 Yes, 1 Maybe, 3 No
4. Carmen Murillo Quiroga – Bolicert – 2 Maybe, 3 No
5. Helga Villanueva - NP Nutra – 4 Maybe, 1 No

Name and Organization	Nominated By:	Brief Description of Nomination
Jake Lewin California Certified Organic Farmers (CCOF)	Peter Nell California Certified Organic Farmers (CCOF) Also nominated by: Georgana Webster Montana Department of Agriculture	• Serves as President of CCOF Certification Services, LLC • 20 years of organic certification experience • Company oversees about 3,500 organic operations throughout North America • Experience overseeing complex supply chain • Implemented process to require their operations who source ingredients from uncertified brokers, traders, wholesales, or distributors to provide audit trail information that traces products back to the last certified organic operation document • Collaborates with domestic and international stakeholders • Serves on the Organic Trade Association's (OTA) Global Organic Supply Chain Integrity Task Force; Participates in the Accredited Certifiers Association's (ACA) Best Practices for Verifying Traceability in the Supply Chain Working Group • Recently presented on "Improving the Integrity of Organic Supply Chains" at the Research Institute of Organic Agriculture's (FiBL) Anti-Fraud Initiative International Conference in Ukraine • Awarded for his outstanding service and contributions to the NOP's development of the National Integrity Database • Complete nomination attached (PDF)
Pedro A. Landa Organización Internacional Agropecuaria S.A.	Self-nominated	• Conducts product trace-back from the export certificate to the field • No additional background provided for nomination
Carmen Murillo Quiroga Bolicert	Self-nominated	• Works across the organic supply chain • Understands organic processes and weaknesses from certification to marketing. • Implemented additional controls for organic operations • Has other ideas for improving on current controls • Would need translator
Helga Villanueva NP Nutra	Kalindi Perez NP Nutra (also recommended by	• Serves as Director of Quality Assurance • Company leads industry in testing and traceability for certified organic products • Company requires screening for each lot of organic ingredients before allowing suppliers to ship the product

Name and Organization	Nominated By:	Brief Description of Nomination
	Sarah Costin, A Bee Organic Certification)	
John Bobbe Organic Farmers' Agency for Relationship Marketing (OFARM)	Self-nominated	• Serves as Executive Director of OFARM, five-member marketing cooperative with certified organic producers in 19 states • Authored the book, "Marketing Organic Grain, A Farmer's Guide" • Met with European organic leaders and spoke at the international conference on "Maintaining Integrity of Organic Supply Chains" in Ukraine • Company works with members to market products and conduct trace-back through complex supply chains; Filed multiple complaints with the NOP regarding potential fraudulent activities with organic grain imports; Identified various weaknesses in the supply chain and reported information to the NOP • Established a number of controls to overcome supply chain weaknesses • Addressed the NOSB with both written and verbal comments regarding the issue of organic import fraud • Relevant Education: Master's degree in agricultural economics • Own a family farm and the Bobbe Sawmill and Lumber Company • Complete nomination attached (MS Word)
Silke Fuchshofen International Organic Inspectors Association (IOIA)	Margaret Scoles International Organic Inspectors Association (IOIA)	• Serves as an Accredited IOIA Inspector • Experience conducting inspections of organic processing operations and traders since 2008 • Extensive experience verifying compliance in complex supply chains, with a specialized focus on products' re-entry into the organic supply chain • Served on multiple Boards of Directors, including the IOIA Board of Directors and the FairTSP Board of Directors • Serves as part of the OTA's Fraud Prevention Task Force • Developed multiple training tools on complex supply chains, including: The Fair Trade Sustainability Alliance program (co-developed); Risk Assessment of Uncertified Vendors; Webinar for organic processors (in development); Presentation to the Accredited Certifier Association (ACA) • Training tools identify supply chain weaknesses and outline suggested processes for additional controls

Name and Organization	Nominated By:	Brief Description of Nomination
		• Relevant Education: Bachelor's degree in International Agriculture • Complete nomination attached (PDF)
Monique Marez Organic Trade Association (OTA)	Gwendolyn Wyard Organic Trade Association (OTA)	• Serves as the Director of International Trade for the Organic Trade Association • Leads OTA's international market access, market promotion, trade policy, and technical assistance projects • Serves as a liaison between buyers and suppliers globally • Serves as a co-chair for OTA's Global Organic Supply Chain Integrity (GOSCI) Task Force • As part of task force, currently developing a handbook and toolkit for vulnerability assessment and mitigation strategy • Leading efforts to create tools that help companies submit actionable complaints to NOP • Relevant Education: Bachelor's degree in Ethics, Politics, Economics, and International Studies; Master's degree in Nutrition, Public Health, and Food Studies with a focus in Food Systems • Complete nomination attached (MS Word)
Erin Heitkamp Pipeline Foods	Gwendolyn Wyard Organic Trade Association (OTA)	• Serves as the Managing Director of Strategy, Sustainability and Assurance for Pipeline Foods • More than 18 years of experience in environmental management and sustainability that includes leading a sustainability consulting practice and providing environmental regulatory oversight • Serves as a member of OTA's GOSCI task force • Company sources organic grains, oilseeds, pulses and ingredients directly from organic farmers across the U.S., Canada, and Argentina • Actively developing relationships with organic farmers in other regions of the world • Company imports organic grains and ingredients for sale to mid-stream processors and food companies • Relevant Education: Master's in Environmental Management (M.E.M) • Complete nomination attached (MS Word)
Peter Carlson US Commodities LLC dba AgMotion	Connie Karr Oregon Tilth Certified Organic (OTCO)	• Provided integral help in OTCO's efforts to understand and implement additional • Has decades of experience working with grain imports to the U.S. and complex grain supply chains • Company sources grains from multiple regions around the world • Company serves as an imports broker/trader who works directly with storage facilities, buyers and transponders throughout the U.S.

Name and Organization	Nominated By:	Brief Description of Nomination
		• Helps OTCO understand the various grain import requirements • Consistently maintains organic integrity • Dedicated to ensuring the long term success of organic • Has lots of ideas on maintaining organic integrity in the supply chain
Mike Dill Organically Grown Company Yes: 111 Maybe: 11 No:	Connie Karr Oregon Tilth Certified Organic (OTCO)	• Provided integral help in OTCO's efforts to understand and implement additional controls for complex supply chains • Works with fruit and vegetable imports from other countries • Has a background in certification, inspecting, and quality control for produce warehouse and distribution
Christine Halbot Canadian Organic Seed Company Ltd	Self-nominated	• No background provided for nomination
Bill Barkley Barkley's Agriculture Consulting	Self-nominated	• Canadian Chair, IOIA • 18 years of experience as an organic inspector; 36 years farming experience; and is currently an organic apple and strawberry farmer in eastern Ontario • Extensive experience inspecting various types of crops, livestock, and processing operations • Completes about 100 inspections for Canadian and U.S. certifiers each year, where operations range from complex manufacturers to small farms. • Conducts inspections for ProCert, QAI, Ecocert, FVO, Demeter, QCS, LFP, and QSC • Completed multiple training courses through IOIA, including advanced, Canadian organic standards, mass balance, non-GMO, and process courses. • Other completed training includes IBD EcoSocial, Biodynamic, Non-GMO, Gluten-Free, and HACCP • Conducted crops training in 2013; Relevant Education: Bachelor's degree in Agriculture
Sam Welsch One Cert	Self-nominated Also nominated by:	• Serves as President of OneCert, Inc. • Has worked internationally with an office in India since 2005 • Actively participates in ACA's best practice and traceability working group

Name and Organization	Nominated By:	Brief Description of Nomination
	Georgana Webster Montana Department of Agriculture	• Developed forms to implement additional controls for uncertified certifiers in the supply chain • No additional background provided for nomination

Nominations for Organic Imports Panel (13 Nominees)
National Organic Standards Board (NOSB) Spring Meeting

Name and Organization	Nominated By: Self OR Name and Organization	Brief Description of Nomination	CACS Assessment: Include on Panel? Yes, No, Maybe
Jake Lewin California Certified Organic Farmers (CCOF)	Peter Nell California Certified Organic Farmers (CCOF) Also nominated by: Georgana Webster Montana Department of Agriculture	• Serves as President of CCOF Certification Services, LLC • 20 years of organic certification experience • Company oversees about 3,500 organic operations throughout North America • Experience overseeing complex supply chain • Implemented process to require their operations who source ingredients from uncertified brokers, traders, wholesales, or distributors to provide audit trail information that traces products back to the last certified organic operation document • Collaborates with domestic and international stakeholders • Serves on the Organic Trade Association's (OTA) Global Organic Supply Chain Integrity Task Force • Participates in the Accredited Certifiers Association's (ACA) Best Practices for Verifying Traceability in the Supply Chain Working Group • Recently presented on "Improving the Integrity of Organic Supply Chains" at the Research Institute of Organic Agriculture's (FiBL) Anti-Fraud Initiative International Conference in Ukraine • Awarded for his outstanding service and contributions to the NOP's development of the National Integrity Database • Complete nomination attached (PDF)	• YES- Harriet
Pedro A. Landa Organización Internacional Agropecuaria S.A.	Self-nominated	• Conducts product trace-back from the export certificate to the field • No additional background provided for nomination	• No- Harriet

Name and Organization	Nominated By: Self OR Name and Organization	Brief Description of Nomination	CACS Assessment: Include on Panel? Yes, No, Maybe
Carmen Murillo Quiroga Bolicert	Self-nominated	• Works across the organic supply chain • Understands organic processes and weaknesses from certification to marketing. • Implemented additional controls for organic operations • Has other ideas for improving on current controls • Would need translator	• No-Harriet
Helga Villanueva NP Nutra	Kalindi Perez NP Nutra (also recommended by Sarah Costin, A Bee Organic Certification)	• Serves as Director of Quality Assurance • Company leads industry in testing and traceability for certified organic products • Company requires screening for each lot of organic ingredients before allowing suppliers to ship the product	• No- Harriet
John Bobbe Organic Farmers' Agency for Relationship Marketing (OFARM)	Self-nominated	• Serves as Executive Director of OFARM, five-member marketing cooperative with certified organic producers in 19 states • Authored the book, "Marketing Organic Grain, A Farmer's Guide" • Met with European organic leaders and spoke at the international conference on "Maintaining Integrity of Organic Supply Chains" in Ukraine • Company works with members to market products and conduct trace-back through complex supply chains • Filed multiple complaints with the NOP regarding potential fraudulent activities with organic grain imports • Identified various weaknesses in the supply chain and reported information to the NOP • Established a number of controls to overcome supply chain weaknesses • Addressed the NOSB with both written and verbal comments regarding the issue of organic import fraud • Relevant Education: Master's degree in agricultural economics • Own a family farm and the Bobbe Sawmill and Lumber Company • Complete nomination attached (MS Word)	• Yes- Harriet

Name and Organization	Nominated By: Self OR Name and Organization	Brief Description of Nomination	CACS Assessment: Include on Panel? Yes, No, Maybe
Silke Fuchshofen International Organic Inspectors Association (IOIA)	Margaret Scoles International Organic Inspectors Association (IOIA)	• Serves as an Accredited IOIA Inspector • Experience conducting inspections of organic processing operations and traders since 2008 • Extensive experience verifying compliance in complex supply chains, with a specialized focus on products' re-entry into the organic supply chain • Served on multiple Boards of Directors, including the IOIA Board of Directors and the FairTSP Board of Directors • Serves as part of the OTA's Fraud Prevention Task Force • Developed multiple training tools on complex supply chains, including: The Fair Trade Sustainability Alliance program (co-developed); Risk Assessment of Uncertified Vendors; Webinar for organic processors (in development); Presentation to the Accredited Certifier Association (ACA) • Training tools identify supply chain weaknesses and outline suggested processes for additional controls • Relevant Education: Bachelor's degree in International Agriculture • Complete nomination attached (PDF)	• Yes- Harriet
Monique Marez Organic Trade Association (OTA)	Gwendolyn Wyard Organic Trade Association (OTA)	• Serves as the Director of International Trade for the Organic Trade Association • Leads OTA's international market access, market promotion, trade policy, and technical assistance projects • Serves as a liaison between buyers and suppliers globally • Serves as a co-chair for OTA's Global Organic Supply Chain Integrity (GOSCI) Task Force • As part of task force, currently developing a handbook and toolkit for vulnerability assessment and mitigation strategy • Leading efforts to create tools that help companies submit actionable complaints to NOP	• Yes- Harriet

Name and Organization	Nominated By: Self OR Name and Organization	Brief Description of Nomination	CACS Assessment: Include on Panel? Yes, No, Maybe
		• Relevant Education: Bachelor's degree in Ethics, Politics, Economics, and International Studies; Master's degree in Nutrition, Public Health, and Food Studies with a focus in Food Systems • Complete nomination attached (MS Word)	
Erin Heitkamp Pipeline Foods	Gwendolyn Wyard Organic Trade Association (OTA)	• Serves as the Managing Director of Strategy, Sustainability and Assurance for Pipeline Foods • More than 18 years of experience in environmental management and sustainability that includes leading a sustainability consulting practice and providing environmental regulatory oversight • Serves as a member of OTA's GOSCI task force • Company sources organic grains, oilseeds, pulses and ingredients directly from organic farmers across the U.S., Canada, and Argentina • Actively developing relationships with organic farmers in other regions of the world • Company imports organic grains and ingredients for sale to mid-stream processors and food companies • Relevant Education: Master's in Environmental Management (M.E.M) • Complete nomination attached (MS Word)	• No- Harriet
Peter Carlson US Commodities LLC dba AgMotion	Connie Karr Oregon Tilth Certified Organic (OTCO)	• Provided integral help in OTCO's efforts to understand and implement additional • Has decades of experience working with grain imports to the U.S. and complex grain supply chains • Company sources grains from multiple regions around the world • Company serves as an imports broker/trader who works directly with storage facilities, buyers and transponders throughout the U.S. • Helps OTCO understand the various grain import requirements • Consistently maintains organic integrity	• Yes- Harriet

Name and Organization	Nominated By: Self OR Name and Organization	Brief Description of Nomination	CACS Assessment: Include on Panel? Yes, No, Maybe
		• Dedicated to ensuring the long term success of organic • Has lots of ideas on maintaining organic integrity in the supply chain	
Mike Dill Organically Grown Company	Connie Karr Oregon Tilth Certified Organic (OTCO)	• Provided integral help in OTCO's efforts to understand and implement additional controls for complex supply chains • Works with fruit and vegetable imports from other countries • Has a background in certification, inspecting, and quality control for produce warehouse and distribution	• Yes-Harriet
Christine Halbot Canadian Organic Seed Company Ltd	Self-nominated	• No background provided for nomination	• No- Harriet
Bill Barkley Barkley's Agriculture Consulting	Self-nominated	• Canadian Chair, IOIA • 18 years of experience as an organic inspector; 36 years farming experience; and is currently an organic apple and strawberry farmer in eastern Ontario • Extensive experience inspecting various types of crops, livestock, and processing operations • Completes about 100 inspections for Canadian and U.S. certifiers each year, where operations range from complex manufacturers to small farms. • Conducts inspections for ProCert, QAI, Ecocert, FVO, Demeter, QCS, LFP, and QSC • Completed multiple training courses through IOIA, including advanced, Canadian organic standards, mass balance, non-GMO, and process courses. • Other completed training includes IBD EcoSocial, Biodynamic, Non-GMO, Gluten-Free, and HACCP • Conducted crops training in 2013 • Relevant Education: Bachelor's degree in Agriculture	• No- Harriet

Name and Organization	Nominated By: Self OR Name and Organization	Brief Description of Nomination	CACS Assessment: Include on Panel? Yes, No, Maybe
Sam Welsch One Cert	Self-nominated Also nominated by: Georgana Webster Montana Department of Agriculture	• Serves as President of OneCert, Inc. • Has worked internationally with an office in India since 2005 • Actively participates in ACA's best practice and traceability working group • Developed forms to implement additional controls for uncertified certifiers in the supply chain • No additional background provided for nomination	• Maybe to Yes- Harriet