National Organic Standards Board
Certification, Accreditation and Compliance Committee
Proposed Recommendation
Inspector Qualifications

September 14, 2011

Background

On June 23, 2011, the Deputy Administrator of the National Organic Program (NOP) issued a memorandum to the chair of the National Organic Standards Board (NOSB) requesting a proposal outlining the criteria that inspectors should be required to meet prior to conducting inspections of organic production and handling operations. The Certification, Accreditation and Compliance Committee (CACC) has reviewed this request and, in consultation with representatives from the organic community, developed this proposal. We believe that it would be appropriate, and in the best interest of the organic community, for the NOP to issue guidance to Accredited Certification Agencies (ACAs) on this subject and respectfully submit our recommendations below.

Relevant Regulatory Text

The NOP regulations require that certifiers use employees and contractors with sufficient expertise in organic production. The following passages represent all of the rule language directly addressing or related to inspector qualifications:

205.501 General requirements for accreditation.

(a) A private or governmental entity accredited as a certifying agent under this subpart must:

> (1) Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part;
>
> (2) Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart; …
>
> (4) Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;
>
> (5) Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.

(6) Conduct an annual performance evaluation of all persons who…perform on-site inspections…

§ 205.504 Evidence of expertise and ability.

A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques…:

(a) *Personnel.*

(1) A copy of the applicant"s policies and procedures for training, evaluating, and supervising personnel;

(2) The name and position description of all personnel to be used in the certification operation, including … certification inspectors, …;

(3) A description of the qualifications, including experience, training, and education in agriculture, organic production, and organic handling, for:

(i) Each inspector to be used by the applicant and…

(4) A description of any training that the applicant has provided or intends to provide to personnel to ensure that they comply with and implement the requirements of the Act and the regulations in this part.

Discussion

Organic inspectors perform a critical function in the ongoing fulfillment the Organic Foods Production Act and the NOP regulations. What professional and technical skills, knowledge and training are necessary to conduct effective inspections? There are currently no specific qualification criteria or standards for what constitutes the "sufficient expertise" called for by the section 205.501(a)(1) of the regulations. This discussion seeks to clarify issues related to defining standard inspector qualifications for all ACAs, and offers a proposal for baseline levels of:

a) pre-requisite experience, training and knowledge,
b) continuing education and training, and
c) performance oversight and assessment .

Because there are a number of different scenarios under which ACAs employ inspectors-including full time employees, part time employees, regular contractors, one-off contractors, etc- we must consider a system that allows for a wide variety of ACA- inspector relationships while ensuring that the inspectors are doing their part to uphold the high levels of integrity expected by the organic community.

In the absence of specific regulatory requirements for the qualifications of organic inspectors, ACAs have instituted a wide range of requirements and criteria in their hiring process, training, and performance monitoring. While the CACC is aware of the requirements of a few ACAs in particular, the actual extent and range of these specific requirements among the 100 worldwide NOP approved ACAs is not fully known.

The International Organic Inspectors Association (IOIA), formed in 1991, offers an organic inspector training program which is broadly recognized among ACAs. The IOIA training is currently the only training of which we are aware that is targeted at organic inspectors. Most ACAs include IOIA training certificate among their baseline inspector qualification criteria. Some ACAs require additional training beyond the IOIA certificate. These commonly include apprentice inspections and/or annual inspector trainings. Some ACAs, especially those located outside the United States, do not require IOIA training.

The CACC believes that targeted training, such as that provided by IOIA, should be strongly encouraged. We suggest that the NOP consider entering in to a Memorandum of Understanding or other recognition agreement or subcontract with IOIA so that IOIA can be formally recognized and authorized by the NOP. This could allow IOIA to create a formal inspector approval for inspectors who have successfully passed their training course and participate in continuing education. While IOIA currently offers an "accredited inspector" status, it is the understanding of the CACC that this designation is not particularly meaningful to ACAs during their hiring process, and that relatively few qualified inspectors seek "accreditation". We believe that having a pool of inspectors which are formally approved by IOIA under the auspices of the NOP would be extremely beneficial to the entire organic community.

It is essential that during the accreditation process, ACAs are verified as hiring only competent, trained inspectors. Anecdotal evidence suggests that while the qualifications of certification personnel are evaluated during current NOP audits, those of contract or part-time inspectors are not often reviewed. The CACC is particularly concerned about situations where an ACA may rely on only one inspector, or a small handful of inspectors, to perform all of the inspections for an ACA. In particular, it is essential that the ACA has sufficient criteria for assigning different types of operations to that inspector.

At minimum, all ACA"s should be required to attend annual NOP trainings and those trainings must include clear direction as to inspector qualification and continuing education. We find arguments that such trainings are cost prohibitive unconvincing. The NOP has been offering these trainings in many locations in the US and abroad for many years and has been clear of their intention to continue to do so. Those ACAs who need to adjust fees or adjust budgets accordingly need to do so. This is essential in

assuring their clients—and thereby the general public—that they are operating on a level playing field in the national and international arena. This is critical to prevent responsible ACAs from falling victim to certifier shopping based on costs which have been subsidized by systematic use of under qualified inspectors who charge less for their services. The training of ACAs is essential to ensuring that they have the opportunity to make judgments about the qualifications of the inspectors they use.

We recognize that there is not absolutely uniform need for training, experience or education for inspector qualifications across all types of inspections. Distinctions are needed according to the types of operations that are being inspected. These can be defined in different layers and to different degrees. The first and broadest categorization is by scope: Crops, Handling, or Livestock. Wild crop harvesting, the fourth scope under the NOP, should be considered a subtype of crop production, as it is of minor prevalence, and an experienced organic crops auditor can effectively perform these inspections after a focused briefing on specific issues and standards related to wild crop harvesting practices.

Within those three major lenses of the scope of production there are then a range of specialties and levels of complexity. Because of the significant diversity of crops and operation types, we cannot reasonably set the same requirements for inspectors of all the possible different crops, processes, products, animals and livestock rearing methods. While a good inspector should be capable of inspecting any operation under the general scope to which they are qualified, some types of production are particularly complicated and may require additional training. Dairy is one sub-category of livestock that arguably calls for a separate qualifications category. Dairy operations often involve unique practices and standards from other livestock production that require special training and experience for the inspector.

An additional challenge posed in appropriately assigning inspectors to operations is balancing the need for familiarity with the production system and ensuring a lack of conflict of interest. Operations being inspected rightfully expect that the inspector understand the fundamentals of the product being produced or handled. For example, an otherwise qualified inspector who is also growing strawberries or has grown strawberries might likely be a qualified inspector to inspect another strawberry farm. However, the strawberry farm being inspected may object to an inspector who currently or previously worked for a business that is in direct market competition. We recognize that this may be less of an issue for ACAs where inspectors are full time employees.

While familiarity of the inspector with the type of operation being inspected is necessary, what is more critical is the type of general auditing skills that are not easily taught. To a large extent, a typical organic inspector is a “general practitioner”. Many of the general auditing skills are applicable across the entire range of organic inspections. Expertise in

one of the three general areas makes it easier for an inspector to increase their scope to include additional types of inspections. We believe that a successful crop inspector can be more quickly trained to also do handling inspections than someone who has no inspection experience. Therefore, we believe that the specific-scope qualification criteria should be more flexible for an experienced inspector who is extending the scope of their existing qualifications.

We believe that ongoing continuing education is essential for organic inspectors. Like many other professions, we believe that organic inspectors should stay up to date on the emerging issues in the field through attending conferences, advanced trainings, or other educational events where either specific or general knowledge can be acquired. While most, if not all, ACAs do not currently require this of their inspectors, we assert that they can, and indeed should.

We recognize that we must be careful to implement requirements that are fair to all ACAs, regardless of size, but also seek to provide a meaningful baseline for hiring inspectors to assure to the greatest degree possible consistency the organic production marketplace an the consumer marketplace. At this time, we suggest that standardized inspector qualifications requirements should remain somewhat broadly defined. The organic inspector profession is not large or deep enough presently to accommodate many narrowly define scopes of qualifications. There is a need for definitions and requirements for baseline qualifications that will meet the needs of having capable knowledgeable inspectors but that are practical and achievable by inspectors and the ACAs.

Beyond the required NOP annual performance evaluation for all inspectors, it is unknown to what extent ACAs monitor inspector performance, provide constructive feedback, and require corrective action when correctable performance issues are detected. Some ACAs provide an evaluation of every inspection report. Some ACAs may require periodic witness audits of their inspectors, however this is currently unusual, perhaps due to limited administrative and over-sight resources within the ACAs. We believe that more rigorous oversight of the inspectors by ACAs would provide value to the organic community. Organic inspectors, especially those that work on contract for a number of ACAs, would likely welcome more feedback about their performance.

It is essential that ACAs are capable of ensuring that only qualified inspectors perform their inspections and assert that annual NOP training is essential for ACAs just as annual inspection training is for inspectors. While some ACAs use complex database systems to match inspector qualifications with the operation type, this can also be accomplished using simpler methods not requiring computerized systems. However it is done, we believe that each ACA must be able to justify why the specific inspector has

been assigned to a particular operation and why they are qualified to perform the inspection.

Proposed Guidance

Baseline Qualification Criteria for Organic Inspectors

A. As fundamental initial "organic inspector" criteria:
   1. Baseline pre-requisite knowledge and expertise for initial „organic inspector" status.
      a. Minimum two years of combined work experience, education, and training in organic production, applicable to the scope of inspections to be initially performed: crops, handling, or livestock.
      b. Must include at least two of the three different criteria: *experience* with the scope of operations to be inspected, *education* relevant to the scope of operations to be inspected, or specific *training* within the scope of operations to be inspected.
      c. Training equivalent to the Independent Organic Inspectors Association (IOIA) basic training, i.e. four days of concentrated training culminating in a qualifying exam.
      d. Apprenticeship consisting of a minimum of three shadow inspections, accompanied by an experienced organic inspector and followed by witness inspections where the apprentice is observed and deemed competent by the experienced inspector or certifying agent.
      e. Must have a good evaluations and recommendations by an experienced organic inspector or certifying agent assessing the inspector understanding of inspection protocols and applicable organic standards.
      f. Once an individual has established themselves as a competent organic inspector in any one of the three general areas, addition of a new scope does not require an additional two years of focused experience and training in that area. General organic inspecting skills are applicable to all areas and can therefore greatly assist the inspector in expanding their scope, while seeking whatever specific additional knowledge is required to sufficiently understand the new area.

B. As continuing organic inspector criteria:
   1. Continuing Education
      a. Annual training by Accredited Certifiers Association (ACA) to update on specific procedures of the ACA as well as National Organic Program (NOP) standards updates and guidelines.
      b. Minimum 8 hours annual continuing education related to the type of inspection work performed. Each hour of curriculum time (e.g. class time,

coursework, field study, testing), equals one hour of continuing education hours. Trainings conducted by ACAs and closed to the general inspection community do not apply toward continuing education hours given their tendency to focus on certifier procedures, rather than broad knowledge such as agronomic and food industry practices, and general auditing skills.

c. In-depth training on the topic of recordkeeping and/or accounting must be included as part of continuing education, and IOIA is encouraged to develop a training to fulfill this need.
d. Continuing education credits include webinars, seminars, workshops, and colleges and university extension programs related to the type of inspection work performed or new scope of inspection interest.

C. ACA accreditation criteria to ensure adequate monitoring and oversight of inspector qualifications:
    1. Annual attendance of NOP trainings.
    2. Documented inspector qualification monitoring program that readily provides verification that all inspectors employed or contracted in the service of the ACAs are qualified according to these criteria.
    3. Provide programmatic and consistent annual training to inspectors regarding processes, policies and procedures specific to the ACA. Training materials used must be available for review during accreditation audits and included in annual ACA updates to the NOP.
    4. Provide all inspectors with performance assessment and oversight accordingly:
        a. Witness audits by ACA to be conducted at a minimum every 300 inspections or 3 years, whichever is less. Results must be documented. Witness audits may be conducted by certification management, senior inspectors or senior reviewers.
        b. Evaluation of every inspection provided to the inspector.
        c. Annual performance evaluation provided to the inspector.
        d. All serious or persistent performance issues that arise during any of the above assessments must be documented by the ACA, and must include documented corrective action and improvement measures as deemed necessary by the ACA.

Committee Vote
Motion: John Foster Second: Barry Flamm
Yes: 6 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Guidance for Industry
Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology

Contains Nonbinding Recommendations

June, 2014

Additional copies are available from:
Office of Policy
Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 301-796-4830
http://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm

You may submit electronic or written comments regarding this guidance at any time. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. All comments should be identified with the docket number (FDA-2010-D-0530) listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document contact: Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, 301-796-4830.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner

June 2014

TABLE OF CONTENTS

Guidance for Industry
Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology[1]

This guidance represents the Food and Drug Administration's (FDA's or the Agency's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. INTRODUCTION AND SCOPE

Nanotechnology is an emerging technology that can be used in a broad array of FDA-regulated products, including medical products (*e.g.* to increase bioavailability of a drug), foods (*e.g.*, to improve food packaging) and cosmetics (*e.g.* to affect the look and feel of cosmetics). Materials in the nanoscale range (i.e., with at least one dimension in the size range of approximately 1 nanometer (nm) to 100 nm) can exhibit different chemical or physical properties, or biological effects compared to larger-scale counterparts. For example, dimension-dependent properties or phenomena may be used for functional effects such as increased bioavailability, decreased dosage, or increased potency of a drug product, decreased toxicity of a drug product, better detection of pathogens, more protective food packaging materials, or improved delivery of a functional ingredient or a nutrient in food (Refs. 1-6). These effects may derive from altered chemical, biological, or magnetic properties, altered electrical or optical activity, increased structural integrity, or other unique characteristics of materials in the nanoscale range not normally observed or expected in larger-scale materials with the same chemical composition (Ref. 7). Materials or end products may also exhibit similar properties or phenomena attributable to a dimension(s) outside the nanoscale range of approximately 1 nm to 100 nm (Refs. 27-30; see also discussion in Section II.B.5).

For the purpose of this guidance only, references to "products that involve the application of nanotechnology" or "nanotechnology products" mean products that contain or are manufactured using materials in the nanoscale range, as well as products that contain or are manufactured using certain materials that otherwise exhibit related dimension-dependent properties or phenomena. Likewise, we use the term "nanomaterial" generally to refer to both materials in the nanoscale

[1] This guidance finalizes the draft guidance, entitled "Draft Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology," which was issued in June, 2011. This guidance was prepared by FDA's Office of Policy in the Office of the Commissioner, in consultation with FDA's Center for Biologics Evaluation and Research, Center for Drugs Evaluation and Research, Center for Devices and Radiological Health, Center for Food Safety and Applied Nutrition, Center for Tobacco Products, Center for Veterinary Medicine, National Center for Toxicological Research, Office of the Chief Scientist, Office of Foods and Veterinary Medicine, Office of Regulatory Affairs, Office of Special Medical Programs, and Nanotechnology Task Force.

range and certain materials that otherwise exhibit related dimension-dependent properties or phenomena. Use of these terms is for the purpose of communicating FDA's current thinking elaborated in this document only.

As used in this guidance, the word "products" (or "FDA-regulated products") is meant to include products, materials, ingredients, and other substances regulated by FDA, including drugs, biological products, medical devices, food substances (including food for animals), dietary supplements, cosmetic products, and tobacco products.[2]

The guidance describes FDA's current thinking on determining whether FDA-regulated products involve the application of nanotechnology. This guidance is intended for manufacturers, suppliers, importers, and other stakeholders. (For convenience, the guidance will refer to these parties as "industry.") FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance documents means that something is suggested or recommended, but not required.

The application of nanotechnology may result in product attributes that differ from those of conventionally-manufactured products, and thus may merit particular examination. However, FDA (or "we") does not categorically judge all products that involve the application of nanotechnology as intrinsically benign or harmful. FDA will regulate nanotechnology products under existing statutory authorities, in accordance with the specific legal standards applicable to each type of product under its jurisdiction. We consider the current framework for safety assessment sufficiently robust and flexible to be appropriate for a variety of materials, including nanomaterials. FDA maintains a product-focused, science-based regulatory policy. Technical assessments will be product-specific, taking into account the effects of nanomaterials in the particular biological and mechanical context of each product and its intended use. As such, the particular policies for each product area, both substantive and procedural, will vary according to the statutory authorities and relevant regulatory frameworks (Ref. 8). We believe that this regulatory policy allows for tailored approaches that adhere to applicable legal frameworks and reflect the characteristics of specific products or product classes and evolving technology and scientific understanding.

This guidance provides an overarching framework for FDA's approach to the regulation of nanotechnology products. It identifies two points to consider when determining whether the FDA-regulated product involves the application of nanotechnology. An affirmative finding to either of the Points to Consider, elaborated in section II below, might suggest the need for particular attention by the Agency and/or industry to the product to identify and address potential implications for safety, effectiveness, public health impact, or regulatory status of the product.

This guidance does not address, or presuppose, what ultimate regulatory outcome, if any, will result in a particular case where the use of these points may indicate that an FDA-regulated product involves the application of nanotechnology. Issues such as the safety, effectiveness,

[2] Nanotechnology may also be applied to combination products (as defined at 21 CFR 3.2(e)).

public health impact, or the regulatory status of nanotechnology products are currently addressed on a case-by-case basis using FDA's existing review processes.[3]

This guidance also does not establish regulatory definitions. Rather, it is intended to help industry and others identify when they should consider potential implications for regulatory status, safety, effectiveness, or public health impact that may arise with the application of nanotechnology in FDA-regulated products. We advise industry to consult with FDA early in the development process to facilitate a mutual understanding of the specific scientific and regulatory issues for their nanotechnology products.

FDA will provide further guidance to industry, as needed, to address the application of nanotechnology as applicable to specific FDA-regulated products or classes of products (such as human foods, drugs, or cosmetics), consistent with existing federal policies (Refs. 9, 10). As appropriate, FDA's product-specific guidance documents will address issues such as the regulatory status, safety, effectiveness, performance, quality, or public health impact of nanotechnology products.[4]

II. DISCUSSION

FDA has not established regulatory definitions of "nanotechnology," "nanomaterial," "nanoscale," or other related terms. These terms are commonly used in relation to the engineering (i.e., deliberate manipulation, manufacture or selection) of materials that have at least one dimension in the size range of approximately 1 nanometers (nm) to 100 nm. For example, the National Nanotechnology Initiative Program defines nanotechnology as "the understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications" (Ref. 11). Various published definitions mention other factors such as function, shape, charge, the ratio of surface area to volume, or other physical or chemical properties.

Based on our current scientific and technical understanding of nanomaterials and their characteristics, FDA believes that evaluations of safety, effectiveness, public health impact, or regulatory status of nanotechnology products should consider any unique properties and behaviors that the application of nanotechnology may impart. This guidance identifies two Points to Consider that should be used to evaluate whether FDA-regulated products involve the application of nanotechnology. These points address both particle dimensions and dimension-dependent properties or phenomena. Product-specific premarket review, when required, offers an opportunity for FDA to apply these points and, where products are not subject to premarket review, industry should consider these points. If either point applies to a given product, industry

[3] It bears noting that the application of nanotechnology may also affect the classification of a product. For example, nanomaterials used in medical products may function through different modes of action than larger-scale materials with the same chemical composition, which may affect the classification of the product, for example as a drug or device.

[4] FDA's guidance documents relevant to nanotechnology, including product-specific guidance documents that focus on nanotechnology applications in specific product sectors, can be found at: http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/default htm

and FDA should consider whether the evaluations of safety, effectiveness, public health impact, or regulatory status of that product have identified and adequately addressed any unique properties or behaviors of the product.

These two Points to Consider are intended to provide an initial screening tool that can be broadly applied to all FDA-regulated products, with the understanding that these points are subject to change in the future as new information becomes available. In particular, FDA may further refine these points, either as applicable broadly to all FDA-regulated products or as applicable to particular products or classes of products, as justified by scientific information. This may include refining particle size parameters or introducing additional parameters such as those related to particle size distribution or specific properties.[5] We will consider future revisions to our approach, including developing regulatory definitions relevant to nanotechnology, as warranted and in keeping with evolving scientific understanding. As previously indicated, FDA also may provide additional guidance, including product-specific guidance documents, to address issues such as the regulatory status, safety, effectiveness, performance, quality, or public health impact of nanotechnology products.

A. Points to Consider

At this time, when considering whether an FDA-regulated product involves the application of nanotechnology, FDA will ask:

1. Whether a material or end product is engineered to have at least one external dimension, or an internal or surface structure, in the nanoscale range (approximately 1 nm to 100 nm);

In addition, as we explain in more detail below, because materials or end products can also exhibit related properties or phenomena attributable to a dimension(s) outside the nanoscale range of approximately 1 nm to 100 nm that are relevant to evaluations of safety, effectiveness, performance, quality, public health impact, or regulatory status of products, we will also ask:

2. Whether a material or end product is engineered to exhibit properties or phenomena, including physical or chemical properties or biological effects, that are attributable to its dimension(s), even if these dimensions fall outside the nanoscale range, up to one micrometer (1,000 nm).[6]

[5] At this time, we do not have an adequate basis on which to determine a particle number threshold or a list of "unique" or "novel" properties that are applicable across the range of FDA-regulated products. In addition, challenges related to measurement methods and biological effects add further complexity to recommending use of particle number, weight, or surface area as the most appropriate units of measure. FDA intends to actively follow scientific developments on this issue and provide additional guidance, as appropriate.

[6] As explained in section II.B.5. below, the use of 1,000 nm as a reference point should not be interpreted to mean that materials or products with dimensions above 1,000 nm cannot exhibit dimension-dependent properties or phenomena of importance to safety, effectiveness, public health impact, or regulatory status of the material or product. See further discussion on this issue in section II.B.5. below.

These considerations apply not only to new products, but also when changes to manufacturing processes alter the dimensions, properties, or effects of an FDA-regulated product or any of its constituent parts.[7]

B. Rationale for Elements within the Points to Consider

1. Material or end product that is *engineered* to have certain dimensions or exhibit certain properties (in Points 1 and 2)

The term "engineered," used in both Points 1 and 2, is used to distinguish products that have been deliberately manipulated by the application of nanotechnology from those products that contain materials that naturally occur in the nanoscale range. FDA is particularly interested in the *deliberate* and *purposeful* manipulation and control of dimensions to produce specific properties, because the emergence of these new properties or phenomena may raise questions about the safety, effectiveness, performance, quality or public health impact that may warrant further evaluation. FDA's interest in materials or products "engineered" to have nanoscale dimensions or related dimension-dependent properties or phenomena is distinct from the more familiar use of biological or chemical substances that may naturally exist at small scales, including at the nanoscale, such as microorganisms or proteins.

The term "engineered" is also used to distinguish products that have been deliberately manipulated by the application of nanotechnology from products that may unintentionally include materials in the nanoscale range.
For example, the incidental presence of particles in the nanoscale range in conventionally-manufactured products[8] is not covered under the scope of this guidance.[9]

2. Material or end product (in Points 1 and 2)

The phrase "material or end product," referred to in both Points 1 and 2, is used to cover different types of articles that are regulated by FDA, such as products, materials, ingredients, and other substances regulated by FDA. This includes finished products (e.g., a drug tablet for administration to a patient) as well as materials that are intended for use in a finished product (e.g., a food additive added to a food during processing). In determining whether a material or end product satisfies either Point 1 or Point 2, FDA will examine the material or end product, and may also consider the constituent parts of the material or end product. Therefore, relevant considerations include whether a material or end product contains or involves in its manufacture the use of materials that meet either Point 1 or Point 2.

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[7] These Points to Consider are not intended to apply to products that have been previously reviewed or approved by FDA and where no changes are made to manufacturing processes that would alter the dimensions, properties or effects of the product or its constituent parts.

[8] For example, small amounts of particles in the nanoscale range have been reported to be present in foods manufactured using conventional food manufacturing practices (Ref. 12).

[9] However, evaluations of conventionally-manufactured products may include a consideration of the effects, if any, of such incidental presence of particles in the nanoscale range on the safety, effectiveness, or public health impact of a product.

3. At least one external dimension, or an internal or surface structure, in the nanoscale range (approximately 1 nm to 100 nm) (in Point 1)

A size range of approximately 1 nm to 100 nm is commonly used in various working definitions or descriptions regarding nanotechnology proposed by the regulatory and scientific community.[10] In this size range, materials can exhibit new or altered physicochemical properties that can enable novel applications (Refs. 11, 13-15). Accordingly, per Point 1, if a material or end product is engineered to have at least one external dimension in the range of 1 nm to 100 nm, or is engineered to have an internal or surface structure in the range of 1 nm to 100 nm, industry and FDA should consider any unique characteristics or biological effects exhibited by the product that may influence its safety, effectiveness, public health impact, or regulatory status. Primary particles engineered with at least one external dimension within the nanoscale range are covered in Point 1. This Point also covers any aggregates or agglomerates formed by such nanoscale primary particles. In addition, coated, functionalized, or hierarchically-assembled engineered structures that include internal or surface discrete and functional nanoscale entities, such as where such entities are embedded or attached to the surface, are encompassed within Point 1.[11] Such engineered structures with discrete and functional nanoscale entities embedded or attached to the surface may have altered properties or phenomena that may affect product safety or effectiveness (Ref. 16). The inclusion of particles, objects, or structures with internal, surface, or external dimension(s) in the nanoscale range is consistent with approaches taken by other scientific and regulatory bodies (Refs. 17-23).

4. Properties or phenomena attributable to dimension(s) (in Point 2)

While size alone, for very small particles, is suggestive of the presence of properties meriting further examination, the identification and assessment of specific dimension-dependent properties and phenomena are ultimately more relevant for purposes of FDA regulatory review and oversight. Point 2, therefore, focuses on the properties of the material and its behavior in biological systems.[12] The phrase "exhibits properties or phenomena . . . that are attributable to its dimension(s)," is used because properties and phenomena of materials in the nanoscale range enable applications that can affect the safety, effectiveness, performance, quality, public health impact, or regulatory status of FDA-regulated products. For example, as noted above, dimension-dependent properties or phenomena may be used for various functional effects such as increased bioavailability or decreased toxicity of drug products, better detection of pathogens,

[10] For example, a size range of approximately 1 nm to 100 nm is used in definitions, working definitions, or descriptions published by the National Nanotechnology Initiative (Ref. 11); Environmental Protection Agency (http://www.epa.gov/pesticides/regulating/nanotechnology html); European Commission (Ref. 17); Health Canada (Ref. 19); International Standards Organization (Ref. 20); Organization for Economic Cooperation and Development's Working Party on Nanotechnology and Working Party on Manufactured Nanomaterials (http://www.oecd.org/sti/nano/); National Cancer Institute (http://www.cancer.gov/dictionary?cdrid=445071); and American National Standards Institute (http://nanostandards.ansi.org/tiki-index.php).

[11] This is not intended to include any incidental presence of internal or surface features with dimensions in the nanoscale range that may be present in conventionally-manufactured substances (for example, internal porosity, surface roughness or surface defects).

[12] Consistent with "Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials," Office of Science and Technology Policy, Office of Management and Budget, and Office of the United States Trade Representative, June 9, 2011 (Ref. 10).

improved food packaging materials, or improved delivery of nutrients. These effects may derive from altered or unique characteristics of materials in the nanoscale range that are not normally observed or expected in larger-scale materials with the same chemical composition (Ref. 7). However, such changes may raise questions about the safety, effectiveness, performance, quality or public health impact of nanotechnology products. In addition, considerations such as routes of exposure, dosage, and behavior in various biological systems (including specific tissues and organs) (Refs. 13, 24) are critical for evaluating the safety, effectiveness, public health impact, or regulatory status of a wide array of products under FDA's jurisdiction. Such evaluations should include a consideration of the specific tests (whether traditional, modified, or new) that may be needed (Refs. 25, 26) to determine the physicochemical properties and biological effects of a product that involves the application of nanotechnology.

5. Dimension(s) of up to one micrometer (1,000 nm) (in Point 2)

Materials or end products can also exhibit properties or phenomena attributable to a dimension(s) outside the nanoscale range of approximately 1 nm to 100 nm. Physical and chemical properties and biological behavior that are relevant to evaluations of safety, effectiveness, performance, quality, public health impact, or regulatory status of products have been observed at dimensions outside the nanoscale range of approximately 1 nm to 100 nm (Refs. 27-30). Therefore, Point 2 focuses on the importance of considering properties or phenomena attributable to dimensions, even where such dimensions may be outside the nanoscale range of approximately 1 nm to 100 nm. FDA's consideration of materials with dimension(s) outside the nanoscale range of approximately 1 nm to 100 nm is consistent with approaches taken by other scientific and regulatory organizations.[13]

[13] For example, the Joint Research Centre and the Scientific Committee on Emerging and Newly Identified Health Risks of the European Commission concluded: "In order to base a nanomaterials definition for regulatory purposes on size alone, the upper nanoscale limit should ideally be high enough to capture all types of materials that would need particular attention for regulation due to their nanoscale size. Upper limits which are often used in existing definitions, for example 100 nm, may require the introduction of one or more qualifiers based on structural features or properties other than size, in order to capture structures of concern (for example agglomerates or aggregates) with a size larger than 100 nm in the regulation" (Ref. 22); "The upper size limit for one or more external dimensions of 100 nm is complicated by the potential exclusion of aggregates, agglomerates and multicomponent assemblies that would have external sizes greater than this" (Ref. 23); and "An upper limit of 100 nm is commonly used by general consensus but there is no scientific evidence to support the appropriateness of this value (Stated as SCENIHR conclusions in the European Commission Recommendation on the definition of nanomaterial, Ref. 17). The European Commission further noted that "it may be necessary to include additional materials, such as some materials with a size . . . greater than 100 nm in the scope of application of specific legislation or legislative provisions suited for a nanomaterial (Ref. 17). In addition, the International Organization for Standardization (ISO) "acknowledged that health and safety considerations associated with intentionally produced and incidental nano-objects do not abruptly end at dimensions of 100 nm. As knowledge expands, it is abundantly clear that a robust terminology will need to capture and convey effectively the performance aspects of intentionally produced nano-objects and nanostructured materials in their definitions, apart from their fundamental size and shape" (Ref. 20). More recently, Health Canada adopted a working definition of nanomaterial that, in part, reflects that it is possible for nanoscale properties/ phenomena to be exhibited outside the 1 nm to 100 nm size range, such as select quantum devices (Ref. 19). Finally, in its second regulatory review on nanomaterials, the European Commission noted that "fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials." Several types of nanomaterials were identified as not matching the EU definition, with an acknowledgment that "there are an increasing number of particles which are engineered to have internal nanoscale features. Examples are core-shell particles and nano-encapsulates. These particles may be designed, for example for pharmaceutical applications, where the inner core particle is "released" in a certain

At the present time, available scientific information does not establish a uniform upper boundary above 100 nm where novel properties and phenomena similar to those seen in materials with dimensions in the nanoscale range cease for all potential materials or end products. For this reason, at this time, FDA finds it reasonable to consider evaluation of materials or end products engineered to exhibit properties or phenomena attributable to dimensions up to 1,000 nm, as a means to screen materials for further examination and to determine whether these materials exhibit properties or phenomena attributable to their dimension(s) and associated with the application of nanotechnology.[14] An upper limit of one micrometer (1,000 nm) applied in the context of properties or phenomena attributable to dimensions serves both to: (1) include materials with dimension(s) outside the nanoscale range of approximately 1 nm to 100 nm that may exhibit dimension-dependent properties or phenomena associated with the application of nanotechnology and distinct from those of macro-scaled materials; and (2) exclude macro-scaled materials that may have properties attributable to their dimension(s) but are not likely associated with the application of nanotechnology.

An upper limit of 1,000 nm, combined with the presence of dimension-dependent properties or phenomena similar to those seen in materials with dimensions in the nanoscale range, provides an initial screening tool to help identify materials or products with properties or phenomena of particular relevance for regulatory review. The use of 1,000 nm as a reference point in this context should not be interpreted to mean that materials or products with dimensions above 1,000 nm cannot exhibit dimension-dependent properties or phenomena of importance to safety, effectiveness, public health impact, or regulatory status of the material or product. As noted above, we may further refine these Points to Consider, including this upper limit, either as applicable broadly to FDA-regulated products or as applicable to specific products or product categories.

III. CONCLUSION

The two Points to Consider elaborated in this guidance should be applied when considering whether an FDA-regulated product involves the application of nanotechnology. An affirmative finding to either of the Points to Consider, elaborated in this guidance, might suggest the need for particular attention to the product by FDA and/or industry for potential implications for safety, effectiveness, public health impact, or regulatory status of the product. We will consider future revisions to our approach, including developing regulatory definitions relevant to nanotechnology, as warranted and in keeping with evolving scientific understanding.

There remains a need to learn more about the potential role and importance of dimensions in the physical and chemical characteristics and biological effects exhibited by FDA-regulated products

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environment. Some of these materials have an external diameter smaller than 100 nm, matching the EU nanomaterial definition, others have an external diameter larger than 100 nm, not matching the EU nanomaterial definition" (Ref. 31).

[14] However, as noted previously, FDA will consider further refinement of these Points to Consider for particular products or classes of products, as scientific information becomes available, including refining particle size parameters.

that involve the application of nanotechnology.[15] Product-specific premarket review, when required, offers an opportunity for FDA to better understand the properties and behavior of products that involve the application of nanotechnology. Where products that involve the application of nanotechnology are not subject to premarket review, we urge industry to consult with the Agency early in the product development process. In this way, any questions about the products' regulatory status, safety, effectiveness, or public health impact can be appropriately and adequately addressed. FDA has and, as needed, will continue to provide additional guidance to industry in more targeted guidance documents to address these considerations.

IV. REFERENCES

We have placed these references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of June 1, 2014, FDA had verified the Web site addresses for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after June 1, 2014.

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National Organic Standards Board Member Guide 2016

March 29, 2007 | Updated: November 30, 2007 | May 22, 2008 | November 19, 2008 | May 6, 2009 | October 28, 2010 | January 23, 2012| February 1, 2013 | October 14, 2016

Welcome new NOSB members

Congratulations and welcome to the National Organic Standards Board (NOSB)! We look forward to working with you over the next five years to advance organic regulations as defined by the Organic Foods Production Act (OFPA) and the USDA National Organic Program (NOP).

Orientation:

NOSB new member orientation is typically one-day long, and is held in early February at the USDA building in Washington, DC. The USDA will cover travel and lodging expenses for you to attend. More on that in the Travel section below. During the training we will discuss all of the documents listed below. Soon after joining the NOSB, you should read and be familiar with the following materials:

Organic Foods Production Act of 1990 (OFPA)

Title XXI of the 1990 Farm Bill, known as the OFPA, established the NOP within the Agriculture Marketing Service (AMS) of the USDA. It also established the NOSB, an advisory body to the NOP. Typically, laws (like OFPA) do not contain a level of detail for their practical implementation. Rather, agencies of the Executive branch have to establish rules, or regulations, to serve as guides in the implementation of laws.

USDA Organic Regulations at 7 CFR 205 Final Rule

The final rule implements OFPA, and includes all USDA organic standards, prohibited practices, requirements, and the National List of Allowed and Prohibited Substances. The December 21, 2000 final rule established the NOP within the AMS, an arm of the U.S. Department of Agriculture (USDA). NOP facilitates domestic and international marketing of fresh and processed food that is organically produced and assures consumers that such products meet consistent, uniform standards. NOP is required to establish national standards for the production and handling of organically produced products, including a National List of substances approved for and prohibited from use in organic production and handling. The final rule also established a national-level accreditation program, labeling requirements, and foreign organic program equivalency requirements.

NOSB Charter

A formal charter must be prepared and filed before an advisory committee can meet or take any action. The purpose of the charter is to specify the Committee's mission or charge, specific duties, and general operational characteristics. The NOSB charter is renewed every two years

NOSB Policy and Procedure Manual (PPM)

The PPM contains procedures and guidance for members of the NOSB. The manual is designed to assist the Board in its responsibilities and is considered mandatory reading. The PPM covers many important issues, such as the NOSB vision statement, duties of the Board and officers, conflict of interest

policies, NOSB principles of organic production and handling, materials review process, technical reports (TRs), the sunset review process, and more. Updates and revisions are incorporated periodically.

NOP Federal Advisory Committee Act (FACA) - See FACA FACTS in Policy & Procedures Manual.

You may also find the following webpages useful:

Agricultural Marketing Service (AMS)/National Organic Program (NOP) - Access to proposed rules, organic regulations, the national list of allowed and prohibited substances, the list of petitioned substances, and the Program Handbook, in which you will find a compilation of guidance documents, policy memos, instructions, and more!

NOSB Webpage. Includes NOSB Policy and Procedures Manual, (PPM) NOSB meeting information, Subcommittee notes, Subcommittee proposals and discussion documents, previous NOSB recommendations, and more!

About the National Organic Standards Board (NOSB)

OFPA authorized the Secretary of Agriculture to appoint a 15-member National Organic Standards Board (NOSB). The NOSB drafts recommendations based on needs of the industry with public and stakeholder input. The Board's main mission is to make recommendations about whether a substance should be allowed or prohibited in organic production or handling, to assist in the development of standards for substances to be used in organic production, and to advise the Secretary on other aspects of OFPA implementation.

The first NOSB was appointed by then Secretary Edward Madigan in January 1992. Members of the initial board served staggered terms of 3, 4, or 5 years; all subsequent Board appointees serve 5-year terms. Per OFPA, the board must consist of 15 members:

- Four individuals who own or operate an organic farming operation;
- Two individuals who own or operate an organic handling operation;
- One individual who owns or operates a retail establishment with significant trade in organic products;
- Three individuals with expertise in areas of environmental protection and resource conservation;
- Three individuals who represent public interest or consumer interest groups;
- One scientist with expertise in the fields of toxicology, ecology, or biochemistry; and
- One individual who is a certifying agent

Selecting NOSB Subcommittees

The majority of the Board's work is done in its six (6) standing subcommittees. Subcommittees meet regularly -- once or twice per month via conference call -- between public meetings to develop proposals and discussion documents for the full NOSB's consideration. Additionally,

the Executive Committee, a subset of the full NOSB, comprised of the three NOSB Officers and each of the 6 Subcommittee Chairs, meets once a month to discuss topics related to the Board's work. In consultation with the NOSB Chairperson, you will select 2-4 of the following standing Subcommittees on which to participate. Generally, it is best to select Subcommittees for which you have expertise.

1. Compliance, Accreditation, & Certification Subcommittee (CACS)
2. Crops Subcommittee (CS)
3. Handling Subcommittee (HS)
4. Livestock Subcommittee (LS)
5. Materials/GMO Subcommittee (MS)
6. Policy Development Subcommittee (PDS)

Periodically the NOSB may also form ad-hoc Subcommittees on which you are welcome to participate. Once you select your Subcommittee assignments, you will receive the conference call schedule and call-in information. Subcommittee Chairpersons can update you on current topics under consideration and provide you with recent meeting notes. Additional information on the different Subcommittees is available in the PPM.

Confidentiality

While Board members are volunteer, private citizens, and not employed by the government, the Board itself is a government entity. As such, the Board is subject to Federal Advisory Committee Act (FACA) and Freedom of Information Act (FOIA) requests. Here are some tips to keep in mind while serving on the Board:

- Use a professional, respectful tone in NOSB email correspondence; remember that all correspondence with government officials is subject to FOIA requests. It's fine to be friendly and casual, but it's a good idea to refrain from talking about subjects that you wouldn't want to see on the front page of the newspaper.
- Refrain from sharing working documents with the public. Working documents are defined as information that a board member gains by reason of participation in the NOSB and that he/she knows, or reasonably should know, has not been made available to the general public (e.g. is not on the NOP or other public websites), or is a draft document under development by an NOSB Subcommittee.
- NOSB Subcommittee calls are not open to anyone besides the NOP and NOSB members, unless an expert is specifically invited to attend. However, summary notes are developed for each NOSB Subcommittee call and are posted on the NOP website after approval by the Subcommittee.
- Formal transcripts are recorded for NOSB public meetings - whatever you say during a public meeting is on the record.

Please see the PPM for more specific guidance about NOSB member professional conduct standards.

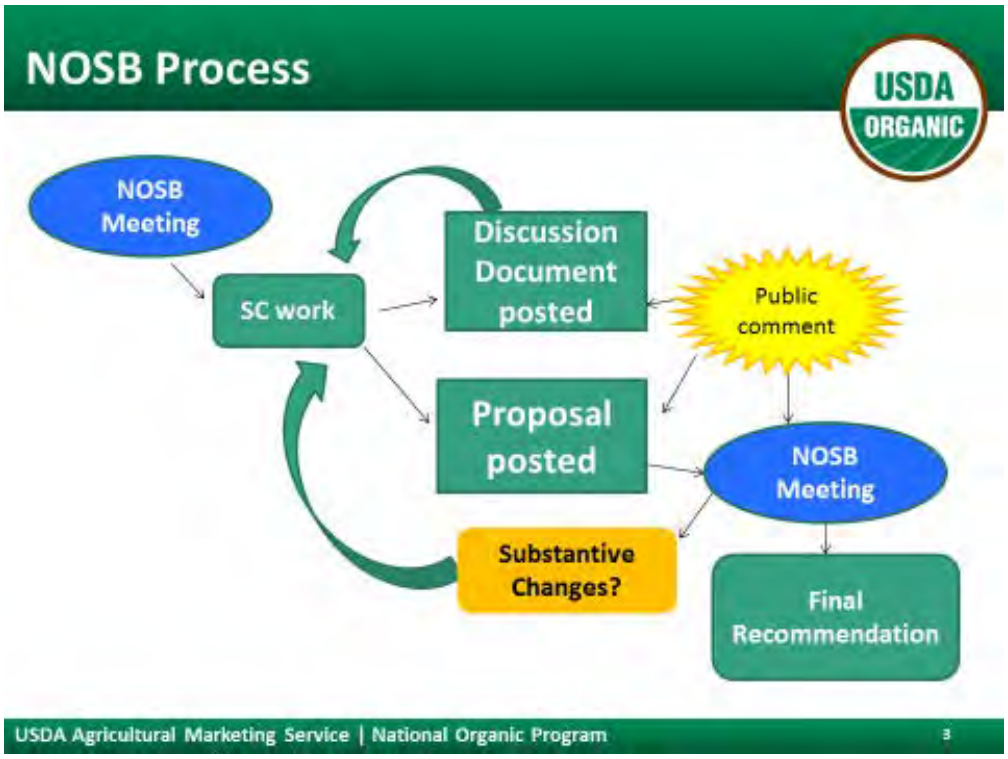
Work of the Subcommittees and the NOSB

Each of the Subcommittees has a work agenda consisting of projects and topics developed in conjunction with the NOP. Please see the PPM for more information about the process for developing work agendas. During your tenure on the Board, you will work on a range of projects; review of substances petitioned for addition to or removal from the National List of Allowed and Prohibited Substances, proposals for policy or procedure changes, discussion documents- used as a vehicle to collect more information before developing a proposal, sunset review of substances, etc.

During the new member training you will have the opportunity to complete hands-on exercises on how to read petitions, evaluate technical reports (TRs), develop proposals and other documents, and analyze public comments.

Prior to each NOSB meeting, discussion documents and proposals are posted for public inspection and written comment. During the spring and fall in-person meetings, the Board hears oral comments from stakeholders, and the Subcommittees present their discussion documents and proposals to the full Board for consideration. The Board then votes on proposals, and if passed by a 2/3 majority, they will become recommendations to the Secretary of Agriculture.

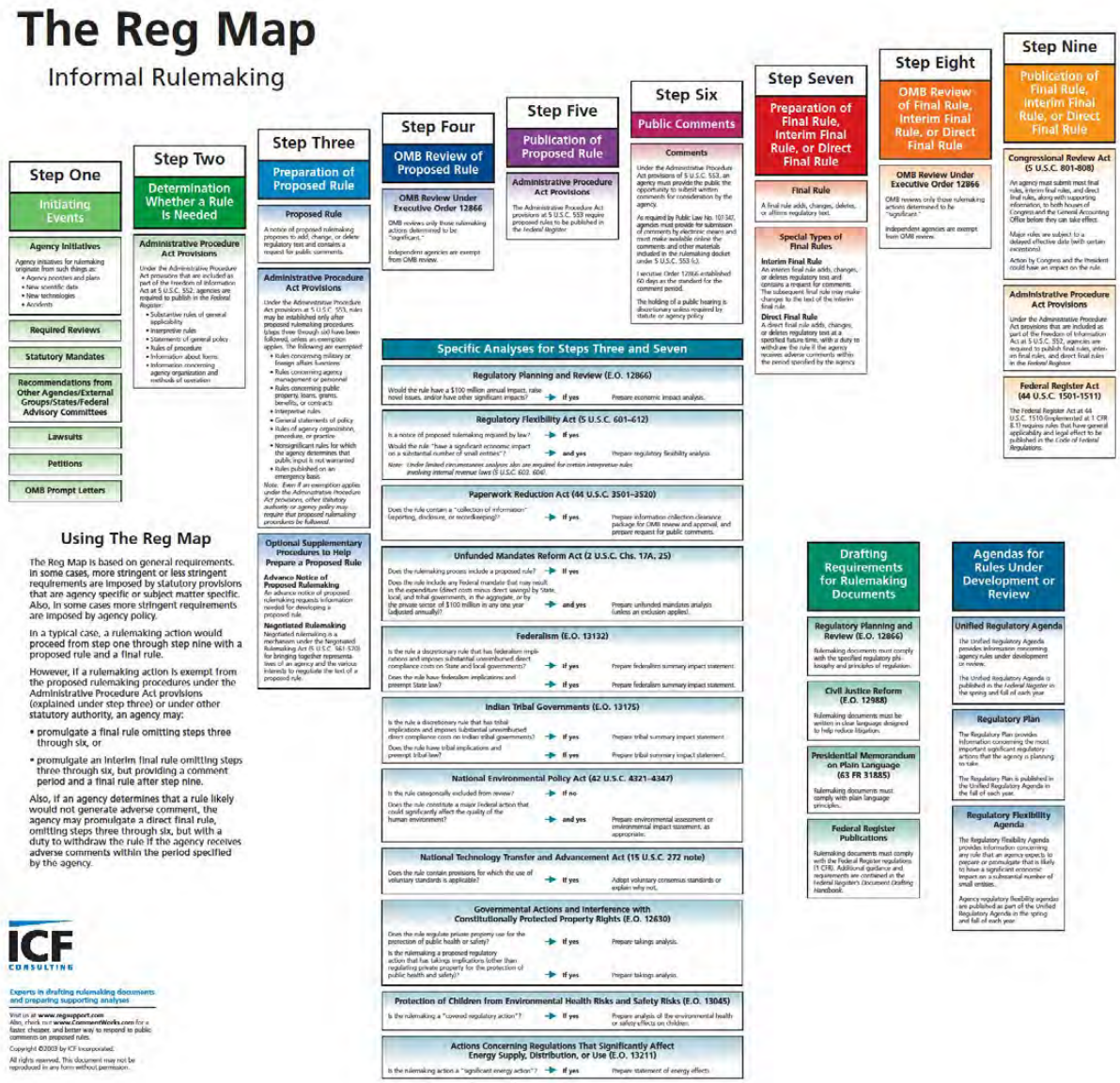
Sample NOSB Workflow



Once NOSB recommendations are submitted to the USDA/NOP, the NOP enters into the rulemaking phase, which is briefly outlined below. Rulemaking specifics will be covered in the new member training.

- Review of NOSB recommendation
- Draft regulatory workplan for Office of Management and Budget (OMB) designation
- Draft proposed rule
- Clearance & federal register publication
- Comment period
- Comment analysis
- Suggested revisions
- Draft final rule
- Clearance & federal register publication
- Issue final rule at least 30 days before effective date.

The rulemaking process. Also found at http://www.reginfo.gov/public/reginfo/Regmap/index.jsp.



Forms and templates for proposals and discussion documents

There are several formats for writing proposals and discussion documents based on the subject under review: petitioned materials, policy or procedure changes, annotation or classification changes, and sunset reviews. You can use previous documents as a starting point for new documents. [See the NOSB proposals webpage for examples.]

Proposals for PETITIONED MATERIALS are completed using the "petitioned material proposal checklist" (see screenshot below, Dropbox and the NOSB recommendations page for various examples: https://www.ams.usda.gov/rules-regulations/organic/nosb/recommendations)

Petitioned material proposals should include the following:

- **National List reference:** This section should identify the relevant Section(s) of the National List Annotations related to the material.

- **Background:** Background should include a brief discussion of the material under review, highlighting its uses, historical context, and past NOSB decisions. It should also include a short description of any current research done by the Subcommittee (e.g., review of technical reports, individual investigation, summary of public comment if available, etc.) and should provide a description of the main arguments supporting the Subcommittee's final decision, including any pertinent sections of the Regulations or OFPA.

- **Proposal:** The motion is the core idea of the proposal and should be stated clearly, including any corresponding annotation(s).

- **Subcommittee Vote:** This section should include the names of the members who moved and seconded the motion, as well as the number of yes votes, no votes, absences, abstentions and recusals. A motion should always be presented in the affirmative. In the case of proposals for petitions to add materials to the National List, two votes should be taken and recorded; the first a classification motion for either synthetic or non-synthetic and the second to list or not list the material.

National Organic Standards Board
[Handling or Livestock] Subcommittee
Petitioned Material Proposal
[Name of Material]

[Date of Vote]

Summary of Petition [link]:
[Include narrative describing petition, use category, any proposed annotations, and relevant history if reviewed previously.]

Summary of Review:
[Provide a summary of SC discussion and vote outcome. Discuss key factors that provided the basis for vote.]

Category 1: Classification

1. Substance is for: _____ **Handling** _____ **Livestock**

2. For HANDLING and LIVESTOCK use:
   a. Is the substance _____ **Agricultural** or _____ **Non-Agricultural?**
      Describe reasoning for this decision using NOP 5033-2 as a guide:

   b. If the substance is **Non-agricultural**, is the substance _____ **Non-synthetic** or ____ **Synthetic?**
      Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide:

3. For **LIVESTOCK**: 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?

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)]

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
[Name of Material]

[Date of Vote]

Summary of Petition [link]:
[Include narrative describing petition, use category, any proposed annotations, and relevant history if reviewed previously.]

Summary of Review:
[Provide a summary of SC discussion and vote outcome. Discuss key factors that provided the basis for vote.]

Category 1: Classification

1. For CROP use: Is the substance _____ **Non-synthetic** or _____ **Synthetic?**
   Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide.

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?

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)]

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)]

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

Proposals for POLICY OR PROCEDURE CHANGES, ANNOTATION OR CLASSIFICATION CHANGES should include the following:

- **Introduction:** The introduction should include a brief summary of the proposal, key issues and relevance to the organic community, as well as the goals and intent of the proposal.

- **Background:** The background section should include information to justify the development of the proposal as well as any relevant work done by the NOSB or former Board members.

- **Relevant areas in the (Regulation):** This section should include references to Sections of the Rule or OFPA that provide the basis for the proposal.

- **Discussion:** The discussion section should be a thorough explanation of the proposal. In this section you should emphasize the strengths, weaknesses, opportunities, and threats (SWOT) of the proposal. Additionally, it is appropriate and advisable to mention any alternatives reviewed by the Subcommittee and any stakeholders that might be affected.

- **Proposal:** The core idea of the proposal should be stated clearly.

- **Subcommittee Vote:** This section should include the names of the members who moved and seconded the motion, as well as the number of yes votes, no votes, absences, abstentions, and recusals. A motion should always be presented in the affirmative. In the case of proposals for petitions to add materials to the National List, two votes should be taken and recorded; the first, a classification motion for either synthetic or non-synthetic, and the second to list or not list the material.

  Minority opinion: A Subcommittee member(s) who holds a dissenting view may develop a minority view for review by all members of the Subcommittee. A minority view should: be short and concise and include reasons for opposing the Subcommittee's proposal; should not include any data or information not introduced on a Subcommittee call; should be submitted in a timely manner and will not be accepted after the Subcommittee has voted on its proposal; and will be included as a separate section at the end of the recommendation.

DISCUSSION DOCUMENTS should include the following:

- **Introduction:** The introduction should include a brief summary of the issue, relevance to the organic community, as well as the goals and intent of the document.

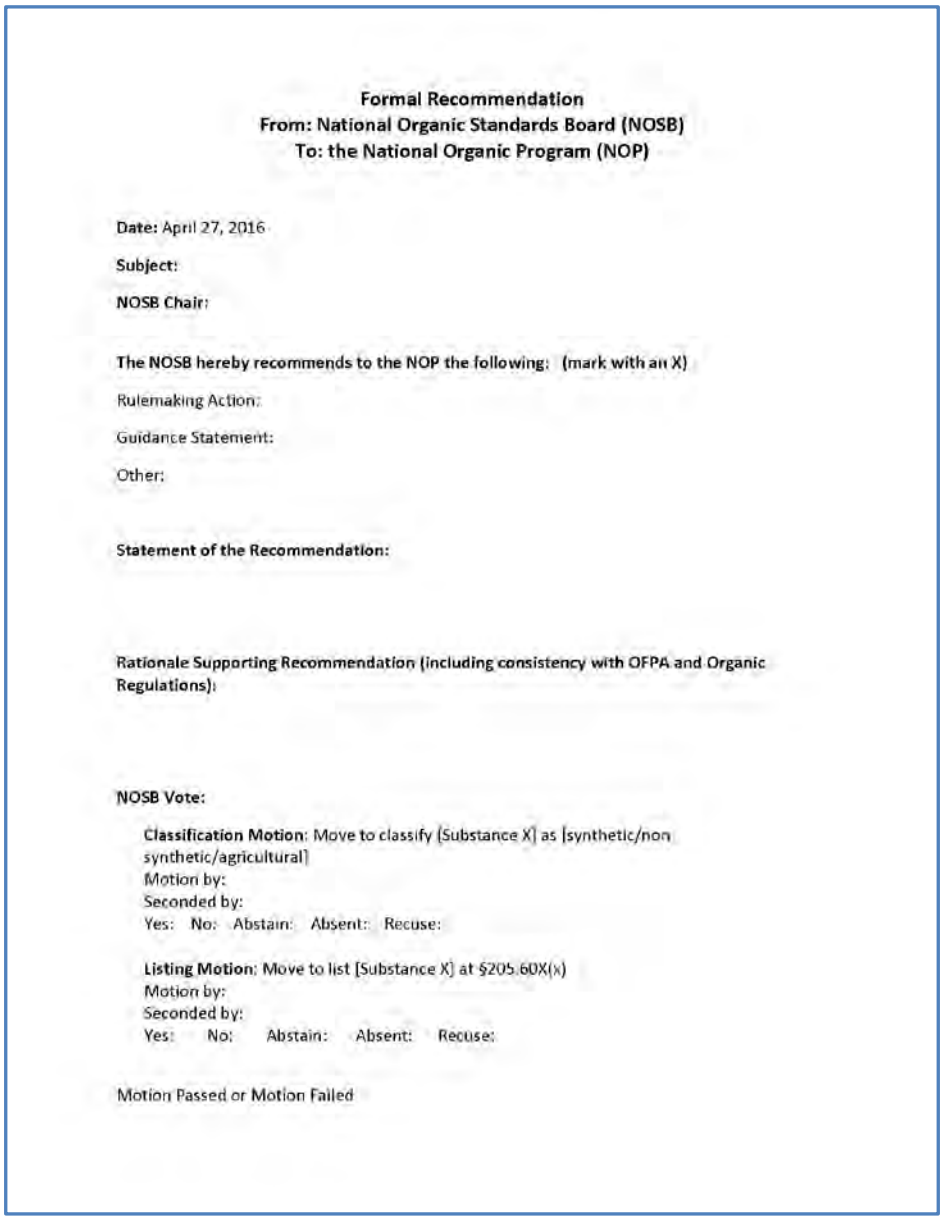
- **Background:** The background section should include information to justify the development of the document as well as any relevant work done by the NOSB or former Board members.

- **Discussion:** The discussion section should be a thorough explanation of the proposal.

- **Discussion Questions:** include questions that you would like answered by stakeholders during public comment.

COVER SHEETS FOR FINAL RECOMMENDATIONS

Once a proposal has been voted on by the NOSB, the final recommendation is posted on the NOSB website with a coversheet. Typically the lead author of the proposal or the Subcommittee Chair will complete the coversheet, and the Chair will submit it to the NOP. See below for a sample coversheet.



Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date: April 27, 2016

Subject:

NOSB Chair:

The NOSB hereby recommends to the NOP the following: (mark with an X)

Rulemaking Action:

Guidance Statement:

Other:

Statement of the Recommendation:

Rationale Supporting Recommendation (including consistency with OFPA and Organic Regulations):

NOSB Vote:

Classification Motion: Move to classify [Substance X] as [synthetic/non synthetic/agricultural]
Motion by:
Seconded by:
Yes: No: Abstain: Absent: Recuse:

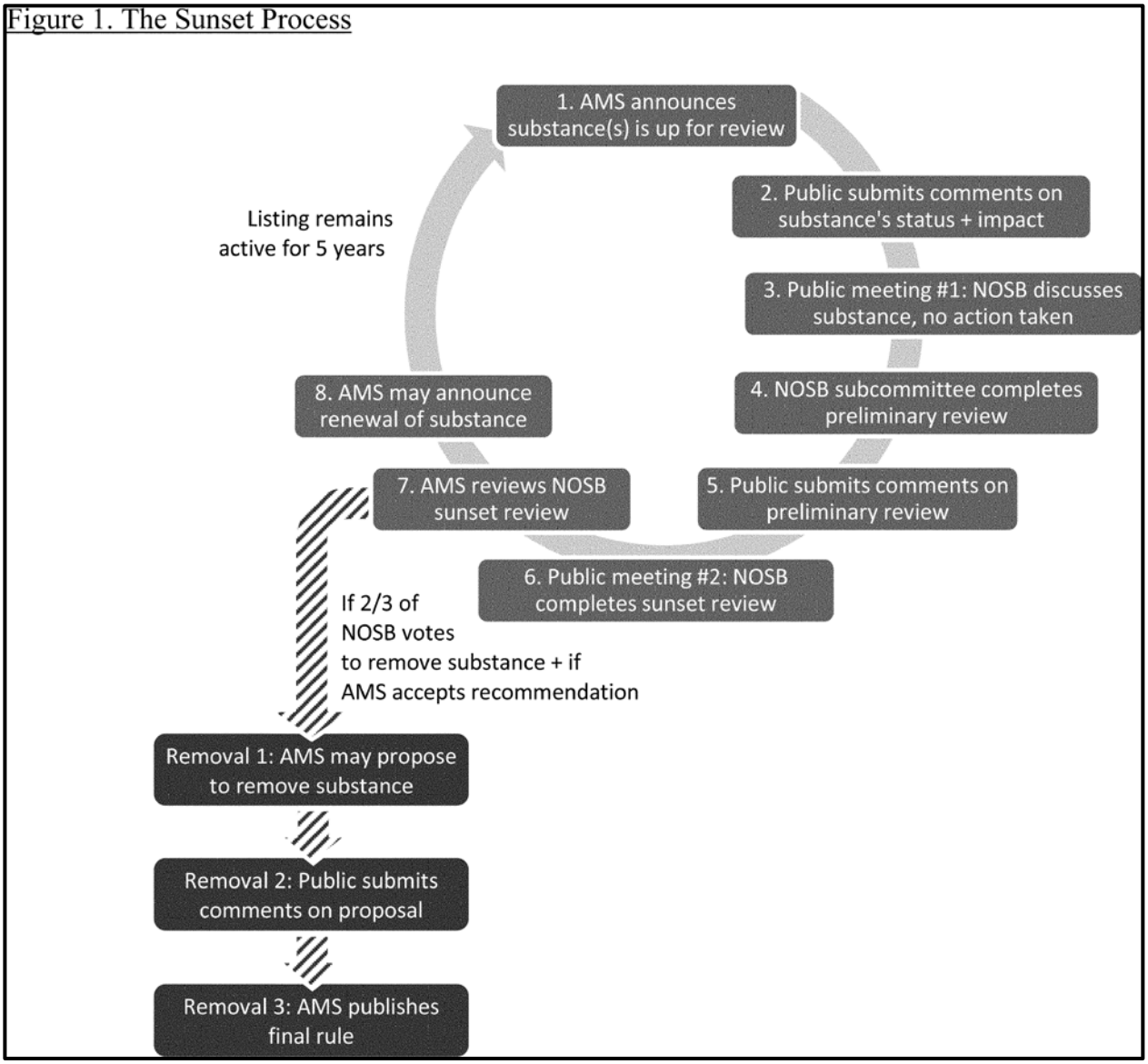
Listing Motion: Move to list [Substance X] at §205.60X(x)
Motion by:
Seconded by:
Yes: No: Abstain: Absent: Recuse:

Motion Passed or Motion Failed

Sunset Reviews: Steps, Documents, Resources

Sunset reviews are similar to discussion documents and proposals but are completed using different forms. Please see Dropbox for forms and resources.

Figure 1. The Sunset Process



Sunset Review Process (Documents are underlined, *Actions are italicized)*

STEPS as per FR Sunset notice	DOCUMENTS / *Actions*
STEP 1: AMS Announces substances for review	NOP posts Crops/Livestock/Handling Sunset Summary • May include requests for specific info from Subcommittees • Grouped by category
Step 2: Public Comments	[posted on regulations.gov]
Step 3: Public Meeting #1	*NOSB discussion* *In Person Public Comments*
Step 4: Subcommittee completes preliminary review	Subcommittee Review • Could be done as separate docs by substance • Compiled for posting Separate ancillary substance proposals NOP posts FR notice announces availability of preliminary reviews, proposals
Step 5: Public comments	[posted on regulations.gov]
Step 6: Public meeting #2	*In-person public comments* *Subcommittee presentation and NOSB discussion* *Vote to remove*, if motion made* *Vote on Ancillary substances*, if previously posted* After meeting: NOSB finalizes Sunset Review MMDDYY *If motion to remove or ancillary proposal is new, vote may be deferred until next meeting
Step 7-8: AMS review of NOSB sunset review	Proposed rule to remove substances, if so voted • Public comments Final rule to remove substances FR Notice announcing substances that remain
Step 9: Public meeting #3 (optional)	*Vote on Deferred Motions to Remove* *Vote on deferred Ancillary substance proposals*

RESOURCES FOR CONDUCTING SUNSET SUBSTANCE REVIEWS

- Go to **PETITIONED SUBSTANCE DATABASE.** If there are no links then look for the date of the first TAP review and/or the date of the meeting at which it was reviewed, and look at the minutes for that meeting (in the example below, that would be Nov 1995)

  Example: Lime, Hydrated

  Lime, Hydrated
  Petition Area and Use: Livestock: Add to 205.603
  Technical Evaluation Report (2015) (PDF)
  Technical Advisory Panel Report (1995) (PDF)
  NOSB Meeting Petition Review: November 1995
  Status: Added to the National List, section 205.603(b)(4), with annotation
  For crop use, see "Hydrated Lime"

  Notes:
  - There were no formal cover sheets in the early days.
  - In the early years (1994-1996) materials were reviewed *without* a petition.
  - Many of the 1995 TAPs were reviewed at the Spring 1996 meeting.
  - There were very few meetings between 1997 and 1999 and almost no materials reviewed then because of expartè during rule writing.
  - If you are having trouble locating documents, such as TAPs mentioned in old meeting minutes that are not posted, please send the info to Lisa Brines or Michelle Arsenault.

- **NOSB RECOMMENDATIONS PAGE:** Here you will find recommendations and meeting minutes FROM 2001 to present. You first have to locate the dates associated with the material's review.

- **NOSB MEETINGS: 1992 to PRESENT**

- **DROPBOX:**
  - NOSBNationalListDatabase 8-28-03 (Summary of materials' decisions up to 2001, provided by Emily/OMRI)
  - 205.605 analysis 2005-ebr (Useful for Handling subcommittee. Summary of all synthetics on NL at time of Harvey lawsuit. Contains info summarized from TAPs, FDA etc. Not a USDA document)
  - Sunset Review Process Handout
  - Samples of Sunset Review Templates (Listing for meeting 1, Preliminary review for meeting 2, Final recommendation)

Best practices and email etiquette

Staying organized

NOSB members typically serve on 2- 4 Subcommittees each year, and as such, receive a lot of materials, mostly via email. Staying organized can be a challenge. For tips about organizing files and folders, please ask existing members. They are a wealth of knowledge and information!

Organizing email

It may be helpful to create folders for each Subcommittee, although you are not required to save every email you receive from NOP or NOSB members.

Tips for Email:

- Use a clear subject line. Include "NOSB" and the appropriate Subcommittee name. This will make filing and searching much easier.
- Make sure all the appropriate people are copied, including relevant NOP staff.
- Please do not overuse "Reply to All".

Conference calls and meetings

Members are based in all regions of the country, so most of the NOSB work is conducted over the phone via conference calls. The call schedule will be provided to you once your appointment begins. Subcommittee calls are not open to public participation. Meeting notes from the calls are available to the public and can be found here: https://www.ams.usda.gov/rules-regulations/organic/nosb/subcommittees. The Subcommittee call schedules remain fairly stable, with the exception of the occasional added call or cancellation. Three of the Subcommittees (Handling, Crops, and Livestock) meet twice a month for an hour each, and the other three (Materials, CACS, and PDS) meet once a month. See below for the current monthly schedules.

1st & 3rd Tue (All times ET)
1:00 Handling
2:00 Crops
3:00 Livestock/Aquaculture

2nd Tue
1:00 MS/GMO ad hoc
2:00 PDS
3:00 CACS

Mon prior to ES call
2:00 Admin Team

2nd Fri
1:00 Executive Committee

The Executive Team, which consists of the NOSB Chair, Vice Chair, Secretary, Subcommittee Chairpersons, and NOP staff, meets once a month. In preparation for each Subcommittee call, the Subcommittee Chair will circulate an agenda and any relevant documents for discussion. The Designated Federal Officer (DFO) will take notes during all conference calls, which are eventually posted to the NOSB website for public access. NOSB members are welcome to listen in to any of the calls, but unless you are a Subcommittee member, you are

not permitted to vote.

Questions?

We know you'll have a lot of questions! Please don't hesitate to contact the Advisory Board Specialist via phone or email if you have any questions. The Board Chairperson will assign you an NOSB mentor prior to your first official meeting to help you transition onto the Board. Your NOSB mentor will be available to you by phone or email to answer questions as they arise.

Administrative paperwork

Soon after your appointment on January 24th, we will need the following items from you and will send a follow up email requesting the information.

- Email address: You will receive a lot of email. You may want to create a separate email for use while you are on the Board. Members have created unique email accounts such as JohnDoe.nosb@gmail com or nosb_mary@gmail.com.
- Biography for the website. For reference, here is the link to the bios for the current members. http://www.ams.usda.gov/rules-regulations/organic/nosb/current-members.
- Picture/headshot for the Organic Integrity Newsletter announcing your appointment.
- Travel profile and reimbursement info. Forms to follow.
- Contact information/mailing address. We keep an **internal-only directory** and will not share your mailing address, email address, or phone numbers with the public. Unless you provide an alternate address, the information you include on the travel profile document will be listed as your mailing address.

NOSB meetings - Travel

In-person NOSB meetings are held twice a year; in spring and fall - typically around the last weeks of April, and October. We hold the meetings in different locations around the country in order to facilitate participation by stakeholders. The meetings are usually 3 days long, with a 2-hour administrative meeting scheduled the evening before the start of the full meeting, so you can expect to be away from home for 4-5 days. If you would like to view the list of previous meeting locations and agendas, you can find them on the NOSB meetings page: https://www.ams.usda.gov/rules-regulations/organic/nosb/meetings.

You will receive comprehensive travel guidance prior to each meeting, but here is a brief overview:

Airline Reservations

The USDA is responsible for paying airline costs associated with attending NOSB meetings and/or training. Members will arrange their own airline reservations via the USDA travel agent. You cannot use personal credit cards to pay for airline tickets or utilize another travel service on behalf of USDA/AMS as you will not be reimbursed. We realize that members often combine travel to an NOSB meeting with work trips, and it is important to notify NOP if you plan to arrive or depart outside of the intended authorized travel dates.

Personally Owned Vehicles (POV)

If you need to travel using your own POV, you will be asked to provide mileage to and from the meeting, as well as arrival and departure dates. Reimbursement is at government per diem rates as per General Services Administration (GSA).

Rental Car and Train Reservations

If you choose to use a rental car or train to get to and from a meeting, you must state why it would be advantageous to the Federal government. If the cost of a rental car (including gas), or a train ticket is less than the cost of an airline ticket this would be advantageous to the Federal government, and the USDA will reimburse you. However, if the rental car or train cost is more than the airline, you will be responsible for paying the difference. We try to reserve hotels in locations within walking distance of restaurants or in places that have good public transit systems so rental cars are unnecessary. Rental car costs are not generally reimbursed for such use.

Meeting Space and Lodging Accommodations

USDA/NOP is responsible for reserving and paying all expenses for the meeting space and lodging. The NOP will reserve a block of rooms, so members should not make their own hotel reservations. You can modify your arrival/departure travel dates for personal reasons, but please let the NOP know so the hotel is aware of travel date modifications. Personal travel is not reimbursable.

What to Pack?

The dress code at NOSB meetings is business casual. The agenda, proposals and any supporting documents will all be available to you electronically, on a thumb drive, or in hard copy prior to the meeting so you do not need to print any materials unless you want to.

Travel reimbursement

Immediately after each meeting, you will submit a post-travel document with applicable receipts for reimbursement.

Receipts required for:

- Rental Car or Train Expense (if applicable)
- Tolls

- Airport parking
- Local Transportation: Shuttle to airport
- Taxi cab fares to/from airport to hotel or residence. Tips are not included as they are part of the per diem incidentals.
- Airline baggage fees

No receipts required:

- Airfare
- Lodging
- Location per diem (Meals + Incidentals)
- Personally Owned Vehicle (POV) mileage to/from airport or meeting at current GSA per diem rates.

National Organic Program – contact information

The staff directory is updated fairly often and can be found here:
https://www.ams.usda.gov/sites/default/files/NOP_Contacts[1].pdf

Historical NOSB documents and other references

NRCS handbook on organic agriculture.

Toward Organic Integrity 1997, Sligh. aka "Green book". Contains a review of key issues raised during the initial development stages, a complete set of NOSB recommendations (1992-1996), and the Codex draft organic guidelines and other resources.

From the Margins to the Mainstream, Advancing Organic Agriculture in the United States: National Organic Action Plan http://www.rafiusa.org/docs/noap.pdf. 2010 document on the growth of organic agriculture in the United States.

NOP COI Memo. See 2013 Memos to the Board.

Indices of all NOSB recommendations. A comprehensive list of all previous NOSB recommendations, and the current status.

Quick links to various references you may find useful when completing

discussion documents and proposals:

OFPA: Organic Foods Production Act of 1990; See sections 6517(c) and 6518(m) for National List evaluation criteria

USDA Organic regulations at 7 CFR 205 final rule/National List of allowed and prohibited substances

Program handbook (NOP Guidance documents (e.g. Synthetic non-synthetic decision tree, policy memos, instructions, etc)

NOSB policy and procedure manual (PPM)

List of petitioned substances (Includes the petitions, any addendums, and any TRs)

Subcommittee meeting notes and proposals

Index of NOSB recommendations (NOSB Practice Standards Recommendations, NOSB National List Recommendations, NOSB Sunset Recommendations)

- **NOSB recommendations 1992 - 2009**
- **NOSB recommendations 2010 - present**

NOSB meeting information (agenda, proposals and discussion documents, transcripts, presentations, etc)

Written public comments on Regulations.gov

EPA Inert Ingredients Overview and Guidance

Parliamentary procedures at a glance

The NOSB adopted the use of Robert's Rules of Order in March 1992 and modified its use in May 1993 as a non-mandatory guide. Roberts Rules may be adapted to meet the special requirements of a group. Because the NOSB is also subject to the OFPA, FACA, and USDA policies, a designated NOP staff member may act as an informal Parliamentarian to advise the NOSB Chair.

TO DO THIS	YOU SAY THIS	May you interrupt speaker?	Must you be seconded?	Is the motion debatable?	Vote required
Adjourn the meeting	I move that we adjourn	no	yes	no	majority
Recess the meeting	I move that we recess until…	no	yes	no	majority
Complain about noise, room temperature, etc.	Question of privilege	yes	no	no	no vote
Suspend further consideration of something	I move that the motion be laid on the table	no	yes	no	majority
End debate	I move the previous question	no	yes	no	2/3 vote
Postpone consideration of something	I move we post pone this matter until…	no	yes	yes	majority
Have something studied further	I move to refer the motion to the Subcommittee	no	yes	yes	majority
Amend a motion	I move to amend…	no	yes	yes	majority
Introduce business (a primary motion)	I move that…	no	yes	yes	majority
Object to procedure or to a personal affront	Point of order	yes	no	no	chair decides
Request information	Point of information	yes	no	no	no vote
Ask for a vote by actual count to verify a voice vote	I call for a division	no	no	no	no vote
Object to the consideration of some undiplomatic matter	I object to the consideration of the question	yes	no	no	2/3 vote
Take up a matter previously tabled	I move to take from the table	no	yes	no	majority
Reconsider something already disposed of	I move to reconsider…	yes	yes	yes	majority
Consider something vote out of its scheduled order	I move we suspend the rules and consider…	no	yes	no	2/3 vote
Vote on a ruling by the chair	I appeal the decision of the chair	yes	yes	yes	majority
Table a motion - take matter from table	I move to take from the table	no	yes	no	majority
Rescind motions – Cancel previous action	I move to rescind	no	yes	yes	2/3 vote

Chemistry

The science of chemistry deals with the structure of matter--material things--and the changes that matter undergoes. Matter can exist in any size, shape, or color. It is solid, liquid, or gas; living or nonliving. Chemistry seeks to identify the simplest parts of matter; how they are separated and purified; how they are put together; how they are rearranged to produce new forms of matter; and what energy is absorbed or released when such rearrangements are made (Matta and Wilbraham, 1986). A distinction should be made between chemical and physical changes. The OFPA and NOS (National Organic Standards) definition of synthetic specifically mentions chemical change but not physical change. A physical property is a quality or condition of a substance that can be observed or measured without changing the substance's composition. It can be specified without reference to any other substance. Other physical properties of matter include color, solubility, mass, odor, hardness, density, electrical conductivity, magnetism, melting point, and boiling point. Physical properties help chemists identify substances (Matta and Wilbraham, 1986). When contractors are hired to conduct technical reviews of substances for the NOSB and USDA/NOP, they typically list the physical properties of the substances in their review because this is the common way in which substances are described.

Physical changes may result when the temperature of a substance changes. Raising the temperature of a solid may turn it into a liquid (i.e., ice turns into water). A conversion without causing a change in the composition of the substance is called a physical change (Matta and Wilbraham, 1986). When ice undergoes the physical change of melting, this change does not change the nature of water. The physical properties are the same for water that has been frozen and melted as for water that has been converted into steam and then condensed (Matta and Wilbraham, 1986). Historically, the organic industry and the NOSB have acknowledged that physical changes do not render a substance synthetic.

However, there are some substances that have been identified for which high temperatures during manufacturing do engender a chemical change in the substance. An example is mined minerals. Historically, the industry and NOSB has recognized that burning or excessive heating of mined mineral is considered to render them synthetic. Formerly, NOSB defined mined minerals as any naturally occurring non-living substance derived from the earth or water. A mined mineral cannot have undergone molecular change through heating, acidification, basification, or fortification with synthetic materials (NOSB Final Recommendation Addendum Number 25, Definitions and Interpretations, Austin, Texas, 1995). Therefore, heat can alter the physical properties of a substance and for other substances act as a catalyst in chemical reactions or change.

In a chemical reaction, the starting substance or substances, referred to as reactants, are changed into new substances or products. Chemists use an arrow as a shorthand form of the phrase "are changed into"; reactants products (Matta and Wilbraham,1986). An example to distinguish between physical and chemical changes is illustrated when sulfur (a solid) is added to iron filings (a solid). They may be separated unchanged from a mixture of the two substances mixed together.. This separation is an example of a physical change. If the mixture of these two substances is heated, a chemical change takes place and the sulfur and iron are

changed into a nonmagnetic substance, iron sulfide: Iron + Sulfur → Iron Sulfide (Matta and Wilbraham, 1986). A substances composition and behavior in chemical reactions--its chemical reactivity--comprise its chemical properties.

What is a substance?
In chemistry, a pure **substance** is a homogenous material that has a definite chemical composition throughout. There are two kinds of pure substances. One kind can be decomposed into two or more different substances by simple chemical change; these are called **compounds**. There are many millions of compounds.

An example of a compound is pure table salt, which can be decomposed into sodium and chlorine by an appropriate process. Many of the substances on the National Lists of Synthetic substances allowed for use in organic crop and livestock production (Sections 205.601 and 205.603) are compounds. Examples include: isopropanol, chlorine dioxide, ammonium carbonate, lime sulfur, and copper sulfate.

The second kind of pure substances are called **elements**, which cannot be decomposed by chemical change. There are 90 natural elements; examples are gold, copper, oxygen, sulfur, and hydrogen. Elements cannot be separated into simpler substances by chemical reactions. An example of an element on the National List is sulfur (elemental) for crop production (205.601(e)(3))(Boikess and Edelson, 1978).

Mixtures consist of a physical blend or two or more substances in which the combined substances retain their identity. Most materials found in nature are mixtures. Mixtures can be either homogeneous (same composition throughout) or heterogeneous (has non-uniform composition). A **solution** is a type of a mixture where there is a homogeneous combination of different substances. The difference between a heterogeneous mixture and a solution is that any sample of a solution has the same composition, while the composition of a mixture is not the same throughout. Solutions may be gaseous, liquid, or solid. Examples of mixtures on the National List are aquatic plants and fish emulsions. The various compounds and elements that make up these products are within the plant, animal, or mineral. When a particular component of the plant is desired for use in an agricultural input, it typically has to be extracted and in many cases undergoes additional chemical reactions to make it into a substance that is functional when combined with other substances.

A distinction should be drawn between a mixture and a compound**.** ***The elements making up a compound cannot be recovered without a chemical change*****.** The substances making up a mixture or solution can. Some mixtures can be separated into their various components by simple physical methods. An example is a gray-colored mixture produced by stirring together powdered yellow sulfur and black iron filings. The individual particles of sulfur and iron can be readily distinguished from one another under a microscope. The mixture is easy to separate because the iron filings can be removed from the mixture with a magnet, leaving sulfur behind. Both the sulfur and the iron are unchanged in composition (example from Matta and Wilbraham, 1986).

The substances making up a mixture or a solution need not be elements. For example, one can prepare a solution by dissolving salt, a compound, in water, another compound. In addition, the substances making up a mixture or a solution can be combined in varying proportions. The elements in a compound have fixed proportions (paragraph found in Boikess and Edelson, 1978). Main groups of compounds can be classified based on similar chemical properties. The following are descriptions of each group (Boikess and Edelson, 1978).

Salts: a compound of a metal and nonmetal, or of a metal with a negative polyatomic group. Compounds that have an ammonium group (NH4+) instead of a metal are also classified as salts. Some salts are NaCl, KCl, KMnO4 and NH4Cl. A salt is an ionic solid a room temperature. Most have two ionic components (a) a cation, which can be a polyatomic group such as ammonium or a monoatomic metal such as Na+, K+, Ca2+ or Mn3+ and (b) an anion, which can be a negative polyatomic group or a monoatomic ion such as Cl- or NH3-. A solid salt consists of ions in close association. When the salt dissolves in water, the ions are separated. Substances that exist as ions in solution are called electrolytes. When NaCl dissolves in water, the correct formula is Na+ + Cl-. This formula treats the component ions of the salts as independent entities, which is approximately how they behave in water solution. Salts are called strong electrolytes because they usually separate completely into ions in water. (Boyd text)

Acids: a compound that is a source of H^+ ions. An acid is usually a compound of hydrogen and a nonmetal or a negative polyatomic group. Unlike salts, acids usually are not aggregates of ions. An acid may be a gas (hydrochloric), liquid (sulfuric), or a solid (oxalic). Like salts, acids tend to form ions when they dissolve in water. When a substance separates into ions, it is said to dissociate. Some acids dissociate completely and are called strong acids. Most acids dissociate only partially when dissolved in water. These are called weak acids; they are weak electrolytes.

Bases: a compound that is a source of OH- ions in water solution. A compound of a cation and the OH- anion is a base. Bases resemble salts in many ways. They are ionic solids that dissociate into ions when dissolved in water. Bases that contain a cation and OH- are generally dissociated completely in water and are classified as strong bases. Some strong bases are NaOH (sodium hydroxide) and KOH (potassium hydroxide). Compounds that do not contain hydroxide ions are defined as bases if they produce OH- ions by a reaction with water. An example is ammonia (NH3), which reacts with water to produce hydroxide ions.

Nonelectrolytes: compounds containing only nonmetals usually exist as discrete molecules, rather than collections of ions. These compounds do not dissociate into ions when they dissolve in water. Many organic compounds are nonelectrolytes, and they will not dissolve appreciably in water, i.e. oil. Some will dissolve in water, although they will not dissociate into ions, i.e. sugar and ethyl alcohol.

Oxides: a binary compound of any element with oxygen, when the oxygen has an oxidation number of $^{-2}$. Almost every element forms at least one oxide. The properties of oxides vary widely; depending on the element, they may resemble a salt, acid, base, or non electrolyte.

What constitutes a chemical change?

The chemical properties of a substance are those that describe the way in which it can undergo change, either alone or in interactions with other substances, to form different materials. Such changes are called chemical reactions. The chemical properties that are characteristic of any substance can be described; iron combines readily with oxygen to form the compound called rust. (Boikess and Edelson, 1978).

The following are common types of chemical reactions that describe what is happening when different substances and compounds interact (Boikess and Edelson, 1978).

- Addition or combination reaction: Two substances combine to form one:
    - $2Na+Cl_2$----2NaCl

- Decomposition reactions: One compound breaks into two or more compounds or elements
- ;
    - $CaCO_3$-------CaO + CO_2

- Displacement reactions: Substances exchange parts. There are many types of these reactions, but one of the most important is called metathesis, which is the exchange of ions by two ionic compounds, with the anion of one compound joining the cation of the other compound and vice versa. AB+CD-AD + CB

    - 1. Hydrolysis is a displacement reaction of a substance or ion with water. Water is a source of both H^+ and OH^- ions. The OH^- anion combines with the positive portion of the compound that is hydrolyzed. This positive portion may be a cation or an atom with a positive oxidation number. The H^+ cation combines with the negative portion of the compound, which may be an anion or an atom with a negative oxidation number.

    - Acid-base reaction: an acid is a substance that can donate a proton, and a base is a substance that can accept a proton.

Since many materials used in organic agriculture are derived from plants and animals, it is important to mention chemical reactions that occur in by-products of these organisms. In living organisms, enzymes play the role in catalyzing a specific reaction or type of reactions.

Proteins are substances extracted from living organisms that may be utilized in materials that are petitioned for use in organic production. Proteins are sensitive to relatively small changes in pH, temperature, or solvent composition, which may cause them to denature. . Denaturation causes physical change; the most observable result is loss of biological activity. Except for cleavage of disulfide bonds, denaturation stems from changes in secondary, tertiary, or quaternary structures through disruption of noncovalent interactions, such as hydrogen bonds, salt linkages, and hydrophobic reactions. Common denaturing agents include the following:

- Heat-- most become denatured when heated above 50-60 degrees C.
- Large changes in pH-- adding concentrated acid or alkali to a protein in a aqueous solution

causes changes in the charged character of ionizable side chains and interferes with salt linkages.

- Detergents-- treating a protein with sodium dodecylsulfate (SDS), a detergent, causes the native conformation to unfold and exposes the nonpolar protein side chains to the aqueous environment. These side chains are then stabilized by hydrophobic interaction with hydrocarbon chains of the detergent.
- Organic Solvents-- such as alcohols, acetone, or ether.
- Mechanical treatment-- most globular proteins denature in aqueous solution if they are stirred or shaken vigorously.
- Urea and guanidine hydrochloride-- these substances can cause disruption of protein hydrogen bonding and hydrophobic interactions.
- Denaturation can be partial or complete. It can also be reversible or irreversible. Irreversible denaturation causes a fundamental change in the protein, in particular destroying any physiological (biological) activity. In the case of reversible denaturation, the change may only be temporary (Brown, 1988).

References:

Boikess, R.S. and Edelson, E. Chemical Principles. Harper and Row, New York, 1978.

Brown, W.H. Introduction to Organic Chemistry. Brooks/Cole Publishing Company, California, 1988.

Matta, Michael, and Wilbraham, A.C. General, Organic and Biological Chemistry. Benjamin/Cummings Publishing Company, California, 1986.

NATIONAL ORGANIC STANDARDS BOARD

POLICY AND PROCEDURES MANUAL

Adopted October 19, 2002
Revised August 18, 2005
Revised March 29, 2007
Revised November 30, 2007
Revised May 22, 2008
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Revised October 28, 2010
Revised April 29, 2011
Revised December 2, 2011
Revised April 11, 2012
Revised April 26, 2016
Revised November 18, 2016

NATIONAL ORGANIC STANDARDS BOARD (NOSB)
POLICY AND PROCEDURES MANUAL

Contents

I. INTRODUCTION/PURPOSE

This document provides procedures for the functioning of the National Organic Standards Board (NOSB) and is designed to assist the NOSB in its responsibilities. This policy and procedures manual does not supersede authority or responsibilities as specified in the Federal Advisory Committee Act or the Organic Foods Production Act (OFPA). NOSB members are encouraged to review this manual in depth as well as to become familiar with the OFPA, the USDA organic regulations at 7 CFR Part 205, and the NOSB Member Guide. Members are advised to periodically review the contents to refresh their understanding of the NOSB's role and duties. NOSB members are entrusted with the responsibility to act in the best interests of all members of the organic community and the public at large. The NOSB's success relies upon the ability to understand each other's respective roles, and to develop successful working relationships.

The primary roles and duties of the National Organic Standards Board (NOSB):

- Serve as a link to the organic community
- Advise USDA on the implementation of OFPA
- Propose amendments to the National List of Allowed and Prohibited Substances
- Protect and defend the integrity of organic standards

A. NOSB VISION STATEMENT

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007).
The NOSB's vision is an agricultural community rooted in organic principles and values that instills trust among consumers, producers, processors, retailers and other stakeholders. Consistent and sustainable organic standards guard and advance the integrity of organic products and practices.

B. NOSB STATUTORY MISSION

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007).
To assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of this title. (OFPA, Sec 2119 (a))

C. NOSB MISSION STATEMENT

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007).
To provide effective and constructive advice, clarification and guidance to the Secretary of Agriculture concerning the National Organic Program (NOP), and the consensus of the organic community.

Key activities of the Board include:

- Assisting in the development and maintenance of organic standards and regulations
- Reviewing petitioned materials for inclusion on or removal from the National List of Approved and Prohibited Substances (National List)
- Recommending changes to the National List
- Communicating with the organic community, including conducting public meetings, soliciting and reviewing public comments
- Communicating, supporting and coordinating with the NOP staff

II. AUTHORIZATION

The National Organic Standards Board (NOSB) is authorized under Section 2119 of the Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6519), part of the Food, Agriculture, Conservation, and Trade Act of 1990 (FACT Act). The OFPA specified that the NOSB be established in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App. 2.

A. ORGANIC FOODS PRODUCTION ACT OF 1990

The Organic Foods Production Act of 1990 (OFPA) authorizes the Secretary of Agriculture to establish a National Organic Standards Board (NOSB) in accordance with the Federal Advisory Committee Act to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of OFPA (OFPA, 7 U.S.C. Section 6518(a)).

B. FEDERAL ADVISORY COMMITTEE ACT

The Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2) and its implementing regulations (41 CFR Part 101-6.10) govern the creation, operation, and termination of advisory committees in the Executive Branch of the Federal Government. The National Organic Standards Board (NOSB) is a Department of Agriculture (USDA) non-discretionary advisory committee required by the Organic Foods Production Act of 1990, as amended.

C. NATIONAL ORGANIC STANDARDS BOARD CHARTER

The Federal Advisory Committee Act requires advisory committees to have an official charter prior to meeting or taking any action. An advisory committee charter is intended to provide a description of an advisory committee's mission, goals, and objectives. The NOSB charter is renewed every two years as a requirement of FACA. The NOSB charter describes the purpose of the NOSB to "assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of OFPA."

III. NOSB ADMINISTRATION

A. NOSB Membership

OFPA specifies the membership composition of the NOSB as follows. The NOSB shall be composed of 15 members, of which:

- Four shall be individuals who own or operate an organic farming operation;
- Two shall be individuals who own or operate an organic handling operation;
- One shall be an individual who owns or operates a retail establishment with significant trade in organic products;
- Three shall be individuals with expertise in areas of environmental protection and resource conservation;
- Three shall be individuals who represent public interest or consumer interest groups;
- One shall be an individual with expertise in the fields of toxicology, ecology, or biochemistry; and
- One shall be an individual who is a certifying agent as identified under OFPA, 7 U.S.C. § 6518(b)

B. Nomination and appointment process

(NOSB recommendation adopted June 10, 1999)

NOSB members are appointed by the Secretary of Agriculture to a five year term. The terms are staggered and the USDA periodically requests nominations to fill upcoming vacancies. Selection

criteria include the following:

- A general understanding of organic principles, and practical experience in the organic community, particularly in the sector for which the person is applying
- Demonstrated experience in the development of public policy such as participation on public or private advisory boards, boards of directors or other comparable organizations
- Participation in standards development and/or involvement in educational outreach activities
- A commitment to the integrity and growth of the organic food and fiber industry
- The ability to evaluate technical information and to fully participate in Board deliberation and recommendations
- The willingness to commit the time and energy necessary to assume Board duties
- Not currently serving (or have been elected to serve) on another USDA advisory committee or research and promotions council/board during your term
- Not registered as a lobbyist with the federal or state government

NOSB members serve without compensation. NOSB members are reimbursed by the USDA for approved travel and associated lodging expenses as determined by official federal government guidelines and regulations. In accordance with USDA policies, equal opportunity practices are followed in all appointments to the NOSB. Membership shall include to the extent possible the diverse groups served by USDA, including minorities, women, and persons with disabilities. The USDA prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, political beliefs, genetic information, reprisal, or because all or part of an individual's income is derived from any public assistance program.

C. Responsibilities of the NOSB

(OFPA, 7 USC 6518(k)):

(1) **In General**. The Board shall provide recommendations to the Secretary regarding the implementation of this chapter.

(2) **National List**. The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary in accordance with section 6517 of this title.

(3) **Technical Advisory Panels**. The Board shall convene technical advisory panels to provide scientific evaluation of the materials considered for inclusion in the National List. Such panels may include experts in agronomy, entomology, health sciences and other relevant disciplines.

(4) **Special Review of Botanical Pesticides**. The Board shall, prior to the establishment of the National List, review all botanical pesticides used in agricultural production and consider whether any such botanical pesticides should be included in the list of prohibited natural substances.

(5) **Product Residue Testing**. The Board shall advise the Secretary concerning the testing of organically produced agricultural products for residues caused by unavoidable residual environmental contamination.

(6) **Emergency Spray Programs.** The Board shall advise the Secretary concerning rules for exemptions from specific requirements of this chapter (except the provisions of section 6511 of

this title) with respect to agricultural products produced on certified organic farms if such farms are subject to a Federal or State emergency pest or disease treatment program.

Requirements. (OFPA 6518(l)) In establishing the proposed National List or proposed amendments to the National List, the Board shall

(1) review available information from the Environmental Protection Agency, the National Institute of Environmental Health Studies, and other sources as appropriate, concerning the potential for adverse human and environmental effects of substances considered for inclusion in the proposed National List;

(2) work with manufacturers of substances considered for inclusion in the proposed National List to obtain a complete list of ingredients and determine whether such substances contain inert materials that are synthetically produced; and

(3) submit to the Secretary, along with the proposed National List or any proposed amendments to such list, the results of the Board's evaluation and the evaluation of the technical advisory panel of all substances considered for inclusion in the National List.

Evaluation. (7 USC 6518(m)) In evaluating substances considered for inclusion on the National List the NOSB shall consider:

1. the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;
2. 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;
3. the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;
4. the effect of the substance on human health;
5. the effects of the substance 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;
6. the alternatives to using the substance in terms of practices or other available materials; and
7. compatibility with a system of sustainable agriculture.

Petitions. (7 USC 6518(n))
The board shall establish procedures for receiving petitions to evaluate substances for inclusion on the List

Sunset Provision. (7 USC 6517 (e)) No exemptions or prohibition contained in the National List shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 years of such exemption or prohibition being adopted or reviewed and the Secretary has renewed such exemption or prohibition.

D. NOSB OFFICERS

Three principal officers, Chair, Vice Chair and Secretary, guide the NOSB. The NOSB members hold an election each fall at the public meeting to elect these three members.

CHAIR

The Chair is responsible for ensuring the integrity of the NOSB process, effectiveness of meetings and adherence to NOSB policies and procedures. The primary duties of the Chair are as follows:

- Schedules meetings of the Executive Subcommittee, in collaboration with the NOP
- Serves as a member of, convenes, and facilitates Executive Subcommittee meetings
- Convenes and presides over NOSB meetings
- Participates in the administrative team meetings
- Drafts NOSB meeting agendas in consultation with Subcommittee chairs and the NOP
- Reviews Subcommittee work agendas
- Reviews NOSB meeting minutes for accuracy
- Assists with the annual election of NOSB officers and announces the new officers

VICE CHAIR

The Vice Chair acts in the absence of the Chair. The primary duties of the Vice Chair are as follows:

- Serves as a member of the Executive Subcommittee
- Participates in the administrative team meetings
- Serves as a member of the Policy Development Subcommittee
- Helps maintain the Policy and Procedures Manual and ensures its accuracy

SECRETARY

The primary duties of the Secretary are as follows:

- Serves as a member of the Executive Subcommittee
- Participates in the administrative team meetings
- Records all NOSB member votes at NOSB meetings, and in collaboration with the Advisory Committee Specialist (ACS), circulates that record to NOSB members for approval
- Assists with the annual election of NOSB officers
- May delegate tasks to others, but retains responsibility for the official record

ADMINISTRATIVE TEAM

The Administrative Team consists of the Chair, Vice Chair, Secretary, and Designated Federal Official/Advisory Committee Specialist. . This group is responsible for coordinating logistics and operations of the Board. The Administrative team meets via teleconference on an as-needed basis, to be determined by the Administrative Team. This team is not a subcommittee and makes no decisions. All items needing further discussion or action are placed on the Executive Subcommittee agenda and are recorded in the Executive Subcommittee notes.

E. NOSB-NOP COLLABORATION

In 1990, the Organic Foods Production Act (OFPA: 7 U.S.C. 6518 (a)) directed the Secretary of Agriculture to "establish a National Organic Standards Board (in accordance with the Federal

Advisory Committee Act (FACA)) ... to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation" of the Act. Section 6503 (a) of the OFPA requires that the Secretary "shall establish an organic certification program … and shall consult with the NOSB" (6503(c)). The National Organic Program (NOP) is the governmental institution responsible for implementing the OFPA and is the means through which the NOSB provides advice and assistance to the Secretary of Agriculture. The NOSB, as a FACA advisory committee, must conduct business in the open, under the requirements of P.L. 94-409, also known as "Government in the Sunshine Act" (5 U.S.C.552b).

The USDA cannot delegate its authority as a regulatory body to private citizens, even when those private citizens are appointed by the Secretary to provide advice. Therefore, the NOSB cannot direct USDA or bind the Secretary through its actions; for example, it cannot obligate funds, contract, make NOP staffing decisions, or initiate policies of its own accord

However, the NOSB has unique statutory authority related to the recommendation of materials as approved or prohibited substances for inclusion on the National List.

The unique nature of the NOSB and its relationship with the NOP, as established through OFPA, requires that the volunteer Board, which regularly receives stakeholder input through public comment, must work collaboratively with the NOP.

Similarly the NOP, as required through OFPA, must consult and collaborate with the NOSB

Team work and collaboration between the NOSB and the NOP, as well as others in the organic community, is needed to maintain, enhance and promote the integrity of organic principles and products. Successful collaboration is dependent on effective communication and constructive feedback. Communication is facilitated by the Advisory Committee Specialist, who participates in all NOSB calls. Additionally, the NOP Deputy Administrator or designee will participate in all ES calls, and in other standing Subcommittee calls upon request and mutual agreement. In addition, each standing Subcommittee will be assigned an NOP staff person to provide technical, legal, and logistical support.

The work of the NOP and NOSB since the 1990 passage of the OFPA clearly demonstrates the need for the high level of collaboration and consultation described above. NOP, NOSB and its associated stakeholders must continuously work to seek common ground, collaborate and consult in order to build organics and maintain organic integrity. Every aspect of this work must take place in a manner which clearly demonstrates mutual respect and positive intent.

F. NOSB WORK AGENDAS

The NOSB Work agenda is a list of projects for the upcoming semester or year for each of the Subcommittees. Agendas are developed via collaboration between the NOSB and the NOP and are revised based on AMS-NOP requests, NOSB priorities, and public comment.

Work agendas are developed based on the following criteria:

- **Within Scope**: Item must be within the scope of OFPA. NOP must have a clear sense of the intent and scope of the work agenda item. The public may petition additions or deletions from the National List that will be added to the work agenda. In addition, the public may submit comments to the NOSB or write to the NOP for potential additions to the work

agenda. For the NOSB, work agenda items may emerge from discussions on current issues.

- **USDA and NOP Priority**: Item must be a priority for the USDA/NOP; something that the NOP is able to implement in a reasonable timeframe.

- **Clear Need**: Item must reflect a clear need for the NOP and/or organic community, for which new or additional information or advice is needed.

The NOSB work agenda establishes Subcommittee work for the upcoming semester or year, and is developed through the following process:

1. NOSB Subcommittees submit to the Executive Subcommittee draft work agenda items based on AMS-NOP requests, NOSB priorities, and requests from public comment.
2. The NOP and Executive Subcommittee review the draft NOSB work agenda. The content and schedule will be reviewed on an ongoing, as needed basis.
3. NOP confirms the final NOSB work agenda, and provides written confirmation. .

Work agenda items should be prioritized accordingly:

1. Substance evaluations (e.g., 5-year sunset review, petitions)
2. NOP requests to the NOSB
3. NOSB requests to NOP
4. Other projects

Below are descriptions of common NOSB work agenda items and the corresponding NOP and NOSB responsibilities.

- **Review of materials proposed to be added to or removed from the National List**
  The NOSB has the statutory authority to consider and recommend materials for addition to, or deletion from, the National List of Approved and Prohibited Substances. The NOSB may also make recommendations to add, remove, or modify annotations restricting the use of such listed materials.

- **Changes to annotation or classification of materials**
  The NOSB may request to review an existing substance on the National List without a new petition when they have justification to support a revision of the annotation or reclassification of the substance. This may happen as a result of the sunset review process, or as new information is provided in a Technical Review, or from public comment**.**

- **Recommendation for modification of existing standards or new standards**
  The NOP may request that the NOSB develop recommendations for new or existing standards. The request should be in writing and include a statement of the problem to be addressed, background, including the current policy or situation, statutory/regulatory authority, legal context, and desired timeframe for receiving the recommendation. The request will be posted on the NOP web site.

- **Advice on NOP policy and interpretation of standards**
  The NOSB may provide comments on guidance or policy memos included in the Program Handbook, or may also make recommendations for new guidance or policies.

- **Compliance and Enforcement**
  The NOP is responsible for compliance and enforcement. The NOP welcomes NOSB input on standards, but NOSB involvement in active investigations or enforcement actions is not appropriate. When timely and appropriate, the NOP reports to the NOSB the status of enforcement actions and also posts the status on the NOP web site.

- **Management Review**
  The NOSB may review the quality management system and internal audits to ensure that the NOP is managed effectively and efficiently. For example, the NOSB may be asked for informal feedback or to work on specific work agenda items that relate to the development or implementation of audit corrective actions.

G. Designated Federal Officer

FACA and its implementing regulations (5 U.S.C. App. 2) govern the roles and responsibilities of NOSB management including meeting coordination and facilitation. The Designated Federal Officer (DFO) is the individual designated to implement advisory committee procedures. The AMS/NOP Deputy Administrator is the DFO for the NOSB.

The NOP Deputy Administrator or designee acts as the Designated Federal Officer (DFO) during public meetings of the NOSB and meetings of the Executive Subcommittee. The Advisory Committee Specialist (ACS) or designee acts as the DFO for all other NOSB Subcommittee meetings. The DFO holds the authority to chair meetings when directed to do so by the official to whom the advisory committee reports.

The DFO's duties include but are not limited to:

- Approving and calling the meeting of the NOSB
- Approving the semi-annual meeting agenda
- Attending the semi-annual meetings
- Adjourning the meetings when such adjournment is in the public interest

H. Advisory Committee Specialist

The Advisory Committee Specialist (ACS) is an NOP staff member who is assigned to support the NOSB. The Advisory Committee Specialist prepares the Advisory Committee's and Subcommittees' meeting agendas and notes, and attends all meetings. The position of Advisory Committee Specialist (formerly called Executive Director) was added in 2005 to facilitate communication and collaboration between the NOP and the NOSB. Advisory Committee Specialist duties include but are not limited to:

- Ensuring that all FACA and OFPA requirements are implemented
- Managing calendars and work agendas to facilitate Subcommittee and NOSB activities
- Arranging, facilitating, and documenting the NOSB Subcommittee conference calls

- Ensuring NOSB members have all necessary materials and information to provide informed, structured and timely recommendations to the NOP
- Conducting meeting planning activities for the semi-annual NOSB meetings, including preparation of Federal Register notices and press releases, and facilitation of public comments
- Coordinating the NOSB nomination and chartering process
- Facilitating training of NOSB members
- Managing information reporting and communication between the NOSB and NOP

I. ADDITIONAL ADMINISTRATIVE ITEMS

- Official to whom the Committee Reports
  The NOSB shall provide recommendations to the USDA Secretary through the Designated Federal Officer, the Agricultural Marketing Service's NOP Deputy Administrator.

- Staff Support
  The NOP shall provide administrative support to the NOSB through the work of an Advisory Committee Specialist, who is a permanent NOP staff member. The NOP may also provide technical support to the NOSB based on need and available resources.

- Estimated Number and Frequency of Meetings
  The NOSB meets approximately twice per year for public meetings. Most NOSB Subcommittees meet approximately twice a month by conference call.

- Recordkeeping
  Records of the NOSB shall be defined and handled in accordance with General Records Schedule 6.2 or other approved agency records disposition schedule. . This schedule is available online at: https://www.archives.gov/records-mgmt/grs/grs06-2.pdf. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552. Requests for records should be handled in accordance with the GSA March 14, 2000 memo that is available online here: http://www.gsa.gov/portal/content/100785. Information about the NOSB is available online at: http://www.ams.usda.gov/rules-regulations/organic/nosb

  While meeting transcripts are not required under FACA, the NOP provides transcripts or meeting notes to support the transparency of NOSB meetings and to support subsequent rulemaking activities. Minutes of each NOSB meeting, as approved by the DFO and the NOSB Chair and Secretary, shall contain a record of the persons present, documents provided to the board, a complete and accurate description of matters discussed and conclusions, and the outcome of voting. If not included in the minutes, a voting summary will be published that contains votes by member.

  FACA requires (5 U.S.C. App. Section 10 (b)): "Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies,

agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist."
Any request for FACA records must be made to the NOP.

While requests for FACA Board records do not have to go through the formal FOIA request process, those records must be reviewed by AMS/NOP before release, to determine whether any FOIA exemptions apply (e.g., personal information, business proprietary information). In addition, OFPA itself requires that no confidential business information be released, so emails and documents need to be reviewed before release to ensure that this requirement is met.

- **Freedom of Information Act** (FOIA; 5 U.S.C. 552). Under this Act, the public may request documents and other information pertaining to USDA actions. NOSB communications with USDA (including email) are subject to these requests, with limited exemptions. Some USDA information is routinely exempt from disclosure in or otherwise protected from disclosure by statute, Executive Order or regulation; is designated as confidential by the agency or program; or has not actually been disseminated to the general public and is not authorized to be made available to the public upon request. When there is a FOIA request for information, the USDA will review all relevant information and determine what qualifies for release, then provide it to the requestor.

J. PROFESSIONAL AND ETHICAL STANDARDS

As appointees of the Secretary, NOSB members must maintain high professional and ethical standards both within and outside of the NOSB. Areas of particular concern include professional conduct and conflict of interest.

1) NOSB Member Professional Conduct Standards

NOSB members shall:

- Observe ethical principles above private gain in the service of public trust.
- Put forth an honest effort in the performance of their NOSB duties.
- Make no commitments or promises of any kind purporting to bind the Government.
- Act impartially and not give preferential treatment to any organization or individual.
- Participate in meetings – Subcommittee conference calls as well as semi-annual meetings
- Serve on Subcommittees as assigned - Each member must be willing to serve on Subcommittees as assigned by the NOSB Chair, and to participate in the work of those Subcommittees.
- Be informed about NOSB business - NOSB members are expected to seek and study the information needed to make reasoned decisions and/or recommendations on all business brought before the NOSB.

To maintain the highest levels of honesty, integrity, and ethical conduct, no NOSB

member shall participate in any "specific party matters" (i.e., matters that are narrowly focused and typically involve specific transactions between identified parties) such as a lease, license, permit, contract, claim, grant, agreement, or related litigation with the Department in which the member has a direct or indirect financial interest. This includes the requirement for NOSB members to immediately disclose to the NOP's Advisory Board Specialist any specific party matter in which the member's immediate family, relatives, business partners, or employer would be directly seeking to financially benefit from the Board's recommendations.

All members receive ethics training annually to identify and avoid any actions that would cause the public to question the integrity of the NOSB's advice and recommendations. The provisions of these paragraphs are not meant to exhaustively cover all Federal ethics laws and do not affect any other statutory or regulatory obligations to which advisory committee members are subject.

2) Additional Standards of Conduct

NOSB members should adhere to the following basic "standards of conduct" while in government service:

- Do not accept improper gifts (from those seeking actions from the Board).
- Do not use board appointments for private gain.
- Do not misuse internal non-public government information.
- Do not use government property and time improperly.
- Do not accept compensation for teaching, speaking, and writing related to your board duties.
- Do not engage in partisan political activities while performing your board duties or while in a federal building.
- Alert the NOSB designated federal officer (DFO) if you or your employer enters into a lawsuit against USDA or its sub-agencies.
- Refrain from sharing working documents with the public. Working documents are defined as information that a board member gains by reason of participation in the NOSB and that he/she knows, or reasonably should know, has not been made available to the general public: e.g. is not on the NOP or other public websites, or is a draft document under development by an NOSB Subcommittee.
- Do not circulate draft Subcommittee documents until they are finalized and publicly available to all on the AMS/NOP website.
- Use a professional, respectful tone in NOSB email correspondence; remember that all correspondence with government officials is subject to FOIA requests.
- To the maximum extent possible, NOSB members should speak with one voice. Although there may be disagreements within NOSB Subcommittees or working group sessions, once NOSB members leave the session, they have the responsibility to support the integrity of the process, whether or not they agree with the final outcome. While NOSB members retain the right to express minority opinions, the public airing of dissension could strain interpersonal relationships and create distrust and conflict among NOSB members. Such stresses could undermine the NOSB's ability to effectively carry out its role as a governmental advisory board.

3) Failure to participate

The NOSB typically has a heavy work load and thus active participation by all 15 members is essential to carry out the mandates in OFPA. When one or more members fail to actively participate in Board work the entire NOSB and the organic community is negatively impacted. If a Board member finds that s/he cannot consistently attend Subcommittee meetings, take on work assignments, complete Subcommittee work in a timely manner, or cannot attend the twice-yearly public meetings and public comment listening sessions, the NOSB Chair shall discuss the matter with the Board member, bring the concerns to the attention of the Executive Subcommittee, and if necessary encourage the Board member to resign.

K. DECLARATION OF INTERESTS/Conflict of Interest

NOSB members are classified as **representatives** under the Federal Advisory Committee Act (FACA). Each representative is appointed to articulate the viewpoints and interests of a particular interest group. The Organic Foods Production Act (OFPA) prescribes these interest groups, which include farmers/growers, handlers, certifiers, environmentalists/conservationists, scientists, consumers and public interest groups, and retailers. Representatives are appointed to speak in "we" terms, serving as the voice of the group represented (e.g., "we farmers/growers believe…"). As such, NOSB members are not expected to provide independent expert advice, but rather advice based on the interests of the groups served.

NOSB members represent the interests of a particular group. As such, many of the interests are **acceptable interests**. An interest is acceptable if it is carried out on behalf of a represented group, and if a Board member receives no disproportionate benefit from expressing the interest. True **conflicts of interest** arise when an interest:

- Directly and disproportionally benefits you or a person associated with that member;
- Could impair your objectivity in representing your group; or
- Has the potential to create an unfair competitive advantage.

The appearance of a personal conflict and loss of impartiality, while not a true conflict, must be considered when conducting NOSB business.

Declarations of Interest/Conflicts of Interest Procedures

Board members are appointed in part because of their interests. As such, each NOSB member needs to actively consider their interests with respect to topics being considered by the Board, and identify whether these interests would create appearance problems. This consideration should occur at two specific points during the Board's work on a particular topic. The first consideration should occur at the Subcommittee level, when a Subcommittee begins work on material or topic. The second is when a discussion document or proposal advances from the Subcommittee to the full Board for consideration.

At the Subcommittee Level

NOSB members represent the diverse interests of a broad stakeholder community, and make recommendations that may have wide-reaching regulatory impacts across all of these interest groups. As such, NOSB member actions are carefully scrutinized.

Given this, the NOP has provided the following guidelines for NOSB members working at the

Subcommittee level:

- Avoid leading projects for which you could reasonably be viewed by others as having a particular interest that would hinder your ability to objectively and fairly represent broader group interests, and to allow other members to represent theirs. If leading a project would likely lead others to believe you are "self-dealing" to benefit yourself or someone close to you, you should refrain from leading.

- If you feel you may have an appearance problem or conflict of interest, you should inform the DFO that a conflict may exist, and describe the nature of that conflict. You should also tell the subcommittee impacted that you may have a conflict; sharing as much or as little about the nature of the conflict with other board members as you wish. After this declaration, you may continue to contribute to the discussion on the topic. As long as it is known there is a conflict of interest, the conflict does not preclude the member from contributing his or her input to the subcommittee.

- If you are uncertain as to whether an interest constitutes an appearance problem or a true conflict, then contact the DFO to discuss it. In this case, the NOP, working with the USDA office of ethics as needed, will make the determination about whether a problem exists.

At the Full Board Level
Once discussion documents and proposals are posted for public comment, each NOSB member is to review the documents across all Subcommittees, and research any potential conflicts of interest due to organizational affiliation or relationships.

The following procedures will take place at the Board level:

1. Approximately 2-4 weeks before the meeting, the NOP's DFO will provide a matrix to all NOSB members that lists the items being considered at the meeting.

2. If you determine that you do have a conflict of interest, use the matrix to disclose that information and to declare a recusal from voting on the item(s).

3. If you are not sure whether an interest is acceptable or poses a problem, or if you are uncertain whether recusal is needed, contact the NOP DFO to discuss. The NOP – working with the USDA office of ethics as needed - will make the determination about whether a conflict of interest exists, and will instruct the member accordingly as to whether to vote or not.

4. Return your completed matrix approximately one week before the board meeting. The NOP will then use these to compile a list of all recusals for the meeting.

5. At the meeting, at the beginning of each subcommittee session or at a time designated at the discretion of the board chair, the DFO will state: "the following board members have a conflict of interest with the following documents, and will not be voting: e.g. Bob has a

conflict and will recuse himself from the proposals CleanGreenA and GreatChemB (etcetera)."

6. Once the DFO completes listing the recusals, the NOSB Subcommittee chair leading the session may invite additional information from members on a voluntary basis, with a statement such as: "if Board members wish to disclose information about their conflict, or any other information about their interests, they are welcome to do so at this time." this is to be stated as a general and voluntary invitation; no specific NOSB member is to be called on.

7. For any documents deferred to the last day of the meeting, the DFO will repeat the declaration of statement above at the start of the voting session for each subcommittee. When it is time to vote, the NOSB member recusing her/his self should state "recuse" when it is his or her time to vote.

IV. SUBCOMMITTEES

Subcommittees play an important role in administering the NOSB's responsibilities to make informed decisions. The Subcommittees are responsible for conducting research and analyses, and drafting proposals for consideration by the full NOSB. No Subcommittees are authorized to act in place of the NOSB. Subcommittees are either standing or ad hoc

A. STANDING SUBCOMMITTEES

The current standing Subcommittees are:

- Executive (ES)
- Certification, Accreditation, and Compliance (CACS)
- Crops (CS)
- Handling (HS)
- Livestock (including Aquaculture) (LS)
- Materials (including GMOs) (MS)
- Policy Development (PDS)

Executive Subcommittee (ES)
The Executive Subcommittee of the NOSB shall be comprised of the Chair, Vice Chair, Secretary, and the Chairs of each of the standing Subcommittees. The Executive Subcommittee provides overall coordination for the NOSB including finalizing the NOSB meeting agenda and NOSB work agendas.

Certification, Accreditation, and Compliance Subcommittee (CACS)
The CACS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the certification, accreditation and compliance sections of the USDA organic regulations and OFPA.

Crops Subcommittee (CS)
The CS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the crop production sections of the USDA organic regulations and

OFPA. The CS reviews substances under sunset review and petitions for addition to, or removal from the National List of Allowed and Prohibited Substances. The CS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic crop production to draft their proposals.

Handling Subcommittee (HS)
The Handling Subcommittee drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the handling and labeling sections of the USDA organic regulations and OFPA. The HS reviews substances under sunset review and petitions for addition to or removal from the National List of Allowed and Prohibited Substances. The HS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic handling to draft their proposals.

Livestock Subcommittee (including Aquaculture) (LS)
The LS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the livestock and livestock feed sections of the USDA organic regulations and OFPA. The LS reviews substances under sunset review and petitions for addition to or removal from the National List of Allowed and Prohibited Substances. The LS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic livestock and aquaculture production to draft their proposals.

Materials Subcommittee (including Genetically Modified Organisms) (MS)
The MS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the pertinent National List sections of the USDA organic regulations and OFPA. The MS works with the NOP and other NOSB Subcommittees in managing the Materials Review Process, which may include determining which Subcommittee will conduct a review, as well as tracking technical reports and the status of reviews for petitions and sunset materials. The MS also drafts proposals and discussion documents regarding the prohibition on the use of Genetically Modified Organisms (excluded methods) under the USDA organic regulations. Research Priorities are also a critical component of the annual work agenda of the MS.
In addition to a Chair, who will be appointed by the NOSB Chair, the MS shall include in its membership a representative from each of the Livestock, Crops, and Handling Subcommittees.

Policy Development Subcommittee (PDS)
The Policy Development Subcommittee provides clarification and proposed changes for NOSB internal policies, and procedures as needed, in collaboration with the NOP. The PDS, in collaboration with the NOP, also updates and revises the NOSB Policy and Procedures Manual and the Member Guide.

B. AD HOC SUBCOMMITTEES
At the discretion of the NOSB Chair, and with approval of the Executive Subcommittee and the DFO, ad hoc NOSB Subcommittees may be formed to develop policy and guidance on specific issues that involve multiple standing Subcommittee jurisdictions, or for issues or tasks that are very large and require additional resources to complete. Ad hoc Subcommittees must be comprised of current NOSB members, and may be either a combination of two or more standing Subcommittees to form a “joint” Subcommittee, or

may be a completely new Subcommittee comprised of selected NOSB members from various standing Subcommittees. Ad hoc Subcommittees can be dissolved at the recommendation of the NOSB chairperson with the approval of the Executive Subcommittee. Ad hoc Subcommittee Chairpersons are non-voting members of the Executive Committee.

C. SUBCOMMITTEE MEETINGS

Subcommittees generally hold meetings once or twice a month via telephone conference calls. Calls are scheduled well in advance on a regular reoccurring interval. Additional meetings can be held if a Subcommittee requests additional time and the NOP agrees to provide the resources to support the additional meeting. A majority of the members of a Subcommittee shall constitute a quorum for the purpose of conducting Subcommittee business.

D. TASK FORCES

The NOSB may request the establishment of a Task Force to explore specific issues or concerns relevant to the organic community and industry, and present to the NOSB draft proposals, discussion documents, or reports. Each task force shall:

- Have a specific work agenda approved by the NOP
- Have a clearly articulated project deliverable
- Include at least one current member of the NOSB
- Record and maintain meeting or conference call minutes, made available to the NOSB and the NOP
- Submit a final report to the NOSB
- Disband when the NOP notifies the Task Force that its work has concluded or when the task force is no longer necessary.
- Have a specific start and end date, which may be extended by the Executive Subcommittee, with concurrence by NOP.

E. DUTIES OF SUBCOMMITTEE CHAIRS AND VICE CHAIRS

Subcommittee Chair duties:

- Appoint a Subcommittee Vice Chair in consultation with Board Chair
- Consult with the Board Chair regarding Subcommittee appointments
- Schedule Subcommittee meetings as needed
- Draft Subcommittee meeting agendas and work agendas in consultation with Subcommittee members, the Executive Committee, and NOP staff
- Convene and preside over Subcommittee meetings
- Ensure Subcommittee meeting notes are recorded
- Ensure that Subcommittee meeting notes are reviewed for accuracy
- Report actions of the Subcommittee to the Executive Subcommittee and Board
- Serve as mentor/trainer for new Subcommittee Chair during transition periods
- Designate a liaison to the Materials Subcommittee to collect, compile and present the research priorities proposals.

Subcommittee Vice Chair duties:

- Provide support in developing and completing Subcommittee work agendas
- Assist in reviewing Subcommittee meeting notes for accuracy

- Represent the Chair in the event of the Chair's absence
- The Vice Chairs of the Crops, Livestock and Handling Subcommittees will serve on the Materials Subcommittee as liaisons for reviewing all petitioned substances.

F. TRANSITION OF SUBCOMMITTEE CHAIRS, VICE CHAIRS, AND MEMBERS (NEW AND CONTINUING)

Subcommittee Chairs shall be appointed to serve annually by the Chair of the Board. Vice Chairs and Subcommittee members shall be appointed by their respective Subcommittee Chair in conjunction with the NOSB Chair. The annual Subcommittee term shall be concurrent with the one-year term established by the Secretary (beginning on January 24 and ending the following January 23). Newly appointed Chairs, Vice Chairs and Subcommittee members will assume their positions at the beginning of the new term, after a period of orientation and mentorship provided by the outgoing Chair, Vice Chair, and members.

To avoid disruption in the quality and volume of work produced by the NOSB, the following procedures will be observed:

After the election of NOSB Officers at the Fall Meeting:

1. **The new NOSB Chair takes Office**
   Immediately after the election, on the final day of the NOSB meeting, the new Chair takes office.

2. **Appointment of Subcommittee Chairs**
   The Board Chair appoints Subcommittee Chairs preferably chosen from members with at least one year of NOSB experience**.**

3. **Appointment of Subcommittee Vice Chair**
   Vice Chairs shall be appointed by the incoming Subcommittee Chair, in conjunction with the Board Chair.

4. **Timeframe for Appointments**
   Subcommittee Chairs shall be appointed by the NOSB Chair and seated within a reasonable time after the newly elected NOSB Chair takes office (or continues in office), and Vice Chairs shall be appointed by Subcommittee Chairs as soon as possible after that.

5. **Review of Subcommittee Files**
   New Subcommittee Chairs should review all work agenda items and active files involving Subcommittee work

6. **Mentorship Period**
   The incoming Chair and Vice Chair of each Subcommittee shall participate in an orientation and mentorship period with the outgoing Chair and Vice Chair of their Subcommittee until seated in their positions at the beginning of the new term on

January 24. The Board Chair, to facilitate an effective transition for new members of the Board and ensure effective participation in Committee and Board deliberations, shall ask incoming Board members to identify a mentor from existing Board members, or, if the Board member prefers, the Board Chair shall assign a mentor.

7. **Appointment of New NOSB Members:**
   The Board Chair will appoint each new NOSB member to appropriate Subcommittees as soon as possible, so that on January 24 all Subcommittees are in place. The NOSB Chair will consult with outgoing and incoming Subcommittee Chairs and other Board officers, with due consideration of the members interest, expertise, and background, as well as the composition and needs of the new Board and scope of Subcommittee work agendas. Once appointed, incoming Subcommittee members shall be included in all email communication pertaining to the Subcommittees on which they serve.

Changing Subcommittee Appointments
Board members who would like to join or leave a Subcommittee shall submit a request to the Board Chair. If the request does not alter the preferred number of Subcommittee members, in the range of five to seven, the expectation is that the request will be approved, unless the Board Chair finds that such a change will interfere with the functioning of the Subcommittee or the Board. The Chair's determination should be made in consultation with Subcommittee Chairs and the Executive Subcommittee.

Filling a Subcommittee Chair and/or Vice Chair vacancy
If a Subcommittee Chair position becomes vacant, the Subcommittee Vice Chair shall assume the position as Chair and the new Subcommittee Chair shall appoint a new Vice Chair in accordance with the consultation procedures cited above.

G. PROCEDURES FOR COMPLETING SUBCOMMITTEE PROPOSALS AND DISCUSSION DOCUMENTS

1. **Development of proposals**
   Each of the NOSB Subcommittees will develop proposals, discussion documents or reports based on the current work agenda.

   - A Subcommittee drafts a proposal or discussion document based on that Subcommittee's work agenda.
   - By a simple majority, the Subcommittee can vote to pass a proposal or discussion document to the full Board for consideration at a subsequent NOSB meeting. In order to be considered for a vote during an NOSB meeting, all proposals must be voted on by the Subcommittee and submitted to the NOP at least forty five (45) days prior to a scheduled NOSB meeting.
   - When it is not possible for a Subcommittee, during its regular deliberations on conference calls, to reach consensus on a proposed document/recommendation as it is being reviewed, and there are substantive irreconcilable differences, a minority of the Subcommittee may develop a written minority view for review by all members of the Subcommittee. The Subcommittee Chair has the responsibility to facilitate the process for the minority view.
     A minority view should:

- Be short and concise, and include reasons for opposing the Subcommittees recommendation;
- Should not include any data or information not introduced on a Subcommittee call;
- Should be submitted in a timely manner, and will not be accepted after the Subcommittee has voted on its recommendation;
- Will be included as a separate section at the end of the recommendation.

- The NOP will post the proposal or discussion document for public comment.
- At any point in the process prior to the Board's vote, a Subcommittee may convene and, by a simple majority, vote to withdraw its proposal from consideration by the Board.
- During a subsequent Board meeting, the Subcommittee presents the proposals and discussion documents as well as a summary of public comments and other relevant information for discussion and consideration by the full Board.

2. **Types of Proposals**
   (See Member Guide for examples)
   There are several formats for writing proposals and discussion documents, based on the subject under review:
   - Proposals related to material petitions, sunset reviews, annotation changes, or classification changes.
   - Proposals for policy or procedure changes
   - Discussion documents

3. **Presenting Subcommittee Proposals and Discussion Documents at NOSB Meetings**
   NOSB Subcommittees and task forces should follow the outline below when presenting proposals or discussion documents for consideration by the Board:

   1. **Introduction**: A brief summary of the issue or statement of the problem.
   2. **Background**: An explanation with sufficient detail and rationale to support the proposal, including reasons why the proposal should be adopted, historical context, and the regulatory framework pertinent to the issue.
   3. **Proposal**: A concise explanation of the recommended action.
   4. **Subcommittee Vote**: The Subcommittee vote shall be reported. In the case of petitions to add materials to the National List, two votes will be reported; one for classification of the material as a synthetic or non-synthetic, and the other a motion to list.
   5. **Public Comment:** A brief summary of the public comments
   6. **Minority View**: If applicable, the minority view of a Subcommittee or task force member shall be reported. After the Subcommittee's proposal has been presented and the motion to adopt has been made, it is usual to allow the minority to present their views. The minority report is presented for information purposes only. If the Board then determines that the minority view has merit, it may send the proposal back to Subcommittee for further work, since it would be a substantive change to the proposal as presented.

H. SUBSTANCE/MATERIALS REVIEW PROCESS

A primary function of the NOSB is "to assist in the development of standards for substances to be used in organic production" (OFPA 6518 (a)). "The Board shall develop the proposed

National List or proposed amendments to the National List for submission to the Secretary …" (OFPA 6518(k)). The OFPA also establishes a petition process by which the public can request additions or deletions to the National List and also provides for a 5 –year "sunset" review by NOSB of all substances on the National List. The Materials Review Process is a collaborative effort between the NOP and NOSB. Some phases of the review process are handled exclusively by NOP and some by the NOSB.

The petition process is open to all. Petitions must be filed in accordance with the most recent Federal Register notice instructions and NOP 3011, Procedure- National List Petition Guidelines, effective March 11, 2016.

In lieu of a formal petition, a subcommittee (Livestock, Crops, Handling) of the NOSB may propose to remove a material from the National List by developing a proposal for consideration by the whole Board, provided that all criteria in OFPA at Section 6518(m) are documented as having been addressed in the proposal. Procedures for such a petition will be the same as for changes to annotations or classification of materials, as amended at H2 in this PPM.

1. Steps in the material review process for a new petition:

1. NOP receives a petition, reviews it for completeness and eligibility according to OFPA and the petition guidelines. NOP forwards the petition to the appropriate Subcommittee with a courtesy copy to the Materials Subcommittee.
2. Subcommittee (SC) determines if a Technical Review (TR) is needed.
3. Technical Report is completed and sent to the Subcommittee for review.
4. TR sufficiency is determined by SC, and the TR is posted on the NOSB website by the NOP.
5. SC reviews substance, develops proposal, discusses proposal and votes, and submits for posting 45 days prior to public meeting.
6. The NOSB members analyze comments and votes on the proposal at the public meeting.
7. The NOSB Chair delivers the final recommendations to NOP.

Step 1: Receipt of Petition

During this phase the NOP will:

- Notify the petitioner via letter and/or electronic mail of receipt of the petition.
- Determine whether the petition is complete and whether the petitioned substance is eligible for petition under the Organic Foods Production Act and its implementing regulations, and whether subject to other agency authority (e.g. EPA, FDA);
- NOP documents this review using two checklists.
    - OFPA Checklist, NOP 3005-1
    - Petition Checklist, NOP 3005-2

Ineligible petitions include:

- Formulated (brand name) products
- Food additive without FDA approval
- Pesticide without EPA tolerance or tolerance exemption

- Requests to add substances already allowed
- Synthetic macronutrient (e.g., NPK) fertilizers
- Materials otherwise prohibited by the USDA organic regulations (e.g., sewage sludge, GMOs, etc.)
- Previously petitioned/rejected materials (if no new information is provided)

Upon determination of completeness and eligibility, NOP will:

- Notify the petitioner, via letter and/or electronic mail, that the petition is complete and eligible;
- Publish the petition on NOP website; and
- Notify the NOSB Subcommittee that the substance is being petitioned for addition or prohibition from the National List and provide the OFPA and petition checklists.
- NOP is the primary point of contact for any correspondence between NOSB and petitioner

Step 2: Determine whether a Third Party Technical Review is required

During this phase, the applicable NOSB Subcommittee has 60 days to review the petition and determine whether a third party technical review is required. This decision is based on the following:

- Is there sufficient information in the petition?
- Can the Subcommittee reasonably research any needed technical information?
- Can sufficient information be obtained from public comment?
- Does the Subcommittee have the expertise needed to address the questions related to the petition? This includes impact on the environment, impact on human health, and sustainability and compatibility with organic principles.

If the Subcommittee decides a Technical Review is needed, the Subcommittee Chair will make the request to the National List Manager. The SC may also submit questions for specific information based on the OFPA evaluation criteria (7 USC 6817(m)), or suggest recommended technical expertise. The NOSB may request more information from the petitioner if needed.

If the Subcommittee decides the Technical Review is not needed, the Subcommittee Chair will inform the National List Manager.

In some cases, the Subcommittee may decide the substance is ineligible for the National List without need for a Technical Review. In this case, they will develop a proposal to reject the substance at the next NOSB meeting, subject to a full board vote.

A limited scope or supplemental TR may be appropriate when the petition is to amend an existing listing, remove a listing, or for purposes of sunset review.

Option for a Technical Advisory Panel (TAP)
OFPA states: "The NOSB shall convene technical advisory panels to provide scientific evaluation of materials considered for the National List."(7 USC 6518 (k)(3))

The NOSB has not convened independent Technical Advisory Panels since 2005. Currently the NOSB is relying on information within the Technical Reports provided by the NOP and public comment to make their final recommendations
In some cases, NOSB may wish to convene a TAP instead of requesting a TR, for review of complex or controversial substances.

Step 3: Third Party Technical Review

During this phase the NOP will:

- Assign a contractor to develop a Technical Review (TR) or Technical Advisory Panel (TAP). The third party contractor must have technical expertise relevant to the petition, and will use the TR template provided by NOP.
- Review all TRs or TAP reports before they are distributed to the Subcommittee to ensure they meet the requirements of the contract.
- Ensure that TRs/TAP reports are sufficient and complete when they are distributed to the Subcommittee

Third party experts may consist of contractors, or employees of the USDA, such as AMS Science and Technology, AMS Agricultural Analytics Division, Agricultural Research Service, or other federal agencies with appropriate expertise, as needed.

Step 4: Technical Review Sufficiency Determination

During this phase the Subcommittee (Crops, Livestock or Handling) will:

Review the draft TR to ensure that it:

- Is consistent in format, level of detail and tone
- Is technically objective and free from opinions or conjecture
- Is written in a style appropriate for non-technical readers (e.g. free of technical jargon)
- Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance
- Is based on the best available information that can be obtained within the designated time frame
- Is thoroughly supported using literature citations
- Addresses all evaluation questions in the TR template

The Subcommittee chair will notify the NOP, within 60 days of receiving the TR, that the TR is sufficient. If the TR is not found sufficient, the Subcommittee must provide the NOP with an explanation of why, including a request for additional information or improvements.
If necessary, the NOP will seek improvements or supplemental information from the contractor.
Once the Technical Reports are deemed sufficient, the NOP will post on the NOP website.

Step 5: Review by the Subcommittee (Crops, Livestock or Handling)

During this phase the Subcommittee conducting the review will:

- Read the review, along with the submitted petition, and any additional information available, such as literature referenced in the Technical Review, personal knowledge, and recommendations of a contracted panel of experts when utilized.
- Subcommittee members will prepare a written review the substance according to the OFPA criteria.
- After discussion, the Subcommittee will vote on classification (e.g., synthetic, nonsynthetic, agricultural) for substances not previously classified, and vote on a proposed action (e.g., add to National List, remove, or amend)
- The review, including record of votes, will be finalized as a proposal for the next meeting.
- All proposals must be submitted to NOP for posting 45 days before the public meeting date.

Step 6: Action by Full NOSB

During this phase the NOP will:

- Publish the proposals on the NOP website and provide a minimum of 30 days of written public comment on the proposal prior to the public NOSB business meeting.
- Include sufficient time on the agenda at the NOSB meeting for the Board to discuss the proposal, listen to public comments, and make a recommendation.

At the NOSB meeting:

- The Subcommittee Chair or delegated lead reviewer for each Subcommittee will present the proposals at the NOSB meeting. The proposals are to be presented in the form of a seconded motion coming from the subcommittee, and the Chair will open the motion for discussion. After discussion board members will vote on the motion.
- Voting may be by show of hands, roll call, or by use of modern voting devices.
- The NOSB Secretary will record the votes of each NOSB member and the Chair will announce whether or not the motion passed.

2. Changes to annotations, classification of materials, or proposal to remove.

The NOSB may request to review an existing substance on the National List without a new petition when they have justification to support a revision of the annotation, a reclassification of the substance, or removal of a substance. This may happen as a result of the sunset review process, or based on new information provided in a Technical Review, or from public comment. The following procedure should be followed:

- The Subcommittee sends a written request for a new work agenda item to the Executive Subcommittee.
- The request should include a summary of the issue, brief justification for the change, and resources in hand or needed for the project.
- The ES considers the request and determines if it should go forward.
- NOP reviews the item for possible addition to the work agenda, and may propose to add to a future meeting schedule depending on NOSB workload.

- The Subcommittee develops a proposal for consideration that is separate from the sunset review of the substance. NOP will then consider rulemaking action in a timely manner, without constraints due to the sunset timeline.

3. Additional considerations concerning Technical Reviews

Basic principles that should be considered when consulting with a third party expert:

- A Subcommittee cannot proceed with a recommendation to list a material if it is determined that there is insufficient valid scientific information on that material's impact on the environment, human health and its compatibility with organic principles.
- The decision to request a third party expert needs to be made independently of the availability of funds. If there is a lack of funding to secure third party expert advice, the Subcommittee has the option to place the review of new petitions on hold.
- The Subcommittee makes a determination on the completeness of the petition and whether a Technical Review is needed.
- The decision to define the expertise of the third party expert is the responsibility of the Subcommittee reviewing the material or issue.
- To incorporate a diversity of opinions and to minimize the risk of bias, a Subcommittee may seek information from a range of technical experts (individuals or institutions). The Subcommittee may also ask questions in their posted proposals, in order to gain needed information from the public.
- The NOP will seek Technical Reviews from a range of experts. The name of the contracted party will appear on the Technical Review. All Federal contracts, including those issued by USDA/NOP to Technical Report contractors, are governed by the Federal Acquisition Regulations (FAR). The FAR includes a "Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions," which requires contractors to identify and prevent personal conflicts of interest for their covered employees. "Personal conflict of interest" means a situation in which a covered employee has a financial interest, personal activity, or relationship that could impair the employee's ability to act impartially and in the best interest of the Government when performing under the contract.
  Link: https://www.acquisition.gov/far/current/pdf/FAR.pdf

4. Definitions

Technical Review - A report prepared by a third party expert under contract addressing the environmental, human, and industrial impact of a petitioned material per the OFPA and regulatory evaluation criteria to aid in the thorough evaluation of that material by the NOSB.

Technical Advisory Panel (TAP) - Group of third party experts convened by the Board to provide a technical review related to a material petition under review by the NOSB.

V. Prioritization of Petitions

Petitions received and deemed eligible and sufficient by the NOP/NOSB will be prioritized as follows:

Priority 1: A petition or proposal to **remove** a material presently on the National list that raises serious health, environmental, or regulatory concerns, including petitions to reconsider previous decisions, will be given the highest priority - **Priority 1,** above all other petitions in the queue of the reviewing Subcommittee (Crops, Handling, or Livestock).

Priority 2: A petition or proposal to **remove** a material presently on the National list not based on serious health, environmental, or regulatory concerns, but based on other new information, such as commercial availability status, would be assigned a **Priority 2,** behind Priority 1 petitions, but above any petitions to list materials that are in the queue of the reviewing Subcommittee (Crops, Handling, or Livestock). This priority assignment would include any removal petitions requesting reconsideration of previous board decisions, if the resubmitted petition contains substantive new information to warrant reconsideration.

Priority 3: A petition to **add** a material to the National List will be considered by the reviewing Subcommittee (Crops, Handling, or Livestock) in the chronological order in which it was received, and will be designated as **Priority 3**.

Priority 4: A petition to **reconsider** adding a material that had previously been rejected by a Board vote would be given the lowest priority - **Priority 4**, and would go to the bottom of the Subcommittee (Crops, Handling, or Livestock) queue of petitioned materials. Petitions submitted for reconsideration must contain substantive new information to warrant reconsideration.

This prioritization guideline is only that, a guideline. When situations occur beyond the control of the reviewing Subcommittee, such as, but not limited to, technical report budgetary constraints, or a delay in the delivery of a technical review for a petitioned substance, the work agenda may require adjustment by the NOSB and NOP.

VI. Withdrawal of a petition by a petitioner

A petition may be withdrawn at any point in the process, prior to the vote by Subcommittee. Once a Subcommittee develops a proposal, the outcome will be posted for public comment and the NOSB will vote at the next public meeting. When a petition is withdrawn by the petitioner prior to Subcommittee proposal, the Subcommittee will suspend its review and recommendation procedure. Withdrawals will not be accepted after the subcommittee votes on a proposal.

If a petition is re-submitted, the NOSB will review it in the order in which it was received. Thus, a re-submitted petition should be considered a new request and will be placed at the end of the queue of materials pending review.

A petitioner has the opportunity to withdraw a petition with the intent of improving it (e.g., conducting additional research), and may also voluntarily submit supplemental information.

VII. Sunset Review Process

The Organic Foods Production Act of 1990 (OFPA) authorizes a National List of Allowed and Prohibited Substances (7 U.S. C. Section 6517). Sections 6517 (e) mandates a Sunset

Provision as follows:

"No exception or prohibition in the National list shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 years of such exemption or prohibition being adopted and the Secretary has renewed such exemption or prohibition."

The NOP published a Federal Register notice on Sept. 16, 2013 (78 FR 56811) describing current procedures for sunset review. Through the sunset review process, the NOSB can recommend to USDA the removal of substances based on adverse impact on human health, the environment, or other criteria under the Organic Foods Production Act (OFPA). If upon review the NOSB believes the substance no longer fits the criteria for an exemption or prohibition, the NOSB can recommend (by a decisive two thirds vote, 7 USC Section 6158 (i)) to remove the substance from the National List. After the NOSB has completed this "sunset" review, the USDA must renew or remove the substances on the National List to complete the process. All substances under sunset review will be considered over two NOSB meetings, to provide ample opportunity for public notice and comment. The NOSB observes the following procedure.

A. Steps in the Sunset Review Process (See Member Guide for forms used in these steps.)

Step 1: The NOSB Subcommittees submit the initial **Sunset List Summary** for posting which may include requests for specific information. The NOP posts the list as well as the NOSB Meeting Announcement in the Federal Register which invites comments, at least 30 days prior to the first public meeting on these sunset substances.

Step 2: The public submits written comments, which are analyzed by Subcommittees.

Step 3 (Public Meeting #1): Subcommittees summarize background and public comment & receive oral comment.

Step 4: Subcommittees analyze written and oral comments from Meeting #1 and prepare a **Preliminary Review** that includes a motion to remove the substance from the National List. The NOP publishes the next meeting announcement in the Federal Register, inviting comment on the **Preliminary Reviews,** which are posted on the NOP website.

Step 5: Written public comments submitted and analyzed by Subcommittees

Step 6 (Public Meeting #2): Subcommittees present **Preliminary Review**, receive oral comment, and discuss the proposal with the full Board. When presented to the full NOSB, reviews will contain a motion and second taken in Subcommittee. Motions for removal based on the **Preliminary Review** are voted on by the full Board, and require a decisive two-thirds (2/3) majority to pass.

- At Meeting #2, the NOSB completes the **Sunset Review** and submits the final documents to the NOP.

Step 7: AMS reviews the NOSB Sunset Review and considers rulemaking action for any recommended removals. This will include a proposed rule open for public comment before a final rule amendment is published.

Step 8: AMS issues Federal Register Notice announcing renewal of applicable substances

Note: this is a regulatory process for determining whether materials already approved or prohibited on the National List should be removed. Due to regulatory process constraints, it is not possible to modify existing listings, add new uses of a listed substance during sunset review, or change annotations. If there is a need to consider changing an annotation or re-classifying a material, a subcommittee may request to develop a separate proposal that will be reviewed separately from the sunset review process. Decisions made through the Sunset review should be transparent, non-arbitrary, based on the best current information and in the interest of the organic community and public at large.

VIII. NOSB PROCEDURES

A. BOARD MEETINGS

All Board meetings, assembled for the purpose of making recommendations to the NOP, are subject to FACA (see appendix B for FACA facts) and as such must be open to the public and must meet public notification requirements. Not all meetings are subject to FACA and do not require public notification. Examples of these exempted meetings include: Subcommittee calls, assemblies for completing work, planning retreats, training or sharing information. The date and location of in-person Board Meetings, currently held twice each year in spring and fall, will to the extent possible, be set at the mutual scheduling convenience of the NOSB and the NOP.

B. CONDUCTING BUSINESS

NOSB public meetings in brief:

- Approximately 3 days long depending on workload
- Meetings are held in various venues across the country to allow for participation by stakeholders that otherwise may not be able to attend due to travel constraints
- A typical meeting agenda includes presentations by the NOP, presentations of proposals and discussion documents by the NOSB Subcommittees, discussion time and votes on each proposal, public comment, NOSB officer elections, and a review of work agendas

Quorum: As specified in OFPA, a majority of the members of the NOSB shall constitute a quorum for the purpose of conducting business. (7 USC 6518 (h)). In cases of a medical situation preventing attendance in person, a virtual presence is permitted.

Decisive votes: As specified in OFPA, two-thirds (2/3) of the votes cast at a meeting of the NOSB at which a quorum is present shall be decisive of any motion (7 USC Section 6518(i)). All abstentions will be recorded as such and will not be included as part of the total vote cast in case of decisive votes. Similarly, all NOSB members who recuse themselves due to conflicts of interest, or are absent, shall be recorded as such and their votes will not be counted towards

the total number of votes cast. Both abstentions and recusals will be considered in order to establish a quorum.

Calculation of Decisive Votes

# Votes Cast	# Recusals and Abstentions	2/3 Majority*
15	0	10
14	1	10
13	2	9
12	3	8
11	4	8
10	5	7
9	6	6
8	7	6

C. PARLIAMENTARY PROCEDURES

No procedures or business of the NOSB shall be taken in conflict with OFPA, FACA or other pertinent laws (herein referred to as governing legislation). For parliamentary procedure, all motions and votes not covered under the governing legislation shall be governed by this Policy and Procedure Manual if directly addressed. If procedures, motions and votes are not directly addressed in the Policy and Procedures Manual, they shall be governed by Robert's Rules of Order Newly Revised. The NOSB adopted the use of Robert's Rules of Order in March 1992, but modified its use as only a non-mandatory guide in May 1993. Roberts Rules may be adapted to meet the special requirements of a group. Because the NOSB is also subject to the OFPA, FACA and USDA, a designated NOP staff member may act as an informal Parliamentarian to advise the Chair.

D. NOSB DELIBERATIONS AND RECOMMENDATIONS

Board actions include but are not limited to: adoption of a proposal as presented by the Subcommittee, non-substantive amendments* and then adoption of a proposal, rejection of a proposal, or referral of the proposal back to Subcommittee for further development.

*** Substantive vs. non-substantive amendments.**

The following criteria shall be considered when determining if a proposal will be amended at the NOSB meeting, or must be referred back to Subcommittee and resubmitted for the next Board meeting. The DFO or designee will determine whether a proposed amendment to a proposal is substantive.

- The extent to which a reasonable person affected by the recommendation would have understood that the published proposal would affect his or her interests
- The extent to which the subject of the recommendation or the issues determined in it are substantially different from the subject or issues involved in the proposal

- The extent to which the effects of the recommendation differ from the effects of the proposal

Procedure for submitting final recommendations to NOP
Within 30 days after the completion of the NOSB meeting all final recommendations must be submitted to the NOP using the following procedure:

Each proposal lead prepares the following documents:

- A recommendation cover sheet (See Member Guide). The cover sheet should contain all appropriate information, including the vote recorded at the meeting. (The NOP can provide the voting record)
- The proposal that was voted on at the meeting

The proposal leads will forward the documents to the appropriate Subcommittee Chair who will review them for accuracy and completeness, sign and date them, and then forward them to the Board Chair and the DFO/ACS.

E. PUBLIC COMMENT

The NOP and NOSB encourage public comment and work collaboratively to increase opportunities for greater participation by a broad range of people, employing various modes of communication and modern technology whenever possible. Individuals may present oral comment at either a pre-meeting electronic webinar or at the in-person NOSB meeting.
Before Public Meetings:
Written comment: All members of the public are encouraged to submit public comment in writing according to the Federal Register Notice. Written submissions: allow NOSB members the opportunity to read comments in advance, eliminate or decrease the need for paper copies to be distributed during the meeting and allow each NOSB member to review and analyze data and information well ahead of the public meeting and possible voting.

Oral Comments
Oral comments: May be received via a virtual meeting/webinar. Public notice of such electronic meetings will be included in the Federal Register notice announcing the public meeting. Such electronic pre-meetings may allow individuals more time to present their data or information, reduce the need to attend the public meeting in person, reduce our carbon footprint, and give the NOSB more time to absorb the information. Such electronic meetings shall be recorded and made available to the public and to NOSB members.

Comments at In-Person Public Meetings:
- All persons wishing to comment at NOSB meetings during public comment periods must, in general, sign-up in advance per the instructions in the Federal Register Notice for the meeting. Persons requesting time after the closing date in the Meeting Notice, or during last minute sign-up at the meeting, will be placed on a waiting list and will be considered at the discretion of the NOP working closely with the NOSB Chair and will depend on availability of time.

- All presenters are encouraged to submit public comment in writing according to the Federal Register Notice. Written submissions allow NOSB members the opportunity to read

comments in advance electronically, and decreases the need for paper copies to be distributed during the meeting.

- Persons will be called upon to speak according to a posted schedule. However speakers should allow for some flexibility. Persons called upon who are absent from the room could potentially miss their opportunity for public comment.

- Time allotment for public comment per person will be four (4) minutes, with the options of reducing to a minimum of three (3) and extending to a maximum of five (5) minutes at the discretion of the NOP, working closely with the NOSB Chair in advance of the meeting.

- Persons must give their names and affiliations for the record at the beginning of their public comment.

- Proxy speakers are not permitted.

- Public comments may be scheduled according to topic.

- Individuals providing public comment shall refrain from making any personal attacks or remarks that might impugn the character of any individual.

- Members of the public are asked to define clearly and succinctly the issues they wish to present before the Board. This will give NOSB members a comprehensible understanding of the speaker's concerns.

Policy for Public Communication between NOSB Meetings (Adopted April 11, 2013)

The NOSB and NOP seek public communication outside of Board biannual meetings and public comment periods to inform the NOSB and NOP of stakeholders' interests, and to comment on the NOSB's and NOP's work activities year around.

F. ELECTION OF OFFICERS

Nominations

- Any NOSB member is eligible for consideration for any officer position
- An NOSB member may self-nominate or may be nominated by another member of the NOSB
- Should the Chair, Vice Chair, or Secretary resign or fail to serve the full term, the Executive Subcommittee shall appoint an interim officer. The interim officer shall serve in that capacity until the next regularly scheduled meeting of the NOSB, during which an election will be held to fill the remainder of the term
- Members may serve more than one term in any officer position.

Voting schedule

- Officers shall be elected for one-year terms by majority vote at the fall NOSB meeting.
- Newly elected officers will assume their positions at the conclusion of the fall NOSB meeting, and assume the responsibilities thereof at that time
- Outgoing NOSB officers will assist the incoming officers with the transition into their new roles, to be completed no later than January 23rd of the following year.

Counting of Votes

- Voting will be by secret ballot immediately following nominations for each office.
- Ballots for officers will be cast in the following order:
    1. Chair
    2. Vice Chair
    3. Secretary
- Ballots will be counted for one office and the Secretary will announce the tally before the next office is opened for nominations.
- The Secretary and Vice chair will prepare and distribute the ballots, then collect them after each vote.
- The Secretary will tally the votes and the Chair will verify the results.
- The first nominee to receive a majority of votes will be elected. If no nominee receives the majority of votes, the nominee with the least votes will be eliminated and a revote will occur with the remaining candidates. This process will be repeated until a nominee obtains a majority.
- In the event of a tie there will be a revote until a nominee obtains a majority. All nominees will be included in the revote.
- Votes will remain confidential, and ballots will be disposed of by the Chair or Secretary.
- A nominee may withdraw at their discretion at any time.
- In the event of only one nominee for office, the vote may be by acclimation.

G. MISCELLANEOUS PROCEDURES

1. Invited Speakers

- Subcommittees, the NOSB or the NOP may identify the need for presentations and speakers regarding subjects of interest or concern to be addressed at NOSB meetings.

- Requests must be made by the NOSB chair to the NOP no less than 60 days prior to the target NOSB meeting.

- Speakers must be approved and invited by the NOP.

  If approved by the NOP, the purpose for the presentation, the subject area and the bio/resume of speaker(s) should be circulated via email to the entire Board at least 2 weeks prior to the Board meeting.

  Current petitioners cannot be invited to be speakers about the topic under discussion, unless invited by the NOSB Chair.
  Speakers are expected to disclose any financial interests that he or she has that can be reasonably assumed to influence his or her presentation content.

2. Surveys Conducted on Behalf of NOSB Subcommittees

- All surveys, including electronic surveys, conducted on behalf of the NOSB, must be approved by the NOSB Executive Subcommittee before they are submitted for approval to USDA, and

- A written report summarizing the results of the survey must be submitted to the full

Board and the NOP as soon as possible after completion.

IX. REVISIONS TO THE POLICY AND PROCEDURES MANUAL

- The PDS will review the PPM each year and, working in collaboration with the NOP, determine if any updates are necessary.
- Proposed changes will be subject to review and approval by the NOP and the full NOSB.

X. APPENDICES

A. Appendix 1: FOUNDATIONS

1. NOSB PRINCIPLES OF ORGANIC PRODUCTION AND HANDLING

(NOSB Recommendation Adopted October 17, 2001)

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.

1.2 An organic production system is designed to:

1.2.1 Optimize soil biological activity;
1.2.2 Maintain long-term fertility;
1.2.3 Minimize soil erosion;
1.2.4 Maintain or enhance the genetic and biological diversity of the production system and its surroundings;
1.2.5 Utilize production methods and breeds or varieties that are well adapted to the region;
1.2.6 Recycle materials of plant and animal origin in order to return nutrients to the land, thus minimizing the use of non-renewable resources;
1.2.7 Minimize pollution of soil, water, and air; and
1.2.8 Become established on an existing farm or field through a period of conversion (transition), during which no prohibited materials are applied and an organic plan is implemented.

1.3 The basis for organic livestock production is the development of a harmonious relationship between land, plants, and livestock, and respect for the physiological and behavioral needs of livestock. This is achieved by:

1.3.1 Providing good quality organically grown feed;
1.3.2 Maintaining appropriate stocking rates;
1.3.3 Designing husbandry systems adapted to the species' needs;
1.3.4 Promoting animal health and welfare while minimizing stress; and
1.3.5 Avoiding the routine use of chemical allopathic veterinary drugs, including antibiotics.

1.4 Organic handling practices are based on the following principles:

1.4.1 Organic processors and handlers implement organic good manufacturing and handling practices in order to maintain the integrity and quality of organic products through all stages of processing, handling, transport, and storage;
1.4.2 Organic products are not commingled with non-organic products, except when combining organic and non-organic ingredients in finished products which contain less than 100% organic ingredients;
1.4.3 Organic products and packaging materials used for organic products do not come in contact with prohibited materials;

1.4.4 Proper records, including accurate audit trails, are kept to verify that the integrity of organic products is maintained; and

1.4.5 Organic processors and handlers use practices that minimize environmental degradation and consumption of non-renewable resources. Efforts are made to reduce packaging; use recycled materials; use cultural and biological pest management strategies; and minimize solid, liquid, and airborne emissions.

1.5 Organic production and handling systems strive to achieve agro-ecosystems that are ecologically, socially, and economically sustainable.

1.6 Organic products are defined by specific production and handling standards that are intrinsic to the identification and labeling of such products.

1.7 Organic standards require that each certified operator must complete, and submit for approval by a certifying agent, an organic plan detailing the management of the organic crop, livestock, wild harvest, processing, or handling system. The organic plan outlines the management practices and inputs that will be used by the operation to comply with organic standards.

1.8 Organic certification is a regulatory system which allows consumers to identify and reward operators who meet organic standards. It allows consumers to be confident that organic products are produced according to approved management plans in accordance with organic standards. Certification requires informed effort on the part of producers and handlers, and careful vigilance with consistent, transparent decision making on the part of certifying agents.

1.9 Organic production and handling operations must comply with all applicable local, state, and federal laws and address food safety concerns adequately.

1.10 Organic certification, production, and handling systems serve to educate consumers regarding the source, quality, and content of organic foods and products. Product labels must be truthful regarding product names, claims, and content.

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 (GE/GMOs) and products produced by or through the use of genetic engineering are prohibited.

1.12 Although organic standards prohibit the use of certain materials such as synthetic fertilizers, pesticides, and genetically engineered organisms, they cannot ensure that organic products are completely free of residues due to background levels in the environment.

2. NOSB GUIDANCE ON COMPATIBILITY WITH A SYSTEM OF SUSTAINABLE AGRICULTURE AND CONSISTENCY WITH ORGANIC FARMING AND HANDLING

(NOSB Recommendation Adopted April 29, 2004)

A significant responsibility of the NOSB is to determine the suitability of materials for use in organic production and handling. Among the criteria the Board must consider, OFPA requires the NOSB to determine the compatibility of a material with organic practices. The following questions were developed by the NOSB to assist in determining the compatibility of materials with organic practices.

In order to determine if a substance, its use, and manufacture are compatible with a system of sustainable agriculture and consistent with organic farming and handling, and in consideration of the NOSB Principles of Organic Production and Handling, the following factors are to be considered:

- Does the substance promote plant and animal health by enhancing the soil's physical chemical, or biological properties?
- Does use of the substance encourage and enhance preventative techniques including cultural and biological methods for management of crop, livestock, and/or handling operations?
- Is the substance made from renewable resources? If the source of the product is non-renewable, are the materials used to produce the substance recyclable? Is the substance produced from recycled materials? Does use of the substance increase the efficiency of resources used by organic farms, complement the use of natural biological controls, or reduce the total amount of materials released into the environment?
- Does use of the substance have a positive influence on the health, natural behavior, and welfare of livestock?
- Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?
- Does the substance allow for an increase in the long-term viability of organic farm operations?
- Is there evidence that the substance is mined, manufactured, or produced through reliance on child labor or violations of applicable national labor regulations?
- If the substance is already on the National List, is the proposed use of the substance consistent with other listed uses of the substance?
- Is the use of the substance consistent with other substances historically allowed or disallowed in organic production and handling?
- Would approval of the substance be consistent with international organic regulations and guidelines, including Codex?
- Is there adequate information about the substance to make a reasonable determination on the substance's compliance with each of the other applicable criteria? If adequate information has not been provided, does an abundance of caution warrant rejection of the substance?
- Does use of the substance have a positive impact on biodiversity?

3. NOSB MEMBER DUTIES

To fulfill their responsibilities, Board members agree to adhere to the following Duties.

Duty of Care

The Duty of Care calls upon a member to participate in the decisions of the Board and to be informed as to the data relevant to such decisions. In essence, the Duty of Care requires that a member:

- Be reasonably informed - It is the duty of all Board members to seek and study the information needed to make a reasoned decision and/or recommendation on all business brought before the Board. The NOP will provide some of that information, but other information must be developed from independent sources.
- Participate in decisions - Board members are bound by responsibility to be active participants in decision making. Absence from a meeting is no protection from the responsibility for decisions made at the meeting.
- Make decisions with the care of an ordinary prudent person in a similar position - The law requires Board members to exercise the judgment of an ordinary prudent person who may be faced with a similar issue.

Duty of Loyalty

The Duty of Loyalty requires Board members to exercise their power in the interest of the organic community and the public at large, and not in their own interest or the interest of another entity or person. In dispatching their Duty of Loyalty, Board members must:

- Address conflicts of interest - Board members bring to the NOSB particular areas of expertise based upon their personal and business interests in organic production and marketing. Because Board members may have interests in conflict with those of the public they must be conscious of the potential for such conflicts and act with candor and care. Board members must abide by the NOSB conflict of interest policy.
- Recognize corporate opportunity - Before a Board member votes upon an issue in which they have a direct financial interest, that Board member must disclose the transaction to the Board in sufficient detail and adequate time to enable the Board to act, or decline to act, in regard to such transaction.

Duty of Obedience

Board members are bound to obey the tenants of the laws and regulations governing organic production, processing and marketing. To this effect, Board members must:

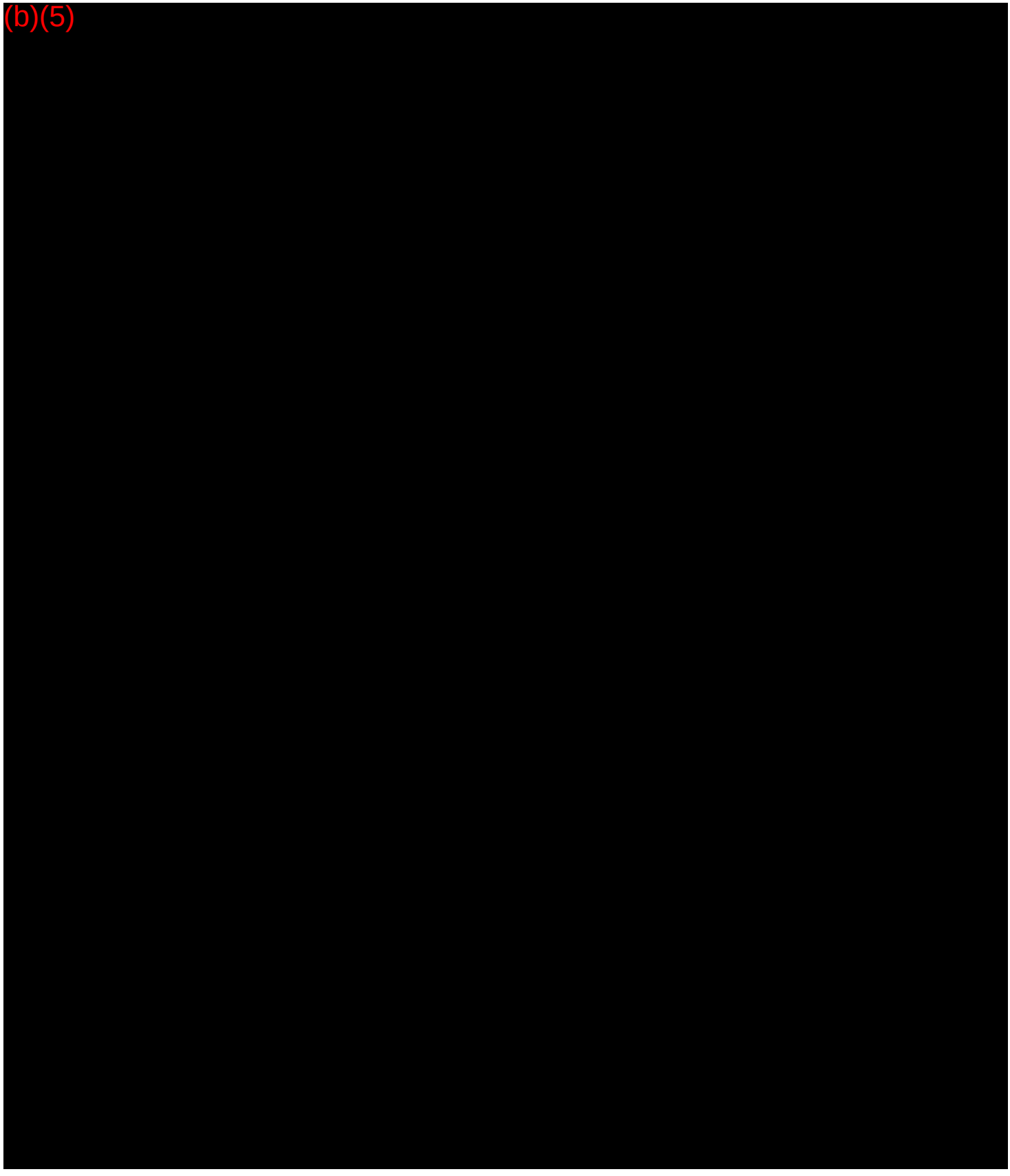
- Act within the requirements of the law - Board members must uphold all state and federal statutes, including the Federal Advisory Committee Act (FACA – 5 U.S.C. App. 2 et seq.)
- Adhere to the responsibilities of the Board as defined by the Organic Foods Production Act of 1990
- Adhere to the requirements specified in the NOSB Policy and Procedures Manual

B. Appendix 2: FACA FACTS

The Federal Advisory Committee Act (FACA) (5 U.S.C. App.2) and its implementing regulations (41 CFR Part 101-6.10) govern the creation, operation, and termination of advisory committees in the Executive Branch of the Federal Government. The National Organic Standards Board (NOSB) is a Department of Agriculture (USDA) non-discretionary advisory committee required by the Organic Foods Production Act of 1990, as amended.

- Advisory committees must be chartered before they can meet or conduct any business. Charters must be renewed every two years or they will be terminated under the sunset provisions of Section 14 of the FACA, unless otherwise provided by law.
- Advisory committee meetings are required to be open to the public, with limited exceptions as provided for in Section 552b of title 5, United States Code. Meetings not subject to FACA include NOSB briefing meetings initiated by the USDA to exchange facts and information, member orientation and training, and NOSB Subcommittee meetings. Such meetings are not subject to FACA because they are not conducted for the purpose of providing the USDA with NOSB advice or recommendations.
- Designated Federal Officers must approve all meetings and agendas, and attend meetings. The Advisory Board Specialist is the NOSB's Designated Federal Officer.
- Meeting notices and agendas must be published in the Federal Register to accommodate public participation. Although not required by FACA, the NOP strives to:
    - Post a provisional agenda on its web site no later than 90 days before the meeting is scheduled to begin
    - Post a final agenda, on its web site, no later than 45 days before the meeting is scheduled to begin
    - The NOP will strive to publish notice of the next NOSB meeting in the Federal Register as early after the previous NOSB meeting as possible. This notice will serve as an "open docket" in which public comment can be received by the NOP and NOSB. Notwithstanding the above, the NOP will publish notice of the meeting in the Federal Register no later than 45 days before the meeting is scheduled to begin
- While meeting transcripts are not required under FACA, the NOP provides transcripts or meeting notes to support the transparency of Board meetings and to support subsequent rulemaking activities. The NOP also issues a short meeting summary, which is required by FACA, after each biannual meeting that summarizes the key issues discussed, and the outcome of voting.
- Advisory committee documents must be available for public inspection and copying until the committee ceases to exist.
- Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to reasonable rules or regulations.
- Additional information may be found at the FACA homepage: http://www.gsa.gov/portal/content/100916

National Organic Standards Board
Compliance, Accreditation and Certification Subcommittee
Inspector Qualifications
February XX, 2107



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National Organic Standards Board
Handling Subcommittee
Bisphenol A (BPA) in Packaging Discussion Document

February 21, 2017

I. INTRODUCTION

The National Organic Standards Board (NOSB) initiated a work agenda item for evaluating packaging materials in 2013. At this time, the Handling Subcommittee (HS) has decided to proceed with a discussion document to collect input from organic stakeholders on this issue while an independent technical report is in process.

Bisphenol A (BPA) is a chemical widely used in manufacturing polycarbonate plastics and epoxy resins used in many industries, including the lining of cans for food. Releases of BPA to the environment exceed 1 million pounds per year (EPA, 2010). It is a known endocrine disruptor, and several studies and biomonitoring programs demonstrate that BPA leaches out of the linings of cans used for food and that human populations are widely exposed (EPA, 2010). For example, BPA was frequently detected in participants in U.S. CDC and California biomonitoring programs (CDC; State of California 2017a) and studies worldwide (Vandenberg LN et al., 2010). Several studies indicate that food contact materials are a primary source of BPA exposure in humans (Carwile et al., 2011; Rudel et al. 2011). For example, in 2011, researchers at the Harvard School of Public Health determined that volunteers who ate a single serving of canned soup a day for five days had ten times the amount of BPA in their bodies as when they ate fresh soup daily (Carwile et al., 2011). Several studies suggest BPA may be harmful to human health at low exposure levels (Sowlat et al., 2016, Rochester JR, 2013, Ejaredar M, 2016) and it is listed as a chemical known to be a reproductive toxicant under the California Safe Drinking Water and Toxic Enforcement Act (State of California 2015).

BPA is currently allowed for use in cans and other packaging containing organic food. In the interest of organic integrity for processed foods, the NOSB is reviewing concerns about BPA in the same way that other synthetic materials that come into contact with organic food are evaluated.

While some organic processors have found alternatives to BPA in their products, the NOSB does not have information on how much BPA is still used in organics and whether alternative packaging materials are widely used. The NOSB would also like to know more about what alternatives to BPA are being used and if any of the alternative materials might raise human health concerns. The Handling Subcommittee and most organic consumers agree that organic food should be produced in a manner that minimizes exposure to toxic materials in any form. Therefore, this discussion document will alert stakeholders to this issue and begin information gathering to determine whether changes are needed in the regulations to ensure harmful substances do not come into contact with organic food.

II. BACKGROUND

In December 2013 a request was submitted by the NOSB Handling Subcommittee to the National Organic Program to add the issue of BPA in packaging to the NOSB work agenda. In November 2014 the NOP issued a Memorandum to the NOSB, titled "*Packaging substances used in organic food handling"*, in which the NOP acknowledged the request and that there were recent studies that raised concern about BPA and similar packaging substances. They suggest:

> "That NOSB start with a discussion paper that provides a review of current literature, evaluation of current uses in the organic market, availability and suitability of alternatives, and impact of removal of these packaging substances on the organic trade."

The memorandum was accompanied by a letter from Senator Dianne Feinstein that supports a ban on BPA.

Additionally, several public comments addressing plastics and BPA were submitted in 2015 and 2016. These comments raised human health and environmental concerns about the use of plastic packaging for organic foods, and many specifically focused on BPA.

A request for a Technical Report (TR) was submitted in August 2015. The following specific issues were posed to the writers of the TR:

- "There is much criticism by both sides of the BPA safety debate over the validity of various research methods, from what breed of rats are used to human cell studies in vitro vs. animal studies. There are also collusion, conflict of interest, and bias contentions in some research efforts. Please examine these objectively using the citations below and others, and give an evaluation of which research is the most valid.
- Evaluate the conclusion from the paper by Yang cited above that they can identify existing compounds, additives, or processing agents that have no detectable estrogenic activity and have similar costs. What are these alternatives?
- Review recent research on some of the BPA alternatives in use, such as Tritan (containing triphenyl phosphate or TPP), Bisphenol S (BPS) and Bisphenol F (BPF) and any others. Some citations are below.
  What is the status of BPA in other countries? How widespread are bans on BPA and are any of the alternatives banned as well? What evidence was used in making those determinations?"

The NOP contracted for the TR in January 2016 with the Agricultural Analytics Division of the USDA AMS. The TR was provided to the NOSB on October 19, 2016. In December of 2016 the HS determined that the report was technically insufficient according to the criteria in the NOSB PPM. In response, NOP issued another statement of work to externally contract this work and OMRI received the award for BPA. The OMRI report is currently in development.

III. RELEVANT AREAS OF THE RULE

§205.272 Commingling and contact with prohibited substance prevention practice standard.

(a) The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances.

(b) The following are prohibited for use in the handling of any organically produced agricultural product or ingredient labeled in accordance with subpart D of this part:

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

(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.

IV. DISCUSSION

In this discussion the NOSB Handling Subcommittee is seeking information from the industry on several points, including whether BPA should be prohibited and how widespread BPA is used in organic foods.

The HS would also like to collect information on the factors that affect the choice of alternatives and what those alternatives are. This information will be considered along with the final TR when it is publically available.

A. Should BPA be prohibited?

A concise summary of the situation regarding BPA is described in the Environmental Protection Agency BPA Action Plan (EPA, 2010).

> "Because BPA is a reproductive, developmental, and systemic toxicant in animal studies and is weakly estrogenic, there are questions about its potential impact particularly on children's health and the environment. Studies employing standardized toxicity tests used globally for regulatory decision-making indicate that the levels of BPA in humans and the environment are below levels of potential concern for adverse effects. However, results of some recent studies using novel low-dose approaches and examining different endpoints describe subtle effects in laboratory animals at very low concentrations. Some of these low-dose studies are potentially of concern for the environment because the concentration levels identified with effects are similar to some current environmental levels to which sensitive aquatic organisms may be exposed.
>
> Regulatory authorities around the world reviewing these low-dose studies have generally concluded that they are insufficient for use in risk assessment because of a variety of flaws in some of the study designs, scientific uncertainty concerning the relevance to health of the reported effects, and the inability of other researchers to reproduce the effects in standardized studies. However, since the low-dose studies do raise questions and concerns, some authorities have taken action to protect sensitive populations, particularly infants and young children."

The latest review from the Food and Drug Administration, published in June 2014 (FDA, 2014), reviewed all the literature since the previous review in 2008:

> "The conclusion of this report is that an adequate margin of safety exists for BPA at current levels of exposure from food contact uses."

FDA also note that there is significant uncertainty associated with extrapolating safety data obtained from rodents and non-mammalian chordates to primates (including humans) because there is a decreased capacity of non-primates to metabolize BPA and there have been large variability in study results.

On the other hand, scientific articles are being published regularly that show that low doses of BPA may be more harmful than higher doses, and that these troubling results are resulting from well conducted research (Johns et al. 2016, Kinch et al. 2015, Science Daily).

For example, human epidemiological studies have shown associations between BPA and a number of adverse outcomes on child behavior, metabolic disorders, and fertility, among other outcomes. Additionally, in 2015 BPA was listed as a chemical known to the state of California to cause reproductive toxicity (Rochester 2013, Johns et al. 2016, Sowlat et al. 2016, Ejaredar et al. 2016, State of California 2015).

There are also concerns about two of the main alternatives to BPA: BPS and BPF. For example, BPS and BPF share similar chemical structures with BPA and may have estrogenic activity and act by similar mechanisms (Hashimoto et al. 2001, Rochester and Bolden 2015, Chen 2002, Kinch et al. 2015).

Individual epidemiologic studies are observational and therefore cannot show causation. However, human studies are most relevant to inform our understanding of human health risks, and a growing

literature suggests that BPA may adversely impact human health, potentially at environmentally relevant levels. Finally, as described above, there is evidence of widespread human exposure with food packaging materials as a primary exposure source.

In summary, as evidence of negative effects on health builds and organic consumers raise concerns about their food choices, evaluation of BPA and similar chemicals by the NOSB is warranted.

B. How much BPA is in use in organic food?

Many, but not all, organic brands have removed BPA from food contact materials (http://www.ewg.org/research/bpa-canned-food). Also, very few companies label their cans as not having BPA so it is hard for consumers to make informed decisions from food labels. A report from the Environmental Working Group provides some information on BPA substitutes used in canned food (EWG, 2015). However, there does not appear to be any independent testing to verify that cans are BPA free. The state of California is developing a database of canned products containing BPA (State of California 2017b), but this data set has not been evaluated in relation to organic products. In summary, more information is needed before the NOSB can make a decision.

C. What alternative materials and practices are being used by organic processors and what factors are prohibiting more products from using alternatives?

- There are can coatings that do not contain epoxy resins, such as those with polyester.
- Baked organic coatings have been used in cans, including oleoresinous, epoxy-amine, and acrylic enamel coatings. Oleoresinous coatings are made from vegetable oil and resin (Deshpande 1995).
- Glass jars are a good alternative although there may still be BPA used in the sealing ring under the lid.
- More BPA migrates from the can lining into the food at higher temperatures and over longer time sitting on the shelf. So processing at lower temperatures and not storing canned goods for long periods will lessen exposure. BPA leaching can also be minimized by increasing the curing time for coatings that contain it. It is not possible for consumers to find out if the curing of the cans for any individual brand was done correctly (Rossi et al. 1970, Lambert et al. 1998).
- Polyethylene and polypropylene packaging can be used instead of BPA cans. These are likely to have less estrogenic activity (Yang et al. 2011). Bioplastics from starch materials, cellulose materials, polylactic acid (Polyester, PLA), polyhydroxy acid (polyester, PHA) that are not only BPA free, but have melting points above 200^{o}C, good moisture barrier characteristics and good compostability and biodegradability properties are now in development (Siracusa et al., 2008) The bioplastics may be combined with nanoscale fillers such as layered silicate nanoclays, e.g. montmorillonite and kaolinite which may also have a role in effective and environmentally friendly food packaging (Rhim et al, 2013). Bioplastics may be problematic for organic food producers because they are often sourced from genetically modified corn. Currently there are no restrictions on these products.

V. REQUEST FOR PUBLIC COMMENT

The NOSB is requesting public comment from both companies who no longer use BPA in packaging, and from those who still think it is necessary. From the former group we would like to hear what is being used instead, and how well it is working. From the latter we would like to know what, if anything, has been tried and rejected, and why. Also, we would like to know reasons why it is still important for specific product categories to allow BPA in packaging. Specific questions include:

A. Should BPA be prohibited?
B. How widespread is the use of BPA in organic canned foods utilizing metal cans?

C. How widespread is the use of BPA in lids or other materials in contact with canned organic food in glass jars?
D. Is BPA present in any other packaging or processing materials that are in contact with organic food?
E. The California Office of Environmental Health Hazard Assessment has compiled a database of canned foods with BPA in metal can liners or jar lids: https://www.p65warnings.ca.gov/bpalist Is this database complete and have any members of the organic community examined this data to determine the prevalence of organic brands using BPA?
F. Are there specific product categories where BPA should be allowed if some uses, such as BPA in linings for canned foods, are prohibited?
G. What alternatives materials and practices have been chosen by organic processors and how well are they working?
H. Have any alternative materials been tried and rejected? If so, why?
I. What factors are prohibiting more products from using alternatives?
J. What are the human health and/or environmental concerns of BPA alternatives, such as BPS and BPF?

The NOSB welcomes comments on the use of BPA in food packaging. Please see https://www.ams.usda.gov/event/nosb-spring-2017-meeting-denver-co for information on how to submit written or oral comments for the Spring 2017 meeting.

Vote in Handling Subcommittee
Motion to accept the BPA discussion document
Motion by: Scott Rice
Seconded by: Lisa de Lima
Yes: 6 No: 0 Abstain: 0 Absent: 2 Recuse: 0

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Approved by Lisa de Lima, Subcommittee Chair, to transmit to NOSB, January 17, 2017

Current 2019 Susnet Cycle (For review in 2017)

National List Section	Substance	Listing	Sunset/ Expiration Date	SC	Current Review Year	Proposed Review Year
205.601(b)	Biodegradable biobased mulch film	Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods.	10/30/2019	CS	2019	2019

Proposed Additions to 2019 Sunset Cycle for addition to work plan (for sunset review in 2019) - Work would start after Fall 2016 meeting but high level review for techenical reports is needed in early summer

National List Section	Substance	Listing	Sunset/ Expiration Date	SC	Current Review Year	Proposed Review Year
205.601(a)	Calcium hypochlorite	Chlorine materials—For pre-harvest use, 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, except that chlorine products may be used in edible sprout production according to EPA label directions.	6/27/2017	CS	2022	2019
205.601(a)	Chlorine dioxide	Chlorine materials—For pre-harvest use, 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, except that chlorine products may be used in edible sprout production according to EPA label directions.	6/27/2017	CS	2022	2019
205.601(a)	Sodium hypochlorite	Chlorine materials—For pre-harvest use, 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, except that chlorine products may be used in edible sprout production according to EPA label directions.	6/27/2017	CS	2022	2019
205.601(b)	Herbicides, soap-based	Herbicides, soap-based—for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops.	6/27/2017	CS	2022	2019
205.601(e)	Boric acid	Boric acid—structural pest control, no direct contact with organic food or crops.	6/27/2017	CS	2022	2019
205.601(e)	Sticky traps/barriers	Sticky traps/barriers.	6/27/2017	CS	2022	2019
205.601(i)	Copper sulfate	Copper sulfate—Substance must be used in a manner that minimizes accumulation of copper in the soil.	6/27/2017	CS	2022	2019
205.601(i)	Coppers, fixed	Coppers, fixed—copper hydroxide, copper oxide, copper oxychloride, includes products exempted from EPA tolerance, Provided, That, copper-based materials must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides.	6/27/2017	CS	2022	2019
205.601(j)	Humic acids	Humic acids—naturally occurring deposits, water and alkali extracts only.	6/27/2017	CS	2022	2019
205.601(j)	Vitamin B1	Vitamins, B1, C, and E.	6/27/2017	CS	2022	2019
205.601(j)	Vitamin C	Vitamins, B1, C, and E.	6/27/2017	CS	2022	2019
205.601(j)	Vitamin E	Vitamins, B1, C, and E.	6/27/2017	CS	2022	2019
205.601(m)	EPA List 4 - Inerts of Minimal Concern	As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances. (1) EPA List 4—Inerts of Minimal Concern.	6/27/2017	CS	2022	2019
205.602(d)	Lead salts	Lead salts.	6/27/2017	CS	2022	2019
205.602(i)	Tobacco dust (nicotine sulfate)	Tobacco dust (nicotine sulfate).	6/27/2017	CS	2022	2019
205.603(a)	Calcium hypochlorite	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.	6/27/2017	LS	2022	2019
205.603(a)	Chlorhexidine	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.	6/27/2017	LS	2022	2019
205.603(a)	Chlorine dioxide	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. (ii) Chlorine dioxide.	6/27/2017	LS	2022	2019
205.603(a)	Glucose	Glucose.	6/27/2017	LS	2022	2019
205.603(a)	Oxytocin	Oxytocin—use in postparturition therapeutic applications.	6/27/2017	LS	2022	2019
205.603(a)	Sodium hypochlorite	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. (iii) Sodium hypochlorite.	6/27/2017	LS	2022	2019
205.603(a)	Tolazoline	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.	6/27/2017	LS	2022	2019
205.603(b)	Copper sulfate	Copper sulfate.	6/27/2017	LS	2022	2019
205.603(b)	Lidocaine	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.	6/27/2017	LS	2022	2019
205.603(b)	Procaine	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.	6/27/2017	LS	2022	2019
205.603(e)	EPA List 4 - Inerts of Minimal Concern	As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances. (1) EPA List 4—Inerts of Minimal Concern.	6/27/2017	LS	2022	2019
205.605(a)	Attapulgite	Attapulgite—as a processing aid in the handling of plant and animal oils.	8/3/2017	HS	2022	2019
205.605(a)	Bentonite	Bentonite.	6/27/2017	HS	2022	2019
205.605(a)	Diatomaceous earth	Diatomaceous earth—food filtering aid only.	6/27/2017	HS	2022	2019
205.605(a)	Nitrogen	Nitrogen—oil-free grades.	6/27/2017	HS	2022	2019
205.605(a)	Sodium carbonate	Sodium carbonate.	6/27/2017	HS	2022	2019
205.605(b)	Acidified sodium chlorite	Acidified sodium chlorite—Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.	3/15/2017	HS	2022	2019
205.605(b)	Calcium hypochlorite	Chlorine materials—disinfecting and sanitizing food contact surfaces, Except, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).	6/27/2017	HS	2022	2019
205.605(b)	Carbon dioxide	Carbon dioxide.	6/27/2017	HS	2022	2019
205.605(b)	Chlorine dioxide	Chlorine materials—disinfecting and sanitizing food contact surfaces, Except, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).	6/27/2017	HS	2022	2019
205.605(b)	Magnesium chloride	Magnesium chloride—derived from sea water.	6/27/2017	HS	2022	2019
205.605(b)	Potassium acid tartrate	Potassium acid tartrate.	6/27/2017	HS	2022	2019
205.605(b)	Sodium hypochlorite	Chlorine materials—disinfecting and sanitizing food contact surfaces, Except, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).	6/27/2017	HS	2022	2019
205.605(b)	Sodium phosphates	Sodium phosphates—for use only in dairy foods.	6/27/2017	HS	2022	2019
205.606	Casings	Casings, from processed intestines.	6/27/2017	HS	2022	2019
205.606	Konjac flour	Konjac flour (CAS # 37220–17–0).	6/27/2017	HS	2022	2019
205.606	Pectin (non-amidated forms only)	Pectin (non-amidated forms only).	6/27/2017	HS	2022	2019

National List Section	Substance	Listing	Sunset/ Expiration Date	SC	Current Review Year	Proposed Review Year
205.601(a)	Calcium hypochlorite	Chlorine materials—For pre-harvest use, 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, except that chlorine products may be used in edible sprout production according to EPA label directions.	6/27/2017	CS	2022	2019
205.601(a)	Chlorine dioxide	Chlorine materials—For pre-harvest use, 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, except that chlorine products may be used in edible sprout production according to EPA label directions.	6/27/2017	CS	2022	2019
205.601(a)	Copper sulfate	Copper sulfate—for use as an algicide in aquatic rice systems, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent	11/3/2018	CS	2018	2018
205.601(a)	Ethanol	Alcohols. (i) Ethanol.	6/27/2017	CS	2022	2020
205.601(a)	Hydrogen peroxide	Hydrogen peroxide.	6/27/2017	CS	2022	2021
205.601(a)	Isopropanol	Alcohols. (ii) Isopropanol.	6/27/2017	CS	2022	2020
205.601(a)	Ozone	Ozone gas—for use as an irrigation system cleaner only.	11/3/2018	CS	2018	2018
205.601(a)	Peracetic acid	Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material. Also permitted in hydrogen peroxide formulations as allowed in § 205.601(a) at concentration of no more than 6% as indicated on the pesticide product label.	5/29/2018	CS	2018	2018
205.601(a)	Soap-based algicide/demossers	Soap-based algicide/demossers.	6/27/2017	CS	2022	2022
205.601(a)	Sodium carbonate peroxyhydrate	Sodium carbonate peroxyhydrate (CAS #–15630–89–4)—Federal law restricts the use of this substance in	6/22/2020	CS	2020	2020
205.601(a)	Sodium hypochlorite	Chlorine materials—For pre-harvest use, 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, except that chlorine products may be used in edible sprout production according to EPA label directions.	6/27/2017	CS	2022	2019
205.601(b)	Herbicides, soap-based	Herbicides, soap-based—for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops.	6/27/2017	CS	2022	2019
205.601(b)	Newspaper or other recycled paper	Newspaper or other recycled paper, without glossy or colored inks.	6/27/2017	CS	2022	2020
205.601(b)	Plastic mulch and covers (petroleum-based other than	Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)).	6/27/2017	CS	2022	2020
205.601(b)	Biodegradable biobased mulch film	Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods.	10/30/2019	CS	2019	2019
205.601(c)	Newspaper or other recycled	As compost feedstocks—Newspapers or other recycled paper, without glossy or colored inks.	6/27/2017	CS	2022	2020
205.601(d)	Soaps, ammonium	As animal repellents—Soaps, ammonium—for use as a large animal repellant only, no contact with soil or edible portion of crop.	6/27/2017	CS	2022	2021
205.601(e)	Ammonium carbonate	Ammonium carbonate—for use as bait in insect traps only, no direct contact with crop or soil.	6/27/2017	CS	2022	2022
205.601(e)	Aqueous potassium silicate	Aqueous potassium silicate (CAS #–1312–76–1)—the silica, used in the manufacture of potassium silicate,	6/22/2020	CS	2020	2020
205.601(e)	Boric acid	Boric acid—structural pest control, no direct contact with organic food or crops.	6/27/2017	CS	2022	2019
205.601(e)	Copper sulfate	Copper sulfate—for use as tadpole shrimp control in aquatic rice production, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.	11/3/2018	CS	2018	2018
205.601(e)	Elemental sulfur	Elemental sulfur.	6/27/2017	CS	2022	2020
205.601(e)	Lime sulfur	Lime sulfur—including calcium polysulfide.	6/27/2017	CS	2022	2020
205.601(e)	Oils, horticultural	Oils, horticultural—narrow range oils as dormant, suffocating, and summer oils.	6/27/2017	CS	2022	2021
205.601(e)	Soaps, insecticidal	Soaps, insecticidal.	6/27/2017	CS	2022	2022
205.601(e)	Sticky traps/barriers	Sticky traps/barriers.	6/27/2017	CS	2022	2019
205.601(e)	Sucrose octanoate esters	Sucrose octanoate esters (CAS #s—42922–74–7; 58064–47–4)—in accordance with approved labeling.	6/27/2017	CS	2022	2020
205.601(f)	Pheromones	As insect management. Pheromones.	6/27/2017	CS	2022	2021
205.601(g)	Vitamin D3	Vitamin D3.	6/27/2017	CS	2022	2022
205.601(h)	Ferric phosphate	As slug or snail bait. Ferric phosphate (CAS # 10045–86–0).	9/12/2016	CS	2021	2021
205.601(i)	Aqueous potassium silicate	Aqueous potassium silicate (CAS #–1312–76–1)—the silica, used in the manufacture of potassium silicate,	6/22/2020	CS	2020	2020
205.601(i)	Copper sulfate	Copper sulfate—Substance must be used in a manner that minimizes accumulation of copper in the soil.	6/27/2017	CS	2022	2019
205.601(i)	Coppers, fixed	Coppers, fixed—copper hydroxide, copper oxide, copper oxychloride, includes products exempted from EPA tolerance, Provided, That, copper-based materials must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides.	6/27/2017	CS	2022	2019
205.601(i)	Elemental sulfur	Elemental sulfur.	6/27/2017	CS	2022	2020
205.601(i)	Hydrated lime	Hydrated lime.	6/27/2017	CS	2022	2020
205.601(i)	Hydrogen peroxide	Hydrogen peroxide.	6/27/2017	CS	2022	2021
205.601(i)	Lime sulfur	Lime sulfur.	6/27/2017	CS	2022	2020
205.601(i)	Oils, horticultural	Oils, horticultural, narrow range oils as dormant, suffocating, and summer oils.	6/27/2017	CS	2022	2021
205.601(i)	Peracetic acid	Peracetic acid—for use to control fire blight bacteria. Also permitted in hydrogen peroxide formulations as allowed in § 205.601(i) at concentration of no more than 6% as indicated on the pesticide product label.	5/29/2018	CS	2018	2018
205.601(i)	Potassium bicarbonate	Potassium bicarbonate.	6/27/2017	CS	2022	2021
205.601(j)	Aquatic plant extracts	Aquatic plant extracts (other than hydrolyzed)—Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount used is limited to that amount necessary for extraction.	6/27/2017	CS	2022	2022
205.601(j)	Elemental sulfur	Elemental sulfur.	6/27/2017	CS	2022	2020
205.601(j)	Humic acids	Humic acids—naturally occurring deposits, water and alkali extracts only.	6/27/2017	CS	2022	2019
205.601(j)	Lignin sulfonate	Lignin sulfonate—chelating agent, dust suppressant.	6/27/2017	CS	2022	2022
205.601(j)	Liquid fish products	Liquid fish products—can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.	6/27/2017	CS	2022	2020
205.601(j)	Magnesium sulfate	Magnesium sulfate—allowed with a documented soil deficiency.	6/27/2017	CS	2022	2021
205.601(j)	Soluble boron products	Soluble boron products.	6/27/2017	CS	2022	2022
205.601(j)	Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt	Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.	6/27/2017	CS	2022	2022
205.601(j)	Sulfurous acid	Sulfurous acid (CAS # 7782-99-2) for on-farm generation of substance utilizing 99% purity elemental sulfur per paragraph (j)(2) of this section.	6/22/2020	CS	2020	2020
205.601(j)	Vitamin B1	Vitamins, B1, C, and E.	6/27/2017	CS	2022	2019

205.601(j)	Vitamin C	Vitamins, B1, C, and E.	6/27/2017	CS	2022	2019
205.601(j)	Vitamin E	Vitamins, B1, C, and E.	6/27/2017	CS	2022	2019
205.601(k)	Ethylene	As plant growth regulators. Ethylene gas—for regulation of pineapple flowering.	6/27/2017	CS	2022	2020
205.601(l)	Lignin sulfonate	Lignin sulfonate.	6/27/2017	CS	removed	removed
205.601(l)	Sodium silicate	Sodium silicate—for tree fruit and fiber processing.	6/27/2017	CS	2022	2022
205.601(m)	EPA List 3 - Inerts of Unknown Toxicity	As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances. (2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.	11/3/2018	CS	2018	2018
205.601(m)	EPA List 4 - Inerts of Minimal Concern	As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances. (1) EPA List 4—Inerts of Minimal Concern.	6/27/2017	CS	2022	2019
205.601(n)	Hydrogen chloride	Seed preparations. Hydrogen chloride (CAS # 7647–01–0)—for delinting cotton seed for planting.	9/12/2016	CS	2021	2021
205.601(o)	Microcrystalline cheesewax	Microcrystalline cheesewax (CAS #'s 64742–42–3, 8009–03–08, and 8002–74–2)–for use in log grown mushroom production. Must be made without either ethylene-propylene co-polymer or synthetic colors.	3/15/2017	CS	2022	2020
205.602(a)	Ash from manure burning	Ash from manure burning.	6/27/2017	CS	2022	2021
205.602(b)	Arsenic	Arsenic.	6/27/2017	CS	2022	2022
205.602(c)	Calcium chloride	Calcium chloride, brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.	11/3/2018	CS	2018	2018
205.602(d)	Lead salts	Lead salts.	6/27/2017	CS	2022	2019
205.602(e)	Potassium chloride	Potassium chloride—unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.	6/27/2017	CS	2022	2020
205.602(f)	Sodium fluoaluminate	Sodium fluoaluminate (mined).	6/27/2017	CS	2022	2021
205.602(g)	Sodium nitrate	Sodium nitrate—unless use is restricted to no more than 20% of the crop's total nitrogen requirement; use in spirulina production is unrestricted until October 21, 2005.	10/21/2012	CS	-	-
205.602(h)	Strychnine	Strychnine.	6/27/2017	CS	2022	2022
205.602(i)	Tobacco dust (nicotine sulfate)	Tobacco dust (nicotine sulfate).	6/27/2017	CS	2022	2019
205.603(a)	Aspirin	Aspirin-approved for health care use to reduce inflammation.	6/27/2017	LS	2022	2020
205.603(a)	Atropine	Atropine (CAS #–51–55–8)—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; and (ii) A meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals.	6/27/2017	LS	2022	2021
205.603(a)	Butorphanol	Butorphanol (CAS #–42408–82–2)—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; and (ii) A meat withdrawal period of at least 42 days after administering to livestock intended for slaughter; and a milk discard period of at least 8 days after administering to dairy animals.	6/27/2017	LS	2022	2022
205.603(a)	Calcium hypochlorite	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.	6/27/2017	LS	2022	2019
205.603(a)	Chlorhexidine	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.	6/27/2017	LS	2022	2019
205.603(a)	Chlorine dioxide	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. (ii) Chlorine dioxide.	6/27/2017	LS	2022	2019
205.603(a)	Electrolytes	Electrolytes—without antibiotics.	6/27/2017	LS	2022	2020
205.603(a)	Ethanol	Alcohols. (i) Ethanol-disinfectant and sanitizer only, prohibited as a feed additive.	6/27/2017	LS	2022	2020
205.603(a)	Fenbendazole	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. 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. (i) Fenbendazole (CAS #43210–67–9)—only for use by or on the lawful written order of a licensed veterinarian.	5/16/2017	LS	2022	2021
205.603(a)	Flunixin	Flunixin (CAS #–38677–85–9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA.	6/27/2017	LS	2022	2022
205.603(a)	Furosemide	Furosemide (CAS #–54–31–9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required that required by the FDA.	6/27/2017	LS	-	-
205.603(a)	Glucose	Glucose.	6/27/2017	LS	2022	2019
205.603(a)	Glycerine	Glycerine—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.	6/27/2017	LS	2022	2020
205.603(a)	Hydrogen peroxide	Hydrogen peroxide.	6/27/2017	LS	2022	2021
205.603(a)	Iodine	Iodine.	6/27/2017	LS	2022	2021
205.603(a)	Isopropanol	Alcohols. (ii) Isopropanol-disinfectant only.	6/27/2017	LS	2022	2020
205.603(a)	Ivermectin	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. 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. (ii.) Ivermectin (CAS #70288–86–7).	6/27/2017	LS	2022	2021
205.603(a)	Magnesium hydroxide	Magnesium hydroxide (CAS #–1309–42–8)—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 use by or on the lawful written order of a licensed veterinarian.	6/27/2017	LS	2022	2022
205.603(a)	Magnesium sulfate	Magnesium sulfate.	6/27/2017	LS	2022	2021
205.603(a)	Moxidectin	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. 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. (iii) Moxidectin (CAS #113507–06–5)—for control of internal parasites only.	5/16/2017	LS	2022	2021
205.603(a)	Oxytocin	Oxytocin—use in postparturition therapeutic applications.	6/27/2017	LS	2022	2019
205.603(a)	Peracetic acid	Peroxyacetic/peracetic acid (CAS #–79–21–0)—for sanitizing facility and processing equipment.	6/27/2017	LS	2022	2021
205.603(a)	Phosphoric acid	Phosphoric acid—allowed as an equipment cleaner, Provided , That, no direct contact with organically managed livestock or land occurs.	6/27/2017	LS	2022	2020
205.603(a)	Poloxalene	Poloxalene (CAS #–9003–11–6)—for use under 7 CFR part 205, the NOP requires that poloxalene only be used for the emergency treatment of bloat.	6/27/2017	LS	2022	2022

205.603(a)	Sodium hypochlorite	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. (iii) Sodium hypochlorite.	6/27/2017	LS	2022	2019
205.603(a)	Tolazoline	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.	6/27/2017	LS	2022	2019
205.603(a)	Vaccines	Biologics—Vaccines.	6/27/2017	LS	2022	2020
205.603(a)	Xylazine	Xylazine (CAS #–7361–61–7)—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) The existence of an emergency; 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.	6/27/2017	LS	2022	2021
205.603(b)	Copper sulfate	Copper sulfate.	6/27/2017	LS	2022	2019
205.603(b)	Formic Acid	Formic acid (CAS # 64-18-6)—for use as a pesticide solely within honeybee hives.	8/3/2017	LS	2022	2022
205.603(b)	Hydrated lime	Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.	6/27/2017	LS	2022	2020
205.603(b)	Iodine	Iodine.	6/27/2017	LS	2022	2021
205.603(b)	Lidocaine	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.	6/27/2017	LS	2022	2019
205.603(b)	Mineral oil	Mineral oil—for topical use and as a lubricant.	6/27/2017	LS	2022	2020
205.603(b)	Procaine	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.	6/27/2017	LS	2022	2019
205.603(b)	Sucrose octanoate esters	Sucrose octanoate esters (CAS #s–42922–74–7; 58064–47–4)—in accordance with approved labeling.	6/27/2017	LS	2022	2020
205.603(d)	Methionine	DL-Methionine, DL-Methionine-hydroxy analog, and DL-Methionine-hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following maximum levels of synthetic methionine per ton of feed Laying and broiler chickens—2 pounds; turkeys and all other poultry—3 pounds.	10/2/2017	LS	2022	2021
205.603(d)	Trace minerals	Trace minerals, used for enrichment or fortification when FDA approved.	6/27/2017	LS	2022	2021
205.603(d)	Vitamins	Vitamins, used for enrichment or fortification when FDA approved.	6/27/2017	LS	2022	2021
205.603(e)	EPA List 4 - Inerts of Minimal Concern	As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances. (1) EPA List 4—Inerts of Minimal Concern.	6/27/2017	LS	2022	2019
205.603(f)	Excipients	Excipients, only for use in the manufacture of drugs used to treat organic livestock when the excipient is Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application.	6/27/2017	LS	2022	2022
205.604(a)	Strychnine	Strychnine.	6/27/2017	LS	2022	2022
205.605(a)	Agar-agar	Agar-agar.	11/3/2018	HS	2018	2018
205.605(a)	Alginic acid	Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic).	6/27/2017	HS	2022	2021
205.605(a)	Animal enzymes	Animal enzymes—(Rennet—animals derived; Catalase—bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin).	11/3/2018	HS	2018	2018
205.605(a)	Attapulgite	Attapulgite—as a processing aid in the handling of plant and animal oils.	8/3/2017	HS	2022	2019
205.605(a)	Bentonite	Bentonite.	6/27/2017	HS	2022	2019
205.605(a)	Calcium carbonate	Calcium carbonate.	6/27/2017	HS	2022	2020
205.605(a)	Calcium chloride	Calcium chloride.	6/27/2017	HS	2022	2021
205.605(a)	Calcium sulfate	Calcium sulfate—mined.	11/3/2018	HS	2018	2018
205.605(a)	Carnauba wax	Waxes—nonsynthetic (Carnauba wax; and Wood resin).	6/27/2017	HS	2022	2022
205.605(a)	Carrageenan	Carrageenan.	11/3/2018	HS	2018	2018
205.605(a)	Egg white lysozyme	Egg white lysozyme (CAS # 9001–63–2).	9/12/2016	HS	-	-
205.605(a)	Citric acid	Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic).	6/27/2017	HS	2022	2021
205.605(a)	Diatomaceous earth	Diatomaceous earth—food filtering aid only.	6/27/2017	HS	2022	2019
205.605(a)	Dairy cultures	Dairy cultures.	6/27/2017	HS	2022	2021
205.605(a)	Enzymes	Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.	6/27/2017	HS	2022	2021
205.605(a)	Flavors	Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.	6/27/2017	HS	2022	2020
205.605(a)	Gellan gum	Gellan gum (CAS # 71010–52–1)—high-acyl form only.	6/22/2020	HS	2020	2020
205.605(a)	Glucono delta-lactone	Glucono delta-lactone—production by the oxidation of D-glucose with bromine water is prohibited.	11/3/2018	HS	2018	2018
205.605(a)	Kaolin	Kaolin.	6/27/2017	HS	2022	2022
205.605(a)	Lactic acid	Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic).	6/27/2017	HS	2022	2021
205.605(a)	L-Malic acid	L-Malic acid (CAS # 97–67–6).	9/12/2016	HS	2021	2021
205.605(a)	Magnesium sulfate	Magnesium sulfate, nonsynthetic sources only.	6/27/2017	HS	2022	2021
205.605(a)	Microorganisms	Microorganisms—any food grade bacteria, fungi, and other microorganism.	9/12/2016	HS	2021	2021
205.605(a)	Nitrogen	Nitrogen—oil-free grades.	6/27/2017	HS	2022	2019
205.605(a)	Oxygen	Oxygen—oil-free grades.	6/27/2017	HS	2022	2020
205.605(a)	Perlite	Perlite—for use only as a filter aid in food processing.	6/27/2017	HS	2022	2021
205.605(a)	Potassium chloride	Potassium chloride.	6/27/2017	HS	2022	2020
205.605(a)	Potassium iodide	Potassium iodide.	6/27/2017	HS	2022	2021
205.605(a)	Sodium bicarbonate	Sodium bicarbonate.	6/27/2017	HS	2022	2022
205.605(a)	Sodium carbonate	Sodium carbonate.	6/27/2017	HS	2022	2019
205.605(a)	Tartaric acid	Tartaric acid—made from grape wine.	11/3/2018	HS	2018	2018
205.605(a)	Wood resin	Waxes—nonsynthetic (Carnauba wax; and Wood resin).	6/27/2017	HS	2022	2022
205.605(a)	Yeast	Yeast—When used as food or a fermentation agent in products labeled as "organic," yeast must be organic	10/21/2017	HS	2022	2021
205.605(b)	Acidified sodium chlorite	Acidified sodium chlorite—Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.	3/15/2017	HS	2022	2019
205.605(b)	Activated charcoal	Activated charcoal (CAS #s 7440–44–0; 64365–11–3)—only from vegetative sources; for use only as a	9/12/2016	HS	2021	2021
205.605(b)	Alginates	Alginates.	6/27/2017	HS	2022	2020
205.605(b)	Ammonium bicarbonate	Ammonium bicarbonate—for use only as a leavening agent.	6/27/2017	HS	2022	2022
205.605(b)	Ammonium carbonate	Ammonium carbonate—for use only as a leavening agent.	6/27/2017	HS	2022	2022
205.605(b)	Ascorbic acid	Ascorbic acid.	6/27/2017	HS	2022	2021

205.605(b)	Calcium citrate	Calcium citrate.	6/27/2017	HS	2022	2021
205.605(b)	Calcium hydroxide	Calcium hydroxide.	6/27/2017	HS	2022	2020
205.605(b)	Calcium hypochlorite	Chlorine materials—disinfecting and sanitizing food contact surfaces, Except, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).	6/27/2017	HS	2022	2019
205.605(b)	Calcium phosphate dibasic	Calcium phosphates (monobasic, dibasic, and tribasic).	6/27/2017	HS	2022	2022
205.605(b)	Calcium phosphate monobasic	Calcium phosphates (monobasic, dibasic, and tribasic).	6/27/2017	HS	2022	2022
205.605(b)	Calcium phosphate tribasic	Calcium phosphates (monobasic, dibasic, and tribasic).	6/27/2017	HS	2022	2022
205.605(b)	Carbon dioxide	Carbon dioxide.	6/27/2017	HS	2022	2019
205.605(b)	Cellulose	Cellulose—for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.	11/3/2018	HS	2018	2018
205.605(b)	Chlorine dioxide	Chlorine materials—disinfecting and sanitizing food contact surfaces, Except, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).	6/27/2017	HS	2022	2019
205.605(b)	Ferrous sulfate	Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).	6/27/2017	HS	2022	2021
205.605(b)	Hydrogen peroxide	Hydrogen peroxide.	6/27/2017	HS	2022	2021
205.605(b)	Glycerides (mono and di)—for use only in drum drying of food.	Glycerides (mono and di)—for use only in drum drying of food.	6/27/2017	HS	2022	2020
205.605(b)	Ethylene	Ethylene—allowed for postharvest ripening of tropical fruit and degreening of citrus.	6/27/2017	HS	2022	2020
205.605(b)	Cyclohexylamine	Cyclohexylamine (CAS # 108–91–8)—for use only as a boiler water additive for packaging sterilization.	9/12/2016	HS	-	-
205.605(b)	Glycerin	Glycerin—produced by hydrolysis of fats and oils.	6/27/2017	HS	2022	2022
205.605(b)	Diethylaminoethanol	Diethylaminoethanol (CAS # 100–37–8)—for use only as a boiler water additive for packaging sterilization.	9/12/2016	HS	-	-
205.605(b)	Magnesium carbonate	Magnesium carbonate—for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic".	6/27/2017	HS	-	-
205.605(b)	Magnesium chloride	Magnesium chloride—derived from sea water.	6/27/2017	HS	2022	2019
205.605(b)	Magnesium stearate	Magnesium stearate—for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic".	6/27/2017	HS	2022	2020
205.605(b)	Nutrient vitamins and minerals	Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.	10/21/2017	HS	2022	2021
205.605(b)	Octadecylamine	Octadecylamine (CAS # 124–30–1)—for use only as a boiler water additive for packaging sterilization.	9/12/2016	HS	-	-
205.605(b)	Ozone	Ozone.	6/27/2017	HS	2022	2022
205.605(b)	Peracetic acid	Peracetic acid/Peroxyacetic acid (CAS # 79–21–0)—for use in wash and/or rinse water according to FDA	9/12/2016	HS	2021	2021
205.605(b)	Phosphoric acid	Phosphoric acid—cleaning of food-contact surfaces and equipment only.	6/27/2017	HS	2022	2020
205.605(b)	Potassium acid tartrate	Potassium acid tartrate.	6/27/2017	HS	2022	2019
205.605(b)	Potassium carbonate	Potassium carbonate.	6/27/2017	HS	2022	2020
205.605(b)	Potassium citrate	Potassium citrate.	6/27/2017	HS	2022	2021
205.605(b)	Potassium hydroxide	Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.	5/29/2018	HS	2018	2018
205.605(b)	Tetrasodium pyrophosphate	Tetrasodium pyrophosphate (CAS # 7722–88–5)—for use only in meat analog products.	9/12/2016	HS	-	-
205.605(b)	Silicon dioxide	Silicon dioxide—Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.	11/3/2018	HS	2018	2018
205.605(b)	Potassium phosphate	Potassium phosphate—for use only in agricultural products labeled "made with organic (specific ingredients	6/27/2017	HS	2022	2021
205.605(b)	Sodium acid pyrophosphate	Sodium acid pyrophosphate (CAS # 7758–16–9)—for use only as a leavening agent.	9/12/2016	HS	2021	2021
205.605(b)	Sodium hydroxide	Sodium hydroxide—prohibited for use in lye peeling of fruits and vegetables.	6/27/2017	HS	2022	2022
205.605(b)	Sodium hypochlorite	Chlorine materials—disinfecting and sanitizing food contact surfaces, Except, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).	6/27/2017	HS	2022	2019
205.605(b)	Sodium phosphates	Sodium phosphates—for use only in dairy foods.	6/27/2017	HS	2022	2019
205.605(b)	Sulfur dioxide	Sulfur dioxide—for use only in wine labeled "made with organic grapes," Provided, That, total sulfite concentration does not exceed 100 ppm.	6/27/2017	HS	2022	2020
205.605(b)	Sodium citrate	Sodium citrate.	6/27/2017	HS	2022	2021
205.605(b)	Tocopherols	Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative.	6/27/2017	HS	2022	2021
205.605(b)	Xanthan gum	Xanthan gum.	6/27/2017	HS	2022	2020
205.606	Arabic gum Guar; Locust bean;	Gums—water extracted only (Arabic; Guar; Locust bean; and Carob bean).	6/27/2017	HS	2022	2020
205.606	Beet juice extract color	Beet juice extract color (pigment CAS # 7659–95–2).	6/27/2017	HS	2022	2022
205.606	Beta-carotene extract color	Beta-carotene extract color—derived from carrots or algae (pigment CAS# 7235-40-7).	5/29/2018	HS	2018	2018
205.606	Black currant juice color	Black currant juice color (pigment CAS #'s 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	6/27/2017	HS	2022	2022
205.606	Black/Purple carrot juice color	Black/Purple carrot juice color (pigment CAS #'s 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	6/27/2017	HS	2022	2022
205.606	Blueberry juice color	Blueberry juice color (pigment CAS #'s 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	6/27/2017	HS	2022	2022
205.606	Carrot juice color	Carrot juice color (pigment CAS # 1393–63–1).	6/27/2017	HS	2022	2022
205.606	Casings	Casings, from processed intestines.	6/27/2017	HS	2022	2019
205.606	Celery powder	Celery powder.	6/27/2017	HS	2022	2021
205.606	Cherry juice color	Cherry juice color (pigment CAS #'s 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3)	6/27/2017	HS	2022	2022
205.606	Fish oil	Fish oil (Fatty acid CAS #'s 10417–94–4, and 25167–62–8)—stabilized with organic ingredients or only with	6/27/2017	HS	2022	2021
205.606	Chokeberry—Aronia juice color	Chokeberry—Aronia juice color (pigment CAS #'s 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	6/27/2017	HS	2022	2022
205.606	Cornstarch (native)	Cornstarch (native).	6/27/2017	HS	2022	2022
205.606	Gelatin	Gelatin (CAS # 9000–70–8).	6/27/2017	HS	2022	2021
205.606	Elderberry juice color	Elderberry juice color (pigment CAS #'s 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	6/27/2017	HS	2022	2022
205.606	Orange pulp, dried	Orange pulp, dried.	3/15/2017	HS	2022	2021
205.606	Fructooligosaccharides	Fructooligosaccharides (CAS # 308066–66–2).	6/27/2017	HS	2022	2020
205.606	Seaweed, Pacific kombu	Seaweed, Pacific kombu.	3/15/2017	HS	2022	2021
205.606	Chia (Salvia hispanica L.)	Chia (Salvia hispanica L.).	6/27/2017	HS	-	-
205.606	Grape juice color	Grape juice color (pigment CAS #'s 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	6/27/2017	HS	2022	2022
205.606	Grape skin extract color	Grape skin extract color (pigment CAS #'s 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	6/27/2017	HS	2022	2022
205.606	Dillweed oil	Dillweed oil (CAS # 8006–75–5).	6/27/2017	HS	-	-
205.606	Kelp	Kelp—for use only as a thickener and dietary supplement.	6/27/2017	HS	2022	2022
205.606	Konjac flour	Konjac flour (CAS # 37220–17–0).	6/27/2017	HS	2022	2019
205.606	Lecithin—de-oiled	Lecithin—de-oiled.	3/15/2017	HS	2022	2020
205.606	Galangal, frozen	Galangal, frozen.	6/27/2017	HS	-	-
205.606	Inulin-oligofructose enriched	Inulin-oligofructose enriched (CAS # 9005–80–5).	6/27/2017	HS	2022	2022
205.606	Orange shellac-unbleached	Orange shellac-unbleached (CAS # 9000–59–3).	6/27/2017	HS	2022	2022
205.606	Paprika color	Paprika color (CAS # 68917–78–2)—dried, and oil extracted.	6/27/2017	HS	2022	2022
205.606	Pectin (non-amidated forms only)	Pectin (non-amidated forms only).	6/27/2017	HS	2022	2019

205.606	Lemongrass-frozen	Lemongrass—frozen.	6/27/2017	HS	-	-
205.606	Pumpkin juice color	Pumpkin juice color (pigment CAS # 127–40–2).	6/27/2017	HS	2022	2022
205.606	Purple potato juice	Purple potato juice (pigment CAS #'s 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	6/27/2017	HS	2022	2020
205.606	Red cabbage extract color	Red cabbage extract color (pigment CAS #'s 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	6/27/2017	HS	2022	2022
205.606	Red radish extract color	Red radish extract color (pigment CAS #'s 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	6/27/2017	HS	2022	2022
205.606	Saffron extract color	Saffron extract color (pigment CAS # 1393–63–1).	6/27/2017	HS	2022	2022
205.606	Peppers (Chipotle chile)	Peppers (Chipotle chile).	6/27/2017	HS	-	-
205.606	Sweet potato starch	Sweet potato starch—for bean thread production only.	6/27/2017	HS	2022	2022
205.606	Tragacanth gum	Tragacanth gum (CAS #–9000–65–1).	6/22/2020	HS	2020	2020
205.606	Wakame seaweed (Undaria	Wakame seaweed (Undaria pinnatifida).	6/27/2017	HS	2022	2021
205.606	Turmeric extract color	Turmeric extract color (CAS # 458–37–7).	6/27/2017	HS	2022	2022
205.606	Turkish bay leaves	Turkish bay leaves.	6/27/2017	HS	2022	2022
205.606	Whey protein concentrate	Whey protein concentrate.	6/27/2017	HS	2022	2022

Current

Count of Current Review Year	Column Labels					
Row Labels	**2018**	**2019**	**2020**	**2021**	**2022**	**Grand Total**
CS	7	1	4	2	52	66
HS	10		2	5	94	111
LS					41	41
Grand Total	**17**	**1**	**6**	**7**	**187**	**218**

Proposed

Count of Proposed Review Year	Column Labels					
Row Labels	**2018**	**2019**	**2020**	**2021**	**2022**	**Grand Total**
CS	7	16	20	13	10	66
HS	10	16	23	30	32	111
LS		11	10	13	7	41
Grand Total	**17**	**43**	**53**	**56**	**49**	**218**

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Fatty Alcohols (Octanol/Decanol mix)
August 1, 2017

Summary of Petition

Green Ag Supply, LLC has petitioned for inclusion of natural fatty alcohols in Section 205.601 of the National Organic Program's (NOP) National List of Allowed and Prohibited Substances. The petitioner intends to use this substance as sucker control on organic crops.

Category: Synthetic Substance Allowed for Use in Organic Crop Production
NOP Reference: 205.601 - Synthetic substances allowed for use in organic crop production.
NOP Section: 205.601(k) - As plant growth regulators
Requested Annotation: As a sucker control on organic crops

Rather than filing separate petitions for octanol (C8) and decanol (C10), the petitioner chose to submit a single petition to focus on the blend of C8C10 fatty alcohol since it is the product that is specifically manufactured for use in the end products N-TAC (EPA Reg. No. 51873-20) and O-TAC PLANT CONTACT AGENT (EPA Reg. No. 51873-18). This blend of fatty alcohols is also marketed under the product name ALFOL 810 (EPA Reg. No. 63896-1). The only other registered uses for individual fatty alcohols is the C10 (decanol) and it is not included in this petition. There is no EPA registered use for C8 (octanol) fatty alcohol.

Summary of Review:

Fatty alcohols (Octanol and Decanol) are monohydric aliphatic alcohols containing 8 and 10 carbons respectfully with a single (-OH) group. The Octyl-Decyl alcohol blend refers to a blend of C8 and C10 alcohol (42.6%/56.7%). According to the petitioner, raw material for the alcohols are derived primarily from Palm Kernel Oil and Palm Oil, not synthetic alcohol.

The petitioner proposes to use the fatty alcohol blend for topping and sucker control on organic crops. The Technical Review indicates the specific use of this fatty alcohol substance is to chemically remove flower buds and suckers from tobacco plants. This process prevents seed formation and causes the plant to focus on leaf production. This is important because tobacco sells by weight, so the heavier the leaves, the greater the profit.

There is no reference in the National List for fatty alcohols. The proposal to add fatty alcohols to the National List specifies 7 CFR 205.601 (k) under the heading plant growth regulator. This section of the National List currently describes the use of the synthetic substance ethylene in organic crop production as a plant growth regulator for regulation of pineapple flowering. Fatty alcohols as aqueous emulsions inhibit terminal or axillary bud growth of tobacco plants. Contact with meristematic tissue affects plant development by preventing the growth flower buds and suckers. The EPA only registers products containing fatty alcohols for tobacco sucker control.

EPA has only approved fatty alcohols for use as a growth regulator on tobacco, and the technical review only covered use of fatty alcohols for use on tobacco.

Category 1: Classification

1. For CROP use: This substance is **synthetic.**
   Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide.

   Fatty alcohols can be produced from natural fats from plants or animals, or from petroleum sources. In either case, chemical changes are required to produce fatty alcohols.

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?

   Fatty alcohols do not fall into any of the OFPA categories. Fatty alcohols produced as a mixture of four aliphatic alcohols are not considered inert by the Environmental Protection Agency nor are they included in List 4. Fatty alcohols may be registered with the EPA only for tobacco sucker control. N-decyl alcohol (decanol) and n-octyl alcohol (octanol) are individually approved by the US Food and Drug Administration (FDA) for food and non-food use as solvents or co-solvents.

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?
   There appears to be no known detrimental chemical interactions between fatty alcohols and other materials used in organic farming systems. Mineral oil, cooking oil or paraffin oil are currently the only topping and suckering substances used by organic crop producers and there is no proven adverse impact with these substances.

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)]

   The log Kow is an indicator of a chemical's tendency to bioaccumulate. The TR reports log Kow's for octanol and decanol at 3.15 and 4.57 respectively, which are moderately low.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]
   According to the Safer Choice determination of the EPA, 1-decanol, 1-octanol, 1-dodecanol and the C_6-C_{12} alcohols are expected to be of low concern for environmental contamination based on experimental and modeled data. Linear fatty alcohols in general are easily biodegradable. The solubility of fatty alcohols in water decreases with an increasing C-chain length. Fatty alcohols possess only moderate acute toxicity for aquatic organisms. In general, in their range of water solubility no toxic effects are observed.

The fatty alcohols from both natural and manufactured sources represent a low risk for environmental contamination.

4. Discuss the effect of the substance on human health.

   There is no evidence to suggest that the aliphatic alcohols cause increased susceptibility to health problems in infants and children. Based on the results of the available studies, no endpoints of toxicological concern have been identified for human health risk assessment purposes. The EPA concluded that there are no human risks of concern for aliphatic alcohols. TR lines 396 – 399.

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)]

   When fatty alcohols are applied to tobacco plants for suckering with a surfactant, an average residue of 1.6 parts per million (ppm) of the applied fatty alcohols and 1.0 ppm of the surfactant remain on the cured leaves. Over 7000 ppm of naturally occurring fatty alcohols are also present in and on the cured leaves. Fatty alcohols induce a low incidence of polynucleate root tip cells or root tip cells with fragmented nuclei. The fatty alcohols are produced naturally, in all living organisms, from bacteria to man, and thus, are widely present throughout the natural world. In any agro-ecosystem, fatty alcohols will be present from natural sources. The introduction of C_6-C_{12} fatty alcohols for topping and suckering may produce short term toxicity to many organisms in the range of 1-100 milligrams/liter, however; because the application rate is intermittent and biodegradability and removal rate are high for this substance no readily observable effects occur in the agroecosystem. TR lines 342-352.

6. Are there any adverse impacts on biodiversity? (§205.200)
   Fatty alcohols are chemicals that naturally occur in all plants and animals. They are known for their high level of biodegradability in the environments. Their derivative products are additionally designed to rapidly degrade after use and are not considered endocrine disrupters.

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)]

   Topping may be done by hand or with special machines that cut the flower heads and sacrifice a few leaves. Topping requires two or three trips over the field to catch all the plants. Suckers can be removed by hand as well as stunted by carefully applying approved soybean oil or mineral oil to the top of the plant. Topping and suckering are the most time-consuming tasks associated with growing organic tobacco, and may be necessary every week for 10 weeks.

2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

   No. The Crops Subcommittee does not think that use of a synthetic growth regulator is compatible with a system of sustainable and organic agriculture.

Classification Motion:

Motion to classify fatty alcohols (octanol/decanol mix) as petitioned as synthetic.
Motion by: Jesse Buie
Seconded by: Emily Oakley
Yes: 8 No: 0 Abstain: 0 Absent: 1 Recuse: 0

National List Motion:

Motion to add fatty alcohols (octanol/decanol mix) as petitioned at §205.601(k)(2) for use in organic crop production.
Motion by: Jesse Buie
Seconded by: Emily Oakley
Yes: 0 No: 8 Abstain: 0 Absent: 1 Recuse: 0

Approved by Francis Thicke, Subcommittee Chair, to transmit to NOSB, August 16, 2017

USDA National Organic Standards Board Research Priorities, 2017

Executive Summary

Overall: The National Organic Standards Board requests that integrated research be undertaken with consideration of the whole farm system, recognizing the interplay of agroecology, the surrounding environment, and both native and farmed species of plants and animals.

Livestock

1. Evaluation of methionine in the context of a system approach in organic poultry production.
2. Prevention and management of parasites, examining breeds, geographical differences, alternative treatments, and pasture species.
3. Organic livestock breeding for animals adapted to outdoor life and living vegetation.

Crops

1. Examination of decomposition rates, the effects of residues on soil biology, and the factors that affect the breakdown of biodegradable biobased mulch film.
2. Organic no-till practices for diverse climates, crops, and soil types.
3. Alternatives to antibiotics (tetracycline and streptomycin) for fire blight control in apples and pears.
4. Alternatives to copper for plant disease and algal control: development of disease-resistant varieties, and particular research on algae control in rice.
5. Plant disease management through crop rotations, sanitation practices, plant spacing and disease-resistant varieties, and biopesticides.
6. Mitigation measures for pesticide residues in compost, including identification of problematic feedstock.
7. Management and control of spotted wing drosophila in fruits.

Coexistence

1. Outcome of genetically engineered (GMO/GE) material in organic compost.
2. Evaluation of public germplasm collections of at-risk crops for the presence of GE traits, and ways to mitigate small amounts of unwanted genetic material in breeding lines.
3. Techniques for preventing adventitious presence of GE material in organic crops, and evaluation of the effectiveness of current prevention strategies.

Food Handling and Processing

1. Comparison of alternatives to chlorine materials in processing: impact mitigation, best management practices, and potential for chlorine absorption by produce.
2. Production of celery for celery powder yielding nitrates sufficient for cured meat applications, and investigation of agriculturally derived alternatives.
3. Suitable alternatives to BPA (Bisphenol-A) for linings of cans used for various products.

National Organic Standards Board Materials Subcommittee Proposal
2017 Research Priorities
August 8, 2017

INTRODUCTION

For the past six years, the National Organic Standards Board (NOSB), has presented a list of research priorities for organic food and agriculture. The priorities are proposed by the NOSB's Livestock, Crops, Handling, and Materials/GMO Subcommittees at its annual fall board meeting. And reflect both written and oral public comments received by the Board. The topics listed below by subcommittee are the 2017 priorities, including some from previous years that the NOSB thinks are still relevant. The older priorities and their dates of adoption can be found in a list at the end of this proposal.

BACKGROUND

Research needs are prioritized along the following criteria: 1) persistent and chronic, 2) challenging, 3) controversial, 4) nebulous, 5) lacking in primary research, and 6) relevant to assessing the need for alternative cultural, biological, and mechanical methods to materials on the National List[1].

The NOSB encourages collaboration with and between laboratories, federal agencies, universities, foundations and organizations, business interests, organic farmers, and the entire organic community to seek solutions to pressing issues in organic agriculture and processing/handling.

PROPOSAL: 2016 RESEARCH PRIORITIES

The NOSB encourages integrated, whole farm research into the following areas:

Livestock

1. Evaluation of Methionine in the Context of a System Approach in Organic Poultry Production

Methionine is an essential amino acid for poultry. Prior to the 1950's, poultry and pigs were fed a plant and meat-based diet without synthetic amino acids such as methionine. One former NOSB member stated, in §205.237(5) (b), "We have seemingly made vegetarians out of poultry and pigs". As the organic community moves toward reducing, removing, or providing additional annotations to synthetic methionine in the diets of poultry, a heightened need exists for the

[1] The National List of Allowed and Prohibited Substances identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic crop and livestock production. It also identifies a limited number of non-organic substances that may be used in or on processed organic products. The NOSB advises the National Organic Program (NOP) on which substances should be allowed or prohibited.

organic community to rally around omnivore producers to assist in marshaling our collective efforts in finding viable alternatives to synthetic methionine and to help find approaches for making them more commercially available.

Continued research on the use of synthetic methionine in the context of a systems approach (nutrition, genetic selection, management practices, etc.) is consistent with the NOSB unanimous resolution passed at the La Jolla, California, Spring 2015 full board meeting. A systems approach that includes industry and independent research by USDA/ARS, on farms, and by agricultural land grant universities is needed for (1) evaluation of the merits of natural alternative sources of methionine such as herbal methionine, high methionine corn, and corn gluten meal in organic poultry production systems, (2) evaluation of poultry breeds selection that could be adaptive to existing organic production systems – inclusive of breeds being able to adequately perform on less methionine, and (3) assessment of management practices for improving existing organic poultry welfare under different conditions. Research findings and collaborations under various climates, housing types, geographical regions, and countries should be noted and researched, where applicable. Certainly, the fruition of these types of research topics could take years to achieve the expressed NOSB resolution; however, an aggressive and/or heightened research focus could lead to findings that can positively impact the organic poultry industry and the organic brand. The continued focus on methionine with a systems approach is imperative and necessary.

The key research areas should include the efficacy and viability of alternatives such as: herbal methionine, corn gluten meal, potato meal, fishmeal, animal by-products, and other non-plant materials. Additional research on the more promising alternatives to bring them into commercial production is also encouraged. Additionally, management practices impacting the flock's demand for methionine should be included, such as flock management practices, access to pastures, and pasture management.

2. Prevention and Management of Parasites

Livestock production places large numbers of cattle, sheep, goats, poultry etc. into relatively close contact with each other on fields and in barns. Organic production does not allow antibiotic use and requires that livestock be raised in a manner which approximates the animal's natural behavior. The organic farmer can use synthetic parasiticides in an emergency but not prophylactically. Synthetic parasiticides have many limitations. Even if prophylactic treatment with parasiticides were possible, it is clear that parasite immunity to chemical control will inevitably occur. Thus, prevention of parasites is critical.

The research question on prevention and management of parasites must be systems based. What farm systems, animal breeds, herd or flock management systems have shown the best results with parasite control over the last 20 years? What regional differences are there in the US in parasite prevention? Are there specific herbal, biodynamic, or other alternative treatments that have been proven to work over time? What are the parasite-resistant breeds? Are there plant species in pastures and scrublands that could be incorporated into the annual grazing system to reduce the spread of parasites or to provide prevention through the flora, fauna, and minerals ingested? Which pasture management systems appear to be best for

parasite prevention in various parts of the country? Are pasture mixes being developed that include plants known to prevent parasites in various breeds?

3. Organic Livestock Breeding (*new in 2017*)

Organic rules require livestock products originate from animals that are not confined and are adapted to outdoor living as well as obtaining feed from living vegetation. A current FAO report states that globally one third of pigs, half of all egg layers, two thirds of milk animals, and three quarters of meat chickens are produced with breeds more suited to confinement or "industrial" production systems than a typical organic farm or ranch. Similar to plant breeding, the organic community sees a great need for regionally-adapted and publicly available livestock breeds that can thrive in organic systems.

Heritage, native regional breeds, and breeds used in the EU and other areas of the world that are typically more adapted to organic systems are still present but in small numbers. Increased research on the breeding, production needs, and improvement of these breeds is needed. Traits for good conversion rates from grazing to milk or meat, meeting consumer expectations for quality, as well as having the constitution and temperament to thrive outdoors would increase both the profitability and resiliency of organic livestock operations. Animal breeds that may have immunity to a variety of diseases and parasites would be useful traits to research and incorporate in a breeding program

Crops

1. Biodegradable Biobased Mulch Film

This type of mulch film was recently approved by the NOSB but did not include a specific percentage of biobased components it must contain. In 2015, NOP issued a Policy Memo[2] that states that certifiers and material organizations should review biodegradable biobased mulch film products to verify that all of the polymer feedstocks are biobased. This requirement makes biobased mulches unavailable to organic producers, due to the petroleum-based polymers in these mulch films. In order to provide a recommendation to the NOP addressing the presence of petroleum-based polymers in these mulches, the answers to the following questions would be useful to develop more clarity on mulch films and possibly develop an additional annotation to address any concerns:

- How rapidly do these mulches fully decompose, and does the percentage of the polymers in the mulch film affect the decomposition rate? Are there metabolites of these mulches that do not fully decompose?
- Are there different cropping systems, climate, soil types, or other factors that affect the decomposition rate?
- What type of effect does the breakdown of these polymers have on soil and plant life as well as livestock that would graze either crop residues or forages grown the subsequent year after this mulch film was used?
- Does the use of these synthetic polymers over time affect the balance of soil biology?
- Is there any cumulative effect if this mulch film is used 3-5 years or more in the same location?

[2] Policy Memo 15-1

- Are the testing regimens available adequate to meet the decomposition standards in our definition and to validate the non-GMO status of source materials?
- Even though petroleum-based polymers may be developed so they are consumed completely by the microbiological life in the soil, is the balance of various nutrients and/or biological life different from the decomposition of biologically-based materials? Is there any comparison between decomposing petroleum-based polymers and the effects that petroleum based fertilizers and other inputs have on soil biological life in nonorganic agricultural systems?

2. Organic No-Till

Organic no-till practices are quite different from herbicide-based no-till systems. Organic no-till, using a terminated cover crop for in-place mulching, can increase soil health and provide for increased biodiversity. Organic no-till preserves and builds soil organic matter, conserves soil moisture, reduces soil erosion, and requires less fuel and labor than standard organic row crop farming. There can also be some challenges from organic no-till using a cover crop, such as occasional insect infestation associated with the cover crop.

Even though this killed-in-place mulch practice has been used for more than a decade, widespread adoption has not occurred. This type of production is also attractive to conservation minded nonorganic farmers, and more practical information could result in the growth of domestic organic production. There are some land grant universities and federal agencies doing research on this type of production, but more work needs to be done. Increased research is needed to develop organic no-till systems that function for a wide variety of crops in diverse climates and soil types. Annual crops such as commodity row crops and specialty crops, as well as perennial crops such as tree fruits, berries, and grapes would all benefit from these organic no-till practices. Research areas that could be covered include:

- Development of plant varieties that have specific characteristics, such as early ripening, to aid in the effectiveness and practicality of organic no-till.
- Which mulch crops, systems, and timing of practices provide specific weed management benefits to support crop growth and yield?
- Research on various techniques that would provide a variety of options for diverse cropping systems including but not limited to: strip tillage within a killed mulch, mowing or other organically approved techniques versus rolling to terminate the cover crop, and living mulches in standing crops.
- Development of systems that allow for either continuous no-till organic crops or for multiple years of organic no-till in the crop rotation.
- How does the lessened soil disturbance of this system contribute to pest, weed, and disease management?
- What specific insect problems can be caused or exacerbated by cover crops used as mulches, and how can those problems best be managed?
- In perennial cropping systems, such as fruits, what are the benefits or drawbacks of using this mulching system on weed, pest and disease management, as well as soil fertility?
- How can the use of this system be managed to improve water infiltration and retention in annual and perennial cropping systems.

- What are the biodiversity benefits to these living and/or killed mulches, and how does this contribute to pest, weed, and disease management?
- Does this system affect the nutrient balance of the soil and subsequent fertilization practices, including use of outside inputs?
- Based on the improved soil health when there is less soil disturbance and more plant decomposition resulting in higher organic matter, how does this system affect soil microbial life and nutrient availability, and does this then result in crops that are less susceptible to disease and pests?

3. Alternatives to Antibiotics (Tetracycline and Streptomycin) for Fire Blight

Prior to October 2014, oxytetracycline and streptomycin were allowed for the control of fire blight in apple and pear trees only. Since 2014, neither substance may be used in any organic practice. Organic apple and pear growers must now find suitable alternatives to control the deadly fire blight disease. Since apples and pears are grown throughout the United States in many regions, these alternatives must work in a variety of climates and management systems. The following research issues are important to investigate: location; planting density; choice of varieties of cultivar and rootstock; soil improvement practices; pruning practices and general sanitation; groundcovers or intercrops; pollinator management; dormant copper sprays; bloom thinning/lime sulfur; early, full bloom, and late sprays with approved organic materials to prevent fire blight establishment; surveys for fire blight activity; and other cultural and preventative techniques.

4. Alternatives to Copper for Disease and Algae Control

Organic producers have fewer alternatives of synthetic chemicals to control diseases. Copper has been used for more than a century to control serious diseases in crops such as late blight in tomatoes and fire blight in pears. Because the copper products degrade to elemental copper, continued use over time can cause copper to accumulate in soil. If used improperly or to excess, copper can be toxic to aquatic life and wildlife.

Alternative materials are not yet available to address the many diseases and crops on which copper is used. Targeted research is needed to identify management practices and less toxic alternative materials for a wide range of crops. More research is needed on many of the crop/disease combinations.

Some avenues for research:

- Comprehensive, systems-based approaches for managing individual crops in a way that decreases the need for copper-based materials, including researching crop rotations, sanitation practices, plant spacing, and other factors that influence disease.
- Breeding plants that are resistant to the diseases that copper controls.
- Developing alternative formulations of materials containing copper so that the amount of elemental copper is reduced.
- Developing biological agents that work on the same diseases that copper is now used on.
- Evaluating plant nutritional strategies to mitigate the impacts of plant diseases.
- Particular research on scum and algae control in rice and whether sodium carbonate peroxyhydrate or other materials are suitable alternatives in an aquatic environment.

5. Plant Disease Management

There is a need for research into plant disease management practices and alternative materials, particularly for the humid areas of the country, that decrease reliance on copper or other substances that might have a negative impact on the soil and health of farmworkers. Genera of pathogens include, but are not limited to: *Alternaria, Erwinia, Pseudomonas, Xanthomonas, Cercospora, Colletotrichum, Cladosporium, powdery mildew, downy mildew, Phytophthora, Pythium, Mycosphaerella, Phomopsis, Taphrina, Elsinoe, Gnomonia, Fusicladium, Nectria, Phyllosticta, Diplocarpon, Albugo, Guignardia, Botrytis, Exobasidium, Entomosporium, Exobasidium, Pestalotia, Phoma, Cristulariella*, and *Monilinia fruticosa*.

Citrus greening, caused by the bacterium *Candidatus liberibacter*, and spread by a disease-infected Asian citrus psyllid, is an emerging problem. Promising avenues of research include disease-resistant varieties, predators and parasites and how they interact with approved materials, nutrition (calcium, boron, and nitrogen have been identified), and botanical oils.

In particular, both biological control of plant diseases and bio-pesticides should be a research priority to support organic growers. A large body of research has shown that plant diseases caused by bacteria and fungi can often be prevented by the application of a non-pathogenic microorganism before infection occurs. Although much basic research has been done to identify microbial biological control agents, there is still a need for commercial development, field testing, and adoption by growers. Biological controls have been researched for late blight of potato and tomato (*Phytophthora infestans*), several diseases caused by *Botrytis cinerea*, and powdery mildew (several species) controlled by mites, fungi, and bacteria.

Although many biological controls and bio-pesticides have demonstrated effectiveness in research plots, they have often not succeeded commercially because they can't compete with inexpensive synthetic chemicals used by non-organic farmers. Biological materials are often more expensive than conventional pesticides, and they need be applied before disease is apparent. In the past, there was little market for biological controls because the organic acreage was limited. Now that organic acreage has increased, the market for alternative plant disease controls has also increased which can spur commercialization of natural methods of disease control. The availability of biological controls for plant diseases can also make it more feasible for conventional farmers to transition to organic, thus benefitting organic consumers.

6. Mitigation Measures for Residues in Compost

Residues of pesticides in compost material are a problem that requires research, according to the Organic Materials Research Institute or OMRI. Because of the importance of compost to organic management systems, research is needed on types of mitigation measure that are efficacious, identification of problematic feedstock (e.g. cotton-based materials and yard waste), types of corrective action, and if thresholds for allowable residues are established, testing guidelines are required. This is more important than ever with events of 2016 regarding contamination in compost.

7. Management and Control of Spotted Wing Drosophila in Fruits (*new in 2017*)

There is a large pool of research on the control of insects and diseases using organic methods. Many controls use a systems approach and are quite effective. The introduction of

new invasive species into cropping systems threatens these systems approaches, and in several cases the organic control options are very limited or nonexistent. Spotted wing drosophila is a relatively recent invasive insect that infests soft fruits, such as berries, and many other fruits as well. Infestation renders fruit unusable since insect larvae feed inside the fruit and may reach critical levels before fruit is harvested. This insect is particularly problematic in that it has the ability to oviposit in green fruit and that it has multiple generations throughout the summer, creating an extensive control period. There is only one control material available, and it is in danger of overuse. The control period may also extend so long that maximum label rates are used before the season ends. A second invasive insect is brown marmorated stink bug, and at this time there are no organic control measures beyond attempts at mass trapping. Research into organic control options for both these invasive pests is critical so that organic growers can integrate controls into their organic systems.

Handling

1. Chlorine Materials and Alternatives

The three chlorine materials currently allowed for use in organic agriculture are widely used in farming and handling to clean and disinfect equipment, surfaces, and produce. There have been some concerns raised about these materials and their impact on the environment and human health when/or if they form trihalomethanes and other toxic compounds. New FDA regulations on food safety (Food Safety Modernization Act) and best management practices for cleaning in handling operations both require a suitable level of cleanliness and disinfection to prevent pathogens from entering the food supply. Producers and handlers are looking for alternatives to chlorine while continuing to provide a safe end product to their customers and the consumer. Addressing food safety while adhering to the fundamental organic principles involving human health and environmental impact is a concern.

The organic industry needs better information on how either alternative materials or appropriate chlorine materials are best suited for a specific use and control measure. This is especially important in determining if the industry can move away from the use of chlorine compounds in the future.

Points of consideration for future research activities:

- Comparison of alternatives to chlorine such as: citric acid, hydrogen peroxide, ethanol, isopropanol, peracetic acid, and ozone. How would each compare to the different chlorine materials for specific uses? The strengths and weaknesses would need to be considered.
- Potential human health and environmental impacts of each chlorine material versus the possible alternative materials listed above. Are there ways that these impacts can be mitigated and still allow the material to work as needed?
- Determination of which of the above mentioned alternatives would NOT be a suitable substitute for chlorine. What specific uses and/or conditions would this apply to?
- Identification of practices that could be used to help reduce the formation of trihalomethanes in those specific situations where chorine is the best material to use.
- Could the rotation of materials for cleaning and disinfecting help lower the risks from chlorine materials and still be effective in providing the desired control of pathogens?

- Research on the absorption of chlorine by produce from its quantity and use in wash tanks, including information about amount of time of exposure. Would this be a persistent residual effect or temporary (if temporary – how long is it a viable residue), and would it be harmful if consumed at these levels?

2. Celery Powder

Celery Powder is used in a variety of processed meat product (hot dogs, bacon, ham, corned beef, pastrami, pepperoni, salami, etc.) to provide "cured" meat attributes without using prohibited nitrites (note: products must still be labeled "uncured"). Celery powder is naturally high in nitrates that are converted to nitrites during fermentation by a lactic acid culture. It has proven difficult to produce celery powder under organic production practices with sufficient levels of nitrates for cured meat applications. Are there growing practices or regions that could produce celery under organic conditions that would yield a crop with sufficient nitrate content for cured meat applications? Are there agriculturally derived substances (other than celery) that could be produced under organic production practices that provide nitrate levels sufficient for cured meat product applications of comparable quality?

3. Alternatives to Bisphenol A (BPA)

The Handling subcommittee is examining the issue of whether to prohibit BPA in packaging materials used for organic foods in light of direct evidence that these uses result in human exposures and mounting evidence that these exposures may be harmful. There is a need for increased research about alternatives for the linings of cans and jars used for organic products that do not result in human exposures and health risks.

<u>Materials/GMO</u>

In previous years, the Materials subcommittee has prioritized the Reduction of Genetically Modified Content of Breeding Lines (2013) and Seed Purity from GMOs (2014). These issues are currently being addressed through a Genetic Integrity of Seeds Ad Hoc Working Group.

1. Fate of Genetically Engineered Plant Material in Compost

What happens to transgenic DNA in the composting process? Materials such as cornstalks from GMO corn or manure from cows receiving rBGH are often composted, yet there is little information on whether the genetically engineered material and traits break down in composting process. Do these materials affect the microbial ecology of a compost pile? Is there trait expression of Bt (*bacillus thuringiensis*) after composting that would result in persistence in the environment or plant uptake?

2. Integrity of Breeding Lines and Ways to Mitigate Small Amounts of Unwanted Genetic Material

Are public germplasm collections that house at-risk crops threatened by transgenic content? Breeding lines may have been created through genetic engineering methods such as doubled haploid technology, or they may have had inadvertent presence of GMOs from pollen drift. The extent of this problem needs to be understood.

3. Prevention of GMO Crop Contamination: Evaluation of effectiveness

How well are some of the prevention strategies proposed by the NOSB working to keep GMOs out of organic crops? For instance, how many rows of buffer are needed for corn? How fast does contamination percentage go up or down if there are more or fewer buffer rows?

Other examples could be whether cleanout of combines and hauling vehicles reduces contamination using typical protocols for organic cleaning, whether situating at-risk crop fields upwind from GMO crops can reduce contamination, and what the role may be of pollinators in spreading GMO pollen.

Lastly, research is needed on a mechanism to provide conventional growers incentives to take their own prevention measures to prevent pollen drift and its impact on organic and identity-preserved crops. This is policy research rather than field research but is equally as important.

Previous Years' Research Priorities

For more detailed information about each topic, please see the relevant research priorities proposals. Each topic's listing year is indicated.

Whole Farm Systems (2012, 2013)
Evaluation of Copper Sulfate for Rice (2012)
Evaluation of Genetically Modified Vaccines (GMO) (2012, 2013)
Organic Aquaculture (2012, 2013)
Carageenan (2012)
Aquatic Biodiversity (2013)
Pastured Poultry and Salmonella (2013)
Commercial Availability Assessments (2013)
Herd and Flock Health (2013, 2014, 2015)
Risk Reduction from Off-Target Exposure to Non-Permitted Materials (2014)
Seed Purity from GMO (2014)
Mastitis (2014)
Pneumonia (2014)
Plant Extracts (2014)
Soil Building Practices (2014)
Consumer Demand (2013, 2016)

Subcommittee Vote:

Motion to adopt the proposal on 2017 NOSB Research Priorities
Motion by: Emily Oakley
Seconded by: Dave
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 0

Dr. Fan-Li Chou serves as the Biotechnology Coordinator for the United States Department of Agriculture (USDA). She provides leadership, coordination, and strategic planning of USDA's biotechnology policy. She works closely with decision makers in USDA, in other Federal agencies, and in Congress on the development and implementation of biotechnology policy. She is a key contact point for biotechnology policy with industry, non-governmental organizations, other Federal and State government agencies, farmers, and other stakeholders. Fan-Li represents USDA at national and international scientific and policy fora that helps to advance public understanding of Department policies and programs; she will represent USDA in domestic and international negotiations involving biotechnology policy. Fan-Li will serve as the Executive Secretary of USDA's Biotechnology Coordinating Committee as well as the Designated Federal Official for the Secretary's Advisory Committee on Biotechnology upon re-chartering. Fan-Li has over ten years of experiences at the USDA, including positions with the Foreign Agricultural Service and the Animal and Plant Health Inspection Service. Fan-Li is an American Association for the Advancement of Science Diplomacy Fellow (2005-2006). She holds a Ph.D. in molecular biology and genetics from the University of Pittsburgh, and completed her post-doctoral fellowship at the Scripps Research Institute and University of California, San Diego. She currently resides in Maryland with her husband, two daughters and her mother.

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)
Compliance, Accreditation & Certification Subcommittee (CACS) Notes
Tuesday December 12, 2017, 3:00 pm ET

Attending: Scott Rice (SR), Chair; Emily Oakley (EO), vice chair; A-dae Romero-Briones (ARB); Tom Chapman (TC); Harriet Behar (HB)
Absent: Jenny Tucker (JT)
Staff: Michelle Arsenault (MA); Devon Pattillo (DP)

Work Agenda

Project	Contact	Status	Discussion, Vote	Meeting
Inspector qualifications proposal	SR	Approved for addition to work agenda 04 21 16. Referred back to CACS at Spr 2017 meeting	Dec 12	Spr 2018
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production. Proposal	HB	Approved for addition to work agenda 07 15 16. Verbal update Fall 2016. DD Spr 2017. Proposal Fall 2017. Referred back to CACS at Fall 2017 meeting	Nov 28	Spr 2018
Imports	ALL	Memo sent to NOSB 08 10 17	Nov 28	Spr 2018

***Discussed** ***Voted**

Agenda

- Approve notes from October 10
- Approve notes from November 28
- Inspector Qualifications next steps
- Imports
- Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production
- Other items
- Adjourn

Discussion

- **Notes from October 10** were approved with no changes.
- **Notes from November 28 notes** were approved with a date correction under the imports topic.
- **Inspector qualifications next steps (SR).** The group discussed some ideas for the next iteration of the proposal on inspector qualifications. Members suggested such things as guidance and best practices for inspectors about scale of operations. A member stressed the importance of such training, which can build stronger and more confident relationships between operations and inspectors. Another member mentioned several other standards, such as Global G.A.P.,

suggesting that it would be helpful to know how other certification schemes address inspector training and qualifications. The lead will develop an outline or draft for the next call.

- **Imports.** The group discussed the next steps with regard to imports. The NOP refined the four broader topics that were proposed at the Fall 2017 meeting to help focus in on areas where the CACS could develop a recommendation(s). Several questions came up during the conversation as the group tried to identify how to best address this broad topic. A member questioned how the EU verified organic certification for goods exported from countries that have been implicated in fraudulent behavior. Another member asked if there could be useful information from the recent meeting in Odessa, Ukraine, and HB agreed to reach out to participants of that meeting.

  As the discussion continued, there was some uncertainty as to how the NOSB could best provide feedback given the size and complexity of the topic. A member felt that the very idea that the USDA/NOSB is attempting to close the gaps could act as a deterrent to fraud. Another member discussed the implicit level of trust that exists within the organic community and suggested that perhaps verification needs to be enhanced, which would also provide a deterrent. The NOSB Chair is reaching out to industry representatives who have experience in international trade in an effort to gather more information. The CACS would also like to invite experts to the Subcommittee calls to provide additional insight. There was a request that the program prioritize the bulleted list of possible topics, and provide additional input about other activities at the USDA regarding imports.
- Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB). The lead discussed the feedback that the CACS received at the Fall 2017 NOSB meeting, and indicated she was developing ideas for the next iteration of the proposal to include some of these suggestions. The lead invited feedback about the path forward. The group discussed the inclusion of a definition of native ecosystem. The NOSB Chair suggested looking at how this issue may be affecting domestic farmers economically as compared to international farmers (given that most destruction of native ecosystems is international). A member urged the group to write the proposal they want to see go forth, with the acknowledgement that it likely won't go forward as rulemaking in the near future.
- **Other items.** None
- **The meeting was adjourned**

Previous CACS Notes

Future Call Schedule (2nd Tuesday 3:00 ET)

November 28, 2017 - additional call
December 12, 2017
Imports
Inspector qualifications
December 26, 2017- additional call
Imports discussion (ALL)
Inspector qualifications (SR)
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)
January 9, 2018
January 23, 2018 - additional call
January 30, 2018 - additional call

February 13, 2018
February 27, 2018 - additional call
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

National Organic Standards Board (NOSB)
Handling Subcommittee (HS) Meeting Notes draft
Tuesday, December 19, 2017 1:00 pm ET

Present: Lisa de Lima (LD), Chair; Scott Rice, Vice Chair (SR); Steve Ela (SE); Asa Bradman (AB); Joelle Mosso (JM); Tom Chapman (TC); A-dae Briones (ARB); Harriet Behar (HB) – observer; Ashley Swaffer – observer
Absent: Michelle Arsenault (MA)
Staff: Devon Pattillo (DP), Lisa Brines (LB)

Work Agenda

Petitioned Substances						
Substance	**National List §**	**Contact**	**TR rqst?**	**Notes***	**Scheduled, Discussed, Voted**	**Meeting**
Sodium dodecylbenzene sulfonate (SDBS) Petition Addendum #1, SDBS (PDF)	205.605(b)	SR	Y	Petition sent to HS on 11 02 15. Response/request for TR due 01 04 16. Petition found suff 12 01 15. No new TR will be requested. Referred back to HS at Apr 2016 NOSB meeting. TR request sent 05 18 16. TR in development - Expected late Dec 2016/early Jan. TR delayed until Spring 2017. TR sent to HS 05 30 17. Response due 08 01 17. Petition addendum sent to HS 07 12 17. The HS found the petition addendum suff 08 01 17	Aug 1, Aug 15 Jan 2	Spr 2018
Sodium Chlorite for the generation of chlorine dioxide gas Petition, Addendum	205.605	SR	Y	Petition for chlorine dioxide dry gas sent to HS on 12 02 15. Response/request for TR due 02 02 16. HS sent request 03 17 16 for additional info from petitioner. Sodium chlorite addendum received 05 05 16. Suff due 07 05 16. Petition found sufficient 06 07 16. Sent back to Subcomm at Fall 2016 meeting. HS requested a TR 06 06 17.	May 16, Jun 6, Jan 2	Spr 2018
Silver Dihydrogen Citrate Petition Addendum #1	205.605(b)	JM	Y	Petition sent to HS 01 24 17. Response/request for TR due 03 28 17. Petition found sufficient 03 07 17. HS requested TR 03 07 14. TR in development. Petition addendum sent to HS 08 03 17. TR sent to HS 10 19 17/ Suff due 12 19 17. HS sent additional questions to TR contractor 12 05 17	Mar 7, Dec 5	Spr 2018

Petitioned Substances						
Substance	National List §	Contact	TR rqst?	Notes*	Scheduled, Discussed, Voted	Meeting
Japones pepper	205.606	ARB	N	Petition sent to HS 02 09 17. Response/request for TR due 04 11 17. Petition found suff 04 04 17. No TR. HS requested additional info from petitioner 07 19 17 & 11 07 19	Apr 4, Jul 18 Oct 3 Nov 7	Spr 2018
Ethiopian pepper	205.606	ARB	N	Petition sent to HS 02 09 17. Response/request for TR due 04 11 17. Petition found suff 04 04 17. No TR. HS requested additional info from petitioner 07 19 17 & 11 07 19	Apr 4 Jul 18 Oct 3 Nov 7	Spr 2018
Tamarind Seed Gum Petition Addendum, August 22, 2017	205.606	SE		Petition sent to HS 02 15 17. Response/request for TR due 04 17 17. HS requested additional info from the petitioner 04 04 17. Petition addendum Rcvd 08 10 17. Response due 10 10 17. Updated petition addendum rcvd 08 22 17. TR requested 10 03 17. TR in contracting.	Apr 4 Sep 5, Oct 3 Feb 20	Spr 2018/Fall 2018

2020 Sunsets TR Requests: July 2017, Summary: Spr 2018, Review: Fall 2018						
Name	National List §	Contact	TAP/TR	Notes	Scheduled, Discussed	Review Meeting
Calcium carbonate	205.605(a)	SR	Y	1995 TAP. TR requested 07 28 17. Low priority	Feb 20	Summary: Spr 2018 Review: Fall 2018
Flavors	205.605(a)	TC	N	2005 TR	Jan 16	"
Gellan Gum	205.605(a)	JM	N	2006 TAP	Feb 20	"
Oxygen	205.605(a)	LD	N	1995 TAP. TR requested 07 28 17. Low priority	Dec 5	"
Potassium chloride	205.605(a)	AS	N	1995 TAP; 2015 TR for Nutrient vitamins and minerals	Dec 5	"
Alginates	205.605(b)	SE	N	1995 TAP; 2015 TR	Dec 19	"
Calcium hydroxide	205.605(b)	AS	N	1995 TAP. TR requested 07 28 17. Low priority	Dec 5	"

Ethylene	205.605(b)	AB	N	1995 TAP; 1999 TAP - Processing. TR requested 07 28 17. Contingent on request from other Subcomms	Dec 19, Jan 2	"
Glycerides: mono and di	205.605(b)	LD	N	1995 TAP; 2015 TR	Dec 5	"
Magnesium stearate	205.605(b)	AB	Y	1995 TAP. TR requested 07 28 17. Low priority	Feb 20	"
Phosphoric acid	205.605(b)	AS	N	2003 TAP. TR requested 07 28 17. Contingent on request from other Subcomms	Dec 5	"
Potassium carbonate	205.605(b)	SR	N	1995 TAP. TR requested 07 28 17. Low priority.	Feb 6	"
Sulfur dioxide	205.605(b)	SE	N	1995 TAP; 2011 TR	Dec 19	"
Xanthan gum	205.605(b)	JM	N	1995 TAP; 2016 TR	Feb 20	"
Fructooligosaccharides (FOS)	205.606	TC	N	2006 TAP; 2015 TR	Jan 16	"
Gums: Arabic, Carob bean, Guar, Locust bean	205.606(k)	JM	Y	1995 TAP. TR requested 07 28 17. TR in contracting.	Feb 20	"
Lecithin - de-oiled	205.606	AB	N	1995 TAP; 2009 TR	Jan 16	"
Tragacanth gum	205.606	JM	Y	None. TR requested 07 28 17. TR in contracting.	Feb 20	"

Other projects			
Name	**Contact**	**Notes***	**Meeting**
Packaging substances used in organic food handling - including BPA	LD/AB	Submitted briefing paper to NOP 01 12 14. Response memo from NOP sent to HS 11 19 14. TR in development, expected mid-Sep - delayed. TR received 9/30/16. In review by the program. TR sent to HS 10 19 16. TR sufficiency due 12 20 16. TR found insufficient 12 20 16. Vote: 02 21 17. New TR in development. Expected July 2017, TR received 07 10 17. Response due 09 08 17. TR found sufficient 08 01 17.	Discussion doc Spr 2018
Nutrient Vitamins and Minerals - annotation change	TC	Pending NOP Approval. Approved 01 12 16. Proposal. On hold.	Spr 2018
Marine materials (marine algae and extracts). Proposal	SR	Pending NOP approval. NOP approved request 01 12 16. TR request sent to NOP 02 05 16. TR expected Jul 2016. TR sent to HS 08 10 16. TR suff due 10 11 16. TR found sufficient 09 06 16. Voted 09 06 16. Proposal in development 12 06 16. Voted 01 17 17. Referred back to HS at Spr 2017 NOSB meeting	TBD

Magnesium chloride Reclassification 205.605(b)	LD	HS requested addition of this item and NOP approved 01 12 16; TR completed 11/30/16.	Spr 2018
Research Priorities	TC/ALL	RPs due to MS Aug 2018	Fall 2018

*Highlight indicates committee action needed. *Highlight indicates review completion and/or vote

Agenda

- Approve December 5, 2017 notes
- Magnesium chloride reclassification (LD) - Discuss
- 2020 sunset: Alginates (SE) - Discuss review
- 2020 sunset: Sulfur dioxide (SE) - Discuss review
- 2020 sunset: Ethylene (AB) - Discuss review
- Other items
- Adjourn

Discussion

- **HS Notes from** December 5, 2017 were approved with one edit to the notes on glycerides.
- **Petitions for 205.606 Ingredients.** The HS asked the Program for some clarification and information about evaluating petitions that request to add non-organic agricultural ingredients to the National List (§ 205.606), including how to evaluate commercial availability. The Program noted that NOP 3011 includes criteria for these petitions but acknowledged it can be difficult for petitioners to demonstrate that the ingredient is not available as organic. The Program noted that the burden to justify the addition of the ingredient to the National List is on the petitioner and encouraged the HS to limit repeated requests to petitioners that repeat the same or similar questions. Members discussed best practices for reviewing petitions, such as asking questions of petitioners before determining that a petition is sufficient.
- **Magnesium chloride reclassification (LD).** The lead described the reasons for the work to consider reclassifying this substance. The lead wrote the proposal to leave the annotation the same (after moving to new section of the National List). It was noted that the CS has separately considered a wider range of sources as nonsynthetic and the lead asked if the HS annotation should better align with CS's determination. Members discussed the relative availability of nonsynthetic vs. synthetic sources of the substance and discussed various methods and sources used to produce nonsynthetic forms of the substance. Members concluded that if it were moved to 605(a), an annotation would not be necessary to further restrict its use to a subset of nonsynthetic forms. The lead will rework the proposal to recommend removal of the annotation and will discuss on the next call.
- **2020 sunset: Alginates (SE).** The lead described the substance, its sources, and current uses. Members discussed whether new alternatives have become available since the 2015 TR. The lead noted that many of the alternatives to alginates are gums, and members also noted carrageenan could be an alternative. A member noted that some gums are better than other gums for specific products, and the lead noted that alginates have characteristics that may be best suited for some products.
- **2020 sunset: Sulfur dioxide (SE).** The lead discussed the substance, current use in "made with organic" wines, health concerns, and international status. The Program noted they have received questions about its use in other types of fruit wine and cider (not permitted with current annotation). Members discussed that a petition was previously received to remove the annotation but did not pass.

- **2020 sunset: Ethylene (AB).** The lead briefly discussed the historical reviews of this substance and questioned if a TR was needed. The Program noted that no TR is currently being developed for the current sunset cycle. Members will continue the discussion on the next call.
- **The meeting was adjourned**

Previous HS Notes

Future Call Schedule (1st and 3rd Tuesdays 1:00 ET)

December 5, 2017
- Debrief from Jacksonville meeting (ALL)
- Silver Dihydrogen Citrate (JM) - TR sufficiency
- 2020 sunset: Oxygen (LD) - Discuss review
- 2020 sunset: Potassium chloride (AS) - Discuss review
- 2020 sunset: Calcium hydroxide (AS) - Discuss review
- 2020 sunset: Glycerides: mono and di (LD) - Discuss review
- 2020 sunset: Phosphoric acid (AS) - Discuss review

December 19, 2017
- Petitions for 205.606 Ingredients
- Magnesium chloride reclassification (LD) – Discuss
- 2020 sunset: Alginates (SE) - Discuss review
- 2020 sunset: Sulfur dioxide (SE) - Discuss review
- 2020 sunset: Ethylene (AB) - Discuss review

January 2, 2018
- SDBS (SR) - Discuss proposal
- 2020 sunset: Ethylene (AB) - Discuss review
- Sodium Chlorite for the generation of chlorine dioxide gas (SR) - discuss proposal

January 16, 2018
- 2020 sunset: Fructooligosaccharides (FOS) (TC) - Discuss review
- 2020 sunset: Lecithin - de-oiled (AB) - Discuss review

February 6, 2018
- BPA (AB) - Discuss
- Marine Materials (SR) - Discuss proposal
- 2020 sunset: Flavors (TC) - Discuss review
- 2020 sunset: Potassium carbonate (SR) - Discuss review

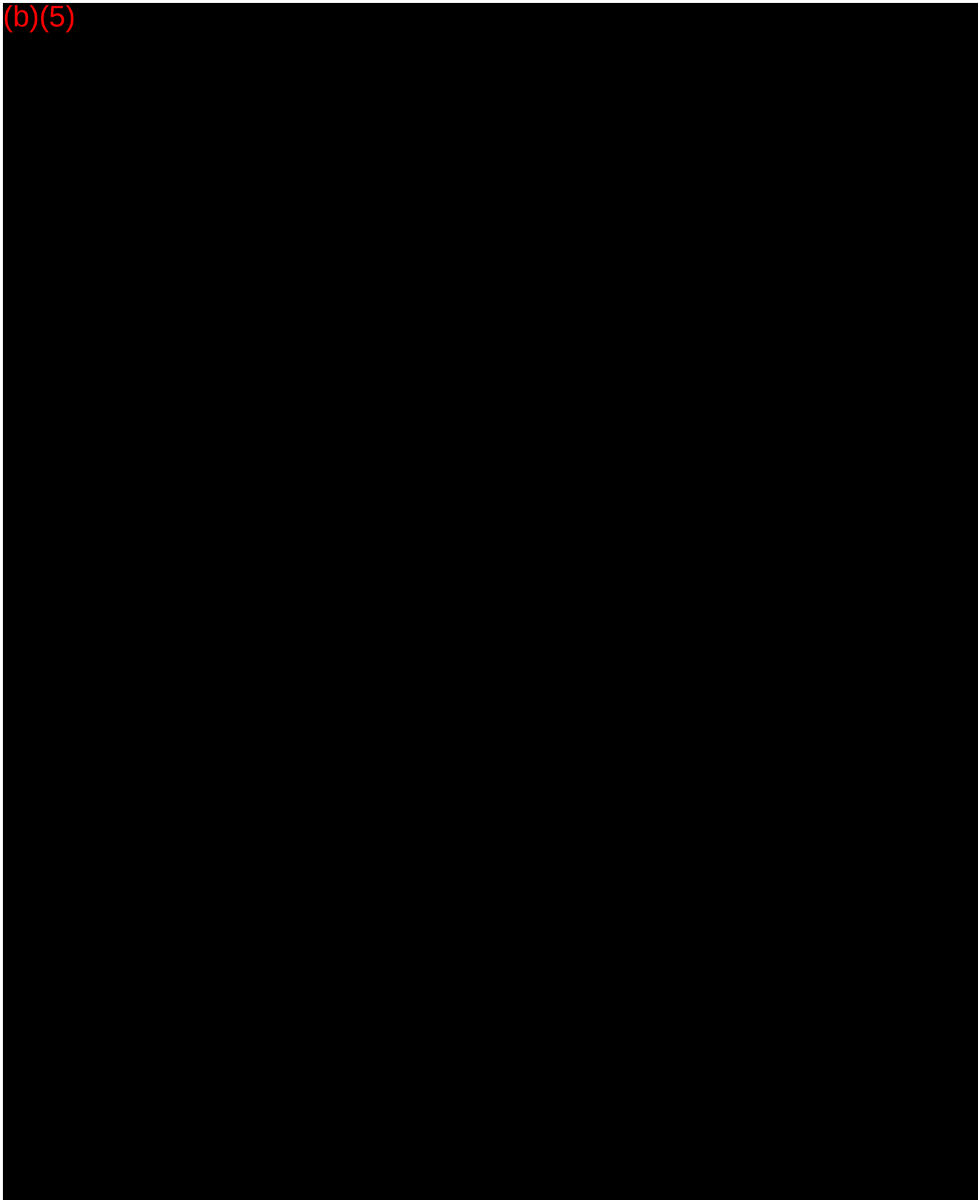
February 20, 2018
- Tamarind seed gum (SE) - TR sufficiency (if available)
- 2020 sunset: Calcium carbonate (SR) - Discuss review
- 2020 sunset: Gellan Gum (JM) - Discuss review
- 2020 sunset: Gums: Arabic, Carob bean, Guar, Locust bean (JM) - Discuss review
- 2020 sunset: Tragacanth gum (JM) - Discuss review
- 2020 sunset: Xanthan gum (JM) - Discuss review
- 2020 sunset: Magnesium stearate (AB) - Discuss review

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

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal - Sodium Dodecylbenzene Sulfonate
January XX, 2018



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National Organic Standards Board (NOSB)
Crops Subcommittee (CS) Meeting Notes
Tuesday January 2, 2018 2:00 pm ET

Present: Steve Ela, Chair (SE); Asa Bradman (AB); Jesse Buie (JB); Dave Mortensen (DM); Harriet Behar (HB); Joelle Mosso (JM); Tom Chapman (TC)
Absent: Michelle Arsenault (MA); Francis Thicke (FT); Emily Oakley (EO); Sue Baird (SB)
Staff: Devon Pattillo (DP); Lisa Brines (LB)

Work Agenda

Petitioned Substances					
Substance	**Con-tact**	**TR request?**	**Notes**	**Discussed, Voted**	**Meeting**
Polyoxin D Zinc salt 205.601	JB	Y	Petition sent to CS 06 16 16. Petition suff/TR request due 08 16 16. Petition found sufficient 08 16 16. Discuss need for Lmt'd scope TR. CS requested Lmt'd scope TR 10 04 16. TR sent to Subcommittee on 12 19 17. Response due 02 20 18.	Feb 6, 2018	Spr 2018
Allyl Isothiocyanate (AITC) Petition (2016) 205.601	JB	Y Lmt'd scope	Petition sent to CS 07 06 16. Petition suff/TR request due 09 06 16. Petition found suff 10 04 16. CS requested Lmt'd scope TR 10 04 16. TR in development. . Expected Feb/Mar 2018. • AITC Petition (2013) (PDF) • NOSB Subcommittee Proposal (2014) (PDF) • Technical Evaluation Report (2014) (PDF)	Feb 6, 2018	Spr 2018
Sodium Citrate 205.601	HB	Y	Petition sent to CS 07 27 16. Petition suff/TR request due 09 27 16. Petition was found sufficient 10 04 16. CS requested a TR 10 04 16. TR in development. TR - Handling, Citric acid and salts (2015). TR sent to CS 08 07 17. Response due 10 06 17. Found TR insufficient 09 19 17. HS sent additional questions to TR contractor 12 11 17. Revised TR sent to CS 12 20 17. Response due 02 19 18	Sep 19, 2017	Spr 2018
Natamycin	HB	Y	Petition sent to CS 09 09 16. Petition suff/TR request due 11 08 16. Petition found sufficient 11 01 16, and CS requested TR 11 01 16. TR in development. Expected October 2017. TR sent to CS 11 3 17. Response due 01 12 18. TR found sufficient 12 5 17.	Dec 5	Spr 2018

Sulfur (as a molluscicide) 205.601	AB	N	Petition sent to CS 06 08 17. Petition suff/TR request due 09 05 17. Petition found sufficient 09 19 17. No TR request.	Sep 19 Jan 16	Spr 2018
Ammonium Citrate 205.601	EO/DM		Petition sent to CS 10 25 17. Petition suff/TR request due 12 26 17. TR requested 11 21 17.	Nov 21	TBD
Ammonium Glycinate 205.601	EO/DM	Y	Petition sent to CS 10 25 17. Petition suff/TR request due 12 26 17. TR requested 11 21 17.	Nov 21	TBD
Calcium Acetate	SB		Petition sent to CS 1 20 17. Petition suff/TR request due 01 17 17.	Jan 16	TBD

Other Topics

Project	Con-tact	Doc type	Notes*	Discussed/ Voted	Meeting
(Manure treatments) Anaerobic Digestate - Food Waste 205.601(j) and other manure issues	EO/HB/JM	Disc Doc	Petition sent to CS 04 08 15. Questions or request for TR due 06 09 15. Petition found sufficient 06 02 15. TR rqst sent to NOP 10 06 15. Petition withdrawn 10 14 15. CS moved project to "other topics" NOP sent memo to board 05 09 16 requesting review. TR request sent to NOP 07 05 16 (see anaerobic digestate above). Waiting for result of FDA's risk assessment.	Aug 1, Aug 15, 2017	Spr 2018
Biodegradable Biobased Mulch annotation change	HB/AB	Disc Doc	Limited scope TR request sent to NOP 08 02 16. TR sent to CS on 12 28 16. TR Suff due 02 27 17. CS found TR suff 01 03 17. Pending further research	Aug 1, 2017	Spr 2018
Prohibition of NPEs in inerts - annotation change/ EPA List 4 Inerts annotation change	HB/EO/ DM/AB	Disc Doc/Prop	IWG recommended NOSB work on NPEs/TR requested July 2014. DD - April 2016. EPA List 4 inerts disc doc (originated from 2017 sunset review conducted in 2015). Pending EPA decision	TBD	Fall 2018
Marine materials (marine algae and extracts) on the National List	EO	Disc doc	NOP approved request 01 12 16. TR request sent to NOP 02 05 16. TR sent to HS 08 10 16. Returned to CS at Spr 2017 NOSB meeting. Referred back to CS at Spr 2017 meeting	Aug 15, Dec 5	Spr 2018
Field and Greenhouse Container Production	JB, HB, FT and EO	TBD		Jan 2	Spr 2018

Strengthen and clarify the requirements for use of organic seed (NOP 5029)	HB	Proposal	Originated in MS. Referred back to CS at Spr 2017 meeting. Referred back to CS at Fall 2017 meeting.		Spr 2018
Research Priorities	All	NA	RPs due to MS Aug 2018		Fall 2018

* Yellow highlight indicates Subcommittee action needed *Highlight indicates review completion

2020 Sunsets TR Requests: July 2017, Summary: Spr 2018, Review: Fall 2018						
Substance		**Contact**	**TR request?**	**Notes**	**Scheduled, Discussed**	**Meeting**
Alcohols: Ethanol Isopropanol	205.601(a)(1)(i), 205.601(a)(1)(ii)	JB	N	1995 TAP; 2014 TR - Ethanol; 2014 TR - Isopropanol	Jan 16	Summary: Spr 2018 Review: Fall 2018
Sodium carbonate peroxyhydrate	205.601(a)	EO	N	2006 TAP; 2014 TR	Dec 5	"
Newspaper or other recycled paper	205.601(b) and (c)	HB	N	2017 TR	Dec 5	"
Plastic mulch and covers	205.601(b)	HB	N	1995 TAP: TR for biodegradable mulch. Low priority	Dec 19, Jan 2	"
Aqueous potassium silicate	205.601(e), 205.601(i)	DM	N	2014 TR	Jan 2	"
Elemental sulfur	205.601(e)(5), 205.601(i)(10), 205.601(j)(2)	AB	Y	1995 TAP; 2017 TR for Livestock. TR requested 07 28 17. In contracting.	Dec 19, Jan 2	"
Lime sulfur	205.601(e)(6), 205.601(i)(6)	SE	N	2014 TR	Dec 19	"
Sucrose octanoate esters	205.601(e)(10)	SB	N	2005 TR	Dec 19	"
Hydrated lime	205.601(i)(4)	DM	N	1995 TAP; 2001 TAP; 2002 TR for Calcium Hydroxide	Jan 2	"
Liquid fish products	205.601(j)	AB	N	1995 TAP; 2006 TR	Jan 16	"
Sulfurous Acid	205.601(j)	SE	N	2010 TAP; 2014 TR	Dec 19	"

Ethylene	205.601(k)	EO	N	2000 Supplemental TAP; 2007 TAP; 2011 Supplemental TR	Dec 19	"
Microcrystalline cheesewax	205.601(o)	SB	Y	None. TR requested 07 28 17. In contracting.	Dec 19	"
Potassium chloride	205.602(e)	JM	N	1995 TAP. Low priority	Jan 16	"

Agenda

- 2020 sunset: Plastic mulch and covers (HB) – Review/vote on proposal
- 2020 sunset: Aqueous potassium silicate (DM) - Discuss review (postponed from Dec 19th call)
- 2020 sunset: Hydrated lime (DM) - Discuss review (postponed from Dec 19th call)
- Sulfur (as a molluscicide) - Review/vote on proposal
- 2020 sunset: Alcohols: Ethanol Isopropanol (JB) - Discuss review
- 2020 sunset: Elemental sulfur (AB) - Discuss review
- 2020 sunset: Liquid fish products (AB) - Discuss review
- 2020 sunset: Potassium chloride (JM) - Discuss review
- Discussion of future options for hydroponics/container proposals. (postponed from Dec 19th call)
- Adjourn

Discussion

- **Notes from December 19, 2017** were approved without change.
- **2020 sunset: Plastic mulch and covers (HB).** The lead discussed changes made to the document since the last call. The lead discussed differences between film type plastic covers and mesh type/woven plastic covers that are more resistant to breakdown. The lead described uses of these products in crop production systems and certifier interpretations of the requirement to remove at the end of the growing or harvest season. Members discussed questions for the document, including a question to solicit input on disposal methods. The lead will recirculate a revised draft.
- **2020 sunset: Aqueous potassium silicate (DM).** The lead summarized the uses of the substance and the last review of the substance by the NOSB. The lead has prepared several questions to include in the document for the spring meeting. Members noted their support for the additional questions and offered refinements.
- **2020 sunset: Hydrated lime (DM).** The lead summarized the use of this listing of the substance on the National List for plant disease control. The lead will review information from the most recent sunset review and update the document. The subcommittee will discuss on the next call.
- **Sulfur (as a molluscicide).** Discussion was postponed to the next call.
- **2020 sunset: Alcohols: Ethanol, Isopropanol (JB).** Discussion was postponed to the next call.
- **2020 sunset: Elemental sulfur (AB).** The lead discussed the substance, its uses, sources, and recent research. The lead noted the substance is widely used (according to CA pesticide use data) and adverse health impacts have been noted. The lead noted that wet and dry formulations of sulfur may have different risks. The NOP noted that a new technical report should be available in the coming weeks. The CS will revisit the document after review of the technical report.
- **2020 sunset: Liquid fish products (AB).** Discussion was postponed to the next call.
- **2020 sunset: Potassium chloride (JM).** Discussion was postponed to the next call.
- **Discussion of future options for hydroponics/container proposals.** Discussion was postponed to the next call.
- **The meeting was adjourned**

Previous CS Notes

Future Call Schedule (1st and 3rd Tuesdays 2:00 ET)

December 19, 2017

- 2020 sunset: Plastic mulch and covers (HB) - Discuss review
- 2020 sunset: Lime sulfur (SE) - Discuss review
- 2020 sunset: Sulfurous Acid (SE) - Discuss review
- 2020 sunset: Ethylene (EO) - Discuss review
- 2020 sunset: Sucrose octanoate esters (SB) - Discuss review
- 2020 sunset: Microcrystalline cheesewax (SB) - Discuss review

January 2, 2018

- 2020 sunset: Plastic mulch and covers (HB) – Review/vote on proposal
- 2020 sunset: Aqueous potassium silicate (DM) - Discuss review (postponed from Dec 19th call)
- 2020 sunset: Hydrated lime (DM) - Discuss review (postponed from Dec 19th call)
- 2020 sunset: Elemental sulfur (AB) - Discuss review

January 16, 2018

- Calcium Acetate (SB) - petition sufficiency/TR request
- Polyoxin D Zinc salt (JB) - TR sufficiency
- Sulfur (as a molluscicide).
- 2020 sunset: Liquid fish products (AB) - Discuss review
- 2020 sunset: Alcohols: Ethanol Isopropanol (JB) - Discuss review
- 2020 sunset: Potassium chloride (JM) - Discuss review
- Discussion of future options for hydroponics/container proposals

February 6, 2018

- Allyl Isothiocyanate (AITC) - TR sufficiency (pending receipt of TR)

February 20, 2018

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

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)
Handling Subcommittee (HS) Meeting Notes
Tuesday, January 2, 2018 1:00 pm ET

Present: Lisa de Lima (LD), Chair; Scott Rice, Vice Chair (SR); Steve Ela (SE); Asa Bradman (AB); Joelle Mosso (JM); Tom Chapman (TC); Harriet Behar (HB)
Absent: Michelle Arsenault (MA); A-dae Briones (ARB)
Staff: Devon Pattillo (DP), Lisa Brines (LB)

Work Agenda

Petitioned Substances

Substance	National List §	Contact	TR rqst?	Notes*	Scheduled, Discussed, Voted	Meeting
Sodium dodecylbenzene sulfonate (SDBS) Petition Addendum #1, SDBS (PDF)	205.605(b)	SR	Y	Petition sent to HS on 11 02 15. Response/request for TR due 01 04 16. Petition found suff 12 01 15. No new TR will be requested. Referred back to HS at Apr 2016 NOSB meeting. TR request sent 05 18 16. TR in development - Expected late Dec 2016/early Jan. TR delayed until Spring 2017. TR sent to HS 05 30 17. Response due 08 01 17. Petition addendum sent to HS 07 12 17. The HS found the petition addendum suff 08 01 17	Aug 1, Aug 15 Jan 2	Spr 2018
Sodium Chlorite for the generation of chlorine dioxide gas Petition, Addendum	205.605	SR	Y	Petition for chlorine dioxide dry gas sent to HS on 12 02 15. Response/request for TR due 02 02 16. HS sent request 03 17 16 for additional info from petitioner. Sodium chlorite addendum received 05 05 16. Suff due 07 05 16. Petition found sufficient 06 07 16. Sent back to Subcomm at Fall 2016 meeting. HS requested a TR 06 06 17.	May 16, Jun 6, Jan 16	Spr 2018
Silver Dihydrogen Citrate Petition Addendum #1	205.605(b)	JM	Y	Petition sent to HS 01 24 17. Response/request for TR due 03 28 17. Petition found sufficient 03 07 17. HS requested TR 03 07 14. TR in development. Petition addendum sent to HS 08 03 17. TR sent to HS 10 19 17/ Suff due 12 19 17. HS sent additional questions to TR contractor 12 05 17	Mar 7, Dec 5	Spr 2018

Petitioned Substances						
Substance	National List §	Contact	TR rqst?	Notes*	Scheduled, Discussed, Voted	Meeting
Japones pepper	205.606	ARB	N	Petition sent to HS 02 09 17. Response/request for TR due 04 11 17. Petition found suff 04 04 17. No TR. HS requested additional info from petitioner 07 19 17 & 11 07 19	Apr 4, Jul 18 Oct 3 Nov 7	Spr 2018
Ethiopian pepper	205.606	ARB	N	Petition sent to HS 02 09 17. Response/request for TR due 04 11 17. Petition found suff 04 04 17. No TR. HS requested additional info from petitioner 07 19 17 & 11 07 19	Apr 4 Jul 18 Oct 3 Nov 7	Spr 2018
Tamarind Seed Gum Petition Addendum, August 22, 2017	205.606	SE		Petition sent to HS 02 15 17. Response/request for TR due 04 17 17. HS requested additional info from the petitioner 04 04 17. Petition addendum Rcvd 08 10 17. Response due 10 10 17. Updated petition addendum rcvd 08 22 17. TR requested 10 03 17. TR in contracting.	Apr 4 Sep 5, Oct 3 Feb 20	Spr 2018/Fall 2018

2020 Sunsets TR Requests: July 2017, Summary: Spr 2018, Review: Fall 2018						
Name	National List §	Contact	TAP/TR	Notes	Scheduled, Discussed	Review Meeting
Calcium carbonate	205.605(a)	SR	Y	1995 TAP. TR requested 07 28 17. Low priority	Feb 20	Summary: Spr 2018 Review: Fall 2018
Flavors	205.605(a)	TC	N	2005 TR	Jan 2	"
Gellan Gum	205.605(a)	JM	N	2006 TAP	Feb 20	"
Oxygen	205.605(a)	LD	N	1995 TAP. TR requested 07 28 17. Low priority	Dec 5	"
Potassium chloride	205.605(a)	AS	N	1995 TAP; 2015 TR for Nutrient vitamins and minerals	Dec 5	"
Alginates	205.605(b)	SE	N	1995 TAP; 2015 TR	Dec 19	"
Calcium hydroxide	205.605(b)	AS	N	1995 TAP. TR requested 07 28 17. Low priority	Dec 5	"

Ethylene	205.605(b)	AB	N	1995 TAP; 1999 TAP - Processing. TR requested 07 28 17. Contingent on request from other Subcomms	Dec 19, Jan 2	"
Glycerides: mono and di	205.605(b)	LD	N	1995 TAP; 2015 TR	Dec 5	"
Magnesium stearate	205.605(b)	AB	Y	1995 TAP. TR requested 07 28 17. Low priority	Feb 20	"
Phosphoric acid	205.605(b)	AS	N	2003 TAP. TR requested 07 28 17. Contingent on request from other Subcomms	Dec 5	"
Potassium carbonate	205.605(b)	SR	N	1995 TAP. TR requested 07 28 17. Low priority.	Feb 6	"
Sulfur dioxide	205.605(b)	SE	N	1995 TAP; 2011 TR	Dec 19	"
Xanthan gum	205.605(b)	JM	N	1995 TAP; 2016 TR	Feb 20	"
Fructooligosaccharides (FOS)	205.606	TC	N	2006 TAP; 2015 TR	Jan 2	"
Gums: Arabic, Carob bean, Guar, Locust bean	205.606(k)	JM	Y	1995 TAP. TR requested 07 28 17. TR in contracting.	Feb 20	"
Lecithin - de-oiled	205.606	AB	N	1995 TAP; 2009 TR	Jan 16	"
Tragacanth gum	205.606	JM	Y	None. TR requested 07 28 17. TR in contracting.	Feb 20	"

Other projects			
Name	**Contact**	**Notes***	**Meeting**
Packaging substances used in organic food handling - including BPA	LD/AB	Submitted briefing paper to NOP 01 12 14. Response memo from NOP sent to HS 11 19 14. TR in development, expected mid-Sep - delayed. TR received 9/30/16. In review by the program. TR sent to HS 10 19 16. TR sufficiency due 12 20 16. TR found insufficient 12 20 16. Vote: 02 21 17. New TR in development. Expected July 2017, TR received 07 10 17. Response due 09 08 17. TR found sufficient 08 01 17.	Discussion doc Spr 2018
Nutrient Vitamins and Minerals - annotation change	TC	Pending NOP Approval. Approved 01 12 16. Proposal. On hold.	Spr 2018
Marine materials (marine algae and extracts). Proposal	SR	Pending NOP approval. NOP approved request 01 12 16. TR request sent to NOP 02 05 16. TR expected Jul 2016. TR sent to HS 08 10 16. TR suff due 10 11 16. TR found sufficient 09 06 16. Voted 09 06 16. Proposal in development 12 06 16. Voted 01 17 17. Referred back to HS at Spr 2017 NOSB meeting	TBD

Magnesium chloride Reclassification 205.605(b)	LD	HS requested addition of this item and NOP approved 01 12 16; TR completed 11/30/16.	Spr 2018
Research Priorities	TC/ALL	RPs due to MS Aug 2018	Fall 2018

*Highlight indicates committee action needed. *Highlight indicates review completion and/or vote

Agenda

- Approve December 19, 2017 notes
- SDBS (SR) - Discuss proposal
- 2020 sunset: Ethylene (AB) - Discuss review
- Sodium Chlorite for the generation of chlorine dioxide gas (SR) - discuss proposal
- Magnesium chloride reclassification (LD) – Discuss
- Sunset 2020: Flavors (TC) – Discuss review
- Sunset 2020: FOS (TC) – Discuss review
- Other items
- Adjourn

Discussion

- **HS Notes from** December 19, 2017, were approved with no changes
- **SDBS Petition (SR).** The lead noted that additional background information has been added to the proposal to summarize the petition review activities since receipt of the petition in 2015. The lead added more information on the manufacturing process and noted that the substance is not rinsed following fruit/vegetable wash. The lead discussed synthetic and nonsynthetic alternatives and other ingredients that may be found in formulated SDBS products. Members discussed, generally, how to assess whether petitioned sanitizers are essential for organic use. A member noted that other regulatory bodies have more expertise and authority to assess risks vs. benefits, and members discussed NOSB's role in the process. Members discussed factors that may affect an organic handler's selection of a particular substance and members discussed comments received on SDBS. Members also discussed potential advantages and the efficacy of the substance. The lead will update the proposal to match the newer proposal format and members will vote on the next call.
- **2020 sunset: Ethylene (AB).** The lead discussed the use of ethylene for post-harvest ripening of tropical fruit and de-greening of citrus. A member asked about the allowance of ethylene under international organic standards, and the lead agreed to add that information to the document, along with other template information.
- **Sodium Chlorite for the generation of chlorine dioxide gas (SR).** Postponed to the next call
- **Magnesium chloride reclassification (LD).** Postponed to the next call
- **Sunset 2020: Flavors (TC).** The lead summarized the listing for flavors. The lead noted that the NOSB passed a recommendation to require a search for organic flavors since the last Sunset review but that no action had been taken by NOP on this recommendation. This listing is being reviewed early to distribute the sunset workload.
- **Sunset 2020: FOS (TC).** The lead summarized the substance, uses, and alternatives. A member noted that inulin (a longer chain polymer) is available in organic form but that organic FOS is not commercially available in organic form.
- **Other Items.** None
- **The meeting was adjourned**

Previous HS Notes

Future Call Schedule (1st and 3rd Tuesdays 1:00 ET)

December 19, 2017
- Petitions for 205.606 Ingredients
- Magnesium chloride reclassification (LD) – Discuss
- 2020 sunset: Alginates (SE) - Discuss review
- 2020 sunset: Sulfur dioxide (SE) - Discuss review
- 2020 sunset: Ethylene (AB) - Discuss review

January 2, 2018
- SDBS (SR) - Discuss proposal
- 2020 sunset: Ethylene (AB) - Discuss review
- 2020 sunset: Flavors (TC) - Discuss review
- 2020 sunset: Fructooligosaccharides (FOS) (TC) - Discuss review

January 16, 2018
- SDBS (SR) – Vote
- Sodium Chlorite for the generation of chlorine dioxide gas (SR) - discuss proposal
- 2020 sunset: Lecithin - de-oiled (AB) - Discuss review

February 6, 2018
- BPA (AB) - Discuss
- Marine Materials (SR) - Discuss proposal
- 2020 sunset: Potassium carbonate (SR) - Discuss review
- Magnesium chloride reclassification (LD) – Discuss

February 20, 2018
- Tamarind seed gum (SE) - TR sufficiency (if available)
- 2020 sunset: Calcium carbonate (SR) - Discuss review
- 2020 sunset: Gellan Gum (JM) - Discuss review
- 2020 sunset: Gums: Arabic, Carob bean, Guar, Locust bean (JM) - Discuss review
- 2020 sunset: Tragacanth gum (JM) - Discuss review
- 2020 sunset: Xanthan gum (JM) - Discuss review
- 2020 sunset: Magnesium stearate (AB) - Discuss review

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
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Work agendas finalized on ES call (last call before fall meeting)	Apr 13, 2018
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National Organic Standards Board (NOSB)
Compliance, Accreditation & Certification Subcommittee (CACS) Notes draft
Tuesday January 9, 2018, 3:00 pm ET

Attending: Scott Rice (SR), Chair; Harriet Behar (HB); Lisa de Lima (LD); A-dae Romero-Briones (ARB); Ashley Swaffar (AS)
Absent: Emily Oakley (EO), vice chair; Tom Chapman (TC)
Staff: Jenny Tucker (JT); Devon Pattillo (DP); Michelle Arsenault (MA)

Work Agenda

Project	Contact	Status	Discussion, Vote	Meeting
Inspector qualifications proposal	SR	Approved for addition to work agenda 04 21 16. Referred back to CACS at Spr 2017 meeting	Dec 12, Jan 9	Spr 2018
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production. Proposal	HB	Approved for addition to work agenda 07 15 16. Verbal update Fall 2016. DD Spr 2017. Proposal Fall 2017. Referred back to CACS at Fall 2017 meeting	Nov 28	Spr 2018
Imports	ALL	Memo sent to NOSB 08 10 17.	Nov 28, Jan 9	Spr 2018

***Discussed** ***Voted**

Agenda

- Approve notes from December 12, 2017
- Imports (All)
- Inspector Qualifications (SR)
- Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)
- Other items
- Adjourn

Discussion

- **Notes from** December 12, 2017 were approved with no changes
- **Imports (JT).** Imports continues to be a high priority for the NOP. In preparation for the imports panel at the Spring 2018 NOSB meeting, the NOP sent a proposed timeline to the CACS for associated tasks, and the group reviewed it. The NOP asked for feedback from the group about high level goals for the panel to help guide the solicitation of volunteers via the certifier community. The CACS members suggested the following: those that have experience with organic imports, certifiers, brokers, and industry members; folks that could identify weaknesses and solutions or gaps in existing resources for certifiers. A member suggested short-term

solutions on oversight. The group discussed a wide array of topics they felt could be useful, including data solutions/data reporting, inventory systems to track yields, and residue and/or GMO testing. JT will synthesize this information to deliver to certifiers, to solicit potential panelists. The NOP also asked the NOSB members to suggest potential panelists, so it is a collaborative effort. Likely they will invite four (4) people. As per the timeline, the NOP would like to seat the panel by mid-to-late March. The NOP encouraged the CACS members to connect any projects they are currently working on to imports. For example, the inspector qualifications proposal. The CACS feels this project is a piece of the larger project on imports, and will work to reframe it.

- **Inspector Qualifications (SR). The lead emphasized that this topic is i**mportant to organic integrity, and while there has been a lot of work done in this area already, by such organizations as the Accredited Certifiers Association (ACA) and International Organic Inspectors Association (IOIA), there are areas where the CACS can contribute. As noted above, the NOP suggested the CACS connect this project to the imports project. The group discussed potential areas on which to focus, such as scale of operations and scope, improvements in best practices for inspectors, better evaluation tools, and remedial training. A member noted that one challenge is the lack of enough qualified inspectors. The lead will work on reframing this to tie it to integrity and imports. The CACS is unsure whether to develop another discussion document at this time.
- **Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)**. The lead asked for feedback on the draft document she circulated, ideally before the next CACS call.
- **Other items.**
- **The meeting was adjourned**

Previous CACS Notes

Future Call Schedule (2nd Tuesday 3:00 ET)

December 26, 2017- cancelled
Imports discussion (ALL)
Inspector qualifications (SR)
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)
January 9, 2018
Imports discussion (ALL)
Inspector qualifications (SR)
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)
January 23, 2018 - additional call
Imports discussion (ALL)
Inspector qualifications (SR)
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)
January 30, 2018 - additional call
Imports discussion (ALL)
Inspector qualifications (SR)
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)
February 13, 2018
February 27, 2018 - additional call
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
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Spring 2018 NOSB meeting – Tucson, AZ	Apr 25-27, 2018

Elemental Sulfur

Crops

Identification of Petitioned Substance

Chemical Names:
Sulfur

Other Name:
Sulphur
Elemental sulfur
Sulfur flowers
Brimstone
Bensulfoids

Trade Names:
N/A

CAS Numbers:
7704-34-9

Other Codes:
EC-No. 231-722-6
Index-No. 016-094-00-1

Summary of Petitioned Use

Elemental sulfur is currently listed on the National List of Allowed and Prohibited Substances as a synthetic substance allowed for use in organic crop production for the following categories:

For uses as an insecticide, including acaricides or mite control. (7 Code of Federal Regulations (CFR) 205.601 (e)(5))

For plant disease control. (7 CFR 205.601(i)(10))

As plant or soil amendments. (7 CFR 205.601(j)(2))

Characterization of Petitioned Substance

Composition of the Substance:

Sulfur is a nonmetallic element of group 16 in the periodic table. Sulfur occurs in several allotropes, physical forms, which possess different chemical properties (e.g., solubility, relative density, crystalline form, etc.) (Steudel 1982).

Source or Origin of the Substance:

Sulfur is one of few elements found in its elemental form in nature, typically in limestone/gypsum formations and limestone/anhydrite formations associated with salt domes, or in volcanic rock (d'Aquin 2007). Elemental sulfur—in nearly pure form, extracted from salt domes—has been obsolete since the late 20th century. Current sulfur production is a side product of other industrial processes, such as oil refining. In these processes, sulfur often occurs as undesired or detrimental compounds, mainly hydrogen sulfide. Hydrogen sulfide is converted into elemental sulfur by the Claus process (Eow 2002).

Properties of the Substance:

Physical and chemical properties of the substance are summarized in Table 1.

Table 1: Physical and Chemical Properties of Sulfur (Lide 2003).

Property	Value
Chemical formula	S
Molar mass	32.06 g/mol

Appearance	Light yellow flakes, crystals, or powder
Solubility, water	insoluble
Melting point	120 °C
Density	2.1 g/cm^3

Sulfur forms polyatomic molecules with different chemical formulas; the best-known allotrope is octasulfur, cyclo-S_8 (Rettig 1987). Octasulfur is a soft, bright-yellow solid that is odorless and sublimes easily (Earnshaw 1997). At elevated temperatures below its melting temperature, cyclo-octasulfur changes from α-octasulfur to the β-polymorph. The structure of the S_8 ring is virtually unchanged by this phase change, which affects the intermolecular interactions. Between its melting and boiling temperatures, octasulfur changes its allotrope again, turning from β-octasulfur to γ-sulfur, accompanied by a lower density but increased viscosity due to the formation of polymers. At higher temperatures, the viscosity decreases as depolymerization occurs. Molten sulfur assumes a dark red color above 200 °C. All stable allotropes of sulfur are excellent electrical insulators.

Sulfur burns with a blue flame with formation of sulfur dioxide, which has a suffocating and irritating odor. Sulfur is insoluble in water but soluble in nonpolar organic solvents, such as carbon disulfide and benzene. Sulfur reacts with nearly all other elements with the exception of gold, platinum, iridium, nitrogen, tellurium, iodine, and the noble gases. Some of those reactions need elevated temperatures (Earnshaw 1997).

Specific Uses of the Substance:

Elemental sulfur is a commonly used pesticide on many American and European farms. It is approved for use on both conventional and organic crops to help control fungus and other pests. It is also used as a soil amendment by using the strong acidifying effect to replace sodium with calcium on high pH alkali spots.

Approved Legal Uses of the Substance:

Elemental sulfur is currently listed on the National List of Allowed and Prohibited Substances as a synthetic substance allowed for use in organic crop production for the following categories:

For uses as an insecticide, including acaricides or mite control. (7 Code of Federal Regulations (CFR) 205.601 (e)(5))

For plant disease control. (7 CFR 205.601(i)(10))

As plant or soil amendments. (7 CFR 205.601(j)(2))

Sulfur is listed as a stabilizer for food use. (40 CFR 180.930)

Sulfur is currently registered for use under the U.S. Environmental Protection Agency's (EPA) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3 as an insecticide and fungicide on a wide range of field and greenhouse-grown food and feed crops, livestock (and livestock quarters), and indoor and outdoor residential sites. Use sites include tree fruit, berries, vegetables, root crops, field crops, pets (dogs), ornamentals, and turf (including residential lawns and golf courses). Sulfur is also one of the active ingredients in four fumigant (gas-producing) cartridge products which are used for rodent control on lawns, golf courses, and in gardens.

Action of the Substance:

Sulfur kills fungi on contact (Turner 2015). The way sulfur works is not completely understood. Some researchers believe sulfur may react with plants or fungi to produce a toxic agent (McCallan 1949).

However, the main theory is that sulfur enters fungi cells and affects cell respiration (Williams 2004). Sulfur can kill insects if they touch it or eat it (NOP 2017). It disrupts their normal body function, altering their ability to produce energy (Sparks 1996).

As a fertilizer, sulfur is readily converted to sulfate (SO_4^{2-}) by autotrophic bacteria for plant uptake. As a soil amendment, sulfur's natural conversion to sulfate in the form of sulfuric acid can be used to lower the pH of alkaline soil to a range of 5.5 to 7.0 that is more suitable for plant growth.

Combinations of the Substance:

Elemental sulfur is not effective unless finely ground sulfur is formed into granules or flakes using additives that bind the small particles together and disintegrate rapidly after soil application. Binding agents include sodium bentonite, sodium sulfate, calcium sulfate (gypsum), and calcium lignosulfate, or combinations of these agents. These flaked materials will contain about 90% sulfur. Finely ground or molten sulfur can be added to anhydrous ammonia or to dry fertilizer during manufacturing. Also, finely ground sulfur can be added to suspension fertilizers.

The common dry fertilizers of this type are ammonium sulfate, gypsum, single superphosphate, and potassium sulfate; the liquid fertilizers are ammonium thiosulfate, ammonium bisulfate, and ammonium polysulfate (Nehb 2005). Sulfur can also be added to some non-sulfur fertilizers (in combination with phosphate rock, sulfur-coated urea, and potassium chloride). Sulfur–bentonite is a new type of fertilizer, typically 10% bentonite and 90% sulfur. The bentonite swells in contact with water, and the sulfur particles disintegrate to particles of varying size, which secures the availability of sulfur to the plant over a long time period (Nehb 2005).

Status

Historic Use:

Sulfur has been known and used as a pesticide since very early times and has been registered for pesticidal use in the United States since the 1920s (EPA 1991). Sulfur plays an important role in agriculture production, both as a fertilizer for supporting plant nutrition and as a natural pesticide. The crop yield in sulfur-deficient areas can be improved by application of sulfur-containing fertilizers. Sulfur is—after nitrogen, phosphorus, and potassium—the fourth major plant nutrient, and is essential for crop growth. Its vital role is to form the amino acids methionine, cystine, and cysteine—which are crucial to the formation of proteins. Sulfur reduces the quantity of nonprotein nitrogen and nitrate; it is also necessary for the formation of chlorophyll, enzymes, and vitamins (Nehb 2005).

Fine elemental sulfur has been used traditionally as a fungicide. Because of the development of highly effective organic fungicides, this use of elemental sulfur is declining. Sulfur—generally applied by spraying—has the advantage of not being consumed by the plant; residues are washed off by rain and act as a nutrient in the soil.

Organic Foods Production Act, USDA Final Rule:

Under the Organic Foods Production Act, elemental sulfur falls under the category of "copper and sulfur compounds". Exemption for sulfur in organic production and handling operations is due to sulfur's classification by the EPA as a minimal risk inert ingredient on their List of Inert Pesticide Ingredients (List 4A) and an exemption from a requirement of a tolerance per 40 CFR 180.1236.

Elemental sulfur is currently listed on the National List of Allowed and Prohibited Substances as a synthetic substance allowed for use in organic crop production for the following categories:

For uses as an insecticide, including acaricides or mite control. (7 Code of Federal Regulations (CFR) 205.601 (e)(5))

For plant disease control. (7 CFR 205.601(i)(10))

As plant or soil amendments. (7 CFR 205.601(j)(2))

International

The Canadian General Standards Board (CGSB) includes non-synthetic elemental sulfur as a permitted substance for organic production systems under CAN/CGSB-32.311-2015 for use as a soil amendment where more buffered sources of sulfur are not appropriate, and as a foliar application. Chemically synthesized substances cannot be added, and chemical treatment is prohibited. The CGSB also permits the use of sulfur for the control of external parasites and sulfur smoke bombs in conjunction with other methods used for rodent control when a full pest control program is maintained but temporarily overwhelmed.

The Codex Alimentarius Commission's "Guidelines for the Production, Processing, Labelling, and Marketing of Organically Produced Foods" (GL 32-1999) lists elemental sulfur as an allowed substance for pest and disease control.

The European Economic Community (EEC) Council Regulation, authorized under Regulation (EEC) No 2092/91 and carried over by Article 16(3)(c) of Regulation (EC) No 834/2007, permits the use of sulfur as a fungicide, acaricide, and repellent in organic food production.

The Japan Agricultural Standard (JAS) for Organic Production (Notification No. 1605 of 2005) permits the use of sulfur as a fertilizer or soil improvement substance, and as a substance for plant pest and disease control.

The International Federation of Organic Agriculture Movement's (IFOAM) Norms for Organic Production and Processing lists sulfur as an approved substance for pest and disease control, for use as fertilizer/soil conditioner, and for use as a crop protectant and growth regulator.

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?

The petitioned substance, elemental sulfur, contains sulfur as an active ingredient that falls under the aforementioned category of "copper and sulfur compounds". Sulfur is classified by the EPA on their List of Inert Pesticide Ingredients (List 4A), as a minimal risk inert ingredient. Sulfur is also a substance exempt from a requirement of a tolerance per 40 CFR 180.1236.

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)).

World resources of sulfur have been estimated at 25×10^9 tons: 4.0% as elemental sulfur; 4.1% in sulfide ores; 83.6% in coal; 3.0% in crude oil; and 5.3% in natural gas (Nehb 2005). Elemental sulfur and sulfur containing ores are found in the upper layers of the Earth's crust and are either of sedimentary or volcanic origin, but ore bodies worthy of large-scale exploitation are restricted to only a few regions. Depending on the geology of the deposit, sulfur ore is excavated by traditional open-pit or underground mining operations. Elemental sulfur can be extracted from sulfur ores by various processes (e.g., flotation, autoclaving, filtration, melting out, etc.). The nature of the deposit and economics dictate the applied extraction process. Deposits of elemental sulfur are directly reclaimed by direct infusion with hot water, known as the Frasch process (Nehb 2005).

The only economic method for extraction of elemental sulfur from natural deposits is the Frasch process. However, technical and economic considerations limit its use to the Gulf region of the United States and Mexican sulfur fields. The process consists of injecting large quantities of hot water directly into the deposit, and then pumping the molten sulfur to the surface (Nehb 2005). By a method akin to that used by the oil industry, a well is drilled through the cap layers and the sulfur-bearing layers at a depth of ca. 50 – 800 m. Three coaxial pipes are introduced into the borehole. The outermost pipe, with a typical diameter of ca. 200 mm, reaches to the bottom of the borehole. The middle (sulfur delivery) pipe is somewhat shorter, ending about halfway down the perforated part of the outer pipe. A collar on the end of the middle pipe closes off the annular space between the two pipes. Water at ca. 165 °C, under sufficient pressure to keep it from boiling (2.5 – 3 MPa), is forced down the annular space between the outer and middle tubes and into the deposit. The water penetrates into the cracks, pores, and larger voids of the sulfur-bearing limestone, and heats and melts the sulfur around the end of the pipe. After a reservoir of molten sulfur has been established (which requires heating for 24 hours or longer), the hot water is turned off and the sulfur can flow through the delivery pipe. Hot compressed air at about 3 MPa is injected, and the resulting foam of sulfur and air is very light and easily rises to the surface. Injection of hot water is continued to maintain the melting process. At the surface, the sulfur froth is deaerated and transferred to a heated storage tank, or to a sulfur-forming device, to be solidified as slates, prills, pellets, or pastilles. The extracted sulfur is quite pure (99.7 – 99.8%) and light yellow in color.

The most prevalent source of sulfur today is fossil resources (d'Aquin 2007). Most fossil fuels—natural gas, petroleum, and coal—contain some chemically combined sulfur. In natural gas, it is present mainly as hydrogen sulfide, with only minor proportions of organic sulfur compounds. Petroleum contains a variety of organic compounds, such as thiols, alkyl and aryl sulfides and disulfides, thiophenes, and more complex condensed aromatic heterocyclic sulfur compounds. These are also present in coal, which usually contains a high proportion of inorganic sulfur as the iron sulfides pyrite and marcasite. In both the desulfurization of fuel oil and the conversion of heavy distillate fractions into light products, organic sulfur compounds are converted mainly into hydrogen sulfide.

Because hydrogen sulfide has few industrial uses and is inherently dangerous, once it has been separated from other useful constituents of the gas mixture, it is normally converted into a more useful form of sulfur (e.g., sulfuric acid or elemental sulfur). The product of choice is typically elemental sulfur, which is cheap and easy to transport. The conversion of hydrogen sulfide to elemental sulfur is accomplished via the Claus process, which converts hydrogen sulfide to elemental sulfur in two steps:

$$H_2S + 3/2\ O_2 \rightarrow SO_2 + H_2O \quad (1)$$
$$2\ H_2S + SO_2 \rightarrow 3/x\ S_x + 2\ H_2O \quad (2)$$

The multi-step Claus process produces elemental sulfur from recovered gaseous hydrogen sulfide from natural gas or derived from refining crude oil (Nehb 2005). In the initial thermal step, hydrogen sulfide is heated to temperatures in excess of 850 °C in the presence of dioxygen, which promotes the flame-free total oxidation of hydrogen sulfide to sulfur dioxide. The generated sulfur dioxide then further reacts with hydrogen sulfide to yield gaseous elemental sulfur and water. Approximately 60–70% of the elemental sulfur is collected in this step. The gas stream is transferred to an additional reactor where the Claus reaction continues in a catalytic step using activated aluminum or titanium oxides as catalysts to boost the sulfur yield. More hydrogen sulfide reacts with the sulfur dioxide formed during combustion in the

thermal step. The gas is then cooled in a condenser in which sulfur solidifies for collection. Thus, the catalytic recovery of sulfur consists of three substeps: heating, catalytic reaction, and cooling plus condensation. These three steps are normally repeated a maximum of three times. Depending on the composition of the petroleum or natural gas feedstock, additional processes such as the scrubbing of ammonia or carbon dioxide are required.

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)).

The most prevalent source of elemental sulfur is fossil resources. Elemental sulfur is manufactured from a chemical process (i.e., the Claus Process), by which hydrogen sulfide from natural gas or petroleum refining is converted to elemental sulfur.

Elemental sulfur can be directly harvested from natural deposits (e.g., the Frasch process).

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)).

The element sulfur is a ubiquitous, natural component of the environment. Humans are all exposed to sulfur, since this element is ubiquitous in the environment. Sulfur in its various forms represents about 1.9% of the total weight of the earth. Most terrestrial and aquatic environments contain high levels of sulfur. This ubiquitous substance does not cause unreasonable adverse effects in the environment when used according to approved labeling, and poses little or no hazard to non-target organisms.

In the 1982 Registration Standard by the EPA, all environmental fate data requirements were waived for sulfur based on the fact that it is a natural component of the environment (EPA 1982). The use of elemental sulfur as a pesticide or a soil amendment is not an environmental concern because it becomes incorporated into the natural sulfur cycle. Elemental sulfur is slowly converted to sulfate in soil by the action of autotrophic bacteria. Thus, elemental sulfur leaches into soil as sulfate at a slow rate. About 3-6% of the sulfur (formulation and purity unspecified) applied at 56 kilograms/hectare (kg/ha) leached through lysimeters of loam soil (soil depth unspecified) as a result of 40 inches of rain over a six-month period. After two years, 23-29% of the applied sulfur had leached (EPA 1982).

A 2004 study summarized risk assessments and findings for sulfur in the environment when used as a plant protection agent (Paulsen 2005). Elemental sulfur has low toxicity for mammals, birds, and fish, and high no-observed-effect-concentration (NOEC) values for plants. Soil application of 10 and 100 kg/ha of sulfur lowered N- and C-mineralization. The legislative limit of a level of 75% of the N- and C-mineralization in sulfur-treated soil in comparison to untreated soil after 100 days was reached after 14 and 66 days, respectively. Sulfur is relatively immobile in soils and is leached as sulfate (SO_4^{2-}) after incorporation and oxidation in the soil sulfur cycle. Sulfur is hydrophobic and not water soluble. When reaching surface waters, it is incorporated in the soil after sedimentation. Additional SO_4-loads to water sources from oxidation under aerobic conditions are irrelevant under consideration of natural water contents.

In fact, there is undoubted evidence of sulfur deficiency in soil in some areas of the world (Lucheta 2012). A slight deficiency affects crop yield and quality, while the symptoms of severe deficiency are yellowing of the leaves and dwarfing of the plant. The main reasons for the sulfur deficiency are:

1. Increasing levels of specific agricultural production, with proportional increase of sulfur uptake.
2. Shift in fertilizer practices, from ammonium sulfate and single superphosphate, to multi-nutrient (compound) fertilizers with little or no sulfur.
3. Decrease in the atmospheric sulfur supply, owing to increasing environmental controls on sulfur dioxide emissions.
4. Decline in the usage of sulfur-based herbicides and pesticides.

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)).

Elemental sulfur has low toxicity for mammals, birds, and fish, and high NOEC values for plants. Elemental sulfur, applied as pesticide or soil amendment, will become incorporated into the natural sulfur cycle. The fate of sulfur is dependent on environmental redox conditions. Under aerobic conditions, elemental sulfur is oxidized to sulfate (SO_4^{2-}) via microbial metabolism. The dissipation of sulfate is dependent on leaching and soil organic matter immobilization. Therefore, elemental sulfur should not pose an environmental problem because it dissipates rapidly into the natural environment.

The major environmental concern with elemental sulfur is that upon oxidation it forms sulfuric acid, which can acidify soil or water ecosystems. In soil management systems, elemental sulfur is a common soil amendment used to acidify calcareous soil and increase the sulfur fertility; it is expected to have a similar effect when used as a pesticide. In soil and water management systems, the application of lime (i.e., $CaCO_3$) is recommended to neutralize the acidity generated via sulfur oxidation.

The dissipation of sulfate is dependent upon leaching and inorganic matter immobilization. In acid and near-neutral soils, sulfate can precipitate as gypsum ($CaSO_4 \cdot 2H_2O$). Gypsum can be a persistent mineral in soils formed under semiarid to arid climatic conditions; otherwise, it is not expected to persist as a secondary soil mineral. Sulfate can be adsorbed to aluminum oxides and silicate clays by ligand binding (replacement of hydroxyl, -OH, groups). These soil retention mechanisms (e.g., precipitation and adsorption) cannot prevent SO_4^{2-} leaching. Since sulfate is a ubiquitous species, it should not pose any environmental risk to ground or surface water pollution. In addition, microbes and plants can assimilate SO_4^{2-} with subsequent immobilization into organic compounds (cysteine, cystine, and methionine).

No additional ecological effects data are required for sulfur. Sulfur is not soluble in water, and the available data indicate low order toxicity to aquatic species (EPA 1991). In addition to the fact that sulfur is ubiquitous in nature and chronic exposure is common, the available ecotoxicity data on terrestrial organisms indicate that sulfur is practically nontoxic on an acute basis.

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)).

Since sulfur is a naturally-occurring element that is ubiquitous in the environment, it appears to pose little risk to non-target species. Available acute toxicity studies support this conclusion (EPA 1991). All other ecological toxicity data requirements have been waived. All environmental fate data requirements for sulfur have been waived because sulfur is a naturally occurring element whose behavior in the environment is well-understood and described in published literature.

However, too much sulfur (e.g., from a sulfur storage or manufacturing facility) will cause the pH of the soil to drop as low as pH 2.5 or lower. Sulfuric acid (H_2SO_4) in the soil can generally diffuse in the soil as a sulfate ion leachate, but the introduction of high levels of sulfur can cause the loss of vegetative ground cover and affect a number of insect species (Cárcamo 1998, Lucheta 2012). High sulfur contamination and subsequent acidification has a clear negative effect on earthworms, snails, and several ground beetle species. Among the beetles, ecological specialists are those most vulnerable to acidification, whereas ecological generalists are more resistant (Cárcamo 2001). Earthworms have an important influence on the sulfur turnover in the soil caused by their burrowing, feeding, digestion, and egestion (Grethe 1996).

The EPA's Ecological Incident Information System (EIIS) lists three incidents associated with the use of sulfur, all resulting in damage to terrestrial plants. In one incident, there was reported damage to 127 acres of citrus treated directly with sulfur. The certainty index for this incident was "probable". A second incident report indicated damage to 44 acres of a grape vineyard treated directly with sulfur and trifloxysrobin. The symptoms noted were spotting and speckling. The certainty index for this incident was

"possible" for sulfur and "probable" for trifloxystrobin. In the third reported incident, a tank mixture of sulfur, fenarimol, and oxyfluorfen applied to a 20-acre plot of grapes may have caused burnt leaves and berries. The certainty index for this incident was "unlikely" for sulfur and fenarimol, and "probable" for oxyfluorfen. No ecological incidents have been reported associated with the use of the rodent control, gas-producing cartridge products of sulfur.

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)).

To the best of our knowledge, there are no known reports that suggest any specific chemical interactions between elemental sulfur and other substances used in organic crop or livestock production or handling. Elemental sulfur does react vigorously with chlorates, nitrates, and other oxidizing agents (Nehb 2005).

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)).

Elemental sulfur is generally used for insecticide applications in granular or finely powdered form. Liquids and mixtures are also in use. Small amounts of dusting sulfur or liquids find their way into soils or water, either as part of the manufacturing process, transport, storage, or application. None of these applications is recognized as an environmental problem (EPA 1991). In soils, sulfur is oxidized to sulfuric acid (H_2SO_4) by soil bacteria mostly of the genus *Thiobacillus*. Important factors for the rate of oxidation include 1) the fineness of the sulfur particles, 2) the resident population of *Thiobacillus* spp., 3) soil temperature, and 4) soil moisture content (Germida 1993). Powdered sulfur is readily oxidized. In general, there is very little effect on the vegetation, soil, or the invertebrate population of the soil from small amounts of sulfur dust. As mentioned, too much sulfur will cause the pH of the soil to drop to pH ≤ 2.5. The introduction of high levels of sulfur can cause the loss of vegetative ground cover and affect a number of insect species (Cárcamo 1998, Lucheta 2012). High sulfur contamination and subsequent acidification has a clear negative effect on earthworms, snails, and several ground beetle species (Grethe 1996, Cárcamo 2001).

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)).

Sulfur in its elemental, reduced, or oxidized forms represents approximately 1.9% of the total weight of the earth. The sulfates and sulfides are common in their various mineral forms. Most aquatic and terrestrial environments are high in sulfur (EPA 1991). Also, sulfur has been shown to be non-mutagenic in microorganisms (EPA 1991). There is no evidence that sulfur poses a risk to the environment when used according to good manufacturing practice regulations.

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)).

We are all exposed to sulfur, since this element is ubiquitous in the environment. Sulfur in its various forms represents about 1.9 percent of the total weight of the earth. Most terrestrial and aquatic environments contain high levels of sulfur. All of EPA's toxicology data requirements for sulfur have been satisfied for a number of years (EPA 1991). Sulfur is known to be of low toxicity, and poses very little if any risk to human health. Short-term studies show that sulfur is of very low acute oral toxicity and does not irritate the skin (it has been placed in Toxicity Category IV, the least toxic category, for these effects). Sulfur also is not a skin sensitizer. However, sulfur can cause some eye irritation, dermal toxicity, and inhalation hazards (it has been placed in Toxicity Category III for these effects). Chronic exposure to elemental sulfur at low levels is generally recognized as safe. Epidemiological studies show that mine workers exposed to sulfur dust and sulfur dioxide throughout their lives often had eye and respiratory

disturbances, chronic bronchitis, and chronic sinus effects. However, no known risks of oncogenic, teratogenic, or reproductive effects are associated with the use of sulfur.

People may be exposed to small amounts of sulfur through the food supply. However, since sulfur does not pose any relevant toxic effects, no dietary risk assessment was performed (EPA 1991). Sulfur is generally recognized as safe, as noted in 40 CFR 180.2(a), so no tolerances (or residue limits) need be established for residues of sulfur in or on food or feed commodities. Sulfur is listed as an inert ingredient applied to animals with an exemption from the requirement of a tolerance (40 CFR 180.930). An exemption from the requirement of a tolerance is established for residues of sulfur (40 CFR 180.1236).

People can be exposed to sulfur while mixing, loading, or applying the pesticide, and while working among treated crops. Based on incidents of skin and eye irritation reported among field workers in California, EPA has determined that a hazard exists for workers reentering fields following foliar application of sulfur dust (EPA 1991). Therefore, a 24-hour reentry interval and protective clothing requirement must be added to the labeling of all outdoor use sulfur products.

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)).

We were unable to locate any non-synthetic treatment options found on the National List for use as a fungicide, insecticide, or soil amendment. Alternative non-synthetic treatment substances not found on the National List that may be used in place of elemental sulfur for use as an insecticide or fungicide include the following: D-Limonene, pyrethrins, diatomaceous earth, garlic powder, soap, oils (canola, soy), and neem oil.

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

There are numerous alternative cultural practices that, in combination, could render the use of elemental sulfur unnecessary (Hill 1989, Katan 2000). Because cultural controls are preventative rather than curative, they are dependent on long-range planning and detailed knowledge of the bio-ecology of the crop-pests-natural controls-environment relationships (Hill 1989). Cultural controls do not afford a solution for all disease or pest prevention and control.

Cultural controls employ practices that promote the pest's natural controls and make the environment less attractive to pests and less favorable for their survival, dispersal, growth, and reproduction. The objective is to achieve reduction in pest numbers, either below economic injury levels, or sufficiently to allow natural or biological controls to take effect. Cultural controls include site selection, planting design and management, site maintenance, and harvesting procedures (Hill 1989, Katan 2000).

Cultural controls are dependable, and are usually specific. Of major importance is the fact that they do not possess some of the detrimental side effects of pesticides, namely the creation of resistance to pesticides, undesirable residues in food, feed crops and the environment, and the killing of non-target organisms. Cultural controls are generally the cheapest of all control measures because they usually only require modifications to normal production practices. Sometimes they do not even require extra labor, only careful planning. Often they are the only control measures that are profitable for high acreage of low value crops.

However, cultural controls require careful timing and long-term planning for greatest effectiveness. They are often based on the substitution of knowledge and skills for purchased inputs and, as such, are more demanding on the farmer's competence. Cultural controls may be effective for one pest, but may be ineffective against a closely related species. The effectiveness of cultural controls is difficult to assess, and they do not always provide complete economic control of pests. Also, some cultural controls have adverse effects on fish and wildlife, and may cause erosion problems.

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
- 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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DRAFT

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Sulfur as Slug and Snail Bait

[Jan 15, 2018]

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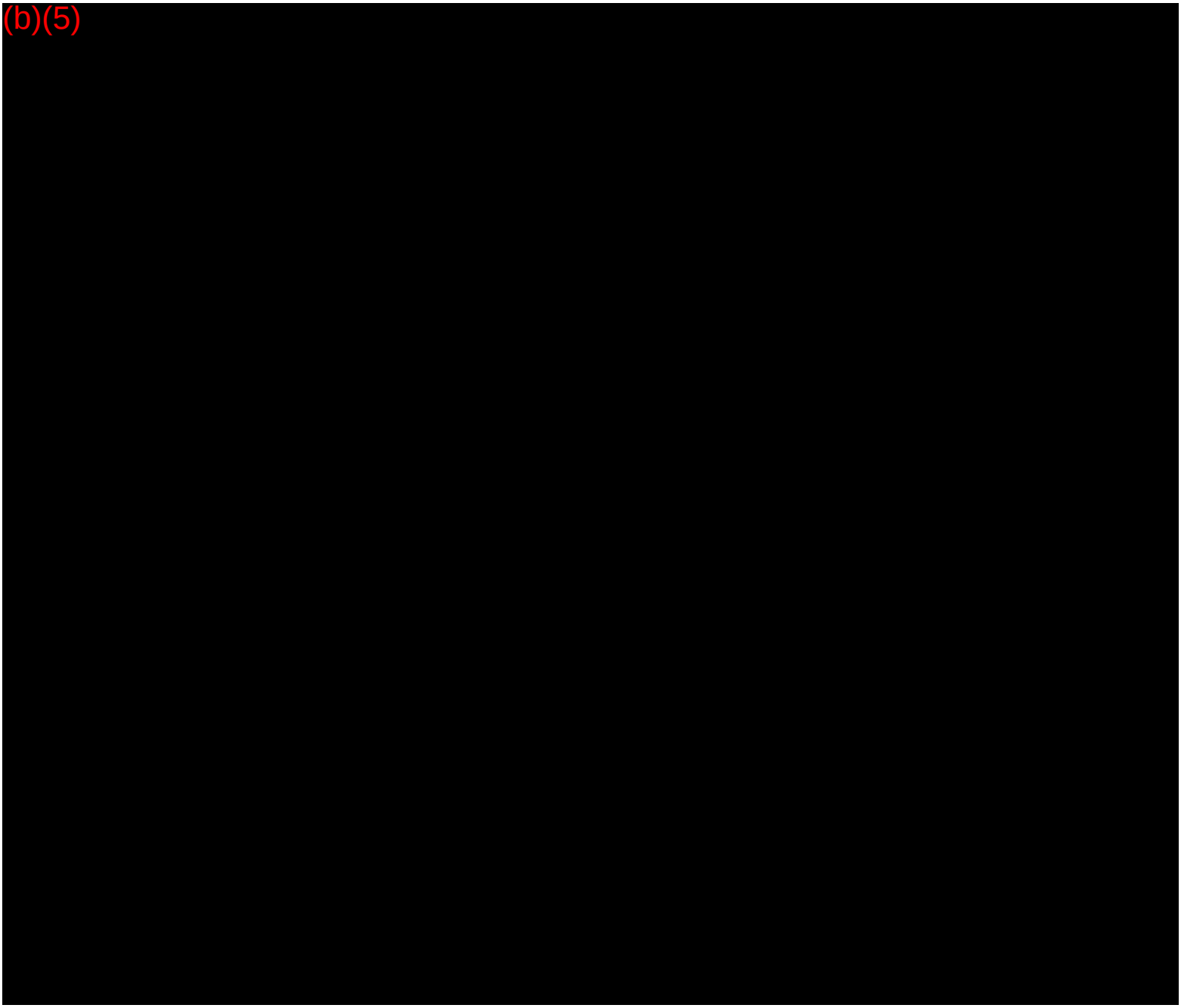
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National Organic Standards Board (NOSB)
Crops Subcommittee (CS) Meeting Notes
Tuesday January 16, 2018 2:00 pm ET draft

Present: Steve Ela, Chair (SE); Asa Bradman (AB); Dave Mortensen (DM); Harriet Behar (HB); Joelle Mosso (JM); Emily Oakley (EO); Sue Baird (SB)
Absent: Jesse Buie (JB); Francis Thicke (FT)
Staff: Devon Pattillo (DP); Michelle Arsenault (MA)

Work Agenda

Petitioned Substances					
Substance	**Con-tact**	**TR request?**	**Notes**	**Discussed, Voted**	**Meeting**
Polyoxin D Zinc salt 205.601	JB	Y	Petition sent to CS 06 16 16. Petition suff/TR request due 08 16 16. Petition found sufficient 08 16 16. Discuss need for Lmt'd scope TR. CS requested Lmt'd scope TR 10 04 16. TR sent to Subcommittee on 12 19 17. Response due 02 20 18.	Feb 6	Spr 2018
Allyl Isothiocyanate (AITC) Petition (2016) 205.601	JB	Y Lmt'd scope	Petition sent to CS 07 06 16. Petition suff/TR request due 09 06 16. Petition found suff 10 04 16. CS requested Lmt'd scope TR 10 04 16. TR in development. . Expected Feb/Mar 2018. • AITC Petition (2013) (PDF) • NOSB Subcommittee Proposal (2014) (PDF) • Technical Evaluation Report (2014) (PDF)	Feb 6	Spr 2018
Sodium Citrate 205.601	HB	Y	Petition sent to CS 07 27 16. Petition suff/TR request due 09 27 16. Petition was found sufficient 10 04 16. CS requested a TR 10 04 16. TR in development. TR - Handling, Citric acid and salts (2015). TR sent to CS 08 07 17. Response due 10 06 17. Found TR insufficient 09 19 17. HS sent additional questions to TR contractor 12 11 17. Revised TR sent to CS 12 20 17. Response due 02 19 18	Sep 19, 2017	Spr 2018
Natamycin	HB	Y	Petition sent to CS 09 09 16. Petition suff/TR request due 11 08 16. Petition found sufficient 11 01 16, and CS requested TR 11 01 16. TR in development. Expected October 2017. TR sent to CS 11 3 17. Response due 01 12 18. TR found sufficient 12 5 17.	Dec 5	Spr 2018

Sulfur (as a molluscicide) 205.601	AB	N	Petition sent to CS 06 08 17. Petition suff/TR request due 09 05 17. Petition found sufficient 09 19 17. No TR request.	Sep 19 Jan 16	Spr 2018
Ammonium Citrate 205.601	EO/DM	Y	Petition sent to CS 10 25 17. Petition suff/TR request due 12 26 17. TR requested 11 21 17.	Nov 21	TBD
Ammonium Glycinate 205.601	EO/DM	Y	Petition sent to CS 10 25 17. Petition suff/TR request due 12 26 17. TR requested 11 21 17.	Nov 21	TBD
Calcium Acetate	SB		Petition sent to CS 1 20 17. Petition suff/TR request due 01 17 17.	Feb 6	TBD

Other Topics

Project	Con-tact	Doc type	Notes*	Discussed/ Voted	Meeting
(Manure treatments) Anaerobic Digestate - Food Waste 205.601(j) and other manure issues	EO/HB/JM	Disc Doc	Petition sent to CS 04 08 15. Questions or request for TR due 06 09 15. Petition found sufficient 06 02 15. TR rqst sent to NOP 10 06 15. Petition withdrawn 10 14 15. CS moved project to "other topics" NOP sent memo to board 05 09 16 requesting review. TR request sent to NOP 07 05 16 (see anaerobic digestate above). Waiting for result of FDA's risk assessment.	Aug 1, Aug 15, 2017	Spr 2018
Biodegradable Biobased Mulch annotation change	HB/AB	Disc Doc	Limited scope TR request sent to NOP 08 02 16. TR sent to CS on 12 28 16. TR Suff due 02 27 17. CS found TR suff 01 03 17. Pending further research	Aug 1, 2017	Spr 2018
Prohibition of NPEs in inerts - annotation change/ EPA List 4 Inerts annotation change	HB/EO/ DM/AB	Disc Doc/Prop	IWG recommended NOSB work on NPEs/TR requested July 2014. DD - April 2016. EPA List 4 inerts disc doc (originated from 2017 sunset review conducted in 2015). Pending EPA decision	TBD	Fall 2018
Marine materials (marine algae and extracts) on the National List	EO	Disc doc	NOP approved request 01 12 16. TR request sent to NOP 02 05 16. TR sent to HS 08 10 16. Returned to CS at Spr 2017 NOSB meeting. Referred back to CS at Spr 2017 meeting	Aug 15, Dec 5	Spr 2018
Field and Greenhouse Container Production	JB, HB, FT and EO	TBD	On hold as per NOP.	Feb 6	Summary of comments Spr 2018

Strengthen and clarify the requirements for use of organic seed (NOP 5029)	HB	Proposal	Originated in MS. Referred back to CS at Spr 2017 meeting. Referred back to CS at Fall 2017 meeting.		Spr 2018
Research Priorities	All	NA	RPs due to MS Aug 2018	NA	Fall 2018

* Yellow highlight indicates Subcommittee action needed *Highlight indicates review completion

2020 Sunsets TR Requests: July 2017, Summary: Spr 2018, Review: Fall 2018						
Substance		**Contact**	**TR request?**	**Notes**	**Scheduled, Discussed**	**Meeting**
Alcohols: Ethanol Isopropanol	205.601(a)(1)(i), 205.601(a)(1)(ii)	JB	N	1995 TAP; 2014 TR - Ethanol; 2014 TR - Isopropanol	Feb 6	Summary: Spr 2018 Review: Fall 2018
Sodium carbonate peroxyhydrate	205.601(a)	EO	N	2006 TAP; 2014 TR	Dec 5	"
Newspaper or other recycled paper	205.601(b) and (c)	HB	N	2017 TR	Dec 5	"
Plastic mulch and covers	205.601(b)	HB	N	1995 TAP: TR for biodegradable mulch. Low priority	Dec 19, Jan 2	"
Aqueous potassium silicate	205.601(e), 205.601(i)	DM	N	2014 TR	Jan 2, Feb 6	"
Elemental sulfur	205.601(e)(5), 205.601(i)(10), 205.601(j)(2)	AB	Y	1995 TAP; 2017 TR for Livestock. TR requested 07 28 17. In contracting. TR sent to CS 01 10 18. TR sufficiency due 03 12 18	Dec 19, Jan 2 Feb 6	"
Lime sulfur	205.601(e)(6), 205.601(i)(6)	SE	N	2014 TR	Dec 19	"
Sucrose octanoate esters	205.601(e)(10)	SB	N	2005 TR	Dec 19	"
Hydrated lime	205.601(i)(4)	DM	N	1995 TAP; 2001 TAP; 2002 TR for Calcium Hydroxide	Jan 2	"
Liquid fish products	205.601(j)	AB	N	1995 TAP; 2006 TR	Jan 16	"
Sulfurous Acid	205.601(j)	SE	N	2010 TAP; 2014 TR	Dec 19	"

Ethylene	205.601(k)	EO	N	2000 Supplemental TAP; 2007 TAP; 2011 Supplemental TR	Dec 19	"
Microcrystalline cheesewax	205.601(o)	SB	Y	None. TR requested 07 28 17. In contracting. TR sent to CS 01 11 18. TR sufficiency due 03 13 18.	Dec 19	"
Potassium chloride	205.602(e)	JM	N	1995 TAP. Low priority	Jan 16	"

Agenda

- Approve notes from January 2 call.
- Calcium Acetate (SB) - petition sufficiency/TR request
- Polyoxin D Zinc salt (JB) - TR sufficiency
- Sulfur (as a molluscicide) (AB) - Discuss proposal.
- 2020 sunset: Hydrated Lime(DM) - Discuss review
- 2020 sunset: Liquid fish products (AB) - Discuss review
- 2020 sunset: Alcohols: Ethanol Isopropanol (JB) - Discuss review
- 2020 sunset: Potassium chloride (JM) - Discuss review
- Discussion of future options for hydroponics/container proposals
- Adjourn

Discussion

- **Notes from January 2, 2018** were approved with no changes.
- **Calcium Acetate (SB).** The discussion was deferred to the next call. A member asked a question regarding the petition, clarifying that the petition is not for blended products and is only for calcium acetate.
- **Polyoxin D Zinc salt (JB) - TR sufficiency.** Deferred to next call.
- **Sulfur (as a molluscicide) (AB).** The lead summarized the use of the material, noting that the toxicology of how it actually kills molluscs is not identified in the petition. The CS found the petition sufficient and the CS did not request a new TR as there are several other TRs available. The lead noted that because this petition is for pelletized sulfur, and therefore does not have human health issues that other forms of sulfur would. As for alternatives, there are manual and cultural methods. On balance the material is compliant with OFPA.

  Sulfur is classified as synthetic

  Motion to add sulfur as petitioned at §205.601(h)
  Motion by: AB
  Seconded by: DM
  Additional discussion: None
  Yes: 7 No: 0 Abstain: 0 Absent: 2 Recuse: 0

- **2020 sunset: Hydrated Lime (DM).** The lead indicated that the last TR was comprehensive. Hydrated lime is used as a foliar application for plant disease suppression in fruit and vegetable crops. The Subcommittee will forward the document for submission to the NOP.
- **2020 sunset: Liquid fish products (AB).** The lead summarized the uses and production of liquid fish products, which are used as fertilizers and nutrients. There is a 1995 TAP and a 2006 TR. The group discussed human health issues, pH, and sustainability. The NOP suggested adding a reference in the review to the recent squid byproduct recommendation, which will be published tomorrow in the Federal Register as part of a proposed rule.
- **2020 sunset: Alcohols: Ethanol Isopropanol (JB**). Deferred to next call.
- **2020 sunset: Potassium chloride (JM).** The lead summarized the use and manufacture of the material, based on information from the TR and the previous reviews. The lead noted that there were no concerning issues regarding this material. A member suggested the addition of a question about necessity and alternatives.
- **Discussion of future options for container proposals.** Deferred to next call.
- **The meeting was adjourned**

Previous CS Notes

Future Call Schedule (1st and 3rd Tuesdays 2:00 ET)

January 2, 2018
- 2020 sunset: Plastic mulch and covers (HB) - Review/vote on proposal
- 2020 sunset: Aqueous potassium silicate (DM) - Discuss review (postponed from Dec 19th call)
- 2020 sunset: Hydrated lime (DM) - Discuss review (postponed from Dec 19th call)
- 2020 sunset: Elemental sulfur (AB) - Discuss review

January 16, 2018
- Calcium Acetate (SB) - petition sufficiency/TR request
- Polyoxin D Zinc salt (JB) - TR sufficiency
- Sulfur (as a molluscicide) (AB) - Discuss proposal.
- 2020 sunset: Hydrated Lime (DM) - Discuss review
- 2020 sunset: Liquid fish products (AB) - Discuss review
- 2020 sunset: Alcohols: Ethanol Isopropanol (JB) - Discuss review
- 2020 sunset: Potassium chloride (JM) - Discuss review
- Discussion of future options for container proposals

February 6, 2018
- 2020 sunset: Alcohols: Ethanol Isopropanol (JB) - Discuss review
- Polyoxin D Zinc salt (JB) - TR sufficiency
- 2020 sunset: Aqueous potassium silicate (DM) - Discuss review
- Calcium Acetate (SB) - petition sufficiency/TR request
- 2020 sunset: Microcrystalline cheesewax (SB) - TR sufficiency
- 2020 sunset: Elemental sulfur TR sufficiency (AB)
- Discussion of future options for container proposals (HB)

February 20, 2018

March 6, 2018
- Allyl Isothiocyanate (AITC) - TR sufficiency (JB)

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

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)
Handling Subcommittee (HS) Meeting Notes draft
Tuesday, January 16, 2018 1:00 pm ET

Present: Scott Rice, Vice Chair (SR); Steve Ela (SE); Asa Bradman (AB); Joelle Mosso (JM); A-dae Briones (ARB); Harriet Behar (HB) - observer
Absent: Lisa de Lima (LD), Chair; Tom Chapman (TC)
Staff: Devon Pattillo (DP); Michelle Arsenault (MA)

Work Agenda

Petitioned Substances						
Substance	**National List §**	**Contact**	**TR rqst?**	**Notes***	**Scheduled, Discussed, Voted**	**Meeting**
Sodium dodecylbenzene sulfonate (SDBS) Petition Addendum #1_SDBS (PDF)	205.605(b)	SR	Y	Petition sent to HS on 11 02 15. Response/request for TR due 01 04 16. Petition found suff 12 01 15. No new TR will be requested. Referred back to HS at Apr 2016 NOSB meeting. TR request sent 05 18 16. TR in development - Expected late Dec 2016/early Jan. TR delayed until Spring 2017. TR sent to HS 05 30 17. Response due 08 01 17. Petition addendum sent to HS 07 12 17. The HS found the petition addendum suff 08 01 17	Aug 1, Aug 15 Jan 2 Jan 16	Spr 2018
Sodium Chlorite for the generation of chlorine dioxide gas Petition, Addendum	205.605	SR	Y	Petition for chlorine dioxide dry gas sent to HS on 12 02 15. Response/request for TR due 02 02 16. HS sent request 03 17 16 for additional info from petitioner. Sodium chlorite addendum received 05 05 16. Suff due 07 05 16. Petition found sufficient 06 07 16. Sent back to Subcomm at Fall 2016 meeting. HS requested a TR 06 06 17. TR sent to HS 01 09 18. Response due 03 13 18.	May 16, Jun 6, Jan 16 Feb 6	Spr 2018

Petitioned Substances						
Substance	**National List §**	**Contact**	**TR rqst?**	**Notes***	**Scheduled, Discussed, Voted**	**Meeting**
Silver Dihydrogen Citrate Petition Addendum #1	205.605(b)	JM	Y	Petition sent to HS 01 24 17. Response/request for TR due 03 28 17. Petition found sufficient 03 07 17. HS requested TR 03 07 14. TR in development. Petition addendum sent to HS 08 03 17. TR sent to HS 10 19 17/ Suff due 12 19 17. HS sent additional questions to TR contractor 12 05 17	Mar 7, Dec 5	Spr 2018
Japones pepper	205.606	ARB	N	Petition sent to HS 02 09 17. Response/request for TR due 04 11 17. Petition found suff 04 04 17. No TR. HS requested additional info from petitioner 07 19 17 & 11 07 19	Apr 4, Jul 18 Oct 3 Nov 7	Spr 2018
Ethiopian pepper	205.606	ARB	N	Petition sent to HS 02 09 17. Response/request for TR due 04 11 17. Petition found suff 04 04 17. No TR. HS requested additional info from petitioner 07 19 17 & 11 07 19	Apr 4 Jul 18 Oct 3 Nov 7	Spr 2018
Tamarind Seed Gum Petition Addendum August 22, 2017	205.606	SE		Petition sent to HS 02 15 17. Response/request for TR due 04 17 17. HS requested additional info from the petitioner 04 04 17. Petition addendum Rcvd 08 10 17. Response due 10 10 17. Updated petition addendum rcvd 08 22 17. TR requested 10 03 17. TR in contracting.	Apr 4 Sep 5, Oct 3 Feb 20	Spr 2018/Fall 2018

2020 Sunsets TR Requests: July 2017, Summary: Spr 2018, Review: Fall 2018						
Name	**National List §**	**Contact**	**TAP/TR**	**Notes**	**Scheduled, Discussed**	**Review Meeting**
Calcium carbonate	205.605(a)	SR	Y	1995 TAP. TR requested 07 28 17. Low priority	Feb 20	Summary: Spr 2018 Review: Fall 2018
Flavors	205.605(a)	TC	N	2005 TR	Jan 2	"

Gellan Gum	205.605(a)	JM	N	2006 TAP	Feb 20	"
Oxygen	205.605(a)	LD	N	1995 TAP. TR requested 07 28 17. Low priority	Dec 5	"
Potassium chloride	205.605(a)	AS	N	1995 TAP; 2015 TR for Nutrient vitamins and minerals	Dec 5	"
Alginates	205.605(b)	SE	N	1995 TAP; 2015 TR	Dec 19	"
Calcium hydroxide	205.605(b)	AS	N	1995 TAP. TR requested 07 28 17. Low priority	Dec 5	"
Ethylene	205.605(b)	AB	N	1995 TAP; 1999 TAP - Processing. TR requested 07 28 17. Contingent on request from other Subcomms	Dec 19, Jan 2	"
Glycerides: mono and di	205.605(b)	LD	N	1995 TAP; 2015 TR	Dec 5	"
Magnesium stearate	205.605(b)	AB	Y	1995 TAP. TR requested 07 28 17. Low priority	Feb 20	"
Phosphoric acid	205.605(b)	AS	N	2003 TAP. TR requested 07 28 17. Contingent on request from other Subcomms	Dec 5	"
Potassium carbonate	205.605(b)	SR	N	1995 TAP. TR requested 07 28 17. Low priority.	Feb 6	"
Sulfur dioxide	205.605(b)	SE	N	1995 TAP; 2011 TR	Dec 19	"
Xanthan gum	205.605(b)	JM	N	1995 TAP; 2016 TR	Feb 20	"
Fructooligosaccharides (FOS)	205.606	TC	N	2006 TAP; 2015 TR	Jan 2	"
Gums: Arabic, Carob bean, Guar, Locust bean	205.606(k)	JM	Y	1995 TAP. TR requested 07 28 17. TR in contracting.	Feb 20	"
Lecithin - de-oiled	205.606	ARB	N	1995 TAP; 2009 TR	Jan 16	"
Tragacanth gum	205.606	JM	Y	None. TR requested 07 28 17. TR in contracting.	Feb 20	"

Other projects

Name	Contact	Notes*	Meeting
Packaging substances used in organic food handling - including BPA	LD/AB	Submitted briefing paper to NOP 01 12 14. Response memo from NOP sent to HS 11 19 14. TR in development, expected mid-Sep - delayed. TR received 9/30/16. In review by the program. TR sent to HS 10 19 16. TR sufficiency due 12 20 16. TR found insufficient 12 20 16. Vote: 02 21 17. New TR in development. Expected July	Discussion doc Spr 2018

		2017, TR received 07 10 17. Response due 09 08 17. TR found sufficient 08 01 17.	
Nutrient Vitamins and Minerals - annotation change	TC	Pending NOP Approval. Approved 01 12 16. Proposal. On hold.	Spr 2018
Marine materials (marine algae and extracts). Proposal	SR	Pending NOP approval. NOP approved request 01 12 16. TR request sent to NOP 02 05 16. TR expected Jul 2016. TR sent to HS 08 10 16. TR suff due 10 11 16. TR found sufficient 09 06 16. Voted 09 06 16. Proposal in development 12 06 16. Voted 01 17 17. Referred back to HS at Spr 2017 NOSB meeting	TBD
Magnesium chloride Reclassification 205.605(b)	LD	HS requested addition of this item and NOP approved 01 12 16; TR completed 11/30/16.	Spr 2018
Research Priorities	TC/ALL	RPs due to MS Aug 2018	Fall 2018

*Highlight indicates committee action needed. *Highlight indicates review completion and/or vote

Agenda

- Approve January 2, 2018 notes
- SDBS (SR) - Discuss/vote
- Sodium Chlorite for the generation of chlorine dioxide gas (SR) - TR sufficiency
- 2020 sunset: Lecithin - de-oiled (AB) - Discuss review
- Other items
- Adjourn

Discussion

- **HS Notes from** January 2, 2018 were approved with no changes.
- **SDBS (SR).** The lead reformatted the review after the last call, using the updated form. The group discussed various sections of the document, including impacts on human health and potential impurities, such as lead and arsenic. The Subcommittee determined that SDBS is not essential, as there are alternatives available. A member raised a concern about the essentiality criteria with regard to sanitizers, given that food safety and sanitizers fall under the purview of several other agencies, such as FDA.

  Motion to classify sodium dodecylbenzene sulfonate (SDBS) as petitioned as synthetic/non agricultural
  Motion by: SR
  Seconded by: ARB
  Additional discussion: none
  Yes: 5 No: 0 Abstain: 0 Absent: 2 Recuse: 0

  Motion to add Sodium dodecylbenzene sulfonate (SDBS) as petitioned at §205.605(b)
  Motion by: JM
  Seconded by: SE
  Additional discussion: None
  Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

- **Sodium Chlorite for the generation of chlorine dioxide gas (SR).** The TR was sent to the Handling Subcommittee on January 9, and members discussed it briefly. The group discussed the human health issues around chlorine gas, as well as alternatives. The group will continue to discuss this substance and determine TR sufficiency on the next call.
- **2020 sunset: Lecithin - de-oiled (AB).** The lead summarized the use of the material and the previous reviews. She made the distinction between forms of lecithin, noting that this review is for the de-oiled, dry form only. She noted there was very little information about manufacturing processes. The lead encouraged the group to reread the last review, as the NOSB vote was split.
- **Other Items. none**
- **The meeting was adjourned**

Commented [AM-A1]: ?

[Previous HS Notes]

Future Call Schedule (1st and 3rd Tuesdays 1:00 ET)

January 2, 2018
- SDBS (SR) - Discuss proposal
- 2020 sunset: Ethylene (AB) - Discuss review
- 2020 sunset: Flavors (TC) - Discuss review
- 2020 sunset: Fructooligosaccharides (FOS) (TC) - Discuss review

January 16, 2018
- SDBS (SR) - Discuss/vote
- Sodium Chlorite for the generation of chlorine dioxide gas (SR) - TR sufficiency
- 2020 sunset: Lecithin - de-oiled (AB) - Discuss review

February 6, 2018
- BPA (AB) - Discuss
- Marine Materials (SR) - Discuss proposal
- 2020 sunset: Potassium carbonate (SR) - Discuss review
- Magnesium chloride reclassification (LD) - Discuss
- Sodium Chlorite for the generation of chlorine dioxide gas (SR) - TR sufficiency, discuss draft proposal

February 20, 2018
- Tamarind seed gum (SE) - TR sufficiency (if available)
- 2020 sunset: Calcium carbonate (SR) - Discuss review
- 2020 sunset: Gellan Gum (JM) - Discuss review
- 2020 sunset: Gums: Arabic, Carob bean, Guar, Locust bean (JM) - Discuss review
- 2020 sunset: Tragacanth gum (JM) - Discuss review
- 2020 sunset: Xanthan gum (JM) - Discuss review
- 2020 sunset: Magnesium stearate (AB) - Discuss review

March 6, 2018
March 20, 2018
April 3, 2018
April 17, 2018
May 1, 2018
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June 19, 2018
July 3, 2018
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Spring 2018 NOSB meeting – Tucson, AZ	Apr 25-27, 2018

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Sodium Dodecylbenzene Sulfonate

January 16, 2018

Summary of Petition https://www.ams.usda.gov/sites/default/files/media/SDBS%20Petition.pdf:
Sodium dodecylbenzene sulfonate (SDBS) is petitioned by Ecolab, Inc. for addition to the National List at §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))", (b) Synthetics Allowed. SDBS is one of two active ingredients (the second is lactic acid) in an antimicrobial formulation for use in treating fruits and vegetables in the premises of organic food retail establishments. The Ecolab, Inc. branded formulated antimicrobial material is labeled as Antimicrobial Fruit & Vegetable Treatment (AFVT). AFVT is used in food retail environments such as restaurants, cafeterias, food service operations, commissaries and kitchens. The petitioner states their product would help to provide the organic users a new reliable antimicrobial.

AFVT is used via a sink-mounted dispensing system, which controls the concentration released into wash water. The proposed use is on raw and processed fruits and vegetables and involves a minimum 90 second immersion in the antimicrobial wash water, followed by a draining stage prior to further processing and/or serving. When used at suggested label rates, the concentration of SDBS is 76-111 ppm. SDBS remains on the produce at produce species dependent levels up to 10 ppm.

SDBS is currently approved for use as an antimicrobial agent in produce wash water by the Food and Drug Administration (FDA) under 21CFR 173.405. It is not listed on FDA's Generally Recognized as Safe (GRAS) List. SDBS has been reviewed by the Environmental Protection Agency's (EPA) Safer Choice Program and is included in the Safe Chemical Ingredients List (SCIL).

SDBS is an anionic surfactant used in industrial, institutional and chemical detergents & cleaners, specialty cleaners, sanitization products, emulsifiers, suspension or wetting agents, absorbents in pesticide and other agricultural chemicals, along with numerous other uses (TOXNET – Toxicology Data Network, 2014).

Summary of Review:
On October 13, 2015 the NOP received a petition from Ecolab, Inc. to add SDBS (CAS #25155-30-0) to the National List at §205.605. The petition was forwarded to the Handling Subcommittee on November 2, 2015 for review. At the time of initial review on December 1, 2015, the Handling Subcommittee deemed the petition sufficient and did not request a technical review (TR).

A proposal was brought to the 2016 Spring NOSB meeting and included several questions for the public to better inform the Board's deliberation:

1. What are retailers currently using to address food safety concerns?
2. Are any of the alternatives mentioned in the petition currently used at the retail level and if so are they effective in addressing these areas of food safety concerns?
3. What are the level (if any) of impurities as mentioned in this (2016) document found in SDBS?

Public comment in advance of and during the Spring meeting did not sufficiently address the above questions. Several comments, including from the petitioner, generally supported the addition of SDBS to

the National List. One commenter noted while SDBS has advantages over other antimicrobials, they believe the NOSB should first conduct a thorough review of all antimicrobials and available products and favor those with fewer health impacts on workers and consumers. Several commenters noted the need for more data regarding potential harm to human health and the environment. Several commenters noted the availability of several alternative, already allowed antimicrobials and felt SDBS did not meet the essentiality criteria of OFPA. One commenter requested a TR be provided any time an antimicrobial material is petitioned.

Based on the comments received and its determination more data was necessary to make a decision, the Board voted to refer the proposal back to the Handling Subcommittee. On May 18, 2016, the Handling Subcommittee requested a TR be commissioned to review SDBS. On May 30, 2017, the Program provided the TR to the Subcommittee, which deemed it sufficient on August 1, 2017. During its August 1, 2017 meeting, the Subcommittee also reviewed and found sufficient a petition addendum submitted by the petitioner.

The TR provided additional information on the manufacture of SDBS, alternatives to its use, and potential impact on human health and the environment. The petition addendum and comments from the petitioner submitted during the Spring 2017 public comment period also address these points. See below for further discussion on these criteria.

Allowance under other Organic Standards

- **Canadian General Standards Board Permitted Substances List**
  SDBS is not listed in the CAN/CGSB-32.311-2015 — Organic production systems - Permitted substances lists.
- **CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)**
  SDBS is not listed in Codex Alimentarius GL 32-1999.
- **European Economic Community (EEC)** Council Regulation, EC No. 834/2007 and 889/2008
  SDBS is not listed in EC No. 834/2007 or 889/2008.
- **Japan Agricultural Standard (JAS) for Organic Production**
  SDBS is not listed in the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) standards for organic production.
- **International Federation of Organic Agriculture Movements (IFOAM)** –
  SDBS is not listed in the IFOAM norms for organic production.

Category 1: Classification

1. Substance is for: _____ Livestock ___X___ Handling

2. For HANDLING and LIVESTOCK use:
   a. Is the substance _____ **Agricultural** or ___X___ **Non-Agricultural**
   Describe reasoning for this decision using NOP 5033-2 as a guide:

   SDBS is not a mineral or bacterial culture, is not a microorganism or enzyme, and is not a crop or livestock product nor derived from crops or livestock. There is no agricultural source or feedstock for the production of SDBS.

b. If the substance is **Non-agricultural**, is the substance _____ **Non-synthetic** or ___X___ **Synthetic**
Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide:

SDBS is not manufactured, produced or extracted from a natural source. It has undergone a chemical change so that it is chemically/structurally different than its source material. The chemical change is not created by a naturally occurring biological process, or by heating or burning biological matter.

The petitioner does not manufacture SDBS, but uses it as 1 of 2 active ingredients in their formulated product AFVT. The petition lists 3 manufacturers of SDBS:

1. Pilot Chemical Company – Santa Fe Springs, CA
2. Stepan Company – Northfield, IL
3. Unger Fabrikker A.S. – Fredrikstad, Norway

SDBS is manufactured from linear alkylbenzenesulfonate (LAS) produced from linear alkylbenzene (LAB). SDBS is the sodium salt of LAS. The manufacturing process determines SDBS's composition and specific application performance level.

SDBS manufacture is based on a chemical synthesis production scheme from petroleum feedstocks: dehydrogenation, alkylation and sulfonation with potentially halogenated intermediates. There is no natural process for producing SDBS. SDBS is produced from kerosene or paraffin, and benzene from crude oil feedstocks. Sulfonation requires the use of sulfuric acids or burning elemental sulfur also from fossil fuel feedstocks. There is no agricultural source or feedstock for the production of SDBS.

Current manufacturing practice for LAS requires chemical catalysis which depending on the specific catalyst used can produce environmental pollution and equipment corrosion. The use of homogeneous zeolite catalysis can reduce much of the pollution associated with current catalytic methods, but the zeolite method is still in the developmental stages and there is still much work ahead in improving the manufacturing process (Aitani et al., 2014).

SDBS contains impurities that include neutral oil (unsulfonated materials), arsenic (As), iron (Fe), and lead (Pb). One of the questions posed to the public during the review of the first proposal requested information regarding the level of impurities in SDBS. The TR notes commercially prepared SDBS is usually greater than 96% pure. In the petition addendum, the petitioner states the SDBS used in their product is 91% pure. SDBS in the form and purity used in produce wash water does not normally contain toxic levels of the heavy metals or contaminants listed by the FDA in its list of chemical contaminants, metals, natural toxins and pesticide guidance documents and regulations, e.g. aflatoxins, acrylamides, dioxins, PCBs, melamine or radionuclides.

3. For LIVESTOCK: What OFPA category is it considered?
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; (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?

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)]

   SDBS is an ingredient in a formulated product for use as an antimicrobial in the preparation and processing of raw fruit and vegetables. Used as directed, there is little potential for detrimental chemical interactions with other materials.

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)]

   Mode of Action
   SDBS acts as a surfactant that disrupts bacterial membranes, subsequently changing their structure, attachability and permeability. It denatures some bacterial proteins and inactivates some bacterial enzymes on the bacterial outer membrane involved in ionic transport.

   Studies of the efficacy of various commercial detergent formulations in reducing human pathogens on inoculated fruits and vegetables and comparisons with other treatments have been reported for apples, strawberries, cantaloupe, tomatoes, and lettuce. Results from these studies indicate that detergent washes sometimes can achieve bacterial population reductions of 100 to 1000 fold, equaling or surpassing sodium hypochlorite, but in other cases showed no greater efficacy than water (Sapers, 2014). For example, a 0.2% (200 ppm) solution of SDBS had the same efficacy as a water wash in reducing Escherichia coli O157:H7 bacterial load on romaine lettuce (Keskinen 144 and Annous, 2011).

   Other studies show that SDBS can be used in combination with phosphoric acid to reduce Escherichia coli O157:H7 on apples (Wright et al., 2000). Treatments with phosphoric acid and SDBS have an antimicrobial effect reducing bacterial populations by 10 to 100 fold (Sapers et al., 2001). Phosphoric acid is allowed in organic production for use as an equipment cleaner, cleaning of food contact surfaces only and to adjust the pH of liquid fish fertilizer [7 CFR §205.605(b), (j)(7)].

   Effect on the Environment
   The process of manufacture may determine the degree of negative impact on the environment, with alternative methods aimed at improving the manufacturing process. After use, surfactants are mainly discharged into sewage treatment systems and dispersed into the environment as effluent discharge into surface waters and sludge disposal on agricultural land (Ying, 2006). LAS, the progenitor of SDBS, is not acutely toxic to organisms at environmental concentrations. Concentrations of LAS found in municipal wastewater treatment systems is 1-10 mg/L (Manousaki et al., 2004). Aquatic chronic toxicity of surfactants occurs at concentrations usually greater than 0.1 mg/L (Ying, 2006).

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

The TR notes the preferred method for disposal of sewage sludge is as a soil fertilizer and so it is important to consider that LAS is slow to biodegrade under anaerobic conditions where oxygen is limited. Biodegrability may be improved through the use of low frequency ultrasound. However, several government public safety evaluators have concluded that LAS does not represent an environmental problem (HERA, 2013; OECD, 2005; EPA, 2006).

4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].

   The TR provides references to studies of LAS exposure, noting LAS is readily absorbed from the gastrointestinal tract. However, the TR also notes most of the absorbed dose is eliminated in the urine. Further, at the concentrations used, LAS is not a sensitizer or an irritant and is not carcinogenic. Exposure to concentrations of LAS higher than label use has shown to be an irritant to the skin and eyes.

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)]

   See information in question 3.

6. Are there any adverse impacts on biodiversity? (§205.200)

   See information in question 2. For further data, refer to the TR, lines 308-329.

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)]

   Preventive practices are an essential aspect of organic production. As noted in the TR, keeping fresh produce free of soil and reducing the potential for bacterial contamination of produce during pre and postharvest is a FDA requirement. The addition of SDBS to produce wash water aids in the removal of bacteria from produce surfaces, however it is easier to prevent contamination than to remove it later (Sapers, 2003).

   Aside from preventive practices during the pre and postharvest stages, there are a number of synthetic and non-synthetic materials available for use as an alternative to SDBS. Electrolyzed water, sodium and calcium hypochlorite and peroxyacetic acid are synthetic alternatives. Non-synthetic alternatives include organic acids (ascorbic acid, citric acid, lactic acid, lactates, tartaric acid, malic acid and organic vinegar (acetic acid)); essential oils such as cinnamon, rosemary, oregano and others; grapefruit seed extract; and egg white lysosome. Each has been shown to reduce microbial levels of Listeria monocytogenes, Salmonella typhimurium, Escherichia coli O157:H7, Shigella dysenteria, Bacillus cereus and Staphylococcus aureus.

   In the petition addendum, the petitioner includes some drawbacks to these alternatives. For peracetic acids, these products are less suitable or manageable in retail and foodservice settings: concerns for worker exposure, impractically large quantities in which they are sold, short storage life. For chlorine dioxide and ozone, the material must be generated onsite, there are concerns regarding worker exposure and use is limited to trained employees. For chlorine, sodium hypochlorite is easy

to use, inexpensive and convenient. However, both the petitioner and TR note the corrosive properties of chlorine solutions as having the potential to shorten the life of stainless steel equipment used in produce processing.

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)]

Category 4: Additional criteria for synthetic substances used in Handling (does not apply to nonsynthetic or agricultural substances used in organic handling)**.**

Describe how the petitioned substance meets or fails to meet each numbered criterion.

(1) The substance cannot be produced from a natural source and there are no organic substitutes; (§205.600(b)(1))

SDBS cannot be manufactured from a natural source. Its manufacture is based on a chemical synthesis production scheme from petroleum feedstocks: dehydrogenation, alkylation and sulfonation with potentially halogenated intermediates. There is no natural process for producing SDBS.

Non-synthetic alternatives/substitutes include organic acids. See Category 3, question 1 above.

(2) The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling; (§205.600(b)(2))

As noted above, SDBS's adverse effects can be minimized in the manner in which it is manufactured and the method of its disposal.

(3) The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations; (§205.600(b)(3)

SDBS is introduced into wash water service to improve the removal of soil and bacteria attached to the surface of produce. If used according to the FDA instructions it does not penetrate into the produce being washed and subsequently its application does not affect the nutritional quality of the food (Sapers, 2014). Adverse effect on health is addressed in Category 2, question 4, above.

(4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law; (§205.600(b)(4))

SDBS is added to fresh produce wash-water as an aid in the removal of surface bacteria. Except for residual SDBS remaining on the produce at produce species dependent levels up to 10 ppm, SDBS does not contribute to the flavor, color, texture or nutritive value of the product (Watanabe et al., 1972).

(5) The substance is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no

residues of heavy metals or other contaminants in excess of tolerances set by FDA; (§205.600(b)(5))

SDBS is included in the FDA Food Additive Status list. It is a substance that has a miscellaneous technical effect and is a food additive for which a petition has been filed and a regulation issued. It is specified in this list for < 0.2% in wash water as a surface active agent in commercial detergents used in washing fruits & vegetables, or to assist in lye peeling these products, 21 CFR 173.315. However, SDBS is not GRAS. SDBS has been reviewed by the Environmental Protection Agency's (EPA) Safer Choice Program and is included in the Safe Chemical Ingredients List (SCIL).

(6) The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6))

SDBS is not essential. There are alternatives available. See Category 3, question 1, above.

(7) In balancing the responses to the criteria in Category 4, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, Compatibility with Organic Production and Handling, April 2004)

The subcommittee notes the availability of allowed synthetic and natural alternatives to this substance. However, the subcommittee also recognizes the importance of having the ability to rotate among several materials in an antimicrobial regime to reduce the incidence of microbial resistance. In the absence of significant public comment advocating for the addition of SDBS to the National List and the availability of alternatives, the subcommittee does not see it as essential to organic production.

Classification Motion:

Motion to classify sodium dodecylbenzene sulfonate as petitioned as nonagricultural, synthetic.
Motion by: Harold V. Austin IV
Seconded by: Ashley Swaffar
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

National List Motion:

Motion to add sodium dodecylbenzene sulfonate as petitioned at 205.605.
Motion by:
Seconded by:
Yes: 0 No: 0 Abstain: 0 Absent: 0 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)
Compliance, Accreditation & Certification Subcommittee (CACS) Notes
Tuesday January 23, 2018, 3:00 pm ET

Attending: Scott Rice (SR), Chair; Emily Oakley (EO), vice chair; Harriet Behar (HB); Lisa de Lima (LD); A-dae Romero-Briones (ARB); Ashley Swaffar (AS)
Absent: Tom Chapman (TC)
Staff: Jenny Tucker (JT); Michelle Arsenault (MA)

Work Agenda

Project	Contact	Status	Discussion, Vote	Meeting
Inspector qualifications proposal	SR	Approved for addition to work agenda 04 21 16. Referred back to CACS at Spr 2017 meeting	Dec 12, Jan 9, Jan 23	Spr 2018
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production proposal	HB	Approved for addition to work agenda 07 15 16. Verbal update Fall 2016. DD Spr 2017. Proposal Fall 2017. Referred back to CACS at Fall 2017 meeting	Nov 28, Jan 23	Spr 2018
Imports	ALL	Memo sent to NOSB 08 10 17.	Nov 28, Jan 9, Jan 23	Spr 2018

***Discussed** ***Voted**

Agenda

- Approve notes from January 9, 2018
- Imports (All)
- Inspector Qualifications (SR)
- Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)
- Other items
- Adjourn

Discussion

- **Notes from** January 9, 2018 were approved with no changes.
- **Imports (All).** The NOP shared a timeline for panel preparation prior to the last call. Members provided some feedback and the group discussed such things as enforcement ability. One goal for the panel is to determine what industry and certifiers are currently doing, and where they see gaps that could be addressed. The NOP asked that the Board members provide suggestions for possible panelists. Several members noted that there are many conferences and in-person

opportunities in the coming weeks to convey this information to the community. The NOP will send the invitation letter to the NOSB for use at conferences.

- **Inspector Qualifications (SR).** The lead is drafting a document and will share it with the group on the next call. The primary challenge is focusing the scope of a very large topic. Members discussed the issue of scale, a potential licensing system for inspectors which would create more uniform standards, and perhaps subcategories for inspectors. For example, a member noted that she is certified as a livestock inspector although she is not necessarily knowledgeable about dairy operations. The group discussed whether they will produce a proposal or discussion document, and will determine what will have the most impact on integrity. The CACS Chair will send out a draft document before the next call. Several members offered assistance in drafting the document.
- **Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB).** The lead reviewed comments from the Fall 2017 NOSB meeting proposal, and proposed some language for the next iteration of the document. This could include ways to document ecosystems, both national and international, guidance about how to find this information, and a list of questions that could be put in an Organic System Plan. The group also discussed the placement of this guidance within OFPA and the regulation.
- **Other items.** None
- **The meeting was adjourned**

Previous CACS Notes

Future Call Schedule (2nd Tuesday 3:00 ET)

January 9, 2018

(b)(5) [redacted]

January 23, 2018 - additional call
Imports discussion (ALL)
Inspector qualifications (SR)
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)

January 30, 2018 - additional call
Imports discussion (ALL)
Inspector qualifications (SR)
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)

February 13, 2018
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)

February 27, 2018 - additional call
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

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)
Compliance, Accreditation & Certification Subcommittee (CACS) Notes
Tuesday January 30, 2018, 3:00 pm ET

Attending: Scott Rice (SR), Chair; Emily Oakley (EO), Vice Chair; Harriet Behar (HB); Tom Chapman (TC); Ashley Swaffar (AS); Lisa de Lima (LD); Dave Mortensen (DM) - observer
Absent: A-dae Romero-Briones (ARB)
Staff: Michelle Arsenault (MA)

Work Agenda

Project	Contact	Status	Discussion, Vote	Meeting
Inspector qualifications proposal	SR	Approved for addition to work agenda 04 21 16. Referred back to CACS at Spr 2017 meeting	Dec 12, Jan 9, Jan 23	Spr 2018
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production proposal	HB	Approved for addition to work agenda 07 15 16. Verbal update Fall 2016. DD Spr 2017. Proposal Fall 2017. Referred back to CACS at Fall 2017 meeting	Nov 28, Jan 23	TBD
Import Oversight	ALL	Memo sent to NOSB 08 10 17.	Nov 28, Jan 9, Jan 23	Spr 2018

***Discussed** ***Voted**

Agenda

- Approve notes from January 23, 2018
- Imports (All)
- Inspector Qualifications (SR)
- Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)
- Other items
- Adjourn

Discussion

- **Notes from** January 23, 2018, (sent on January 12) were approved with no changes.
- **Imports (All).** The CACS Chair shared information about the panel at the recent EcoFarm conference, and noted that there was a lot of interest from stakeholders. The NOSB Chair will reach out to NOP about the status of the invitations for prospective panelists.
- **Inspector Qualifications (SR).** Several members and the NOP provided feedback on the draft proposal, and the group discussed it. The lead will make modifications to the document and recirculate it for discussion on the next CACS call.

- **Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB).** The document is nearly complete and the members would like to discuss this on the next call in the event that it will go forward to the Spring meeting.
- **Other items.** None.
- **The meeting was adjourned**

[Previous CACS Notes]

Future Call Schedule (2nd Tuesday 3:00 ET)

January 23, 2018 - additional call
- Imports discussion (ALL)
- Inspector qualifications (SR)
- Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)

January 30, 2018 - additional call
- Imports discussion (ALL)
- Inspector qualifications (SR)
- Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)

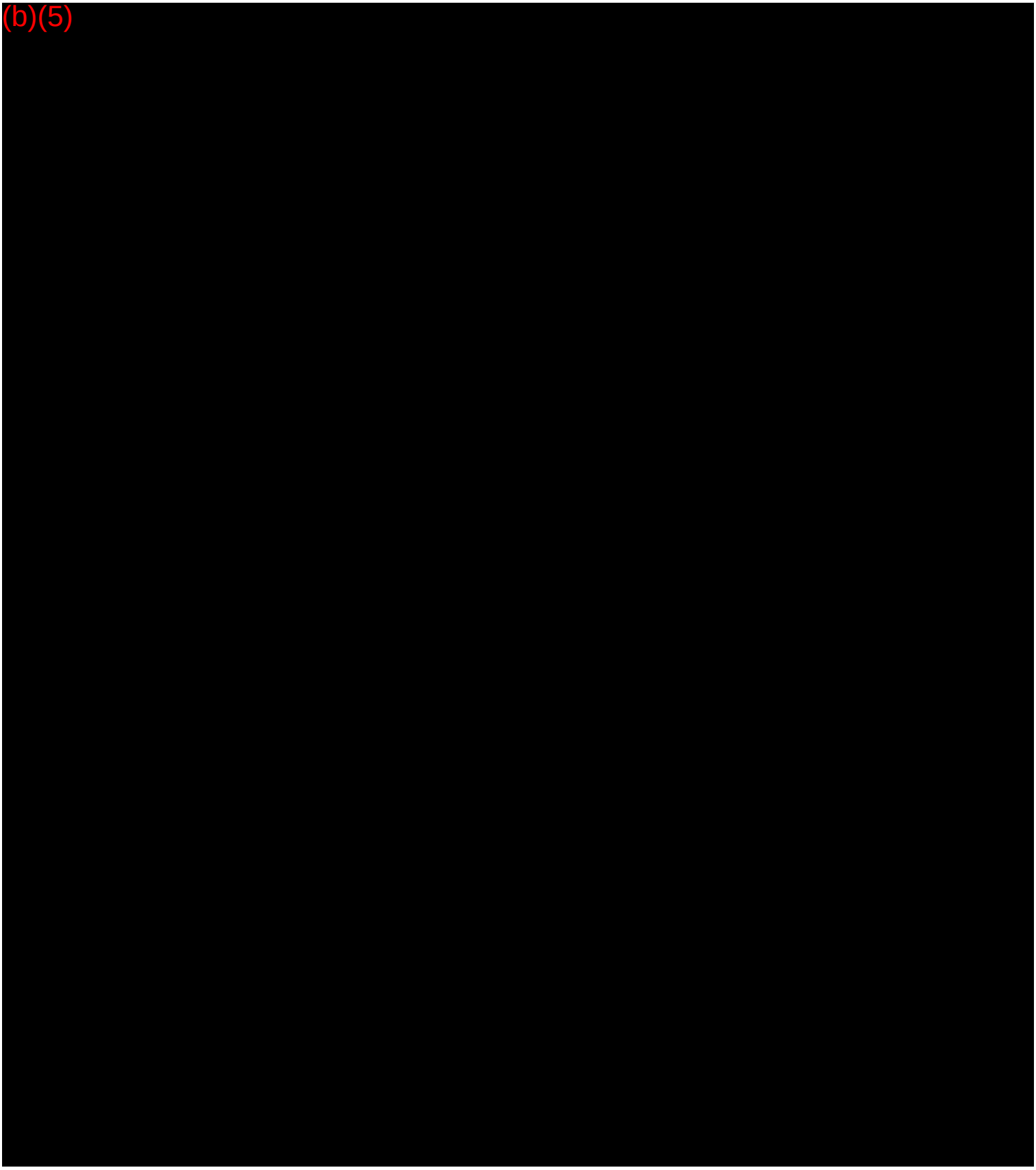
February 13, 2018
- Inspector qualifications (SR)
- Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)

February 27, 2018 - additional call
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

National Organic Standards Board
Compliance, Accreditation and Certification Subcommittee
Inspector Qualifications
February XX, 2011~~087~~



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Compliance, Accreditation and Certification Subcommittee
Inspector Qualifications
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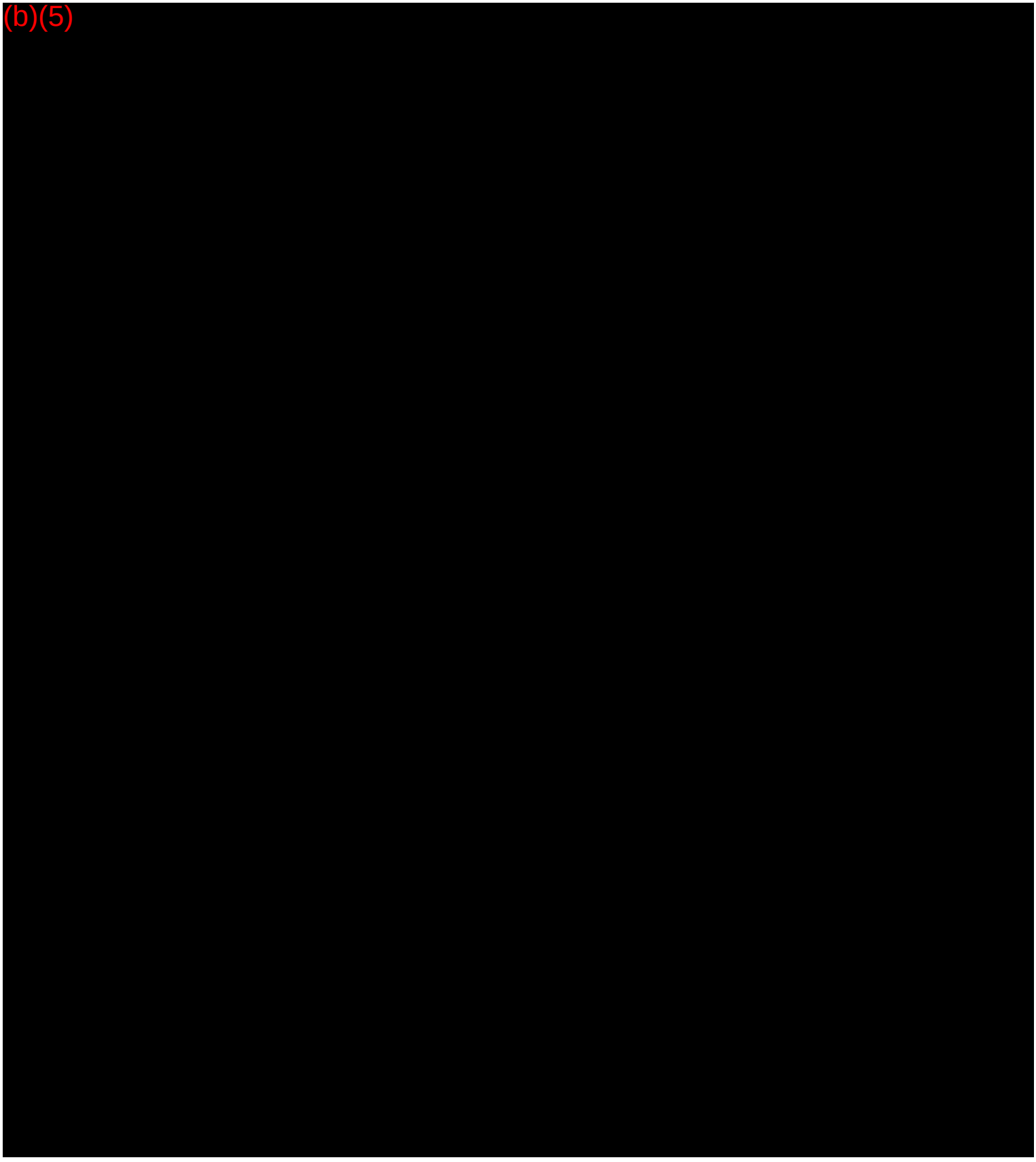

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National Organic Standards Board (NOSB)
Crops Subcommittee (CS) Meeting Notes
Tuesday February 6, 2018 2:00 pm ET

Present: Steve Ela, Chair (SE); Emily Oakley, Vice Chair (EO); Sue Baird (SB); Harriet Behar (HB); Asa Bradman (AB); Jesse Buie (JB); Dave Mortensen (DM)
Absent: Joelle Mosso (JM)
Staff: Michelle Arsenault (MA)

Work Agenda

Petitioned Substances					
Substance	**Con-tact**	**TR request?**	**Notes**	**Discussed, Voted**	**Meeting**
Polyoxin D Zinc salt 205.601	JB	Y	Petition sent to CS 06 16 16. Petition suff/TR request due 08 16 16. Petition found sufficient 08 16 16. Discuss need for Lmt'd scope TR. CS requested Lmt'd scope TR 10 04 16. TR sent to Subcommittee on 12 19 17. Response due 02 20 18.	Feb 6, Feb 20	Spr 2018
Allyl Isothiocyanate (AITC) Petition (2016) 205.601	JB	Y Lmt'd scope	Petition sent to CS 07 06 16. Petition suff/TR request due 09 06 16. Petition found suff 10 04 16. CS requested Lmt'd scope TR 10 04 16. TR in development. Expected Feb/Mar 2018. • AITC Petition (2013) (PDF) • NOSB Subcommittee Proposal (2014) (PDF) • Technical Evaluation Report (2014) (PDF)	Mar 6	Spr 2018
Sodium Citrate 205.601	HB	Y	Petition sent to CS 07 27 16. Petition suff/TR request due 09 27 16. Petition was found sufficient 10 04 16. CS requested a TR 10 04 16. TR in development. TR - Handling, Citric acid and salts (2015). TR sent to CS 08 07 17. Response due 10 06 17. Found TR insufficient 09 19 17. HS sent additional questions to TR contractor 12 11 17. Revised TR sent to CS 12 20 17. Response due 02 19 18. TR found sufficient 02 06 18.	Sep 19, 2017, Feb 6, 2018	Fall 2018

Natamycin	HB	Y	Petition sent to CS 09 09 16. Petition suff/TR request due 11 08 16. Petition found sufficient 11 01 16, and CS requested TR 11 01 16. TR in development. Expected October 2017. TR sent to CS 11 3 17. Response due 01 12 18. TR found sufficient 12 5 17.	Dec 5	Spr 2018
Sulfur (as a molluscicide) 205.601	AB	N	Petition sent to CS 06 08 17. Petition suff/TR request due 09 05 17. Petition found sufficient 09 19 17. No TR request.	Sep 19 Jan 16	Spr 2018
Ammonium Citrate 205.601	EO/DM	Y	Petition sent to CS 10 25 17. Petition suff/TR request due 12 26 17. TR requested 11 21 17.	Nov 21	TBD
Ammonium Glycinate 205.601	EO/DM	Y	Petition sent to CS 10 25 17. Petition suff/TR request due 12 26 17. TR requested 11 21 17.	Nov 21	TBD
Calcium Acetate	SB		Petition sent to CS 1 20 17. Petition suff/TR request due 01 17 17. Petition found suff 02 06 18. CS requested TR 02 06 18.	Feb 6	TBD

Other Topics

Project	Con-tact	Doc type	Notes*	Discussed/ Voted	Meeting
(Manure treatments) Anaerobic Digestate - Food Waste 205.601(j) and other manure issues	EO/HB/JM	Disc Doc	Petition sent to CS 04 08 15. Questions or request for TR due 06 09 15. Petition found sufficient 06 02 15. TR rqst sent to NOP 10 06 15. Petition withdrawn 10 14 15. CS moved project to "other topics" NOP sent memo to board 05 09 16 requesting review. TR request sent to NOP 07 05 16 (see anaerobic digestate above). Waiting for result of FDA's risk assessment.	Aug 1, Aug 15, 2017	Spr 2018
Biodegradable Biobased Mulch annotation change	HB/AB	Disc Doc	Limited scope TR request sent to NOP 08 02 16. TR sent to CS on 12 28 16. TR Suff due 02 27 17. CS found TR suff 01 03 17. Pending further research	Aug 1, 2017	TBD
Prohibition of NPEs in inerts - annotation change/ EPA List 4 Inerts annotation change	HB/EO/DM/AB	Disc Doc/Prop	IWG recommended NOSB work on NPEs/TR requested July 2014. DD - April 2016. EPA List 4 inerts disc doc (originated from 2017 sunset review conducted in 2015). Pending EPA decision	TBD	Fall 2018

Marine materials (marine algae and extracts) on the National List	EO	Disc doc	NOP approved request 01 12 16. TR request sent to NOP 02 05 16. TR sent to HS 08 10 16. Returned to CS at Spr 2017 NOSB meeting. Referred back to CS at Spr 2017 meeting	Aug 15, Dec 5	TBD
Field and Greenhouse Container Production	JB, HB, FT and EO	TBD	On hold as per NOP Jan 2018.	Feb 20	Summary of comments Spr 2018
Strengthen and clarify the requirements for use of organic seed (NOP 5029)	HB	Proposal	Originated in MS. Referred back to CS at Spr 2017 meeting. Referred back to CS at Fall 2017 meeting.		TBD
Research Priorities	All	NA	RPs due to MS Aug 2018	NA	Fall 2018

* Yellow highlight indicates Subcommittee action needed *Highlight indicates review completion

2020 Sunsets **TR Requests: July 2017, Summary: Spr 2018, Review: Fall 2018**						
Substance		**Contact**	**TR request?**	**Notes**	**Scheduled, Discussed**	**Meeting**
Alcohols: Ethanol Isopropanol	205.601(a)(1)(i), 205.601(a)(1)(ii)	JB	N	1995 TAP; 2014 TR - Ethanol; 2014 TR - Isopropanol	Feb 6	Summary: Spr 2018 Review: Fall 2018
Sodium carbonate peroxyhydrate	205.601(a)	EO	N	2006 TAP; 2014 TR	Dec 5	"
Newspaper or other recycled paper	205.601(b) and (c)	HB	N	2017 TR	Dec 5	"
Plastic mulch and covers	205.601(b)	HB	N	1995 TAP: TR for biodegradable mulch. Low priority	Dec 19, Jan 2	"
Aqueous potassium silicate	205.601(e), 205.601(i)	DM	N	2014 TR	Jan 2, Feb 6	"
Elemental sulfur	205.601(e)(5), 205.601(i)(10), 205.601(j)(2)	AB	Y	1995 TAP; 2017 TR for Livestock. TR requested 07 28 17. In contracting. TR sent to CS 01 10 18. TR sufficiency due 03 12 18	Dec 19, Jan 2 Feb 20	"

Lime sulfur	205.601(e)(6), 205.601(i)(6)	SE	N	2014 TR	Dec 19	"
Sucrose octanoate esters	205.601(e)(10)	SB	N	2005 TR	Dec 19	"
Hydrated lime	205.601(i)(4)	DM	N	1995 TAP; 2001 TAP; 2002 TR for Calcium Hydroxide	Jan 2	"
Liquid fish products	205.601(j)	AB	N	1995 TAP; 2006 TR	Jan 16,	"
Sulfurous Acid	205.601(j)	SE	N	2010 TAP; 2014 TR	Dec 19	"
Ethylene	205.601(k)	EO	N	2000 Supplemental TAP; 2007 TAP; 2011 Supplemental TR	Dec 19	"
Microcrystalline cheesewax	205.601(o)	SB	Y	None. TR requested 07 28 17. In contracting. TR sent to CS 01 11 18. TR sufficiency due 03 13 18.	Dec 19, Feb 20	"
Potassium chloride	205.602(e)	JM	N	1995 TAP. Low priority	Jan 16	"

Agenda

- Approve notes from January 16 call.
- 2020 sunset: Alcohols: Ethanol Isopropanol (JB) - Discuss review
- Polyoxin D Zinc salt (JB) - TR sufficiency
- 2020 sunset: Aqueous potassium silicate (DM) - Discuss review
- Calcium Acetate (SB) - petition sufficiency/TR request
- 2020 sunset: Microcrystalline cheesewax (SB) - TR sufficiency
- 2020 sunset: Elemental sulfur TR sufficiency (AB)
- Discussion of future options for container proposals (HB)
- Sodium Citrate (HB)
- Adjourn

Discussion

- **Notes from January 16, 2018** were.
- **2020 sunset: Alcohols: Ethanol and Isopropanol (JB).** The lead summarized the two alcohols, including history and uses. There are alternatives, however, the NOSB determined that alcohols are straightforward and not controversial, and it is important to keep them on the list as a tool to combat bacteria.
- **Polyoxin D Zinc salt (JB).** The NOP is awaiting an addendum to the petition. The HS will defer the TR sufficiency and discuss this again on the next call, once the addendum is received.
- **2020 sunset: Aqueous potassium silicate (DM).** The CS discussed this substance in January. The lead summarized the uses and the group discussed additional questions for public comment for the first phase of the review.
- **Calcium Acetate (SB).** The lead summarized calcium acetate (CAS #62544) which was petitioned as a soil amendment, plant micronutrient, and as a soil pH adjuster. The members noted that the petitioner includes multi-uses, and the petition contains classified business information regarding the use of calcium acetate in a proprietary mix. The CS accepted the petition as sufficient and will

request a TR. NOP will provide additional information regarding the mention of CBI in the petition. The CS would like to verify that they are reviewing only calcium acetate for the stated uses.

- **2020 sunset: Microcrystalline cheesewax (SB).** Deferred to the next call
- **2020 sunset: Elemental sulfur TR sufficiency (AB).** Deferred to the next call
- **Discussion of future options for container proposals (HB).** Deferred to the next call
- **Sodium Citrate (HB).** The group discussed the substance and found the TR sufficient. The CS will complete a proposal for the Fall 2018 meeting.
- **Other items.**
    - The Marine Materials document is nearly complete, and the group discussed the path forward. The NOP has directed the NOSB to focus on petitions and sunset reviews. The lead will contact NOP and follow up on the status before the Executive call on Friday.
    - The Field and Greenhouse Container Production document is also being put on hold by the program. The lead would like to re-scope the project to focus on recycling.
- **The meeting was adjourned**

Previous CS Notes

Future Call Schedule (1st and 3rd Tuesdays 2:00 ET)

January 16, 2018
- Calcium Acetate (SB) - petition sufficiency/TR request
- Polyoxin D Zinc salt (JB) - TR sufficiency
- Sulfur (as a molluscicide) (AB) - Discuss proposal.
- 2020 sunset: Hydrated Lime (DM) - Discuss review
- 2020 sunset: Liquid fish products (AB) - Discuss review
- 2020 sunset: Alcohols: Ethanol Isopropanol (JB) - Discuss review
- 2020 sunset: Potassium chloride (JM) - Discuss review
- Discussion of future options for container proposals

February 6, 2018
- 2020 sunset: Alcohols: Ethanol Isopropanol (JB) - Discuss review
- Polyoxin D Zinc salt (JB) - TR sufficiency
- 2020 sunset: Aqueous potassium silicate (DM) - Discuss review
- Calcium Acetate (SB) - petition sufficiency/TR request
- 2020 sunset: Microcrystalline cheesewax (SB) - TR sufficiency
- 2020 sunset: Elemental sulfur TR sufficiency (AB)
- Discussion of future options for container proposals (HB)

February 20, 2018
- 2020 sunset: Microcrystalline cheesewax (SB) - TR sufficiency
- 2020 sunset: Elemental sulfur (AB) - TR sufficiency
- Polyoxin D Zinc salt (JB) - Review petition addendum/TR sufficiency
- Discussion of future options for container proposals (HB)

March 6, 2018
- Allyl Isothiocyanate (AITC) - TR sufficiency (JB)

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

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)
Handling Subcommittee (HS) Meeting Notes draft
Tuesday, February 6, 2018 1:00 pm ET

Present: Lisa de Lima (LD), Chair; Asa Bradman (AB); Steve Ela (SE); A-dae Briones (ARB); Harriet Behar (HB) - observer; Jesse Buie (JB) - observer
Absent: Tom Chapman (TC); Scott Rice, Vice Chair (SR); Joelle Mosso (JM)
Staff: Michelle Arsenault (MA)

Work Agenda

Petitioned Substances						
Substance	**National List §**	**Contact**	**TR rqst?**	**Notes***	**Scheduled, Discussed, Voted**	**Meeting**
Sodium dodecylbenzene sulfonate (SDBS) Petition Addendum #1 SDBS (PDF)	205.605(b)	SR	Y	Petition sent to HS on 11 02 15. Response/request for TR due 01 04 16. Petition found suff 12 01 15. No new TR will be requested. Referred back to HS at Apr 2016 NOSB meeting. TR request sent 05 18 16. TR in development - Expected late Dec 2016/early Jan. TR delayed until Spring 2017. TR sent to HS 05 30 17. Response due 08 01 17. Petition addendum sent to HS 07 12 17. The HS found the petition addendum suff 08 01 17	Aug 1, Aug 15 Jan 2 Jan 16	Spr 2018
Sodium Chlorite for the generation of chlorine dioxide gas Petition, Addendum	205.605	SR	Y	Petition for chlorine dioxide dry gas sent to HS on 12 02 15. Response/request for TR due 02 02 16. HS sent request 03 17 16 for additional info from petitioner. Sodium chlorite addendum received 05 05 16. Suff due 07 05 16. Petition found sufficient 06 07 16. Sent back to Subcomm at Fall 2016 meeting. HS requested a TR 06 06 17. TR sent to HS 01 09 18. Response due 03 13 18.	May 16, Jun 6, Jan 16 Feb 20	Spr 2018

Petitioned Substances						
Substance	**National List §**	**Contact**	**TR rqst?**	**Notes***	**Scheduled, Discussed, Voted**	**Meeting**
Silver Dihydrogen Citrate Petition Addendum #1	205.605(b)	JM	Y	Petition sent to HS 01 24 17. Response/request for TR due 03 28 17. Petition found sufficient 03 07 17. HS requested TR 03 07 14. TR in development. Petition addendum sent to HS 08 03 17. TR sent to HS 10 19 17/ Suff due 12 19 17. HS sent additional questions to TR contractor 12 05 17	Mar 7, Dec 5	Fall 2018
Japones pepper	205.606	ARB	N	Petition sent to HS 02 09 17. Response/request for TR due 04 11 17. Petition found suff 04 04 17. No TR. HS requested additional info from petitioner 07 19 17 & 11 07 19	Apr 4, Jul 18 Oct 3 Nov 7	Spr 2018
Ethiopian pepper	205.606	ARB	N	Petition sent to HS 02 09 17. Response/request for TR due 04 11 17. Petition found suff 04 04 17. No TR. HS requested additional info from petitioner 07 19 17 & 11 07 19	Apr 4 Jul 18 Oct 3 Nov 7	Spr 2018
Tamarind Seed Gum Petition Addendum August 22, 2017	205.606	SE		Petition sent to HS 02 15 17. Response/request for TR due 04 17 17. HS requested additional info from the petitioner 04 04 17. Petition addendum Rcvd 08 10 17. Response due 10 10 17. Updated petition addendum rcvd 08 22 17. TR requested 10 03 17. TR in development - expected March 2018	Apr 4 Sep 5, Oct 3 Mar 6	Fall 2018

Commented [AM-A1]: TBD. Waiting for response from Petitioner

Commented [AM-A2]: TBD. Waiting for response from Petitioner

Commented [AM-A3]: I updated this based on the latest Materials report. I also moved it to the Mar 6 call. Doubtful it will be ready by then.

2020 Sunsets TR Requests: July 2017, Summary: Spr 2018, Review: Fall 2018						
Name	**National List §**	**Contact**	**TAP/TR**	**Notes**	**Scheduled, Discussed**	**Review Meeting**
Calcium carbonate	205.605(a)	SR	Y	1995 TAP. TR requested 07 28 17. Low priority. TR sent to HS 01 29 18. Suff due 03 30 18	Feb 20	Summary: Spr 2018 Review: Fall 2018
Flavors	205.605(a)	TC	N	2005 TR	Jan 2	"

Gellan Gum	205.605(a)	JM	N	2006 TAP	Feb 20	"
Oxygen	205.605(a)	LD	N	1995 TAP. TR requested 07 28 17. Low priority	Dec 5	"
Potassium chloride	205.605(a)	AS	N	1995 TAP; 2015 TR for Nutrient vitamins and minerals	Dec 5	"
Alginates	205.605(b)	SE	N	1995 TAP; 2015 TR	Dec 19	"
Calcium hydroxide	205.605(b)	AS	N	1995 TAP. TR requested 07 28 17. Low priority	Dec 5	"
Ethylene	205.605(b)	AB	N	1995 TAP; 1999 TAP - Processing. TR requested 07 28 17. Contingent on request from other Subcomms	Dec 19, Jan 2	"
Glycerides: mono and di	205.605(b)	LD	N	1995 TAP; 2015 TR	Dec 5	"
Magnesium stearate	205.605(b)	AB	Y	1995 TAP. TR requested 07 28 17. Low priority. TR sent to HS 01 29 18. Suff due 03 30 18	Feb 20	"
Phosphoric acid	205.605(b)	AS	N	2003 TAP. TR requested 07 28 17. Contingent on request from other Subcomms	Dec 5	"
Potassium carbonate	205.605(b)	SR	N	1995 TAP. TR requested 07 28 17. Low priority.	Feb 20	"
Sulfur dioxide	205.605(b)	SE	N	1995 TAP; 2011 TR	Dec 19	"
Xanthan gum	205.605(b)	JM	N	1995 TAP; 2016 TR	Feb 20	"
Fructooligosaccharides (FOS)	205.606	TC	N	2006 TAP; 2015 TR	Jan 2	"
Gums: Arabic, Carob bean, Guar, Locust bean	205.606(k)	JM	Y	1995 TAP. TR requested 07 28 17. TR in contracting. TR sent to HS 01 30 18. Suff due 04 02 18	Feb 20	"
Lecithin - de-oiled	205.606	ARB	N	1995 TAP; 2009 TR	Jan 16	"
Tragacanth gum	205.606	JM	Y	None. TR requested 07 28 17. TR in contracting. TR sent to HS 01 30 18. Suff due 04 02 18	Feb 20	"

Other projects			
Name	**Contact**	**Notes***	**Meeting**
Packaging substances used in organic food	LD/AB	Submitted briefing paper to NOP 01 12 14. Response memo from NOP sent to HS 11 19 14. TR in development, expected mid-Sep - delayed. TR received 9/30/16. In review by the program. TR sent to HS 10 19 16. TR sufficiency due 12 20 16. TR found insufficient	Discussion doc TBD

Commented [AM-A4]: As per NOP

handling - including BPA		12 20 16. Vote: 02 21 17. New TR in development. Expected July 2017, TR received 07 10 17. Response due 09 08 17. TR found sufficient 08 01 17.	
Nutrient Vitamins and Minerals - annotation change	TC	Pending NOP Approval. Approved 01 12 16. Proposal. On hold.	TBD
Marine materials (marine algae and extracts). Proposal	SR	Pending NOP approval. NOP approved request 01 12 16. TR request sent to NOP 02 05 16. TR expected Jul 2016. TR sent to HS 08 10 16. TR suff due 10 11 16. TR found sufficient 09 06 16. Voted 09 06 16. Proposal in development 12 06 16. Voted 01 17 17. Referred back to HS at Spr 2017 NOSB meeting	TBD
Magnesium chloride reclassification 205.605(b)	LD	HS requested addition of this item and NOP approved 01 12 16; TR completed 11/30/16. Petitioned. Voted 02 06 18	Spr 2018
Research Priorities	TC/ALL	RPs due to MS Aug 2018	Fall 2018

Commented [AM-A5]: As per NOP

*Highlight indicates committee action needed. *Highlight indicates review completion and/or vote

Agenda

- Approve January 16, 2018 notes
- Reassign Ashley's sunset materials - (LD)
- Magnesium chloride reclassification (LD) - Discuss & vote
- BPA (AB) - Discuss
- 2020 sunset: Potassium carbonate (SR) - Discuss review
- Sodium Chlorite petition sufficiency (SR) - Discuss & decide on sufficiency
- Marine Materials (SR) - Discuss proposal/update
- Other items
- Adjourn

Discussion

- **HS Notes from** January 16, 2018 were approved with no changes
- **Sanitizers (HB).** The HS Chair mentioned the sanitizers work agenda item (In the Materials Subcommittee) and asked for feedback about potential sources for technical information.
- **Reassign Ashley's sunset materials (LD).** Deferred to next call?
- **Magnesium chloride reclassification (LD).** The group briefly discussed the reclassification of magnesium chloride and moved to a vote. Magnesium chloride is available in a non-synthetic form. The Handling Subcommittee proposes the annotation "derived from seawater" be removed since there are multiple sources from which non-synthetic magnesium chloride can be derived.

  Motion to reclassify magnesium chloride as non-synthetic and move its listing from 605(b) to 605(a)
  Motion by: LD
  Seconded by: SE
  Additional discussion:
  Yes: 4 No: 0 Abstain: 0 Absent: 3 Recuse: 0

- **BPA (AB).** The lead summarized current information about regulatory changes in CA and the EU regarding BPA. The HS received a few substantive comments at the last NOSB meeting, and most were in support of the proposal to regulate packaging materials. The TR was found sufficient, and

the group discussed whether to repost this as a discussion document for the spring meeting to glean more comment. The group discussed USDA jurisdiction and one member suggested that this is a food contact issue. The group also discussed market disruption and economic factors. The lead author will make some modifications and recirculate the draft document for further discussion.

- **2020 sunset: Potassium carbonate (SR).** Deferred to next call
- **Sodium Chlorite petition sufficiency (SR).** Deferred to next call
- **Marine Materials (SR).** Deferred to next call
- **Other Items.** None
- **The meeting was adjourned**

Previous HS Notes

Future Call Schedule (1st and 3rd Tuesdays 1:00 ET)

January 16, 2018
- SDBS (SR) - Discuss/vote
- Sodium Chlorite for the generation of chlorine dioxide gas (SR) - TR sufficiency
- 2020 sunset: Lecithin - de-oiled (AB) - Discuss review

February 6, 2018
- BPA (AB) - Discuss
- Marine Materials (SR) - Discuss proposal
- 2020 sunset: Potassium carbonate (SR) - Discuss review
- Magnesium chloride reclassification (LD) - Discuss
- Sodium Chlorite for the generation of chlorine dioxide gas (SR) - TR sufficiency, discuss draft proposal

February 20, 2018
- 2020 sunset: Potassium carbonate (SR) - Discuss review
- Marine Materials (SR) - Discuss proposal/update
- Sodium Chlorite for the generation of chlorine dioxide gas (SR) - TR sufficiency, discuss draft proposal
- 2020 sunset: Calcium carbonate (SR) - Discuss review
- 2020 sunset: Gellan Gum (JM) - Discuss review
- 2020 sunset: Gums: Arabic, Carob bean, Guar, Locust bean (JM) - Discuss review
- 2020 sunset: Tragacanth gum (JM) - Discuss review
- 2020 sunset: Xanthan gum (JM) - Discuss review
- 2020 sunset: Magnesium stearate (AB) - Discuss review

March 6, 2018
- Tamarind seed gum (SE) - TR sufficiency

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

DRAFT

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Sulfur as Slug and Snail Bait

[Feb 6, 2018]

(b)(5)

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DRAFT

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Sulfur as Slug and Snail Bait

[Feb 6, 2018]

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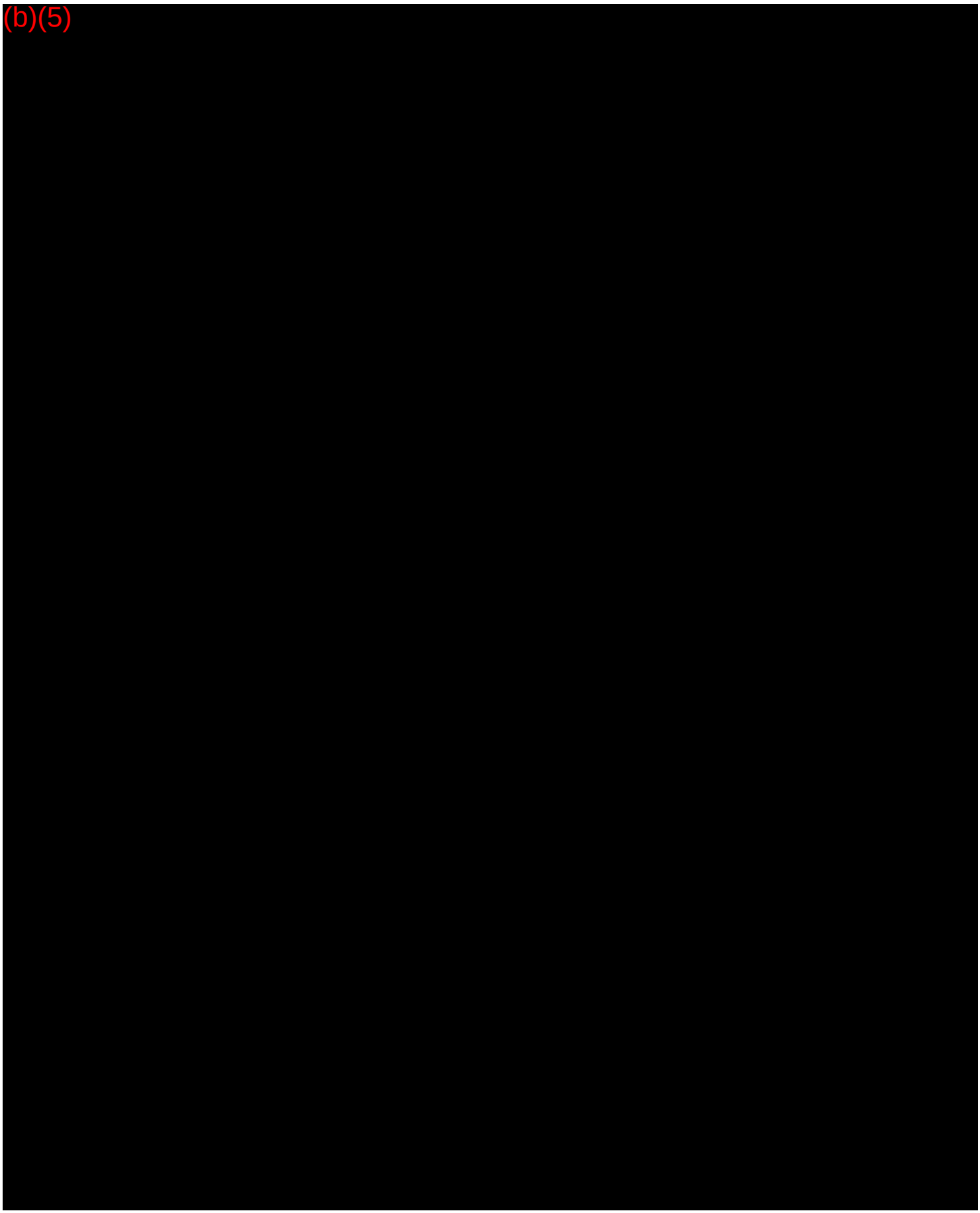
DRAFT

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Calcium Acetate
[February 6, 2018]

(b)(5)

(b)(5)



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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)
Compliance, Accreditation & Certification Subcommittee (CACS) Notes for CACS
Tuesday February 13, 2018, 3:00 pm ET

Attending: Scott Rice (SR), Chair; Emily Oakley (EO), Vice Chair; Harriet Behar (HB); Ashley Swaffar (AS); Lisa de Lima (LD); A-dae Romero-Briones (ARB); Tom Chapman (TC)
Absent: none
Staff: Michelle Arsenault (MA)

Work Agenda

Project	Contact	Status	Discussion, Vote	Meeting
Inspector qualifications proposal	SR	Approved for addition to work agenda 04 21 16. Referred back to CACS at Spr 2017 meeting	Dec 12, Jan 9, Jan 23 Feb 13	Spr 2018
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production proposal	HB	Approved for addition to work agenda 07 15 16. Verbal update Fall 2016. DD Spr 2017. Proposal Fall 2017. Referred back to CACS at Fall 2017 meeting	Nov 28, Jan 23	Spr 2018
Import Oversight	ALL	Memo sent to NOSB 08 10 17.	Nov 28, Jan 9, Jan 23. Feb 13	Disc doc Spr 2018

***Discussed** ***Voted**

Agenda

- Approve notes from January 30, 2018
- Imports (All)
- Inspector Qualifications (SR)
- Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)
- Other items
- Adjourn

Discussion

- **Notes from** January 30, 2018, were approved with no changes.
- **Imports (All).** The NOP will be sending the panelist invitation letter to the NOSB so they can share with the certifier community.
- **Inspector Qualifications (SR).** The lead noted that the NOP was supportive of sharing the work that IOIA completed for the NOP regarding inspector training, and the CACS discussed how best

to include this in the document. The group moved to a vote. The chair will finalize the document and forward it to NOP for posting.

Motion to accept the document on inspector qualifications
Motion by: HB
Seconded by: AS
Additional discussion: none
Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

- **Import oversight**. The NOSB Chair suggested ideas for the Spring 2018 NOSB meeting, and the group discussed various broad topics as identified in the December email from the NOP. The CACS is seeking information from the community, and would like to put forth a series of questions. The CACS will review the potential questions on the 27th and submit the document for posting.
- **Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB).** The lead requested feedback from the Subcommittee members so she can continue to develop the document. It may not be completed for the Spring meeting.
- **Other items.** None
- **The meeting was adjourned**

Previous CACS Notes

Future Call Schedule (2nd Tuesday 3:00 ET)

January 30, 2018 - additional call
Imports discussion (ALL)
Inspector qualifications (SR)
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)
February 13, 2018
Inspector qualifications (SR)
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)
February 27, 2018 - additional call
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
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Spring 2018 NOSB meeting – Tucson, AZ	Apr 25-27, 2018

National Organic Standards Board
Certification, Accreditation and Compliance Subcommittee
Discussion Document
Eliminating the Incentive to Convert Native Ecosystems to Organic Production
February 14, 2018

I INTRODUCTION

The Organic Food Production Act (OFPA) of 1990 (as amended) and Regulations promulgated by the NOP to implement the Statute, NOP Policy documents, and NOSB Recommendations and Principles include a clear bias towards protection of the natural resources present on an organic operation, including the physical, hydrological, and biological features of the farm. The soil, water, wetlands, woodlands, and wildlife must be maintained or improved by the organic operator through production practices implemented in accordance with the Act and Regulations. This bias towards ecosystem preservation is also found within the organic marketplace with consumer expectations that organic farms and ranches will be examples of excellent land stewardship.

Along with this strong environmental protection within the regulatory framework that oversees organic production, is the requirement that land cannot produce organic crops or livestock until 36 months have passed between the application of a prohibited substance and the harvest of an organic crop. Using land that has not had any prohibited substances applied to it provides an immediate entry into the organic marketplace for crops or livestock, without the three years wait. The lack of the three-year transition timeframe is an incentive to convert native ecosystems, with fragile or endangered habitat, to immediate agricultural production. Over the last three years, the NOSB has received public comment describing loss of this high value conservation acreage, or native ecosytems, when farmers transition to organic production..

The NOSB discussion document from January 10, 2016 and proposal of August 2017 resulted in significant numbers of public comment from a wide cross-section of stakeholders. This discussion document responds to the improvements sought by the public to the proposal of August 2017.

II BACKGROUND

The NOP provided Guidance on Biodiversity in 2016 (NOP 5020) encouraging the protection and maintenance of a high level of biodiversity on farms because it brings benefits not only to the entire ecosystem in that geographic area, but also to the farmer. This discussion document deals with the High Value Conservation Lands and native ecosystems that were specifically not included in the NOP Biodiversity Guidance, but were mentioned as an area that should have continued attention.

III RELEVANT AREAS OF THE STATUTE, RULE and RELATED DOCUMENTS

The Organic Food Production Act (OFPA) of 1990, as amended, 7 USC, Chapter 94:

7 USC 6504 (2) …not be produced on land to which any prohibited substances, including synthetic chemicals have been applied during the 3 years immediately preceding the harvest of the agricultural products;

7 USC 6513(f) Management of wild crops; (2) include a 3 year history of the management of the area showing that no prohibited substances have been applied; (3) include a plan for the harvesting and

gathering of wild crops assuring that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop;

The OFPA Preamble to the Final Rule establishing the NOP states: "[t]he use of 'conserve' [in the definition of organic production] establishes that the producer must initiate practices to support biodiversity and avoid, to the extent practicable, any activities that would diminish it. Compliance with the requirement to conserve biodiversity requires that a producer incorporate practices in his or her organic system plan that are beneficial to biodiversity on his or her operation." (76 FR 80563)

Previous documents on this issue have provided numerous instances of unaltered native ecosystems that are either at risk or have been destroyed for agricultural production. Numerous examples were provided that this destruction is occurring on land that subsequently is used for organic production, and therefore this issue must be addressed. There are other regulations within the U.S. law that seek to protect specific areas, such as the "sodsaver" provision[1], which specifically addresses the protection of prairie potholes in the United States.

IV DISCUSSION and PUBLIC COMMENT

The August proposal of 2017 recommended rule making under 205.200 with this statement.

(a) A native ecosystem site that has not been previously grazed or cultivated cannot be certified as organic as provided for under this regulation for a period of 10 years from the date of conversion to crop or livestock production.

The vast majority of public comments supported the Wild Farm Alliance's approach to this issue, which included a definition and a rule change.

Their suggested definition is as follows:

Native ecosystems can be recognized in the field as retaining both dominant and characteristic plant species as described by established classifications of natural and seminatural vegetation. These will tend to be on lands that has not been previously cultivated, cleared, drained or otherwise irrevocably altered. However, they could include areas that had been substantially altered over 50-100 years ago, but have since recovered expected plant species composition and structure.

Their suggested regulatory change is as follows:

205.200 (a) A site supporting a native ecosystem cannot be certified for organic production as provided for under this regulation for a period of 10 years from the date of conversion.

The public and NOSB subcommittee understand the challenge presented by the public to determine if a native ecosystem had been destroyed for the purpose of growing organic crops. However, there are numerous governmental and privately available aerial photos and ecosystem surveys for both domestic and international production that can aid in determining what had been grown on any specific agricultural parcel for at least the past 50 years and even beyond. Areas where there was no agricultural

production, have also been surveyed although there may not be as much detail. NRCS has a database of the possible locations of endangered and threatened species they refer to when allowing manipulation of lands and wetlands. FSA has aerial photos of agricultural land going back to 1938, with photos taken approximately once per decade. The U.S. geological service has aerial photos of nonagricultural land going back to the 1950s. NatureServe and other international organizations have similar items for international tracking.

In addition, organic certification agencies would need to add a few questions to their organic system plan applications, to address this issue. Certifiers could provide the readily accessible websites where the various sources of aerial photos and ecosystem tracking could be found, to aid operators in answering the questions in their OSP.

IV DISCUSSION QUESTIONS

1. **Would the definition and rule change below be practical and enforceable? Please provide comments or improvements.**

Definition Native Ecosystem: *Native ecosystems can be recognized in the field as retaining both dominant and characteristic plant species as described by established classifications of natural and semi natural vegetation. These will tend to be on lands that has not been previously cultivated, cleared, drained or otherwise irrevocably altered. However, they could include areas that had been substantially altered over 50-100 years ago, but have since recovered expected plant species composition and structure.*

205.200 (a) A site supporting a native ecosystem cannot be certified for organic production as provided for under this regulation for a period of 10 years from the date of conversion.

2. **Below are sample questions that could be added to an OSP native ecosystem determination section to determine if a native ecosystem had been in place from 40 years ago to the present day. Please provide comments or improvements.**

A. Has the area been tilled, cleared, drained, intentionally burned or transplanted into in the past 40 years? *If yes, then ignore the rest of this section.*
B. Has the land been managed by people for crop production or other purpose such as grazing in the past 40 years? *If yes, then ignore the rest of this section.*
C. Did the land, 10 years ago to the present day, have a majority non-native or invasive species present? *If yes, then ignore the rest of this section.*
D. Ten years ago, were native species present in this area and found in sufficient numbers, diversity and vitality to continually regenerate and maintain the biodiversity present? *If no, go to the next section of the OSP. If yes, then this land may be regulated under 205.200 (a). Further information may be requested by your organic certification agency, based upon publicly available aerial photos and ecosystem survey information.*

3. **Can you provide further resources to help track where native ecosystems may have been in place in the past 10 years?**

Motion to approve this discussion document for posting, and work in conjunction with the Certification, Accreditation and Compliance Subcommittee on the proposal.

Motion by

Seconded by

Yes: No: Abstain: Absent: Recuse:

Approved by , Subcommittee Chair, to transmit to NOSB , 2018

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Polyoxin D Zinc Salt
February 19, 2018

Summary of Petition for Polyoxin D Zinc Salt (needs hyperlink)

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). At the April 2013 National Organic Standards Board meeting, the NOSB was unable to reach the required 10 votes to place this material as an approved synthetic on 205.601, by a vote of 9 yes and 6 no. The NOSB found this material non-essential, and there were concerns over its broad-spectrum mode of action as well as environmental concerns for soil bacteria, fungi and overall environmental health.

The second petition, May 2016, brought forward data to evaluate the effects on beneficial soil organisms and insects as well as an analysis by the petitioner of grower need.

Summary of Review:

Polyoxin d zinc salt is categorized as a biofungicide or biochemical pesticide. While the polyoxin d might be considered a nonsynthetic product, the addition of the zinc salt makes it a synthetic. The zinc salt makes this product more useful by lessening its water solubility and prevent the product from washing off the application area too quickly to have much effectiveness.

The petitioner has made a case that there are few to no alternatives for some fungal diseases on various species of plants, such as cottonball disease on cranberries, black rot, downy mildew, powdery mildew and bunch rot on grapes, mummyberry on blueberries, phomopsis leaf spot on strawberries, downy mildew on basil as well as a host of other fungal diseases on fruits. The petitioner states there are OMRI listed alternatives, but their product is either more effective or offers another tool for producers in rotation to prevent resistance.

<u>Category 1: Classification</u>

1. **Substance is for: Crops**

   a. Is the substance _____ Non-synthetic or __x__ Synthetic?
   Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide:

2. **For CROPS: 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.

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)]**

The petitioner acknowledges polyoxin D zinc salt could kill beneficial soil fungi and specific brand name products (Bio-Tam and Rootshield) used by organic producers would be rendered ineffective if they were in contact with polyoxin D zinc salt. However, in their own studies, they found little to no toxic effects on beneficial soil fungi.

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)]**
   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)]**
   There is no concern during the manufacture, use or disposal other than this product should not be used nearby to, or in water since it is moderately toxic to aquatic invertebrates and fish. A brand name product label (VEGGIETURBO 5SC Suspension Concentrate Fungicide) containing polyoxin d zinc salt has this warning

   "*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)].**

   The Technical Review of polyoxin d zinc salt from December 2017 states there is very low acute toxicity to humans by oral, dermal or inhalation routes and it did not demonstrate mutagenic

potential. However, there are warnings on the label about possible skin irritation effects as well as eye irritation.

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)]**

In response to NOSB questions of toxicity to beneficial soil fungi, honeybees or ladybird beetles, the petitioner, Kaken, commissioned their own studies and found no negative effects on any of these organisms. (Petition addendum from May 2016)

6. **Are there any adverse impacts on biodiversity? (§205.200)**

The Technical Review states this product rapidly degrades in the environment, approximately 2-3 days, and therefore it was concluded there was low environmental risk.

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)]**

There are numerous OMRI and certifier approved materials that can be used, as well as cultural methods to control fungal disease. The petitioner has stated that practices and OMRI listed alternative materials are insufficient to meet organic grower needs.

2. **In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]**

Jesse states yes. Subcommittee should give some feedback here.

Subcommittee vote:

Classify this material as a synthetic?

Motion to add Polyoxin D Zinc Salt as petitioned to §205.601
Motion by: Jesse Buie
Seconded by:
Yes: No: Abstain: Absent: Recuse:

Approved by Steve Ela, Crops Subcommittee Chair, to transmit to NOP

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal
Glycolic Acid

2/20/18

Summary of Petition:

A petition was received for the use of glycolic acid as a component of pre and post milking teat dips to control mastitis (205.603(a) Synthetic substances allowed for use in organic livestock production as disinfectants, sanitizer and medical treatment as applicable).

Summary of Review:

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. *Stapylococcus 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.

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 US Environmental Protection Agency 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 (§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 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 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 trifuoride 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?**
   c.

All glycolic acid commercially available today is made by one of three processes:

1. 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.
2. 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.

3. 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 205.605 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 minipigs for 15 min 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 process 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, 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)]

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. The subcommittee 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 controlling mastitis?

Classification Motion:

Motion to classify Glycolic Acid as Synthetic
Motion by: Ashley Swaffar
Seconded by:
Yes: 0 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National List Motion:

Motion to add Glycolic Acid as petitioned at 205.603
Motion by: Ashley Swaffar
Seconded by:
Yes: 0 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board (NOSB)
Crops Subcommittee (CS) Meeting Notes
Tuesday February 20, 2018 2:00 pm ET

Present: Emily Oakley, Vice Chair (EO); Sue Baird (SB); Harriet Behar (HB); Asa Bradman (AB); Jesse Buie (JB); Tom Chapman (TC) - observer
Absent: Steve Ela, Chair (SE); Dave Mortensen (DM)
Staff: Michelle Arsenault (MA)

Work Agenda

Petitioned Substances					
Substance	**Con-tact**	**TR request?**	**Notes**	**Discussed, Voted**	**Meeting**
Polyoxin D Zinc salt 205.601 Petition Addendum #1 Petition Addendum #2	JB	Y	Petition sent to CS 06 16 16. Petition suff/TR request due 08 16 16. Petition found sufficient 08 16 16. Discuss need for Lmt'd scope TR. CS requested Lmt'd scope TR 10 04 16. TR sent to Subcommittee on 12 19 17. Response due 02 20 18. TR found sufficient 02 20 18.	Feb 6, Feb 20	Spr 2018
Allyl Isothiocyanate (AITC) Petition (2016) 205.601	JB	Y Lmt'd scope	Petition sent to CS 07 06 16. Petition suff/TR request due 09 06 16. Petition found suff 10 04 16. CS requested Lmt'd scope TR 10 04 16. TR in development. Expected Feb/Mar 2018. Lmtd scope TR sent to CS 02 16 18. Response due 04 18 18. • AITC Petition (2013) (PDF) • NOSB Subcommittee Proposal (2014) (PDF) • Technical Evaluation Report (2014) (PDF)	Mar 6	Fall 2018
Sodium Citrate 205.601	HB	Y	Petition sent to CS 07 27 16. Petition suff/TR request due 09 27 16. Petition was found sufficient 10 04 16. CS requested a TR 10 04 16. TR in development. TR - Handling, Citric acid and salts (2015). TR sent to CS 08 07 17. Response due 10 06 17. Found TR insufficient 09 19 17. HS sent additional questions to TR contractor 12 11 17. Revised TR sent to CS 12 20 17. Response due 02 19 18. TR found sufficient 02 06 18.	Sep 19, 2017, Feb 6, 2018	Fall 2018

Natamycin	HB	Y	Petition sent to CS 09 09 16. Petition suff/TR request due 11 08 16. Petition found sufficient 11 01 16, and CS requested TR 11 01 16. TR in development. Expected October 2017. TR sent to CS 11 3 17. Response due 01 12 18. TR found sufficient 12 5 17.	Dec 5	Fall 2018
Sulfur (as a molluscicide) 205.601	AB	N	Petition sent to CS 06 08 17. Petition suff/TR request due 09 05 17. Petition found sufficient 09 19 17. No TR request.	Sep 19 Feb 20	Spr 2018
Ammonium Citrate 205.601	EO/DM	Y	Petition sent to CS 10 25 17. Petition suff/TR request due 12 26 17. TR requested 11 21 17.	Nov 21	TBD
Ammonium Glycinate 205.601	EO/DM	Y	Petition sent to CS 10 25 17. Petition suff/TR request due 12 26 17. TR requested 11 21 17.	Nov 21	TBD
Calcium Acetate	SB	Y	Petition sent to CS 1 20 17. Petition suff/TR request due 01 17 17. Petition found suff 02 06 18. CS requested TR with specific questions 02 06 18.	Feb 6	TBD

Other Topics

Project	Con-tact	Doc type	Notes*	Discussed/ Voted	Meeting
(Manure treatments) Anaerobic Digestate - Food Waste 205.601(j) and other manure issues	EO/HB/JM	Disc Doc	Petition sent to CS 04 08 15. Questions or request for TR due 06 09 15. Petition found sufficient 06 02 15. TR rqst sent to NOP 10 06 15. Petition withdrawn 10 14 15. CS moved project to "other topics" NOP sent memo to board 05 09 16 requesting review. TR request sent to NOP 07 05 16 (see anaerobic digestate above). Waiting for result of FDA's risk assessment.	Aug 1, Aug 15, 2017	Fall 2018
Biodegradable Biobased Mulch annotation change	HB/AB	Disc Doc	Limited scope TR request sent to NOP 08 02 16. TR sent to CS on 12 28 16. TR Suff due 02 27 17. CS found TR suff 01 03 17. Pending further research	Aug 1, 2017	TBD
Prohibition of NPEs in inerts - annotation change/ EPA List 4 Inerts annotation change	HB/EO/DM/AB	Disc Doc/Prop	IWG recommended NOSB work on NPEs/TR requested July 2014. DD - April 2016. EPA List 4 inerts disc doc (originated from 2017 sunset review conducted in 2015). Pending EPA decision	TBD	Fall 2018

Marine materials (marine algae and extracts) on the National List	EO	Disc doc	NOP approved request 01 12 16. TR request sent to NOP 02 05 16. TR sent to HS 08 10 16. Returned to CS at Spr 2017 NOSB meeting. Referred back to CS at Spr 2017 meeting	Aug 15, Dec 5	TBD
Field and Greenhouse Container Production	JB, HB, FT and EO	TBD	On hold as per NOP Jan 2018.	Feb 20	TBD
Strengthen and clarify the requirements for use of organic seed (NOP 5029)	HB	Proposal	Originated in MS. Referred back to CS at Spr 2017 meeting. Referred back to CS at Fall 2017 meeting.		TBD
Research Priorities	All	NA	RPs due to MS Aug 2018	NA	Fall 2018

* Yellow highlight indicates Subcommittee action needed *Highlight indicates review completion

2020 Sunsets **TR Requests: July 2017, Summary: Spr 2018, Review: Fall 2018**						
Substance		**Contact**	**TR request?**	**Notes**	**Scheduled, Discussed**	**Meeting**
Alcohols: Ethanol Isopropanol	205.601(a)(1)(i), 205.601(a)(1)(ii)	JB	N	1995 TAP; 2014 TR - Ethanol; 2014 TR - Isopropanol	Feb 6	Summary: Spr 2018 Review: Fall 2018
Sodium carbonate peroxyhydrate	205.601(a)	EO	N	2006 TAP; 2014 TR	Dec 5	"
Newspaper or other recycled paper	205.601(b) and (c)	HB	N	2017 TR	Dec 5	"
Plastic mulch and covers	205.601(b)	HB	N	1995 TAP: TR for biodegradable mulch. Low priority	Dec 19, Jan 2	"
Aqueous potassium silicate	205.601(e), 205.601(i)	DM	N	2014 TR	Jan 2, Feb 6	"

Elemental sulfur	205.601(e)(5), 205.601(i)(10), 205.601(j)(2)	AB	Y	1995 TAP; 2017 TR for Livestock. TR requested 07 28 17. In contracting. TR sent to CS 01 10 18. TR sufficiency due 03 12 18. CS sent additional questions to the TR contractor.	Dec 19, Jan 2 Feb 20	"
Lime sulfur	205.601(e)(6), 205.601(i)(6)	SE	N	2014 TR	Dec 19	"
Sucrose octanoate esters	205.601(e)(10)	SB	N	2005 TR	Dec 19	"
Hydrated lime	205.601(i)(4)	DM	N	1995 TAP; 2001 TAP; 2002 TR for Calcium Hydroxide	Jan 2	"
Liquid fish products	205.601(j)	AB	N	1995 TAP; 2006 TR	Jan 16,	"
Sulfurous Acid	205.601(j)	SE	N	2010 TAP; 2014 TR	Dec 19	"
Ethylene	205.601(k)	EO	N	2000 Supplemental TAP; 2007 TAP; 2011 Supplemental TR	Dec 19	"
Microcrystalline cheesewax	205.601(o)	SB	Y	None. TR requested 07 28 17. In contracting. TR sent to CS 01 11 18. TR sufficiency due 03 13 18.	Dec 19, Feb 20	"
Potassium chloride	205.602(e)	JM	N	1995 TAP. Low priority	Jan 16	"

Agenda

- Approve notes from February 6 call.
- 2020 sunset: Microcrystalline cheesewax (SB) - TR sufficiency
- 2020 sunset: Elemental sulfur (AB) - TR sufficiency
- Polyoxin D Zinc salt (JB) - Review petition addendum/TR sufficiency
- Discussion of marine materials (EO)
- Discussion of future options for container proposals (HB)
- Other items
- Adjourn

Discussion

- **Notes from** February 6 were approved by the Subcommittee.
- **Update on work agenda for spring.** The NOSB Chair updated the members about the work agenda, and which items will be presented at the spring 2018 meeting, and which will be deferred to the fall meeting and beyond.
- **2020 sunset: Microcrystalline cheesewax (SB).** The CS Chair will communicate to the NOP that the Crops Subcommittee found the TR for Microcrystalline cheesewax sufficient. The lead will add an additional question about International Standards and resend the document to the NOP.
- **2020 sunset: Elemental sulfur (AB).** The CS will send a couple of questions to the TR contractor for additional information.

- **Polyoxin D Zinc salt (JB).** The Crops Chair will relay to the NOP that the Subcommittee reviewed the additional information that was provided by the petitioner, and found the TR for Polyoxin D Zinc salt sufficient. Several members will continue to work on the format of the proposal, based on the discussion. The CS will vote, and leave the vote open for absent members.

  Motion to classify Polyoxin D Zinc salt as petitioned as (synthetic
  Motion by: JB
  Seconded by: EO
  Additional discussion: none
  Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

  Motion to add Polyoxin D Zinc salt as petitioned at §205.601
  Motion by: JB
  Seconded by: SB
  Additional discussion: none
  Yes: 3 No: 1 Abstain: 2 Absent: 1 Recuse: 0

  ABS note: Two absent members cast votes via email, and votes were recorded above.

- **Discussion of future options for container proposals (HB).** Not discussed.
- **Discussion of marine materials (EO).** The Crops and Handling Subcommittees will combine the proposals on Marine materials, and send them to the Materials Subcommittee for further development. The Materials Subcommittee will bring the proposal to the Fall 2018 NOSB meeting.
- **Sulfur (as a molluscicide)** - petitioned. The CS moved to a vote on the proposal, as noted below.

  Motion to add sulfur as petitioned at §205.601
  Motion by: AB
  Seconded by: HB
  Additional discussion: Sulfur is already allowed for various uses, and the pelletized form, as petitioned here, is noted to be less likely to expose human as compared to dust form.
  Yes: 5 No: 0 Abstain: 0 Absent: 2 Recuse: 0

- **Other items.** None
- **The meeting was adjourned**

Previous CS Notes

Future Call Schedule (1st and 3rd Tuesdays 2:00 ET)

February 6, 2018
- 2020 sunset: Alcohols: Ethanol Isopropanol (JB) - Discuss review
- Polyoxin D Zinc salt (JB) - TR sufficiency
- 2020 sunset: Aqueous potassium silicate (DM) - Discuss review
- Calcium Acetate (SB) - petition sufficiency/TR request
- 2020 sunset: Microcrystalline cheesewax (SB) - TR sufficiency
- 2020 sunset: Elemental sulfur TR sufficiency (AB)
- Discussion of future options for container proposals (HB)

February 20, 2018
- 2020 sunset: Microcrystalline cheesewax (SB) - TR sufficiency
- 2020 sunset: Elemental sulfur (AB) - TR sufficiency
- Polyoxin D Zinc salt (JB) - Review petition addendum/TR sufficiency
- Discussion of future options for container proposals (HB)

March 6, 2018
- Allyl Isothiocyanate (AITC) (JB) - TR sufficiency
- Sodium Citrate (HB) - Discuss proposal
- Natamycin (HB) - Discuss proposal

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**

Hydrogen peroxide	205.601(a), 205.601(i)			2015 Hydrogen Peroxide (Crops) 2017 NOSB Recommendation		Summary: Spr 2019 Review: Fall 2019
Soaps, ammonium	205.601(d)			1996 TAP 2017 NOSB Recommendation		"
Oils, horticultural (Narrow range oils)	205.601(e), 205.601(i)			1995 TAP 2017 NOSB Recommendation		"
Pheromones	205.601(f)			2012 TR 2017 NOSB Recommendation		"
Ferric phosphate	205.601(h)			2012 TR 2016 NOSB Recommendation		"
Potassium bicarbonate	205.601(i)			2015 TR 2017 NOSB Recommendation		"
Magnesium sulfate	205.601(j)			2011 TR 2017 NOSB Recommendation		"
~~Lignin sulfonate~~	~~205.601(l)~~			2011 TR 2017 NOSB Recommendation (Removed from 205.601(l) as a floating agent: 82 FR 31241)		"
Hydrogen chloride	205.601(n)			2014 Lmtd Scope TR 2016 NOSB Recommendation		"
Ash from manure burning	205.602(a)			2016 sunset rec 2017 NOSB Recommendation		"
Sodium fluoaluminate	205.602(f)			None. 2017 NOSB Recommendation		"

National Organic Standards Board (NOSB)
Crops Subcommittee (CS) Meeting Notes
Tuesday February 20, 2018 2:00 pm ET

Present: Emily Oakley, Vice Chair (EO); Sue Baird (SB); Harriet Behar (HB); Asa Bradman (AB); Jesse Buie (JB); Tom Chapman (TC) - observer
Absent: Steve Ela, Chair (SE); Dave Mortensen (DM)
Staff: Michelle Arsenault (MA)

Work Agenda

Petitioned Substances					
Substance	**Con-tact**	**TR request?**	**Notes**	**Discussed, Voted**	**Meeting**
Polyoxin D Zinc salt 205.601 Petition Addendum #1 Petition Addendum #2	JB	Y	Petition sent to CS 06 16 16. Petition suff/TR request due 08 16 16. Petition found sufficient 08 16 16. Discuss need for Lmt'd scope TR. CS requested Lmt'd scope TR 10 04 16. TR sent to Subcommittee on 12 19 17. Response due 02 20 18. TR found sufficient 02 20 18.	Feb 6, Feb 20	Spr 2018
Allyl Isothiocyanate (AITC) Petition (2016) 205.601	JB	Y Lmt'd scope	Petition sent to CS 07 06 16. Petition suff/TR request due 09 06 16. Petition found suff 10 04 16. CS requested Lmt'd scope TR 10 04 16. TR in development. Expected Feb/Mar 2018. Lmtd scope TR sent to CS 02 16 18. Response due 04 18 18. • AITC Petition (2013) (PDF) • NOSB Subcommittee Proposal (2014) (PDF) • Technical Evaluation Report (2014) (PDF)	Mar 6	Fall 2018
Sodium Citrate 205.601	HB	Y	Petition sent to CS 07 27 16. Petition suff/TR request due 09 27 16. Petition was found sufficient 10 04 16. CS requested a TR 10 04 16. TR in development. TR - Handling, Citric acid and salts (2015). TR sent to CS 08 07 17. Response due 10 06 17. Found TR insufficient 09 19 17. HS sent additional questions to TR contractor 12 11 17. Revised TR sent to CS 12 20 17. Response due 02 19 18. TR found sufficient 02 06 18.	Sep 19, 2017, Feb 6, 2018	Fall 2018

Natamycin	HB	Y	Petition sent to CS 09 09 16. Petition suff/TR request due 11 08 16. Petition found sufficient 11 01 16, and CS requested TR 11 01 16. TR in development. Expected October 2017. TR sent to CS 11 3 17. Response due 01 12 18. TR found sufficient 12 5 17.	Dec 5	Fall 2018
Sulfur (as a molluscicide) 205.601	AB	N	Petition sent to CS 06 08 17. Petition suff/TR request due 09 05 17. Petition found sufficient 09 19 17. No TR request.	Sep 19 Feb 20	Spr 2018
Ammonium Citrate 205.601	EO/DM	Y	Petition sent to CS 10 25 17. Petition suff/TR request due 12 26 17. TR requested 11 21 17.	Nov 21	TBD
Ammonium Glycinate 205.601	EO/DM	Y	Petition sent to CS 10 25 17. Petition suff/TR request due 12 26 17. TR requested 11 21 17.	Nov 21	TBD
Calcium Acetate	SB	Y	Petition sent to CS 1 20 17. Petition suff/TR request due 01 17 17. Petition found suff 02 06 18. CS requested TR with specific questions 02 06 18.	Feb 6	TBD

Other Topics

Project	Con-tact	Doc type	Notes*	Discussed/ Voted	Meeting
(Manure treatments) Anaerobic Digestate - Food Waste 205.601(j) and other manure issues	EO/HB/JM	Disc Doc	Petition sent to CS 04 08 15. Questions or request for TR due 06 09 15. Petition found sufficient 06 02 15. TR rqst sent to NOP 10 06 15. Petition withdrawn 10 14 15. CS moved project to "other topics" NOP sent memo to board 05 09 16 requesting review. TR request sent to NOP 07 05 16 (see anaerobic digestate above). Waiting for result of FDA's risk assessment.	Aug 1, Aug 15, 2017	Fall 2018
Biodegradable Biobased Mulch annotation change	HB/AB	Disc Doc	Limited scope TR request sent to NOP 08 02 16. TR sent to CS on 12 28 16. TR Suff due 02 27 17. CS found TR suff 01 03 17. Pending further research	Aug 1, 2017	TBD
Prohibition of NPEs in inerts - annotation change/ EPA List 4 Inerts annotation change	HB/EO/DM/AB	Disc Doc/Prop	IWG recommended NOSB work on NPEs/TR requested July 2014. DD - April 2016. EPA List 4 inerts disc doc (originated from 2017 sunset review conducted in 2015). Pending EPA decision	TBD	Fall 2018

Marine materials (marine algae and extracts) on the National List	EO	Disc doc	NOP approved request 01 12 16. TR request sent to NOP 02 05 16. TR sent to HS 08 10 16. Returned to CS at Spr 2017 NOSB meeting. Referred back to CS at Spr 2017 meeting	Aug 15, Dec 5	TBD
Field and Greenhouse Container Production	JB, HB, FT and EO	TBD	On hold as per NOP Jan 2018.	Feb 20	TBD
Strengthen and clarify the requirements for use of organic seed (NOP 5029)	HB	Proposal	Originated in MS. Referred back to CS at Spr 2017 meeting. Referred back to CS at Fall 2017 meeting.		TBD
Research Priorities	All	NA	RPs due to MS Aug 2018	NA	Fall 2018

* Yellow highlight indicates Subcommittee action needed *Highlight indicates review completion

2020 Sunsets **TR Requests: July 2017, Summary: Spr 2018, Review: Fall 2018**						
Substance		**Contact**	**TR request?**	**Notes**	**Scheduled, Discussed**	**Meeting**
Alcohols: Ethanol Isopropanol	205.601(a)(1)(i), 205.601(a)(1)(ii)	JB	N	1995 TAP; 2014 TR - Ethanol; 2014 TR - Isopropanol	Feb 6	Summary: Spr 2018 Review: Fall 2018
Sodium carbonate peroxyhydrate	205.601(a)	EO	N	2006 TAP; 2014 TR	Dec 5	"
Newspaper or other recycled paper	205.601(b) and (c)	HB	N	2017 TR	Dec 5	"
Plastic mulch and covers	205.601(b)	HB	N	1995 TAP: TR for biodegradable mulch. Low priority	Dec 19, Jan 2	"
Aqueous potassium silicate	205.601(e), 205.601(i)	DM	N	2014 TR	Jan 2, Feb 6	"

Elemental sulfur	205.601(e)(5), 205.601(i)(10), 205.601(j)(2)	AB	Y	1995 TAP; 2017 TR for Livestock. TR requested 07 28 17. In contracting. TR sent to CS 01 10 18. TR sufficiency due 03 12 18. CS sent additional questions to the TR contractor.	Dec 19, Jan 2 Feb 20	"
Lime sulfur	205.601(e)(6), 205.601(i)(6)	SE	N	2014 TR	Dec 19	"
Sucrose octanoate esters	205.601(e)(10)	SB	N	2005 TR	Dec 19	"
Hydrated lime	205.601(i)(4)	DM	N	1995 TAP; 2001 TAP; 2002 TR for Calcium Hydroxide	Jan 2	"
Liquid fish products	205.601(j)	AB	N	1995 TAP; 2006 TR	Jan 16,	"
Sulfurous Acid	205.601(j)	SE	N	2010 TAP; 2014 TR	Dec 19	"
Ethylene	205.601(k)	EO	N	2000 Supplemental TAP; 2007 TAP; 2011 Supplemental TR	Dec 19	"
Microcrystalline cheesewax	205.601(o)	SB	Y	None. TR requested 07 28 17. In contracting. TR sent to CS 01 11 18. TR sufficiency due 03 13 18.	Dec 19, Feb 20	"
Potassium chloride	205.602(e)	JM	N	1995 TAP. Low priority	Jan 16	"

Agenda

- Approve notes from February 6 call.
- 2020 sunset: Microcrystalline cheesewax (SB) - TR sufficiency
- 2020 sunset: Elemental sulfur (AB) - TR sufficiency
- Polyoxin D Zinc salt (JB) - Review petition addendum/TR sufficiency
- Discussion of marine materials (EO)
- Discussion of future options for container proposals (HB)
- Other items
- Adjourn

Discussion

- **Notes from** February 6 approved with no changes.
- **Update on work agenda for spring.** The NOSB Chair updated the members about the work agenda, and which items will be presented at the spring 2018 meeting, and which will be deferred to the fall meeting and beyond. The NOP would like to reduce the number of times a project is discussed as a discussion document before it becomes a proposal and is voted on. Marine materials will be delayed to the Fall 2018 meeting, and may be combined with the HS version and have it come forward in Materials.
- **2020 sunset: Microcrystalline cheesewax (SB).** The lead summarized the material uses and the TR. The CS found the TR sufficient. The lead will add an additional question about International Standards and resend the document to the NOP.

- **2020 sunset: Elemental sulfur (AB).** The CS will send a couple of questions to the TR contractor for additional information.
- **Polyoxin D Zinc salt (JB).** The lead summarized the additional information that was recently provided by the petitioner in the petition addendum. The TR was found sufficient, and the group further discussed the substance and draft proposal. Polyoxin D was classified as synthetic by a previous NOSB. Several members will continue to work on the format of the proposal, and the CS will vote and leave the vote open for absent members.

  Motion to classify Polyoxin D Zinc salt as petitioned as (synthetic
  Motion by: JB
  Seconded by: EO
  Additional discussion: none
  Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

  Motion to add Polyoxin D Zinc salt as petitioned at §205.601
  Motion by: JB
  Seconded by: SB
  Additional discussion: none
  Yes: 3 No: 1 Abstain: 2 Absent: 1 Recuse: 0

  ABS note: Two absent members cast votes via email, and votes were recorded above.

- **Discussion of future options for container proposals (HB).** Deferred
- **Discussion of marine materials (EO).** As the NOSB Chair noted on the Handling call, this project will go forth for the fall meeting, and will be combined with the Handling proposal to be brought forth by the Materials Subcommittee.
- **Sulfur (as a molluscicide)** - Petitioned. The lead noted that sulfur is already allowed for various uses, and it is being petitioned as a molluscicide in pelletized form.

  Motion to add sulfur as petitioned at §205.601
  Motion by: AB
  Seconded by: HB
  Additional discussion: Sulfur is already allowed for various uses, and this form, pelletized, is noted to be less likely to expose humans compared to dust form.
  Yes: 5 No: 0 Abstain: 0 Absent: 2 Recuse: 0

- **Other items.** None
- **The meeting was adjourned**

Previous CS Notes

Future Call Schedule (1st and 3rd Tuesdays 2:00 ET)

February 6, 2018

2020 sunset: Alcohols: Ethanol Isopropanol (JB) - Discuss review
Polyoxin D Zinc salt (JB) - TR sufficiency
2020 sunset: Aqueous potassium silicate (DM) - Discuss review
Calcium Acetate (SB) - petition sufficiency/TR request
2020 sunset: Microcrystalline cheesewax (SB) - TR sufficiency
2020 sunset: Elemental sulfur TR sufficiency (AB)
Discussion of future options for container proposals (HB)

February 20, 2018

2020 sunset: Microcrystalline cheesewax (SB) - TR sufficiency
2020 sunset: Elemental sulfur (AB) - TR sufficiency
Polyoxin D Zinc salt (JB) - Review petition addendum/TR sufficiency
Discussion of future options for container proposals (HB)

March 6, 2018
Allyl Isothiocyanate (AITC) (JB) - TR sufficiency
Sodium Citrate (HB) - Discuss proposal
Natamycin (HB) - Discuss proposal

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

National Organic Standards Board (NOSB)
Handling Subcommittee (HS) Meeting Notes
Tuesday, February 20, 2018 1:00 pm ET

Present: Lisa de Lima (LD), Chair; Scott Rice, Vice Chair (SR); Asa Bradman (AB); Tom Chapman (TC); A-dae Briones (ARB); Harriet Behar (HB) - observer; Jesse Buie (JB) - observer
Absent: Steve Ela (SE)
Staff: Michelle Arsenault (MA); Devon Pattillo (DP)

Work Agenda

Petitioned Substances						
Substance	**National List §**	**Contact**	**TR rqst?**	**Notes***	**Scheduled, Discussed, Voted**	**Meeting**
Sodium dodecylbenzene sulfonate (SDBS) Petition Addendum #1, SDBS (PDF)	205.605(b)	SR	Y	Petition sent to HS on 11 02 15. Response/request for TR due 01 04 16. Petition found suff 12 01 15. No new TR will be requested. Referred back to HS at Apr 2016 NOSB meeting. TR request sent 05 18 16. TR in development - Expected late Dec 2016/early Jan. TR delayed until Spring 2017. TR sent to HS 05 30 17. Response due 08 01 17. Petition addendum sent to HS 07 12 17. The HS found the petition addendum suff 08 01 17	Aug 1, Aug 15 Jan 2 Jan 16	Spr 2018
Sodium Chlorite for the generation of chlorine dioxide gas Petition, Addendum	205.605	SR	Y	Petition for chlorine dioxide dry gas sent to HS on 12 02 15. Response/request for TR due 02 02 16. HS sent request 03 17 16 for additional info from petitioner. Sodium chlorite addendum received 05 05 16. Suff due 07 05 16. Petition found sufficient 06 07 16. Sent back to Subcomm at Fall 2016 meeting. HS requested a TR 06 06 17. TR sent to HS 01 09 18. Response due 03 13 18.	May 16, Jun 6, Jan 16 Mar 6	Fall 2018

Petitioned Substances						
Substance	**National List §**	**Contact**	**TR rqst?**	**Notes***	**Scheduled, Discussed, Voted**	**Meeting**
Silver Dihydrogen Citrate Petition Addendum #1	205.605(b)	TC	Y	Petition sent to HS 01 24 17. Response/request for TR due 03 28 17. Petition found sufficient 03 07 17. HS requested TR 03 07 14. TR in development. Petition addendum sent to HS 08 03 17. TR sent to HS 10 19 17/ Suff due 12 19 17. HS sent additional questions to TR contractor 12 05 17. TR under revision. TR sent to HS 02 21 18. Response due 04 23 18.	Mar 7, Dec 5	Fall 2018
Japones pepper	205.606	ARB	N	Petition sent to HS 02 09 17. Response/request for TR due 04 11 17. Petition found suff 04 04 17. No TR. HS requested additional info from petitioner 07 19 17 & 11 07 19	Apr 4, Jul 18 Oct 3 Nov 7	Fall 2018
Ethiopian pepper	205.606	ARB	N	Petition sent to HS 02 09 17. Response/request for TR due 04 11 17. Petition found suff 04 04 17. No TR. HS requested additional info from petitioner 07 19 17 & 11 07 19	Apr 4 Jul 18 Oct 3 Nov 7	Fall 2018
Tamarind Seed Gum Petition Addendum, August 22, 2017	205.606	SE		Petition sent to HS 02 15 17. Response/request for TR due 04 17 17. HS requested additional info from the petitioner 04 04 17. Petition addendum Rcvd 08 10 17. Response due 10 10 17. Updated petition addendum rcvd 08 22 17. TR requested 10 03 17. TR in development - expected March 2018	Apr 4 Sep 5, Oct 3 Mar 6	Fall 2018

2020 Sunsets TR Requests: July 2017, Summary: Spr 2018, Review: Fall 2018						
Name	**National List §**	**Contact**	**TAP/TR**	**Notes**	**Scheduled, Discussed**	**Review Meeting**
Calcium carbonate	205.605(a)	SR	Y	1995 TAP. TR requested 07 28 17. Low priority. TR sent to HS 01 29 18. Suff due 03 30 18. TR found suff 02 20 18	Feb 20	Summary: Spr 2018 Review: Fall 2018

Flavors	205.605(a)	TC	N	2005 TR	Jan 2	"
Gellan Gum	205.605(a)	LD	N	2006 TAP	Feb 20	"
Oxygen	205.605(a)	LD	N	1995 TAP. TR requested 07 28 17. Low priority	Dec 5	"
Potassium chloride	205.605(a)	ARB	N	1995 TAP; 2015 TR for Nutrient vitamins and minerals	Dec 5	"
Alginates	205.605(b)	SE	N	1995 TAP; 2015 TR	Dec 19	"
Calcium hydroxide	205.605(b)	ARB	N	1995 TAP. TR requested 07 28 17. Low priority	Dec 5	"
Ethylene	205.605(b)	AB	N	1995 TAP; 1999 TAP - Processing. TR requested 07 28 17. Contingent on request from other Subcomms	Dec 19, Jan 2	"
Glycerides: mono and di	205.605(b)	LD	N	1995 TAP; 2015 TR	Dec 5	"
Magnesium stearate	205.605(b)	AB	Y	1995 TAP. TR requested 07 28 17. Low priority. TR sent to HS 01 29 18. Suff due 03 30 18. TR found sufficient 02 20 18.	Feb 20	"
Phosphoric acid	205.605(b)	ARB	N	2003 TAP. TR requested 07 28 17. Contingent on request from other Subcomms	Dec 5	"
Potassium carbonate	205.605(b)	SR	N	1995 TAP. TR requested 07 28 17. Low priority.	Feb 20	"
Sulfur dioxide	205.605(b)	SE	N	1995 TAP; 2011 TR	Dec 19	"
Xanthan gum	205.605(b)	LD	N	1995 TAP; 2016 TR	Feb 20	"
Fructooligosaccharides (FOS)	205.606	TC	N	2006 TAP; 2015 TR	Jan 2	"
Gums: Arabic, Carob bean, Guar, Locust bean	205.606(k)	LD	Y	1995 TAP. TR requested 07 28 17. TR in contracting. TR sent to HS 01 30 18. Suff due 04 02 18. TR found sufficient 02 20 18.	Feb 20	"
Lecithin - de-oiled	205.606	ARB	N	1995 TAP; 2009 TR	Jan 16	"
Tragacanth gum	205.606	LD	Y	None. TR requested 07 28 17. TR in contracting. TR sent to HS 01 30 18. Suff due 04 02 18. TR found sufficient 02 20 18.	Feb 20	"

Other projects			
Name	**Contact**	**Notes***	**Meeting**
Packaging substances used in organic food handling - including BPA	LD/AB	Submitted briefing paper to NOP 01 12 14. Response memo from NOP sent to HS 11 19 14. TR in development, expected mid-Sep - delayed. TR received 9/30/16. In review by the program. TR sent to HS 10 19 16. TR sufficiency due 12 20 16. TR found insufficient 12 20 16. Vote: 02 21 17. New TR in development. Expected July 2017, TR received 07 10 17. Response due 09 08 17. TR found sufficient 08 01 17.	Discussion doc TBD
Nutrient Vitamins and Minerals - annotation change	TC	Pending NOP Approval. Approved 01 12 16. Proposal. On hold.	TBD
Marine materials (marine algae and extracts). Proposal	SR	Pending NOP approval. NOP approved request 01 12 16. TR request sent to NOP 02 05 16. TR expected Jul 2016. TR sent to HS 08 10 16. TR suff due 10 11 16. TR found sufficient 09 06 16. Voted 09 06 16. Proposal in development 12 06 16. Voted 01 17 17. Referred back to HS at Spr 2017 NOSB meeting	TBD
Magnesium chloride reclassification 205.605(b)	LD	HS requested addition of this item and NOP approved 01 12 16; TR completed 11/30/16. Petitioned. Voted 02 06 18	Spr 2018
Research Priorities	TC/ALL	RPs due to MS Aug 2018	Fall 2018

*Highlight indicates committee action needed. *Highlight indicates review completion and/or vote

Agenda

- Approve February 6, 2018 notes
- Reassignment of Joelle's assignments
- 2020 sunset: Calcium carbonate (SR) - Discuss review
- 2020 sunset: Potassium carbonate (SR) - Discuss review
- 2018 Gums TR (LD) - TR sufficiency
- 2020 sunset: Gellan Gum (LD) - Discuss review
- 2020 sunset: Gums: Arabic, Carob bean, Guar, Locust bean (LD) - Discuss review
- 2020 sunset: Tragacanth gum (LD) - Discuss review
- 2020 sunset: Xanthan gum (LD) - Discuss review
- 2020 sunset: Magnesium stearate (AB) - Discuss review
- BPA (AB) – Discuss & vote
- Sodium Chlorite (SR) – TR sufficiency, draft proposal discussion (?)
- Marine Materials (SR) - Update on status
- Other items
- Adjourn

Discussion

- **HS Notes from** February 6, 2018 were approved with minor changes
- **Materials reassignment.** AS's materials were reassigned to ARB

- **Materials reassignment.** Joelle Mosso resigned due to time commitments and conflicts with a new position. She completed her sunset reviews prior to her departure, and the HS Chair reassigned her materials to others**.**
- **2020 sunset: Calcium carbonate (SR).** Calcium carbonate is a mined mineral. Previous comments indicated that it is still in wide use. The HS requested a TR to update the 1995 TAP, and found the new TR sufficient.
- **2020 sunset: Potassium carbonate (SR).** A TR for potassium carbonate was requested but was not contracted. The lead summarized the uses, including international uses.
- **2018 Gums TR (LD).** The TR was deemed sufficient. The HS Chair will convey that to the NOP.
- **2020 sunset: Gellan Gum (LD).** The lead summarized the uses and allowances, noting that gellan gum has two unique features as compared to other gums. A member noted that solvents are used in extraction of gellan and xanthan gums, although it was not mentioned in the TR, and that the Canadian standards have restrictions on the solvents. The HS added one question for public comment.
- **2020 sunset: Gums: Arabic, Carob bean, Guar, Locust bean, Tragacanth gum (LD).** The lead summarized the gums. The TR contained information about food safety, while pointing out that there is not enough information available to evaluate that criteria. Added question about organic alternatives**.**
- **2020 sunset: Tragacanth gum (LD).** The lead summarized the uses of tragacanth. There are no environmental or health concerns in the manufacturing process. The HS will add a question about organic alternatives.
- **2020 sunset: Xanthan gum (LD).** Discussed with other gums
- **2020 sunset: Magnesium stearate (AB).** The lead discussed the summary and will modify it with some additional information from the technical report. The TR was found sufficient.
- **BPA (AB).** The group discussed modifying some of the questions and posting it as is for additional comment. HS will defer this project to Fall 2018 meeting.
- **Sodium Chlorite (SR) - TR sufficiency, draft proposal discussion.** Deferred to next call.
- **Marine Materials (SR) - Update on status.** Deferred to next call. Will bring forth along with Crops MM document.
- **Other Items.**
- **The meeting was adjourned**

Previous HS Notes

Future Call Schedule (1st and 3rd Tuesdays 1:00 ET)

February 6, 2018

BPA (AB) - Discuss
Marine Materials (SR) - Discuss proposal
2020 sunset: Potassium carbonate (SR) - Discuss review
Magnesium chloride reclassification (LD) - Discuss
Sodium Chlorite for the generation of chlorine dioxide gas (SR) - TR sufficiency, discuss draft proposal

February 20, 2018

2020 sunset: Potassium carbonate (SR) - Discuss review
Marine Materials (SR) - Discuss proposal/update
Sodium Chlorite for the generation of chlorine dioxide gas (SR) - TR sufficiency, discuss draft proposal
2020 sunset: Calcium carbonate (SR) - Discuss review

2020 sunset: Gellan Gum (LD) - Discuss review
2020 sunset: Gums: Arabic, Carob bean, Guar, Locust bean (JM) - Discuss review
2020 sunset: Tragacanth gum (LD) - Discuss review
2020 sunset: Xanthan gum (LD) - Discuss review
2020 sunset: Magnesium stearate (AB) - Discuss review

March 6, 2018

Tamarind seed gum (SE) - TR sufficiency

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**
Alginic acid	205.605(a)			2015 TR 2017 NOSB Recommendation		Summary: Spr 2019 Review: Fall 2019
Calcium chloride	205.605(a)			1995 TAP 2017 NOSB Recommendation		"
Citric acid	205.605(a)			2015 TR 2017 NOSB Recommendation		"
Dairy cultures	205.605(a)			1995 TAP 2017 NOSB Recommendation		"
Enzymes	205.605(a)			2015 TR 2017 NOSB Recommendation		"
Lactic acid	205.605(a)			2015 TR 2017 NOSB Recommendation		"
L-Malic acid	205.605(a)			2003 TAP 2015 NOSB Recommendation		"
Magnesium sulfate	205.605(a)			2011 TR 2017 NOSB Recommendation		"
Microorganisms	205.605(a)			2014 TR 2015 NOSB Recommendation		"
Perlite	205.605(a)			1996 TAP 2017 NOSB Recommendation		"
Potassium iodide	205.605(a)			2011 TR 2017 NOSB Recommendation		"
Yeast	205.605(a)			2014 TR 2017 NOSB Recommendation		"
Activated charcoal	205.605(b)			2002 TR 2015 NOSB Recommendation		"
Ascorbic acid	205.605(b)			1995 TAP 2017 NOSB Recommendation		"
Calcium citrate	205.605(b)			2015 TR 2017 NOSB Recommendation		"

Ferrous sulfate	205.605(b)			1995 TR 2017 NOSB Recommendation		“
Hydrogen peroxide	205.605(b)			2015 Hydrogen Peroxide (Crops) 2017 NOSB Recommendation		“
Nutrient vitamins and minerals	205.605(b)			2015 TR 2017 NOSB Recommendation		“
Peracetic acid	205.605(b)			2016 TR 2015 NOSB Recommendation		“
Potassium citrate	205.605(b)			2015 TR 2017 NOSB Recommendation		“
Potassium phosphate	205.605(b)			1995 TAP 2017 NOSB Recommendation		“
Sodium acid pyrophosphate	205.605(b)			2001 TAP 2015 NOSB Recommendation		“
Sodium citrate	205.605(b)			2015 TR 2017 NOSB Recommendation		“
Tocopherols	205.605(b)			2015 TR 2017 NOSB Recommendation		“
Celery powder	205.606			None 2017 NOSB Recommendation		“
Fish oil	205.606			2015 TR 2017 NOSB Recommendation		“
Gelatin	205.606			2002 TAP 2017 NOSB Recommendation		“
Orange pulp, dried	205.606			None 2017 NOSB Recommendation		“
Seaweed, Pacific kombu	205.606			None 2017 NOSB Recommendation		“
Seaweed, Wakame (Undaria pinnatifida)	205.606			None 2017 NOSB Recommendation		“

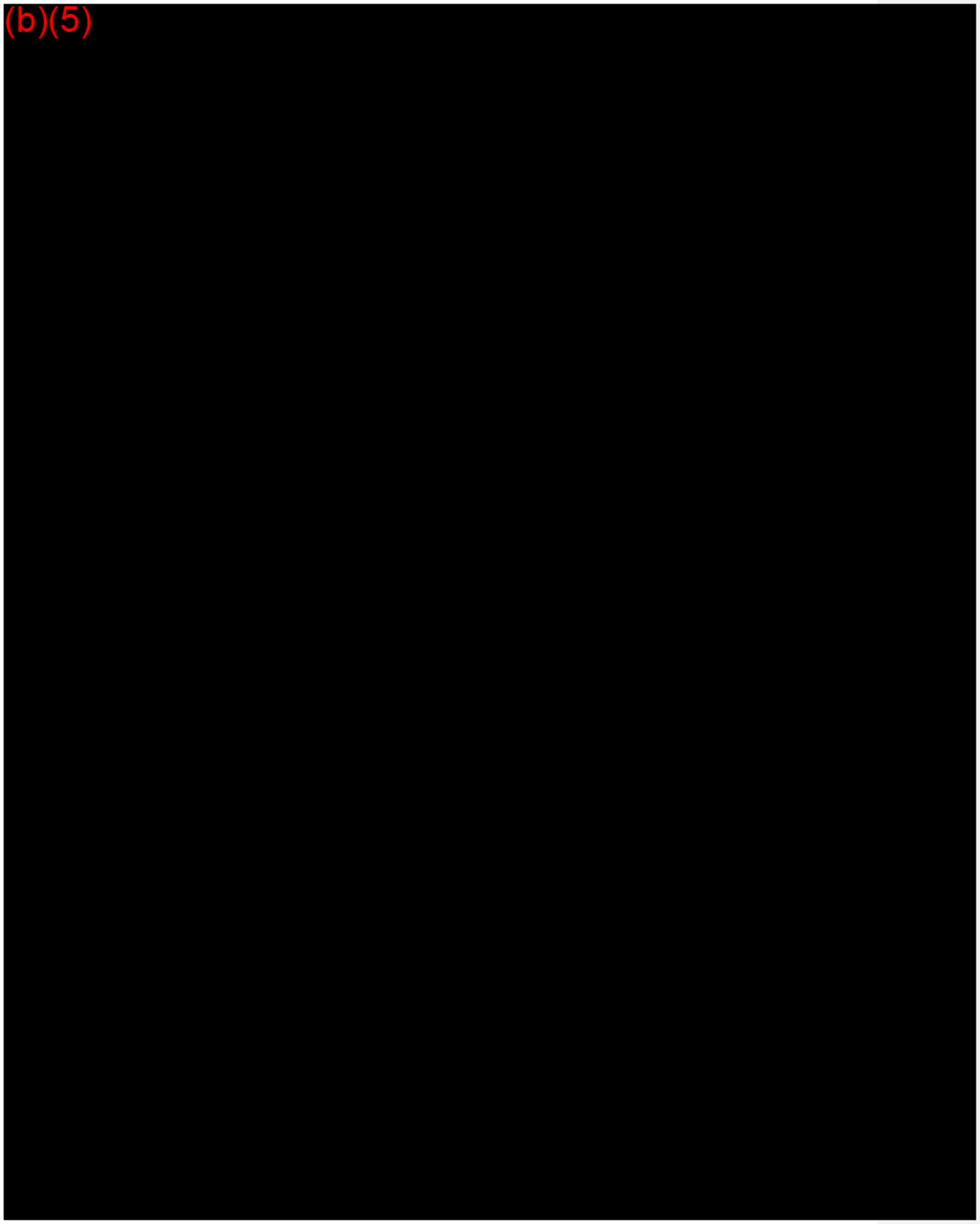
2021 Sunsets TR Requests: July 2018, Summary: Spr 2019, Review: Fall 2019						
Substance	**National List §**	**Con-tact**	**TR re-quest?**	**Notes**	**Scheduled, Discussed**	**Meeting**
Hydrogen peroxide	205.601(a), 205.601(i)			2015 Hydrogen Peroxide (Crops) 2017 NOSB Recommendation		Summary: Spr 2019 Review: Fall 2019
Soaps, ammonium	205.601(d)			1996 TAP 2017 NOSB Recommendation		"
Oils, horticultural (Narrow range oils)	205.601(e), 205.601(i)			1995 TAP 2017 NOSB Recommendation		"
Pheromones	205.601(f)			2012 TR 2017 NOSB Recommendation		"
Ferric phosphate	205.601(h)			2012 TR 2016 NOSB Recommendation		"
Potassium bicarbonate	205.601(i)			2015 TR 2017 NOSB Recommendation		"
Magnesium sulfate	205.601(j)			2011 TR 2017 NOSB Recommendation		"
~~Lignin sulfonate~~	~~205.601(l)~~			2011 TR 2017 NOSB Recommendation (Removed from 205.601(l) as a floating agent: 82 FR 31241)		"
Hydrogen chloride	205.601(n)			2014 Lmtd Scope TR 2016 NOSB Recommendation		"
Ash from manure burning	205.602(a)			2016 sunset rec 2017 NOSB Recommendation		"
Sodium fluoaluminate	205.602(f)			None. 2017 NOSB Recommendation		"

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Sulfur as Slug and Snail Bait

Feb 20, 2018

(b) (5)

(b) (5)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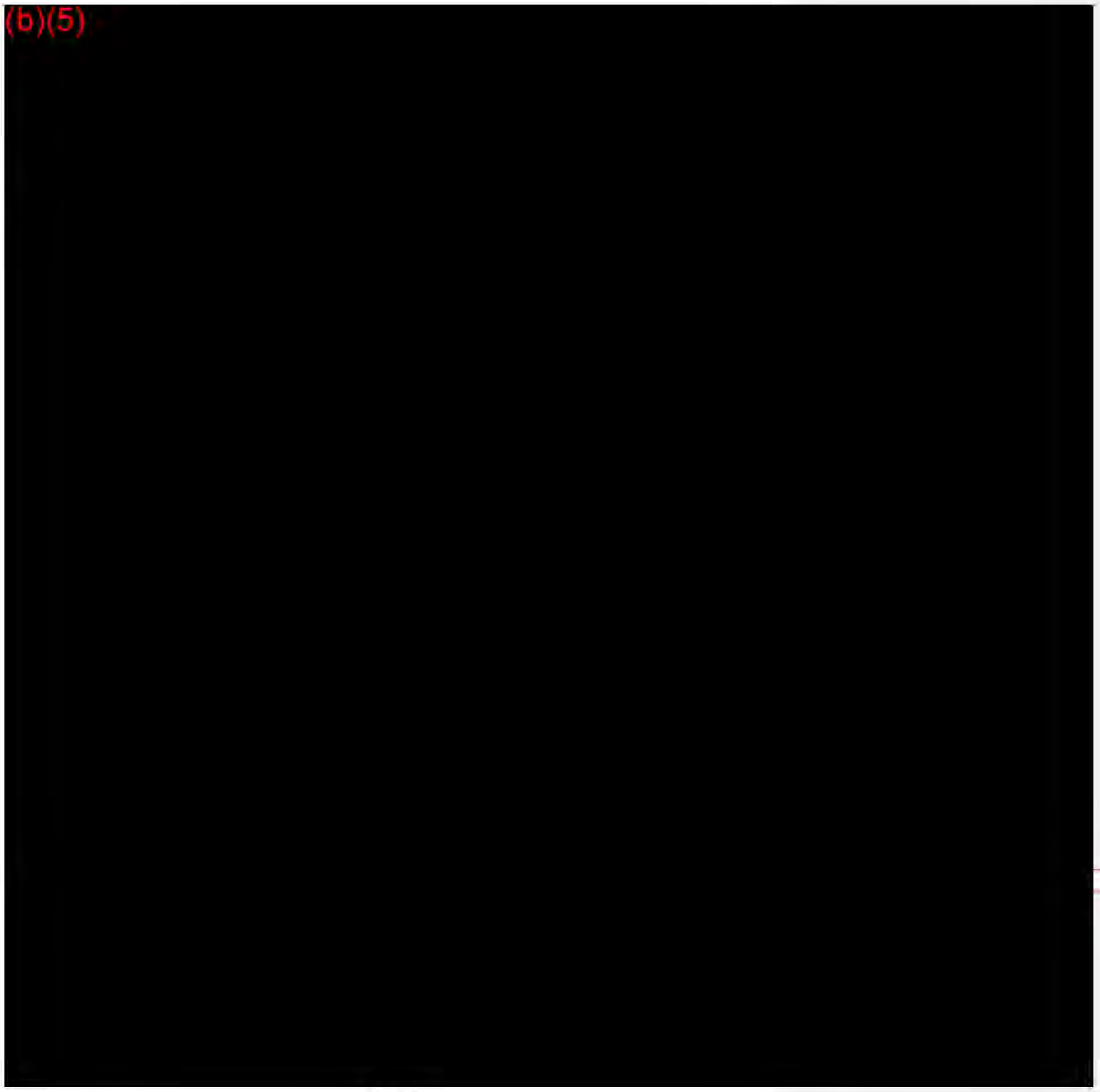
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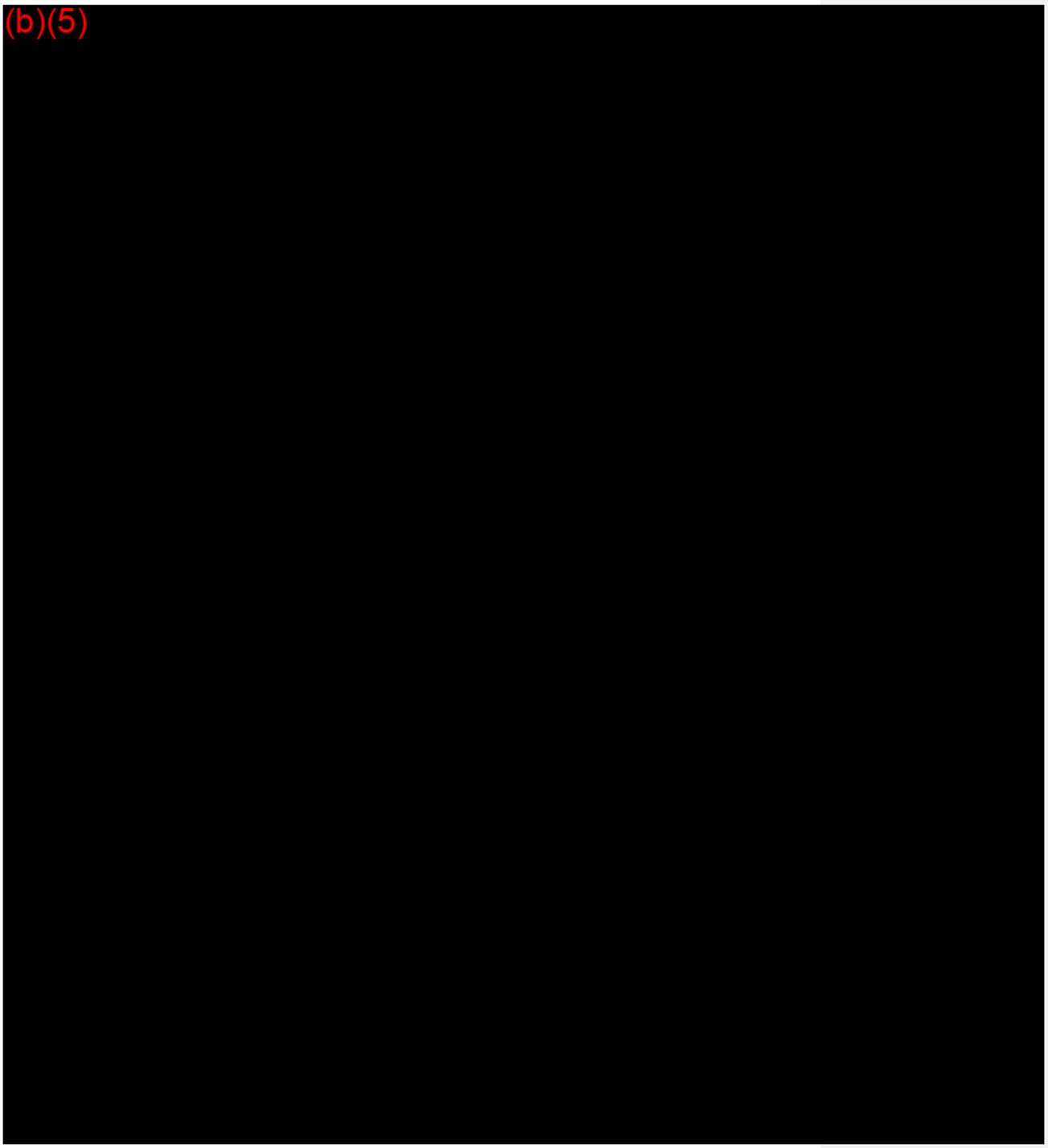

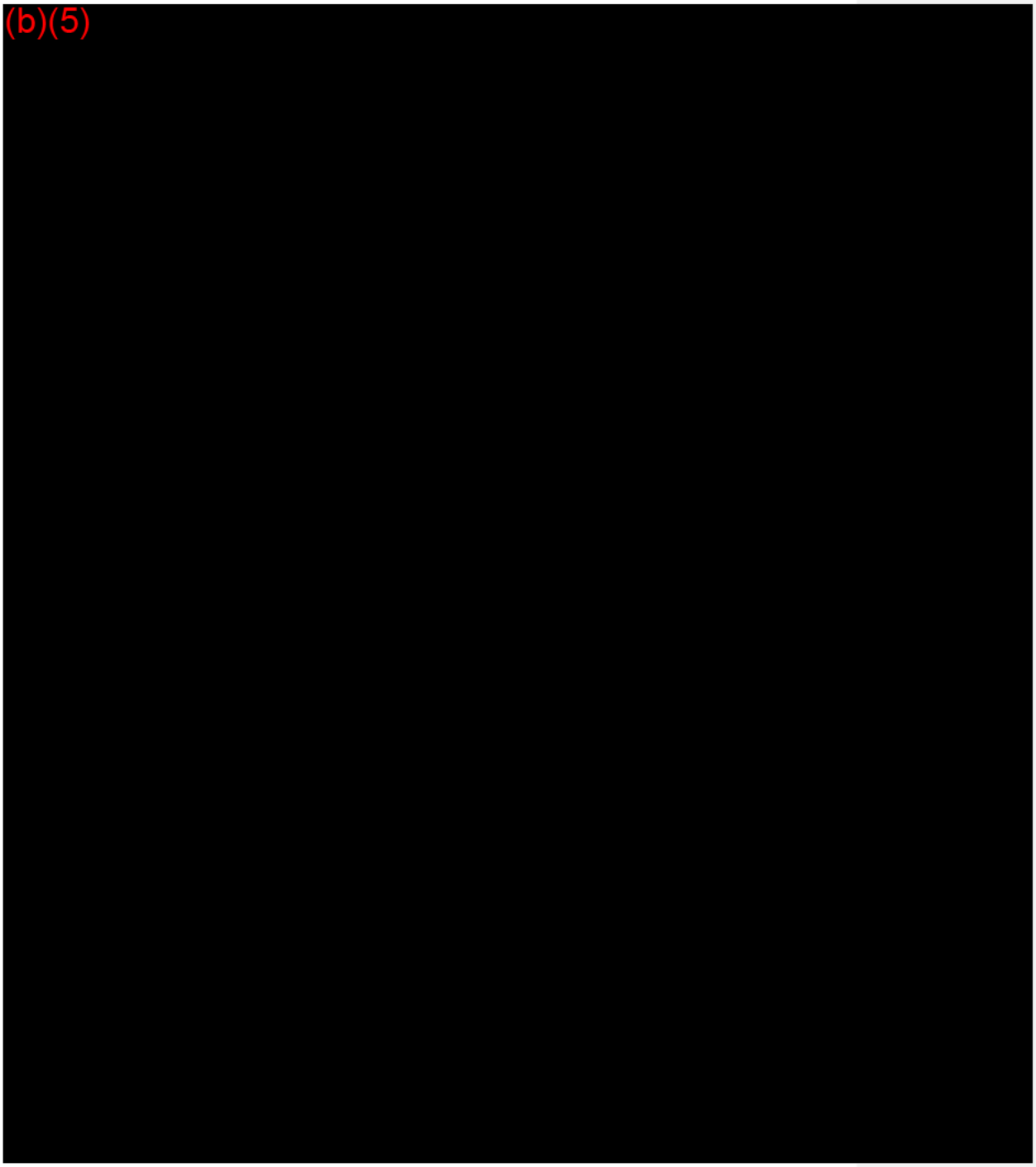
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National Organic Standards Board
Handling Subcommittee
Bisphenol A (BPA) in Packaging Discussion Document

February 201~~7~~ 20187

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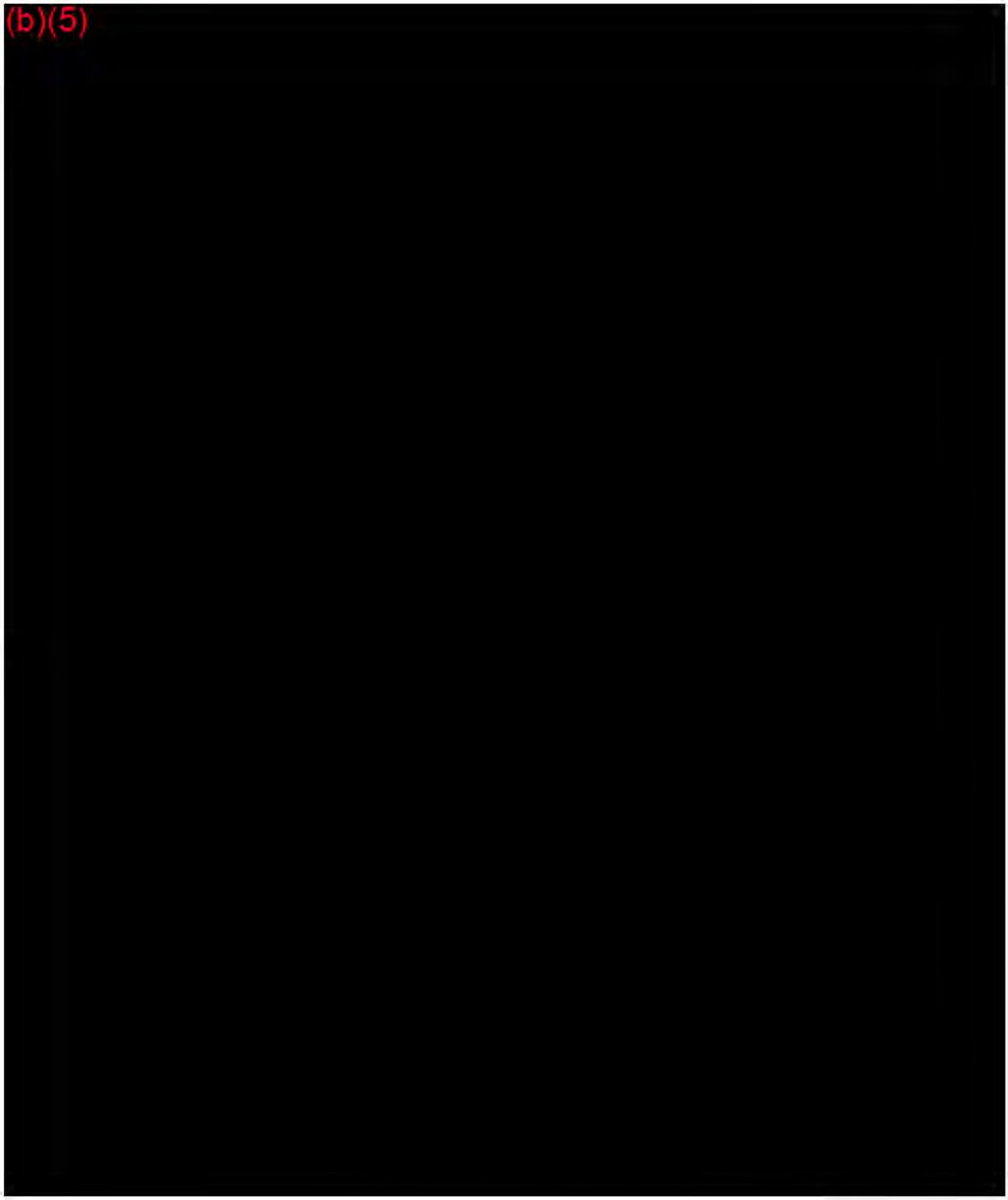
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National Organic Standards Board
Certification, Accreditation and Compliance Subcommittee
Proposal
Eliminating the Incentive to Convert Native Ecosystems to Organic Production
February 22, 2018

(b)(5)

[redacted]

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National Organic Standards Board
Compliance, Accreditation and Certification Subcommittee
Import Oversight Discussion Document
February 25, 2018

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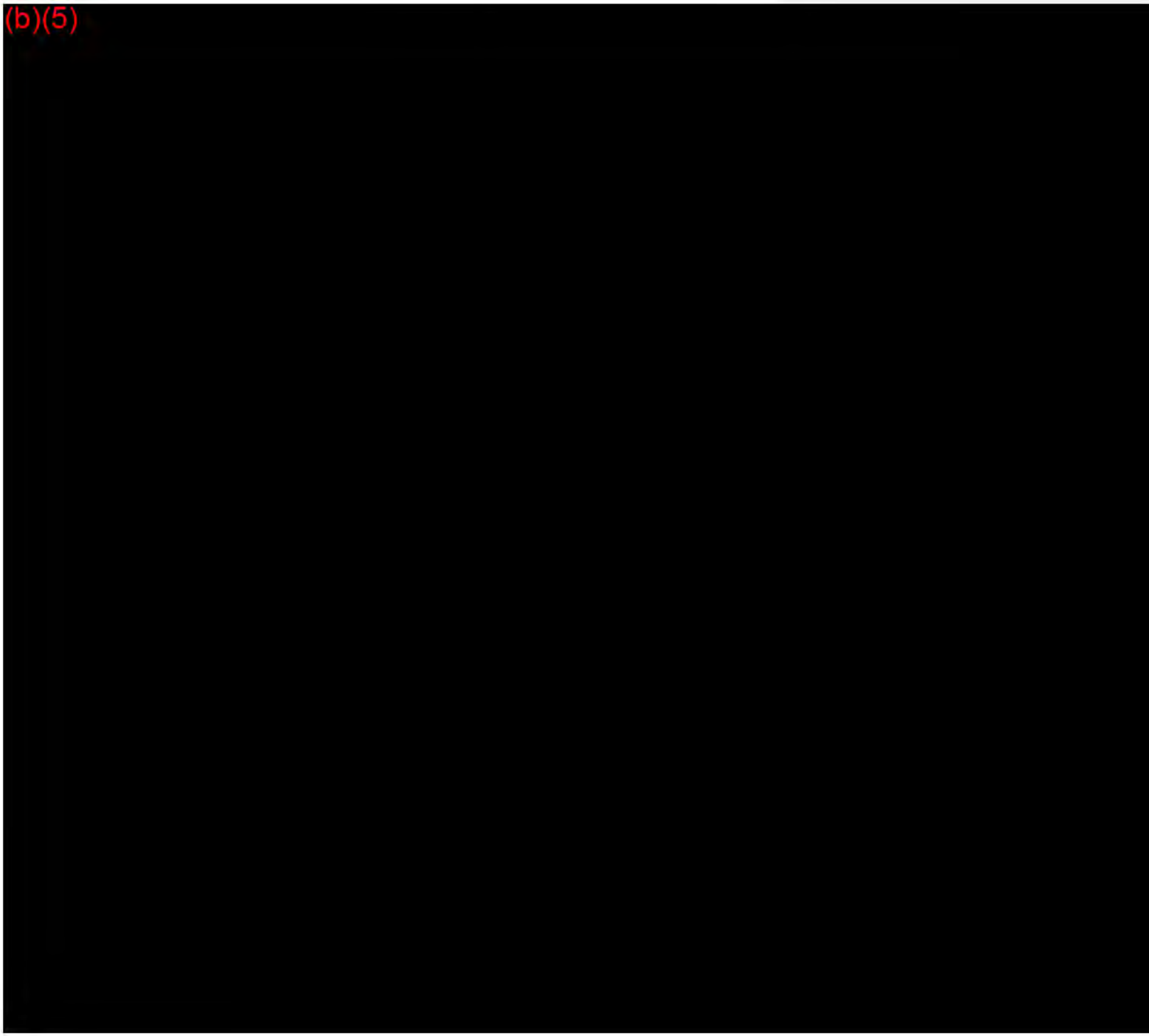
National Organic Standards Board
Compliance, Accreditation and Certification Subcommittee
Import Oversight Discussion Document
February 25, 2018



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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)
Compliance, Accreditation & Certification Subcommittee (CACS) Notes for CACS
Tuesday February 27, 2018, 3:00 pm ET

Attending: Scott Rice (SR), Chair; Emily Oakley (EO), Vice Chair; Harriet Behar (HB); Ashley Swaffar (AS); Lisa de Lima (LD); Tom Chapman (TC)
Absent: A-dae Romero-Briones (ARB)
Staff: Michelle Arsenault (MA); Jenny Tucker (JT); Devon Pattillo (DP)

Work Agenda

Project	Contact	Status	Discussion, Vote	Meeting
Inspector qualifications proposal	SR	Approved for addition to work agenda 04 21 16. Referred back to CACS at Spr 2017 meeting	Dec 12, Jan 9, Jan 23, Feb 13	Spr 2018
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production proposal	HB	Approved for addition to work agenda 07 15 16. Verbal update Fall 2016. DD Spr 2017. Proposal Fall 2017. Referred back to CACS at Fall 2017 meeting	Nov 28, Jan 23 Feb 27	Spr 2018
Import Oversight	ALL	Memo sent to NOSB 08 10 17.	Nov 28, Jan 9, Jan 23. Feb 13, Feb 27	Disc doc Spr 2018

***Discussed** ***Voted**

Agenda

- Approve notes from February 13, 2018
- Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)
- Imports (All)
- Other items
- Adjourn

Discussion

- **Approvel of the notes from** February 13, 2018 were deferred
- **Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB).** The CACS discussed the addition of an appendix of recources, and the lead will add that, and submit to the NOP. Vote recorded below.

Motion to approve the proposal on Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production.
Motion by: HB
Seconded by: EO
Additional discussion: none
Yes: 5 No: 1 Abstain: 0 Absent: 1 Recuse: 0

- **Import oversight discussion document.** The group discussed the draft document and contributions made by each of the Subcommittee members and NOP. TC will make some edits and submit the final document to the NOP.

  Motion to accept the document on import oversight
  Motion by: TC
  Seconded by: AS
  Additional discussion: none
  Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

- **Other items.** None
- **The meeting was adjourned**

Previous CACS Notes

Future Call Schedule (2nd Tuesday 3:00 ET)
February 13, 2018
Inspector qualifications (SR)
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production (HB)
February 27, 2018 - additional call
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

National Organic Standards Board
Certification, Accreditation and Compliance Subcommittee
Proposal
Eliminating the Incentive to Convert Native Ecosystems to Organic Production
February 27, 2018

I INTRODUCTION

The Organic Foods Production Act (OFPA) of 1990 (as amended) and Regulations promulgated by the NOP to implement the Statute, NOP Policy documents, and NOSB Recommendations and Principles include a clear bias towards protection of the natural resources present on an organic operation, including the physical, hydrological, and biological features of the farm. The soil, water, wetlands, woodlands, and wildlife must be maintained or improved by the organic operator through production practices implemented in accordance with the Act and Regulations. This bias towards ecosystem preservation is also found within the organic marketplace with consumer expectations that organic farms and ranches will be examples of excellent land stewardship.

Along with this strong environmental protection within the regulatory framework that oversees organic production, is the requirement that land cannot produce organic crops or livestock until 36 months have passed between the application of a prohibited substance and the harvest of an organic crop. Using land that has not had any prohibited substances applied to it provides an immediate entry into the organic marketplace for crops or livestock, without the three year wait period. The lack of the three-year transition timeframe is an incentive to convert native ecosystems, some with fragile or endangered habitat, to immediate agricultural production. Over the last three years, the NOSB has received substantial public comment describing loss of native ecosystems when farmers transition to organic production.

The NOSB discussion document from January 10, 2016 and proposal of August 2017 resulted in significant numbers of public comment and support from a wide cross-section of stakeholders. This proposal responds to the improvements sought by the public to the proposal of August 2017.

II BACKGROUND

The NOP provided Guidance on Biodiversity in 2016 (NOP 5020) encouraging the protection and maintenance of a high level of biodiversity on farms because it brings benefits not only to the entire ecosystem in that geographic area, but also to the farmer. This proposal deals with native ecosystems that were specifically not included in the NOP Biodiversity Guidance but were mentioned as an area that should have continued attention.

Many certification agencies around the world address this issue in their standards by banning converted native ecosystems from using the certified organic label at any time after this conversion. These certifiers were listed in the previous discussion document and proposal. The NOSB is not suggesting an outright ban. There may be issues, such as the area may have been converted by a different operator, that should not keep the current operator from choosing to use the environmentally beneficial practices of organic production and being rewarded with the use of the organic label. The NOSB feels the 10-year wait period between conversion of a native ecosystem and subsequent organic certification proposed in its August 2017 proposal, if all other requirements are met, is a strong disincentive to conversion of these precious areas to organic production.

III RELEVANT AREAS OF THE STATUTE, RULE and RELATED DOCUMENTS

The Organic Foods Production Act (OFPA) of 1990, as amended, 7 USC, Chapter 94:

7 USC 6504 (2) …not be produced on land to which any prohibited substances, including synthetic chemicals have been applied during the 3 years immediately preceding the harvest of the agricultural products;

7 USC 6513(f) Management of wild crops; (2) include a 3 year history of the management of the area showing that no prohibited substances have been applied; (3) include a plan for the harvesting and gathering of wild crops assuring that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop;

The OFPA Preamble to the Final Rule establishing the NOP states: "[t]he use of 'conserve' [in the definition of organic production] establishes that the producer must initiate practices to support biodiversity and avoid, to the extent practicable, any activities that would diminish it. Compliance with the requirement to conserve biodiversity requires that a producer incorporate practices in his or her organic system plan that are beneficial to biodiversity on his or her operation." (76 FR 80563)

Previous documents on this issue have provided numerous instances of unaltered native ecosystems that are either at risk or have been destroyed for agricultural production. Numerous examples were provided that this destruction is occurring on land that subsequently is used for organic production, and therefore this issue must be addressed. There are other regulations within the U.S. law that seek to protect specific areas, such as the "sodsaver" provision[1], which specifically addresses the protection of prairie potholes in the United States.

IV PUBLIC COMMENT

The August proposal of 2017 recommended rule making under 205.200 with this statement.

(a) A native ecosystem site that has not been previously grazed or cultivated cannot be certified as organic as provided for under this regulation for a period of 10 years from the date of conversion to crop or livestock production.

The vast majority of public comments supported the Wild Farm Alliance's response to the NOSB proposal above, which included the definition and a rule change below.

The suggested definition is as follows:

Native ecosystems can be recognized in the field as retaining both dominant and characteristic plant species as described by established classifications of natural and seminatural vegetation. These will tend to be on lands that have not been previously cultivated, cleared, drained or otherwise irrevocably altered. However, they could include areas that had been substantially altered over 50-100 years ago, but have since recovered expected plant species composition and structure.

The suggested regulatory change is as follows:

205.200 (a) A site supporting a native ecosystem cannot be certified for organic production as provided for under this regulation for a period of 10 years from the date of conversion.

V SUBCOMMITEE DISCUSSION

The public and NOSB understand the challenge presented by the public to determine if a native ecosystem has been destroyed for the purpose of growing organic crops. However, there are numerous governmental and privately available aerial photos and ecosystem surveys for both domestic and international production that can aid in determining what had been grown on any specific agricultural parcel for at least the past 50 years and even beyond. Areas where there was no agricultural production have also been surveyed, although there may not be as much detail. The Natural Resources Conservation Service (NRCS) has a database of the possible locations of endangered and threatened species they refer to when allowing manipulation of lands and wetlands. The Farm Service Agency (FSA) has aerial photos of agricultural land going back to 1938, with photos taken approximately once per decade. The U.S. geological service has aerial photos of nonagricultural land going back to the 1950s. NatureServe and other international organizations have similar items for international tracking. Links to many of these websites were provided in previous NOSB documents on this subject.

In addition, organic certification agencies would need to add a few questions to their organic system plan applications to address this issue. Certifiers could provide the readily accessible websites where the various sources of aerial photos and ecosystem tracking could be found to aid operators in answering the questions in their OSP. The questions listed below are examples for organic certifiers to use or modify, to aid them in implementing the proposed regulation of this proposal. These questions are not part of any regulatory change.

A. Has the area been tilled, cleared, drained, intentionally burned or transplanted into in the past 50 years? *If yes, then ignore the rest of this section.*
B. Has the land been managed by people for crop production or other purpose such as grazing in the past 50 years? *If yes, then ignore the rest of this section.*
C. Did the land, 10 years ago to the present day, have a majority non-native or invasive species present? *If yes, then ignore the rest of this section.*
D. Ten years ago, were native species present in this area and found in sufficient numbers, diversity and vitality to continually regenerate and maintain the biodiversity present? *If no, go to the next section of the OSP. If yes, then this land may be regulated under 205.200 (a). Further information may be requested by your organic certification agency, based upon publicly available aerial photos and ecosystem survey information.*
E. Are you aware of any conversions from a native ecosystem in the past ten years on the land under application?

VI MOTION TO APPROVE THIS PROPOSAL

Add this definition to §205.2

<u>Native Ecosystem</u>: ***Native ecosystems can be recognized in the field as retaining both dominant and characteristic plant species as described by established classifications of natural and semi natural vegetation. These will tend to be on lands that have not been previously cultivated, cleared, drained or otherwise irrevocably altered. However, they could include areas that had been substantially altered over 50-100 years ago, but have since recovered expected plant species composition and structure.***

Add this language to §205.200 General– addition is in bold

§205.200 The producer or handler of a production or handling operation intending to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must comply with the applicable provisions of this subpart. Production practices implemented in accordance with this subpart must maintain or improve the natural resources of the operation, including soil and water quality.

(a) A site supporting a native ecosystem cannot be certified for organic production as provided for under this regulation for a period of 10 years from the date of conversion.

Motion to approve this proposal.
Motion by Harriet Behar
Seconded by
Yes: No: Abstain: Absent: Recuse:
Approved by Scott Rice , Subcommittee Chair, to transmit to NOSB , 2018

National Organic Standards Board (NOSB)
Crops Subcommittee (CS) Meeting Notes
Tuesday March 6, 2018 2:00 pm ET draft

Present:); Steve Ela, Chair (SE); Emily Oakley, Vice Chair (EO); Harriet Behar (HB); Asa Bradman (AB); Dave Mortensen (DM); Jesse Buie (JB)
Absent: Sue Baird (SB)
Staff: Michelle Arsenault (MA)

Work Agenda

Petitioned Substances					
Substance	**Con-tact**	**TR request?**	**Notes**	**Discussed, Voted**	**Meeting**
Polyoxin D Zinc salt 205.601 Petition Addendum #1 Petition Addendum #2	JB	Y	Petition sent to CS 06 16 16. Petition suff/TR request due 08 16 16. Petition found sufficient 08 16 16. Discuss need for Lmt'd scope TR. CS requested Lmt'd scope TR 10 04 16. TR sent to Subcommittee on 12 19 17. Response due 02 20 18. TR found sufficient 02 20 18.	Feb 6, Feb 20	Spr 2018
Allyl Isothiocyanate (AITC) Petition (2016) 205.601	JB	Y Lmt'd scope	Petition sent to CS 07 06 16. Petition suff/TR request due 09 06 16. Petition found suff 10 04 16. CS requested Lmt'd scope TR 10 04 16. TR in development. Expected Feb/Mar 2018. Lmtd scope TR sent to CS 02 16 18. Response due 04 18 18. TR found sufficient 03 06 18 • AITC Petition (2013) (PDF) • NOSB Subcommittee Proposal (2014) (PDF) • Technical Evaluation Report (2014) (PDF)	Mar 6	Fall 2018
Sodium Citrate 205.601	HB	Y	Petition sent to CS 07 27 16. Petition suff/TR request due 09 27 16. Petition was found sufficient 10 04 16. CS requested a TR 10 04 16. TR in development. TR - Handling, Citric acid and salts (2015). TR sent to CS 08 07 17. Response due 10 06 17. Found TR insufficient 09 19 17. HS sent additional questions to TR contractor 12 11 17. Revised TR sent to CS 12 20 17. Response due 02 19 18. TR found sufficient 02 06 18.	Sep 19, 2017, Feb 6, 2018 Mar 6	Fall 2018

Natamycin	HB	Y	Petition sent to CS 09 09 16. Petition suff/TR request due 11 08 16. Petition found sufficient 11 01 16, and CS requested TR 11 01 16. TR in development. Expected October 2017. TR sent to CS 11 3 17. Response due 01 12 18. TR found sufficient 12 5 17.	Dec 5, Mar 3	Fall 2018
Sulfur (as a molluscicide) 205.601	AB	N	Petition sent to CS 06 08 17. Petition suff/TR request due 09 05 17. Petition found sufficient 09 19 17. No TR request.	Sep 19 Feb 20	Spr 2018
Ammonium Citrate 205.601	EO/DM	Y	Petition sent to CS 10 25 17. Petition suff/TR request due 12 26 17. TR requested 11 21 17.	Nov 21	TBD
Ammonium Glycinate 205.601	EO/DM	Y	Petition sent to CS 10 25 17. Petition suff/TR request due 12 26 17. TR requested 11 21 17.	Nov 21	TBD
Calcium Acetate	SB	Y	Petition sent to CS 1 20 17. Petition suff/TR request due 01 17 17. Petition found suff 02 06 18. CS requested TR with specific questions 02 06 18.	Feb 6	TBD

Other Topics

Project	Con-tact	Doc type	Notes*	Discussed/ Voted	Meeting
(Manure treatments) Anaerobic Digestate - Food Waste 205.601(j) and other manure issues	EO/HB/JM	Disc Doc	Petition sent to CS 04 08 15. Questions or request for TR due 06 09 15. Petition found sufficient 06 02 15. TR rqst sent to NOP 10 06 15. Petition withdrawn 10 14 15. CS moved project to "other topics" NOP sent memo to board 05 09 16 requesting review. TR request sent to NOP 07 05 16 (see anaerobic digestate above). Waiting for result of FDA's risk assessment.	Aug 1, Aug 15, 2017	Fall 2018
Biodegradable Biobased Mulch annotation change	HB/AB	Disc Doc	Limited scope TR request sent to NOP 08 02 16. TR sent to CS on 12 28 16. TR Suff due 02 27 17. CS found TR suff 01 03 17. Pending further research	Aug 1, 2017	TBD
Prohibition of NPEs in inerts - annotation change/ EPA List 4 Inerts annotation change	HB/EO/DM/AB	Disc Doc/Prop	IWG recommended NOSB work on NPEs/TR requested July 2014. DD - April 2016. EPA List 4 inerts disc doc (originated from 2017 sunset review conducted in 2015). Pending EPA decision	TBD	Fall 2018

Marine materials (marine algae and extracts) on the National List	EO	Disc doc	NOP approved request 01 12 16. TR request sent to NOP 02 05 16. TR sent to HS 08 10 16. Referred back to CS at Spr 2017 meeting. Moved to MS 03 16 18.	Aug 15, Dec 5	TBD
Field and Greenhouse Container Production	JB, HB, FT and EO	TBD	On hold as per NOP Jan 2018.	TBD	TBD
Strengthen and clarify the requirements for use of organic seed (NOP 5029)	HB	Proposal	Originated in MS. Referred back to CS at Spr 2017 meeting. Referred back to CS at Fall 2017 meeting.	TBD	TBD
Research Priorities	All	NA	RPs due to MS Aug 2018	NA	Fall 2018

* Yellow highlight indicates Subcommittee action needed *Highlight indicates review completion

2020 Sunsets **TR Requests: July 2017, Summary: Spr 2018, Review: Fall 2018**						
Substance		**Contact**	**TR request?**	**Notes**	**Scheduled, Discussed**	**Meeting**
Alcohols: Ethanol Isopropanol	205.601(a)(1)(i), 205.601(a)(1)(ii)	JB	N	1995 TAP; 2014 TR - Ethanol; 2014 TR - Isopropanol	Feb 6	Summary: Spr 2018 Review: Fall 2018
Sodium carbonate peroxyhydrate	205.601(a)	EO	N	2006 TAP; 2014 TR	Dec 5	"
Newspaper or other recycled paper	205.601(b) and (c)	HB	N	2017 TR	Dec 5	"
Plastic mulch and covers	205.601(b)	HB	N	1995 TAP: TR for biodegradable mulch. Low priority	Dec 19, Jan 2	"
Aqueous potassium silicate	205.601(e), 205.601(i)	DM	N	2014 TR	Jan 2, Feb 6	"

Elemental sulfur	205.601(e)(5), 205.601(i)(10), 205.601(j)(2)	AB	Y	1995 TAP; 2017 TR for Livestock. TR requested 07 28 17. In contracting. TR sent to CS 01 10 18. TR sufficiency due 03 12 18. CS sent additional questions to the TR contractor. TR final draft expected April 2018.	Dec 19, Jan 2 Feb 20	"
Lime sulfur	205.601(e)(6), 205.601(i)(6)	SE	N	2014 TR	Dec 19	"
Sucrose octanoate esters	205.601(e)(10)	SB	N	2005 TR	Dec 19	"
Hydrated lime	205.601(i)(4)	DM	N	1995 TAP; 2001 TAP; 2002 TR for Calcium Hydroxide	Jan 2	"
Liquid fish products	205.601(j)	AB	N	1995 TAP; 2006 TR	Jan 16,	"
Sulfurous Acid	205.601(j)	SE	N	2010 TAP; 2014 TR	Dec 19	"
Ethylene	205.601(k)	EO	N	2000 Supplemental TAP; 2007 TAP; 2011 Supplemental TR	Dec 19	"
Microcrystalline cheesewax	205.601(o)	SB	Y	None. TR requested 07 28 17. In contracting. TR sent to CS 01 11 18. TR found sufficient 02 20 18.	Dec 19, Feb 20	"
Potassium chloride	205.602(e)	HB	N	1995 TAP. Low priority	Jan 16	"

Agenda

- Approve notes from February 20 call.
- Allyl Isothiocyanate (AITC) (JB) - TR sufficiency
- Sodium Citrate (HB) - Discuss proposal
- Natamycin (HB) - Discuss proposal
- Other items
    - Marine materials update
    - Strengthen and clarify the requirements for use of organic seed (NOP 5029) update
- Assign leads to 2021 sunsets
- Adjourn

Discussion

- **Notes from** February 20 were approved with a correction to the entry about marine materials.
- **Potassium chloride** was reassigned to HB.
- **Allyl Isothiocyanate (AITC) (JB).** The Subcommittee requested a limited scope TR with specific questions, and the CS found it sufficient. The lead will begin drafting a proposal and the group will discuss it on a later call.
- **Sodium Citrate (HB).** The lead will make some additional edits to the draft proposal based on feedback during the discussion, and bring it forth for a vote on a later call.

- **Natamycin (HB).** The group discussed classification and how to move forward with the proposal. The lead invited feedback. Several members will reach out to other members and stakeholders to for additional feedback, and discuss it during the next call. The NOP will provide feedback on the next call about the process, if the substance is classified as nonsynthetic.
- **Other items**
    - Marine materials update. The Crops and Handling proposals on marine materials will be combined and sent to the Materials Subcommittee for completion, and will be submitted as a proposal for the Fall NOSB meeting. The Crops version has been completed, and the lead will work on completing the Handling version and will send it to Materials. The Subcommittee asked NOP for options to post this document ahead of that meeting for public viewing and feedback. MA will ask if posting to the docket is still an option.
    - Strengthen and clarify the requirements for use of organic seed (NOP 5029) update. Deferred.
- **Assign leads to 2021 sunsets.** Deferred to April 3 call.
- **Other.** The CS cancelled the March 20 call.
- **The meeting was adjourned**

Previous CS Notes

Future Call Schedule (1st and 3rd Tuesdays 2:00 ET)

February 20, 2018
- 2020 sunset: Microcrystalline cheesewax (SB) - TR sufficiency
- 2020 sunset: Elemental sulfur (AB) - TR sufficiency
- Polyoxin D Zinc salt (JB) - Review petition addendum/TR sufficiency
- Discussion of future options for container proposals (HB)

March 6, 2018
- Allyl Isothiocyanate (AITC) (JB) - TR sufficiency
- Sodium Citrate (HB) - Discuss proposal
- Natamycin (HB) - Discuss proposal

March 20, 2018 - cancelled call

April 3, 2018
- Sodium Citrate (HB). Discuss and vote
- Assign leads to 2021 sunsets
- Natamycin (HB) - Discuss proposal
- Discuss public comment

April 17, 2018 - NOSB public comment webinar

May 1, 2018
- Allyl Isothiocyanate (AITC) (JB) - Discuss proposal

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
Hydrogen peroxide	205.601(a), 205.601(i)			2015 Hydrogen Peroxide (Crops) 2017 NOSB Recommendation		Summary: Spr 2019 Review: Fall 2019
Soaps, ammonium	205.601(d)			1996 TAP 2017 NOSB Recommendation		"
Oils, horticultural (Narrow range oils)	205.601(e), 205.601(i)	SE		1995 TAP 2017 NOSB Recommendation		"
Pheromones	205.601(f)	SE		2012 TR 2017 NOSB Recommendation		"
Ferric phosphate	205.601(h)			2012 TR 2016 NOSB Recommendation		"
Potassium bicarbonate	205.601(i)			2015 TR 2017 NOSB Recommendation		"
Magnesium sulfate	205.601(j)			2011 TR 2017 NOSB Recommendation		"

~~Lignin sulfonate~~	~~205.601(l)~~			2011 TR 2017 NOSB Recommendation (Removed from 205.601(l) as a floating agent: 82 FR 31241)		“
Hydrogen chloride	205.601(n)			2014 Lmtd Scope TR 2016 NOSB Recommendation		“
Ash from manure burning	205.602(a)			2016 sunset rec 2017 NOSB Recommendation		“
Sodium fluoaluminate	205.602(f)			None. 2017 NOSB Recommendation		“

National Organic Standards Board (NOSB)
Handling Subcommittee (HS) Meeting Notes draft
Tuesday, March 6, 2018 1:00 pm ET

Present: Lisa de Lima (LD), Chair; Scott Rice, Vice Chair (SR); Asa Bradman (AB); Tom Chapman (TC); Steve Ela (SE); Harriet Behar (HB) - observer; Jesse Buie (JB) - observer
Absent: A-dae Briones (ARB)
Staff: Michelle Arsenault (MA)

Work Agenda

Petitioned Substances						
Substance	**National List §**	**Contact**	**TR rqst?**	**Notes***	**Scheduled, Discussed, Voted**	**Meeting**
Sodium dodecylbenzene sulfonate (SDBS) Petition Addendum #1, SDBS (PDF)	205.605(b)	SR	Y	Petition sent to HS on 11 02 15. Response/request for TR due 01 04 16. Petition found suff 12 01 15. No new TR will be requested. Referred back to HS at Apr 2016 NOSB meeting. TR request sent 05 18 16. TR in development - Expected late Dec 2016/early Jan. TR delayed until Spring 2017. TR sent to HS 05 30 17. Response due 08 01 17. Petition addendum sent to HS 07 12 17. The HS found the petition addendum suff 08 01 17	Aug 1, Aug 15 Jan 2 Jan 16	Spr 2018
Sodium Chlorite for the generation of chlorine dioxide gas Petition, Addendum	205.605	SR	Y	Petition for chlorine dioxide dry gas sent to HS on 12 02 15. Response/request for TR due 02 02 16. HS sent request 03 17 16 for additional info from petitioner. Sodium chlorite addendum received 05 05 16. Suff due 07 05 16. Petition found sufficient 06 07 16. Sent back to Subcomm at Fall 2016 meeting. HS requested a TR 06 06 17. TR sent to HS 01 09 18. Response due 03 13 18. TR found sufficient 03 06 18.	May 16, Jun 6, Jan 16 Mar 6	Fall 2018

Petitioned Substances						
Substance	**National List §**	**Contact**	**TR rqst?**	**Notes***	**Scheduled, Discussed, Voted**	**Meeting**
Silver Dihydrogen Citrate Petition Addendum #1	205.605(b)	TC	Y	Petition sent to HS 01 24 17. Response/request for TR due 03 28 17. Petition found sufficient 03 07 17. HS requested TR 03 07 14. TR in development. Petition addendum sent to HS 08 03 17. TR sent to HS 10 19 17/ Suff due 12 19 17. HS sent additional questions to TR contractor 12 05 17. TR under revision. TR sent to HS 02 21 18. Response due 04 23 18. HS sent additional questions to the TR contractor 03 06 18. Waiting for response.	Mar 7, Dec 5 Mar 6	Fall 2018
Japones pepper	205.606	ARB	N	Petition sent to HS 02 09 17. Response/request for TR due 04 11 17. Petition found suff 04 04 17. No TR. HS requested additional info from petitioner 07 19 17 & 11 07 17	Apr 4, Jul 18 Oct 3 Nov 7	Fall 2018
Ethiopian pepper	205.606	ARB	N	Petition sent to HS 02 09 17. Response/request for TR due 04 11 17. Petition found suff 04 04 17. No TR. HS requested additional info from petitioner 07 19 17 & 11 07 17	Apr 4 Jul 18 Oct 3 Nov 7	Fall 2018
Tamarind Seed Gum Petition Addendum, August 22, 2017	205.606	SE		Petition sent to HS 02 15 17. Response/request for TR due 04 17 17. HS requested additional info from the petitioner 04 04 17. Petition addendum Rcvd 08 10 17. Response due 10 10 17. Updated petition addendum rcvd 08 22 17. TR requested 10 03 17. TR in development - expected March 2018	Apr 4 Sep 5, Oct 3 Apr 3	Fall 2018
Pullulan	205.605(a)	LD		Petition sent to HS 02 27 18/ Sufficiency due 04 30 18	Apr 3	TBD

2020 Sunsets TR Requests: July 2017, Summary: Spr 2018, Review: Fall 2018						
Name	**National List §**	**Contact**	**TAP/TR**	**Notes**	**Scheduled, Discussed**	**Review Meeting**
Calcium carbonate	205.605(a)	SR	Y	1995 TAP. TR requested 07 28 17. Low priority. TR sent to HS 01 29 18. Suff due 03 30 18. TR found suff 02 20 18	Feb 20	Summary: Spr 2018 Review: Fall 2018
Flavors	205.605(a)	TC	N	2005 TR	Jan 2	"
Gellan Gum	205.605(a)	LD	N	2006 TAP	Feb 20	"
Oxygen	205.605(a)	LD	N	1995 TAP. TR requested 07 28 17. Low priority	Dec 5	"
Potassium chloride	205.605(a)	ARB	N	1995 TAP; 2015 TR for Nutrient vitamins and minerals	Dec 5	"
Alginates	205.605(b)	SE	N	1995 TAP; 2015 TR	Dec 19	"
Calcium hydroxide	205.605(b)	ARB	N	1995 TAP. TR requested 07 28 17. Low priority	Dec 5	"
Ethylene	205.605(b)	AB	N	1995 TAP; 1999 TAP - Processing. TR requested 07 28 17. Contingent on request from other Subcomms	Dec 19, Jan 2	"
Glycerides: mono and di	205.605(b)	LD	N	1995 TAP; 2015 TR	Dec 5	"
Magnesium stearate	205.605(b)	AB	Y	1995 TAP. TR requested 07 28 17. Low priority. TR sent to HS 01 29 18. Suff due 03 30 18. TR found sufficient 02 20 18.	Feb 20	"
Phosphoric acid	205.605(b)	ARB	N	2003 TAP. TR requested 07 28 17. Contingent on request from other Subcomms	Dec 5	"
Potassium carbonate	205.605(b)	SR	N	1995 TAP. TR requested 07 28 17. Low priority.	Feb 20	"
Sulfur dioxide	205.605(b)	SE	N	1995 TAP; 2011 TR	Dec 19	"
Xanthan gum	205.605(b)	LD	N	1995 TAP; 2016 TR	Feb 20	"
Fructooligosaccharides (FOS)	205.606	TC	N	2006 TAP; 2015 TR	Jan 2	"
Gums: Arabic, Carob bean, Guar, Locust bean	205.606(k)	LD	Y	1995 TAP. TR requested 07 28 17. TR in contracting. TR sent to HS 01 30 18. Suff due 04 02 18. TR found sufficient 02 20 18.	Feb 20	"

Lecithin - de-oiled	205.606	ARB	N	1995 TAP; 2009 TR	Jan 16	"
Tragacanth gum	205.606	LD	Y	None. TR requested 07 28 17. TR in contracting. TR sent to HS 01 30 18. Suff due 04 02 18. TR found sufficient 02 20 18.	Feb 20	"

Other projects			
Name	**Contact**	**Notes***	**Meeting**
Packaging substances used in organic food handling - including BPA	LD/AB	Submitted briefing paper to NOP 01 12 14. Response memo from NOP sent to HS 11 19 14. TR in development, expected mid-Sep - delayed. TR received 9/30/16. In review by the program. TR sent to HS 10 19 16. TR sufficiency due 12 20 16. TR found insufficient 12 20 16. Vote: 02 21 17. New TR in development. Expected July 2017, TR received 07 10 17. Response due 09 08 17. TR found sufficient 08 01 17.	Discussion doc TBD
Nutrient Vitamins and Minerals - annotation change	TC	Pending NOP Approval. Approved 01 12 16. Proposal. On hold.	TBD
Marine materials (marine algae and extracts). Proposal	SR	Pending NOP approval. NOP approved request 01 12 16. TR request sent to NOP 02 05 16. TR expected Jul 2016. TR sent to HS 08 10 16. TR suff due 10 11 16. TR found sufficient 09 06 16. Voted 09 06 16. Proposal in development 12 06 16. Voted 01 17 17. Referred back to HS at Spr 2017 NOSB meeting	TBD
Magnesium chloride reclassification 205.605(b)	LD	HS requested addition of this item and NOP approved 01 12 16; TR completed 11/30/16. Petitioned. Voted 02 06 18	Spr 2018
Research Priorities	TC/ALL	RPs due to MS Aug 2018	Fall 2018

*Highlight indicates committee action needed. *Highlight indicates review completion and/or vote

Agenda

- Approve February 20, 2018 notes
- Sodium chlorite (SR)
- Tamarind seed gum (SE) - TR sufficiency
- Pullulan petition - assign lead
- Discuss 2021 Sunsets (All)
- Other items
- Adjourn

Discussion

- **HS Notes from** February 20, 2018 were approved with a couple of changes to dates, and lead reviewer initials.

- **Sodium chlorite (SR).** The HS found the TR sufficient, as it addressed questions that both the Board and public commenters had. The Chair will alert the NOP as to sufficiency.
- **Tamarind seed gum (SE).** Awaiting TR. Rescheduled discussion to April 3
- **Pullulan petition.** The HS Chair will lead the review.
- **Discuss 2021 Sunsets (All).** The 2021 sunset materials have been added below. The HS will assign leads on the next call, and will discuss the deadline for TR requests.
- **Other Items.**
    - The Crops and Handling proposals for marine materials will be combined and Handling will bring the document forward.
    - The HS canceled the March 20 call
- **The meeting was adjourned**

Previous HS Notes

Future Call Schedule (1st and 3rd Tuesdays 1:00 ET)

February 20, 2018

2020 sunset: Potassium carbonate (SR) - Discuss review
Marine Materials (SR) - Discuss proposal/update
Sodium Chlorite for the generation of chlorine dioxide gas (SR) - TR sufficiency, discuss draft proposal
2020 sunset: Calcium carbonate (SR) - Discuss review
2020 sunset: Gellan Gum (LD) - Discuss review
2020 sunset: Gums: Arabic, Carob bean, Guar, Locust bean (JM) - Discuss review
2020 sunset: Tragacanth gum (LD) - Discuss review
2020 sunset: Xanthan gum (LD) - Discuss review
2020 sunset: Magnesium stearate (AB) - Discuss review

March 6, 2018
March 20, 2018 - cancelled
April 3, 2018

Tamarind seed gum (SE) - TR sufficiency
Pullulan (LD) - petition sufficiency
Sodium Chlorite for the generation of chlorine dioxide gas (SR) discuss proposal

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**
Alginic acid	205.605(a)			2015 TR 2017 NOSB Recommendation		Summary: Spr 2019 Review: Fall 2019
Calcium chloride	205.605(a)			1995 TAP 2017 NOSB Recommendation		"
Citric acid	205.605(a)			2015 TR 2017 NOSB Recommendation		"
Dairy cultures	205.605(a)			1995 TAP 2017 NOSB Recommendation		"
Enzymes	205.605(a)			2015 TR 2017 NOSB Recommendation		"
Lactic acid	205.605(a)			2015 TR 2017 NOSB Recommendation		"
L-Malic acid	205.605(a)			2003 TAP 2015 NOSB Recommendation		"
Magnesium sulfate	205.605(a)			2011 TR 2017 NOSB Recommendation		"
Microorganisms	205.605(a)			2014 TR 2015 NOSB Recommendation		"
Perlite	205.605(a)			1996 TAP 2017 NOSB Recommendation		"
Potassium iodide	205.605(a)			2011 TR 2017 NOSB Recommendation		"
Yeast	205.605(a)			2014 TR 2017 NOSB Recommendation		"
Activated charcoal	205.605(b)			2002 TR 2015 NOSB Recommendation		"
Ascorbic acid	205.605(b)			1995 TAP 2017 NOSB Recommendation		"
Calcium citrate	205.605(b)			2015 TR 2017 NOSB Recommendation		"

Ferrous sulfate	205.605(b)			1995 TR 2017 NOSB Recommendation		“
Hydrogen peroxide	205.605(b)			2015 Hydrogen Peroxide (Crops) 2017 NOSB Recommendation		“
Nutrient vitamins and minerals	205.605(b)			2015 TR 2017 NOSB Recommendation		“
Peracetic acid	205.605(b)			2016 TR 2015 NOSB Recommendation		“
Potassium citrate	205.605(b)			2015 TR 2017 NOSB Recommendation		“
Potassium phosphate	205.605(b)			1995 TAP 2017 NOSB Recommendation		“
Sodium acid pyrophosphate	205.605(b)			2001 TAP 2015 NOSB Recommendation		“
Sodium citrate	205.605(b)			2015 TR 2017 NOSB Recommendation		“
Tocopherols	205.605(b)			2015 TR 2017 NOSB Recommendation		“
Celery powder	205.606			None 2017 NOSB Recommendation		“
Fish oil	205.606			2015 TR 2017 NOSB Recommendation		“
Gelatin	205.606			2002 TAP 2017 NOSB Recommendation		“
Orange pulp, dried	205.606			None 2017 NOSB Recommendation		“
Seaweed, Pacific kombu	205.606			None 2017 NOSB Recommendation		“
Seaweed, Wakame (Undaria pinnatifida)	205.606			None 2017 NOSB Recommendation		“

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)
Compliance, Accreditation & Certification Subcommittee (CACS) Notes draft for CACS
Tuesday March 13, 2018, 3:00 pm ET

Attending: Scott Rice (SR), Chair; Emily Oakley (EO), Vice Chair; Ashley Swaffar (AS); Harriet Behar (HB); Tom Chapman (TC)
Absent: Lisa de Lima (LD); A-dae Romero-Briones (ARB)
Staff: Michelle Arsenault (MA); Jenny Tucker (JT)

Work Agenda

Project	Contact	Status	Discussion, Vote	Meeting
Inspector qualifications proposal	SR	Approved for addition to work agenda 04 21 16. Referred back to CACS at Spr 2017 meeting	Dec 12, Jan 9, Jan 23, Feb 13	Spr 2018
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production proposal	HB	Approved for addition to work agenda 07 15 16. Verbal update Fall 2016. DD Spr 2017. Proposal Fall 2017. Referred back to CACS at Fall 2017 meeting	Nov 28, Jan 23, Feb 27	Spr 2018
Import Oversight	ALL	Memo sent to NOSB 08 10 17.	Nov 28, Jan 9, Jan 23, Feb 13, Feb 27	Disc doc Spr 2018

***Discussed** ***Voted**

Agenda

- Approve notes from February 13, 2018
- Approve notes from February 27, 2018
- Discuss import panel logistics
- Other items
- Adjourn

Discussion

- **Notes from February 13, 2018** were approved with no changes.
- **Notes from February 27, 2018** were approved with no changes.
- **Discuss import panel logistics.** The group reviewed the list of potential panelists and the NOP will reach out to them with an initial invitation.
    - SR will seek a potential panelist who has expertise as a foreign certifier.
    - The CACS will continue to develop questions for the panel.

- The NOP will finalize the panelist list by March 15.
- The NOP will host a preparation meeting on Monday, April 16 to run through logistics with the panelists, the NOSB Chair, and the moderator (SR).

- **Other items.** None
- **The meeting was adjourned**

Previous CACS Notes

Future Call Schedule (2nd Tuesday 3:00 ET)
February 27, 2018 - additional call
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 Petition Guidelines Checklist

Petitioned Substance: Collagen gel
Date Petitioned: January 23, 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); ☒ 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: Click here to enter text.
	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:** Collagen gel
☒ 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:** for co-extrusion systems for sausage
☒ 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:** (b)(5) [redacted]
☒ 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:** Skipped -
☒ 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:** Petitioner states no previous reviews
☒ Yes ☐ No ☐ N/A	**8.** Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers? **Notes:** (b)(5) [redacted]

☒ 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:** Labels and CAS number provided
☒ 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:** MSDS attached
☒ 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: 3/19/2018	
Notes:	

NOP Petitioned Substance Checklist for OFPA Exemptions and 7 C.F.R. § 205.600(b)

Petitioned Substance: Collagen gel
Date Petitioned: January 23, 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: (b)(5) [redacted]	(b)(5) [redacted]
(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? *Petitioned as an agricultural ingredient.*	☐ Yes ☒ No ☐ TBD
NOP Staff Reviewer: Devon Pattillo		
Date: 3/19/2018		
Notes:		

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.

DOI/COIs						NOP Conflict of Interest Memo March 2013													
NOSB Spring 2018 Proposals and Discussion Documents						Baird	Behar	Bradman	Buie	Chapman	De Lima	Ela	Mortense	Oakley	Rice	Romero	Seitz	Swaffar	
Subcommittee	Substance	NL Section/Guidance	Doc Type (All NOSB proposals	Motion by:	Seconded by:														
CACS	Inspector Qualifications	NA	Proposal	Harriet Behar	Ashley Swaffar														
CACS	Eliminating the incentive to convert native ecosystems to organic production	NA	Proposal	Harriet Behar	Emily Oakley														
CACS	Import Oversight	NA	DD	Tom Chapman	Ashley Swaffar	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
CS	Alcohols: ethanol, isopropanol	205.601(a)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
CS	Sodium carbonate peroxyhydrate	205.601(a)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
CS	Newspaper or other recycled paper	205.601(b)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
CS	Plastic mulch and covers	205.601(b)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
CS	Aqueous potassium silicate	205.601(e)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
CS	Elemental sulfur	205.601(e)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
CS	Lime sulfur	205.601(i)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
CS	Sucrose octanoate esters	205.601(i)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
CS	Hydrated lime	205.601(j)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
CS	Liquid fish products	205.601(j)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
CS	Sulfurous acid	205.601(j)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
CS	Ethylene	205.601(j)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
CS	Microcrystalline cheesewax	205.601(j)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
CS	Potassium chloride	205.602(d)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
CS	Polyoxin D zinc salt - petitioned. Motion to add.	205.602(i)	Proposal	Jesse Buie	Sue Baird														
CS	Sulfur (as a molluscicide) - petitioned. Motion to add	205.601	Proposal	Asa Bradman	Harriet Behar														
LS	Alcohols: ethanol, isopropanol	205.603(a)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
LS	Aspirin	205.603(a)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
LS	Biologics, vaccines	205.603(a)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
LS	Electrolytes	205.603(a)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	

LS	Glycerine	205.603(a)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
LS	Phosphoric acid	205.603(b)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
LS	Lime, hydrated	205.603(b)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
LS	Mineral oil	205.603(b)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
LS	Sucrose octanoate esters	205.603	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
LS	Glycolic acid - petitioned. **Classification:** synthetic	205.603	Proposal	Ashley Swaffar	Harriet Behar	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
LS	Glycolic acid - petitioned. **Motion to add**	205.603	Proposal	Ashley Swaffar	Jesse Buie													
LS	Clarifying "emergency" for use of synthetic parasiticides in organic livestock production	NA	Proposal	Harriet Behar	Jesse Buie	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
HS	Calcium carbonate	205.605(a)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
HS	Flavors	205.605(a)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
HS	Gellan gum	205.605(a)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
HS	Oxygen	205.605(a)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
HS	Potassium chloride	205.605(a)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
HS	Alginates	205.605(b)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
HS	Calcium hydroxide	205.605(b)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
HS	Ethylene	205.605(b)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
HS	Glycerides (mono and di)	205.605(b)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
HS	Magnesium stearate	205.605(b)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
HS	Phosphoric acid	205.605(b)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
HS	Potassium carbonate	205.605(b)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
HS	Sulfur dioxide	205.605(b)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
HS	Xanthan gum	205.605(b)	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
HS	Fructooligosaccharides (FOS)	205.606	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
HS	Gums: Arabic, Carob bean, Guar, Locust bean	205.606	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
HS	Lecithin - de-oiled	205.606	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
HS	Tragacanth gum	205.606	2020 Sunset	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	

HS	Sodium dodecylbenzene sulfonate (SDBS) **Classification:** non agricultural, synthetic	205.605(b)	Proposal	Scott Rice	A-dae Briones	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
HS	Sodium dodecylbenzene sulfonate (SDBS) **Motion to add** to 605(b)	205.605(b)	Proposal	Joelle Mosso	Steve Ela														
HS	Magnesium chloride reclassification 205.605(b)	205.605(b)	Proposal	Lisa de Lima	Steve Ela														
MS	Non-GMO organic seed integrity	NA	DD	Dan Seitz	Dave Mortensen	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	

Agricultural Marketing Service

United States Department of Agriculture

Agricultural Marketing Service

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Room 2648-S, Mail Stop 0268
Washington, D.C. 20250-0268

March 29, 2013

MEMORANDUM TO THE NATIONAL ORGANIC STANDARDS BOARD

FROM: Miles V. McEvoy
Deputy Administrator
National Organic Program (NOP)

SUBJECT: Conflict of Interest Guidelines

This memorandum provides guidelines to National Organic Standards Board (NOSB) members about recognizing and reporting conflicts of interest and appearance concerns.

Background

NOSB members (you) are classified as **representatives** under the Federal Advisory Committee Act (FACA). Each representative is appointed to articulate the viewpoints and interests of a particular interest group. For the NOSB, the Organic Foods Production Act (OFPA) lists what these interest groups are. They include farmers/growers, handlers, certifiers, environmentalists/conservationists, scientists, consumers and public interest groups, and retailers. Representatives are appointed to speak in "we" terms, serving as the voice of the group represented (e.g., "we farmers/growers believe…"). As such, you are not expected to provide independent expert advice, but rather advice based on the interests of the groups served.

The NOSB's Policies and Procedures Manual includes language about conflicts of interest. In the past year, however, the Board has worked on alternative language to further define conflict of interest and to outline procedures for managing conflicts as they are identified. The Board has not been successful in passing new language. As such, the National Organic Program (NOP) is issuing this memorandum to describe how the USDA views conflict of interest and appearance concerns, and to present the NOP's expectations for how you are to evaluate and report these conflicts in the future.

Guidelines and Examples

As a member of a Government Board, your commitment in upholding the integrity of the Board's deliberations and recommendations during and after your Board service ends is important, and will help maintain public confidence in Agricultural Marketing Service decision making, and in the quality of the Board's work.

Even if there is no financial conflict of interest, your outside relationships (such as your spouse, close family member, or a business partner) may at times raise questions in the public's mind about how fair you can be while working on a particular board matter. The essential point is to avoid participating in those particular matters in which you could reasonably be viewed by others as engaging in "self-dealing" to benefit yourself or someone close to you. In general, you should be alert for situations when you are asked to work on a Board matter and one of the following persons or entities will be **specifically affected** by your Board's activities:

- a member of your household;
- a former employer or a prospective employer;

- a client of yours or your spouse;
- a person or organization with which you have some kind of business or contract relationship; or
- your spouse's employer.

In addition, you should adhere to the following basic "Standards of Conduct" while in Government service:

- Don't accept improper gifts (from those seeking actions from the Board).
- Don't use board appointments for private gain.
- Don't misuse internal non-public Government information.
- Use Government property and time properly.
- Don't accept compensation for teaching, speaking, and writing related to your board duties.
- Don't engage in partisan political activities while performing your board duties or while in a Federal building.
- Alert the NOSB Designated Federal Officer (DFO) (also known as the Advisory Board Specialist) if you or your employer enters into a lawsuit against USDA or its subagencies.

As noted above, you were appointed to the Board to represent the interests of a particular group. As such, many of the interests that you hold are **acceptable interests**. An interest is acceptable if you carry it on behalf of a represented group, and if you receive no disproportionate benefit from expressing the interest. Interests create appearance problems, often referred to as **conflicts of interest,** when an interest: directly and disproportionally benefits you or a person associated with that member; could impair your objectivity in representing your group; or has the potential to create an unfair competitive advantage. Conflict of interest is as much about the appearance of a personal conflict and loss of impartiality as it is about direct financial gain.

Here are examples of the differences between acceptable interests and appearance problems, or conflicts of interest:

- The Board is considering relisting or removing Substance X on the National List as part of a sunset process. An NOSB member works for Company A, which uses Substance X to produce organic foods. Other companies use Substance X too. This would *not* constitute a conflict of interest, because while the NOSB member's company would benefit from the addition of Substance X, other companies would too. As such, there is no disproportionate benefit, nor the potential for an unfair competitive advantage. This is an acceptable interest, where the NOSB member is free to represent the interests of his or her group.

- In considering a petition to add Substance X to the National List, an NOSB member learns that his employer, Company A, holds an exclusive license with Substance X's manufacturer that gives Company A access to Substance X that other companies do not have. This means that the NOSB member's company would receive a disproportionate benefit from the addition of Substance X to the National List. This interest *does* constitute a conflict of interest, because the member's company would disproportionately benefit from the addition of Substance X, creating an unfair competitive advantage.

- An NOSB member is on the leadership team of a non-profit organization. The organization regularly accepts donations from people and organizations that belong to interest groups that the Board member represents. Regular donations given to advance the non-profit's mission would be considered an acceptable interest, as these donations are unlikely to impair the Board member's objectivity, or create an

unfair financial advantage for the Board member, the non-profit organization, or any individual donor.

- Two months before a Board meeting, this same non-profit organization receives a large ($5,000+) donation from a special interest group that has expressed a strong position on a topic being considered at the upcoming NOSB meeting. This *would* likely be considered a conflict of interest, as a reasonable person is likely to assume that such a large donation from a specific group could reasonably be seen as a gift given to shape a Board member's decision.

Procedures

Board members are appointed in part because of their interests. As such, you need to actively consider your interests with respect to topics being considered by the Board, and identify whether these interests would create appearance problems. This consideration will happen at two specific points of the Board's work on a particular topic. The first point is at the subcommittee level, when a subcommittee begins working on a workplan item. The second is when a discussion document or proposal advances from the subcommittee to the full Board for consideration.

<u>At the Subcommittee Level</u>

NOSB members represent the diverse interests of a broad stakeholder community, and make recommendations that may have wide-reaching regulatory impacts across all of these interest groups. As such, your actions are carefully scrutinized from the time work starts on a topic, through the time it is voted on. Even if there is no direct financial conflict of interest, your outside relationships may raise questions in the public's mind about how fair you can be while working on a particular subcommittee matter.

Given this, the NOP provides the following guidelines for topics at the subcommittee level:

- You should avoid leading projects for which you could reasonably be viewed by others as having a particular interest that would hinder your ability to objectively and fairly represent broader group interests, and to allow other members to represent theirs. If leading a project would likely lead others to believe you are "self-dealing" to benefit yourself or someone close to you, you should refrain from leading.

- As soon as you identify that you may have an appearance problem or conflict of interest with respect to a topic being worked on, you should inform the NOP Associate Deputy Administrator that a conflict may exist and the nature of that conflict. You should also tell the subcommittee impacted that you have a conflict, sharing as much or as little about the nature of the conflict with other Board members as you wish.[1] Even after this declaration, you may continue to contribute to the discussion on the topic. As long as it is known there is a conflict of interest, the conflict does not preclude the member from contributing his or her input in the subcommittee.

[1] Previous public comments to the NOSB urged members to fully disclosure the nature of their conflicts of interest to other NOSB members and the public. While NOSB members may share whatever information they wish with other Board members and the public, this level of disclosure is voluntary. For both legal and ethical reasons, the NOP respects the privacy of its volunteers, and does not require full disclosure of the nature of conflicts of interest to parties outside the NOP.

- If you are uncertain as to whether an interest constitutes an appearance problem or conflict, then contact the NOP Associate Deputy Administrator to discuss. In this case, the NOP, working with the USDA Office of Ethics as needed, will make the determination about whether a problem exists.[2]

At the Full Board Level

Once discussion documents and proposals are posted for public comment, each NOSB member is to review the documents across all subcommittees, and research any conflicts of interest due to organizational affiliation or relationships.

The following procedures will take place at the Board level:

1. Approximately 2-4 weeks before the meeting, the NOP's DFO will provide a matrix to all NOSB members in advance of the meeting that lists the documents being voted on at the meeting.

2. If you identify that a conflict of interest exists on any item(s) on the matrix, use the columns on the matrix to disclose having a conflict of interest and to declare a recusal from voting on the item(s).

3. If you are not sure whether an interest is acceptable or poses a problem, or if you are uncertain whether recusal is needed, contact the NOP Associate Deputy Administrator to discuss. In this case, the NOP – working with the USDA Offices of Ethics as needed - will make the determination about whether a conflict of interest exists, and will instruct the member accordingly as to whether to vote or not.

4. Return your completed matrix approximately one week before the Board meeting. The NOP will then use these to compile a list of all recusals for the meeting.

5. At the meeting, at the beginning of each subcommittee session, DFO will state: "The following Board members have a conflict of interest with the following documents, and will not be voting: "Bob has a conflict and will recuse himself from the proposals CleanGreenA and GreatChemB (etcetera)."

6. Once the DFO completes listing the recusals, the NOSB subcommittee chair leading the session may invite additional information from members on a voluntary basis, with a statement such as: "If Board members wish to disclose information about their conflict, or any other information about their interests, they are welcome to do so at this time." This is to be stated as a general and voluntary invitation; no specific NOSB member is to be called on.

7. For any documents deferred to the last day of the meeting, the DFO will repeat the declaration of statement above at the start of the voting session for each subcommittee. When it is time to vote, the NOSB member recusing is to simply state "Recuse" when it is his or her time to vote.

[2] Previous public comments favored NOSB members as a group making decisions on conflict of interest when there is a question as to whether someone should recuse him or herself. It is, however, the USDA – not Board members - that is at risk if a member votes on something for which he or she has a conflict of interest. As such, the NOP, working with the USDA Office of Ethics, is the arbiter of conflict of interest questions.

Conclusion

The organic community has voiced great interest in establishing clear definitions and procedures related to conflict of interest, particularly with respect to NOSB operations. Upfront identification of appearance concerns is a critical part of each NOSB member's role. Effective from the date of this memorandum, if an NOSB member fails to disclose having a conflict of interest and votes on the item where a conflict exists, and that conflict of interest is later revealed, it may lead to a reconsideration of the impacted vote by the NOP.[3] As such, the NOP strongly encourages NOSB members to adequately assess any potential conflicts, and to discuss scenarios with the NOP as needed.

Thank you for your ongoing support and hard work in advancing organic integrity.

[3] This policy will not be applied retroactively to undo deliberations and/or votes taken before this memorandum is published.

Sunset 2020 Review
Meeting 1 - Request for Public Comment
Handling Substances
April 2018

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 handling that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2020. 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 2018 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2018 public meeting. These comments should be provided through www.regulations.gov by April 4, 2018 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 crop 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:

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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
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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.

For Comments on Nonorganic Agricultural Substances at Section 205.606.
For nonorganic agricultural substances on section 205.606, the NOSB Handling Subcommittee requests current industry information regarding availability of and history of unavailability of an organic form of the substance in the appropriate form, quality, or quantity of the substance. The NOSB Handling Subcommittee would like to know if there is a change in supply of organic forms of the substance or demand for the substance (i.e. is an allowance for the nonorganic form still needed), as well as any new information about alternative substances that the NOSB did not previously consider.

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Sunset 2020 Review Summary
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Reference: 7 CFR 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)).''

§205.605(a) Nonsynthetics allowed:
Calcium carbonate
Flavors
Gellan Gum
Oxygen
Potassium chloride

§205.605(b) Synthetics allowed:
Alginates
Calcium hydroxide
Ethylene
Glycerides: mono and di
Magnesium stearate
Phosphoric acid
Potassium carbonate
Sulfur dioxide
Xanthan gum

Reference: 7 CFR §205.606

Fructooligosaccharides
Gums: Arabic, Carob bean, Guar, Locust bean
Lecithin - de-oiled
Tragacanth gum

Calcium carbonate

Reference: 205.605(a)

Technical Report: 1995 TAP; INSERT 2018 TER LINK

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 renewal notice published 03/21/17 (82 FR 14420)

Sunset Date: 3/15/2022

Use:

Calcium carbonate is widely used as a dietary supplement, antacid, dough conditioner, as an acidity regulator in wines, food stabilizer, anticaking agent, gelling agent, glazing and release agent, thickener, bulking agent, and as a nutritional fortification additive. The FDA allows the use of calcium carbonate as a binding agent in meat and poultry pieces. Calcium carbonate is also a precursor to the substance calcium citrate, which is identified on the National List. Calcium carbonate has been used as a coloring agent. However, in historic organic food processing, both within the United States and internationally, calcium carbonate is not allowed for coloration purposes.

Manufacture:

Calcium carbonate is a fine, white microcrystalline mined powder which is stable in air. It is a mined mineral of at least 98% purity that is ground and screened.

International Equivalency:

Canada - Canadian General Standards Board Permitted Substances List; CAN/CGSB-32.311-2015

- Allowed, prohibited for use as a coloring agent

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

- Appears on Table 3, Additives permitted for use under specified conditions in certain organic food categories or individual food items
- Appears on Table 4, Processing aids which may be used for the preparation of products of agricultural origin referred to in Section 3

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

- Appears in Annex VII, Section A - Food additives including carriers, shall not be used for colouring or calcium enrichment of products
- Appears in Annex VII, Section B – Processing aids and other products, which may be used for processing other ingredients of agricultural origin from organic production

Japan Agricultural Standard (JAS) for Organic Production

- Appears in Table 1, Food additives, Limited to be used for confectionary, sugar, processed bean foods, noodles and bread, or for dairy products as neutralizing substance

International Federation of Organic Agriculture Movements (IFOAM)

- Appears in Appendix 4 – Table 1: List of approved additives and processing/post-harvest handing aids

Environmental/Health Issues:
The mining and processing of calcium carbonate can have negative environmental impacts. These may be impacts on above and below ground water systems. Mining may have impacts on biological diversity as the mining may draw down the water table and impact surface water features that play host to a variety of species.

Inhalation of calcium carbonate dust may cause upper respiratory irritation, and exposure may cause eye irritation. Personal protective equipment will avoid these issues. 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.

Flavors

Reference: 205.605(a), nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.
Technical Report: 2005 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Additional information requested by NOSB

Gellan gum

Reference: 7 CFR 205.605(a) – high acyl form only - As a nonagricultural (nonorganic) substance allowed as ingredient in or on processed products.

Technical Report: 2006 TAP

Petition(s): 2004 Gellan gum

Past NOSB Actions: 2007 Formal Recommendation; 2014 sunset recommendation

Regulatory Background: Proposed rule (including justification) published 06/03/09 (74 FR 26591), Added to National List 12/13/2010 (75 FR 7751). Sunset renewal notice published 06/22/2015 (80 FR 35177)

Sunset Date: 6/22/20

Background from Subcommittee:

Additional information requested by NOSB

Oxygen

Reference: 205.605(a) - oil-free grades.

Technical Report: 1995 TAP

Petition(s): N/A

Past NOSB Actions: 04/1995 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 renewal notice published 03/21/17 (82 FR 14420)

Sunset Date: 3/15/2022

Background from Subcommittee:

Additional information requested by NOSB

Potassium chloride

Reference: (a) Nonsynthetics allowed:

Technical Report: 1995 TAP; 2015 TR Nutrient Vitamins and Minerals

Petition(s): N/A

Past NOSB Actions: 04/1995 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 renewal notice published 03/21/17 (82 FR 14420)

Sunset Date: 3/15/2022

Background from Subcommittee:
Additional information requested by NOSB

§205.605(b) Synthetics allowed:

Alginates

Reference: 205.605(b) Synthetics allowed
Technical Report: 1995 TAP; 2015 TR
Petition(s): 1995 Alginates
Past NOSB Actions: 04/1995 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 renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Additional information requested by NOSB

Calcium hydroxide

Reference: 205.605(b)
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 renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Additional information requested by NOSB

Ethylene

Reference: 205.605(b) allowed for postharvest ripening of tropical fruit and degreening of citrus.

Technical Report: 1995 TAP; 1999 TAP - Processing

Petition(s): 1995 N/A, 2008 Ethylene (for use with pears)

Past NOSB Actions: 10/1995 NOSB minutes and vote; 10/1999 NOSB minutes and vote (add tropical fruit and citrus); 11/2005 sunset recommendation; 11/2008 recommendation for pears; 10/2010 sunset recommendation; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)

Sunset Date: 3/15/2022

Background from Subcommittee:

Additional information requested by NOSB

Glycerides (mono and di)

Reference: 205.605(b) for use only in drum drying of food.

Technical Report: 1995 TAP; 2015 TR

Petition(s): N/A

Past NOSB Actions: 04/1995 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 renewal notice published 03/21/17 (82 FR 14420)

Sunset Date: 3/15/2022

Background from Subcommittee:

Additional information requested by NOSB

Magnesium stearate

Reference: 205.605(b) - for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic".

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 renewal notice published 03/21/17 (82 FR 14420)

Sunset Date: 3/15/2022

Background from Subcommittee:

Additional information requested by NOSB

Phosphoric acid

Reference: 205.605(b) - cleaning of food-contact surfaces and equipment only

Technical Report: 2003 TAP

Petition(s):N/A

Past NOSB Actions: 10/1999 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 renewal notice published 03/21/17 (82 FR 14420)

Sunset Date: 3/15/2022

Background from Subcommittee:

Additional information requested by NOSB

Potassium carbonate

Reference: 205.605(b)

Technical Report: 1995 TAP

Petition(s): N/A

Past NOSB Actions: 04/1995 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 renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Additional information requested by NOSB

Sulfur dioxide

Reference: 205.605(b) for use only in wine labeled "made with organic grapes," Provided, That, total sulfite concentration does not exceed 100 ppm.

Technical Report: 1995 TAP; 2011 TR
Petition(s): 1995 N/A; 2010 Sulfur Dioxide
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 12/2011 annotation change; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Additional information requested by NOSB

Xanthan gum

Reference: 205.605(b)

Technical Report: 1995 TAP; 2016 TR

Petition(s): N/A
Past NOSB Actions: 04/1995 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 renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Additional information requested by NOSB

Reference: 7 CFR §205.606

Fructooligosaccharides

Reference: 205.606(h) Fructooligosaccharides (CAS # 308066-66-2)
Technical Report: 2006 TAP; 2015 TR
Petition(s): 2006 Petition
Past NOSB Actions: 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Additional information requested by NOSB

Gums: (Arabic, Guar, Locust bean , and Carob bean)

Reference: 205.606(k) Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean)
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420)
Sunset Date: 3/15/2022

Background from Subcommittee:
Additional information requested by NOSB

Lecithin -de-oiled

Reference: 205.606(o) Lecithin – de-oiled

Technical Report: 1995 TAP; 2009 TR

Petition(s): Lecithin, bleached (remove 2008)

Past NOSB Actions: 04/1995 NOSB minutes and vote; 05/2009 recommendation (remove from 605b); 05/2009 Recommendation (amend 606); 10/2015 sunset recommendation

Recent Regulatory Background: Annotation change effective 03/15/2012 (77 FR 8089); Sunset renewal notice published 03/21/17 (82 FR 14420)

Sunset Date: 3/15/2022

Background from Subcommittee:

Additional information requested by NOSB

Tragacanth gum

Reference: 7 CFR 205.606(x) - As nonorganically produced agricultural product allowed as ingredient in or on processed products.

Technical Report: none

Original Petition: 2007 Tragacanth Gum

Past NOSB Actions: 2008 Final Recommendation; 2014 sunset recommendation

Regulatory Background: Proposed rule (including justification) published 06/03/09 (74 FR 26591), Added to National List 12/13/2010 (75 FR 7751). Sunset renewal notice published 06/22/2015 (80 FR 35177)

Sunset Date: 06/22/20

Background from Subcommittee:

Additional information requested by NOSB

Sunset 2020 Review
Meeting 1 - Request for Public Comment
Handling Substances
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Ethylene

Reference: 205.605(b) allowed for postharvest ripening of tropical fruit and degreening of citrus.

Technical Report: 1995 TAP; 1999 TAP - Processing

Petition(s): 1995 N/A, 2008 Ethylene (for use with pears)

Past NOSB Actions: 10/1995 NOSB minutes and vote; 10/1999 NOSB minutes and vote (add tropical fruit and citrus); 11/2005 sunset recommendation; 11/2008 recommendation for pears; 10/2010 sunset recommendation; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published XXXXX; Sunset renewal notice published XX/XX/XX (XX FR XXXXX)

Sunset Date:

Subcommittee Review

Use

Ethylene gas (CAS # 74-85-1) is currently listed as a 205.605(b) material allowed for postharvest ripening of tropical fruit and degreening of citrus.

Manufacture

Ethylene ($CH_2=CH_2$) is a colorless gas at room temperature. It is produced naturally in small amounts by some plants and functions as a ripening agent. The commercially used form, which is synthetic, is chemically identical to the natural occurring form. The synthetic form is produced from hydrocarbon feedstocks, such as natural gas liquids or crude oil, and may also be derived from liquid ethanol.

Use of ethylene naturally produced by fruits has not been commercialized. Amounts produced for agriculture are small compared to emissions from car exhaust, petrochemical plants, or fires. It is used in the post-harvest ripening of tropical fruit and the de-greening of citrus.

International (acceptance/nonacceptance) by other international certification agencies

Canada: allowed for post-harvest ripening of tropical fruit and degreening of citrus.
Japan: Limited to be used for after-ripening banana and kiwifruits.
IFOAM: De-greening of citrus and ripening
EU: Degreening bananas, kiwis and kakis; Degreening of citrus fruit only as part of a strategy for the prevention of fruit fly damage in citrus.

CODEX: For degreening of citrus for fruit fly prevention. As sprouting inhibitor for potatoes and onions.

Environment/Health Issues

Ethylene is potentially flammable, and also an asphyxiate if high concentrations displace oxygen, but significant impacts on human health and the environment are likely minimal based on previous reviews.

Discussion

Previous handling subcommittee discussions considered removing its allowed use for the de- greening of citrus. However, historically there has been no opposition to relisting of ethylene. The 2015 NOSB approved continued use of ethylene as a post-harvest ripening tool. The current subcommittee found no change in the compatibility of ethylene use with current organic processing standards.

Questions

The NOSB requests input on the continuing need for ethylene as a fruit ripening tool.

Motion to Remove

This proposal to remove ethylene will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of Ethylene from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: XXXX

Vote in Subcommittee

Motion by:

Seconded by:

Yes: No: Abstain: Absent: Recuse:

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Flavors
Gellan Gum
Oxygen
Potassium chloride

§205.605(b) Synthetics allowed:
Alginates
Calcium hydroxide
Ethylene
Glycerides: mono and di
Magnesium stearate
Phosphoric acid
Potassium carbonate
Sulfur dioxide
Xanthan gum

Reference: 7 CFR §205.606

Fructooligosaccharides
Gums: Arabic, Carob bean, Guar, Locust bean
Lecithin - de-oiled
Tragacanth gum

Flavors

Gellan gum

Reference: 7 CFR 205.605(a) – high acyl form only - As a nonagricultural (nonorganic) substance allowed as ingredient in or on processed products.

Technical Report: 2006 TAP

Commented [JM1]: Need new TR link once available

Petition(s): 2004 Gellan gum

Past NOSB Actions: 2007 Formal Recommendation; 2014 sunset recommendation

Regulatory Background: Proposed rule (including justification) published 06/03/09 (74 FR 26591), Added to National List 12/13/2010 (75 FR 7751). Sunset renewal notice published 06/22/2015 (80 FR 35177)

Sunset Date: 6/22/20

Material Use:

Gellan gum is water soluble, heat stable, low pH stable, and is able to form thicker gels when positive ions (cations) are added to a solution (2006 TR 32-34, Petition pg 10). Gellan gum is considered a hydrocolloid and is very useful as a thickening and gelling agent in food products, including bakery fillings, confections, dairy products, dessert gels, frostings, icings, glazes, jams, and personal care items (2018 TR 182-187, 2006 TR 37-41, Petition pg 2). Typical use of gellan gum is at <0.5% of a finished product formula (Petition pg 2). The firmness of the gel can be enhanced by the additions of cationic materials such as potassium, calcium, etc. and this gives it numerous applications in different areas of food products.

Manufacture:

Gellan gum is a high molecular weight polysaccharide gum produced through fermentation by the bacterium *Sphingomonas elodea*. This aerobic, gram-negative bacterium produces the material through fermentation and then separation of the gellan gum by isopropyl alcohol or ethanol (2006 TR 16-19, 66-70, 2018 TR 648-660). The 2018 Technical report notes that no known genetically modified strain of this bacteria exists (2018 TR 662-670). Isopropyl alcohol cannot be at greater than 0.075% in the finished materials as dictated by FDA (2006 TR 54-55). The firmness of the gellan gum can be adjusted by the removal of acetyl groups through addition of cations (e.g. potassium, calcium, magnesium); these

deacylated forms are not approved on 205.605(a) (2006 TR 109-112). As a result, the generation of gellan gum approved for 205.605(a) is through a naturally-occurring biological process (2006 TR 107-117).

International Equivalency:

The material is FDA approved as a direct food additive in accordance with 21 CFR 172.665; it is also approved in many countries worldwide in food and non-food items. Gellan gum is listed by the World Health Organization Joint Expert Committee for Food Additives (Petition pg 5).

Canadian Organic Regime's Canadian General Standards Board Permitted Substances List (Nov 2015 ed.) allows the use of gellan gum as long as it is derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 TR 491-496).

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

Gellan gum is allowed and the CODEX General Standard for Food Additives (GSFA) 502 describes the compliant uses (2018 TR 498-504).

European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008

Gellan gum is allowed for use as compliant with Annex II and III in processed organic foods and as a food additive in the preparation of foodstuffs of plant or animal origin (2018 TR 506-515).

Japan Agricultural Standard (JAS) for Organic Production

Gellan gum is neither listed as allowed, nor as prohibitied (2018 TR 525-536).

International Federation of Organic Agriculture Movements (IFOAM)

Gellan gum is not listed as allowed, nor prohibited (2018 TR 538-541).

Other international standards

East African Organic Product Standard uses IFOAM and thus gellan gum is not prohibited, nor allowed (2018 TR 543-541).

Ancillary Substances:

According to the 2018 TR (434-438) no information was found indicating that any additional materials are generally added to commercially available forms of the gums. However, according to the 2016 TR on xanthan gum two exceptions were identified during a review of publically available specification sheets: glucose used to standardize a xanthan and guar gum blend, and polysorbate 60 in GRINSTED®.

Background Information:

The two available TRs did not list any notable human health or environmental concerns regarding the use of gellan gum.

Public comment in 2014 supported the ongoing essentiality of this material.

Additional information requested by NOSB

1. Is gellan gum still necessary for organic products?

[redacted]

[redacted]

§205.605(b) Synthetics allowed:

[redacted]

[redacted]

[redacted]

Xanthan gum

Reference: 205.605(b)

Technical Report: 1995 TAP; 2016 TR

Petition(s): N/A

Past NOSB Actions: 04/1995 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 renewal notice published XX/XX/XX (XX FR XXXXX)

Sunset Date: 06/27/2017 (NOP renewal pending)

Material Use:

Xanthan gum is used in numerous foods products as a hydrocolloid (i.e. substances that disperse water, giving a thickening or gelling effect) including but not limited to: baked goods, beverages, dairy products, dressings, nutritional supplements, frozen foods, etc. (TR 758-759, 135-137). The gum is used in small percentages of the finished products, usually at <0.5% by weight (TR 145-146). Xanthan gum is used along with other gums to achieve the desired viscosities and product structures for firmness, water binding, flavor delivery, etc. (TR 229-236); it is particularly effective in frozen and chilled products where it can impart thickness, freeze-thaw protection, and stability during processing and shelf-life (TR 251-256). Common synergistic gums used along with xanthan gum are locust bean gums, guar gums, carrageenan gums (TR 229-236).

Manufacture:

Xanthan gum is a high-molecular weight polysaccharide produced though natural fermentation by *Xanthomonas campestris* and precipitation through addition of an alcohol; it subsequently is dewatered, possibly washed in a salt solution, dried and milled (TR 36-38, 90-97). The gum is water soluble, stable at numerous pH, salt and temperature ranges (including frozen temperatures) (TR 120-124). The side chains carry negative charges and will associate with positive cations to increase the firmness of the solution (TR 50-55). Overall, the structure of xanthan gum is such that it is a cellulose chain with trisaccharide side chains. In solution, the side chains wrap around the cellulose backbone and aid in the ability for xanthan gum to be stable in low pH and high salinity solutions (TR 48-50). In addition to its wide applicability under differing food mediums, it also has pseudo-plastic characteristics which under shear force make the solution less viscous and thus easier to move during processing. When the shear force is removed, the solution will again exhibit its characteristic thickness. Xanthan gum is not a gelling agent, and as a result it is often used in combination with other materials including locust bean gum, guar gum, starches, carrageenan and konjac glucomannan to increase viscosity (2018 Gums TR 424-432).

International Equivalency:

FDA has approved the use of xanthan gum as a food additive since 1969 without restrictions on quantity in finished applications (TR 162-163, 637-638); it must be isolated by isopropyl alcohol precipitation and made into a sodium, potassium, or calcium salt (TR 164-166). It is approved by FDA with 21 CFR 172.695 but is not GRAS; though three FDA notices for GRAS allow isolation of xanthan gum by ethanol and pyruvate, and in combination of konjac glucomannan and sodium alginate (TR 651-659).

Canadian Organic Regime's Canadian General Standards Board Permitted Substances List (Nov 2015 ed.) allows the use of xanthan gum as long as it is derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 Gums TR 491-496).

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

Xanthan gum is allowed and the CODEX General Standard for Food Additives (GSFA) 502 describes the compliant uses (2018 Gums TR 498-504).

European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008

Xanthan gum is allowed for use as compliant with General Standard for Food Additives Annex II and III in processed organic foods and as a food additive in the preparation of foodstuffs of plant or animal origin (2018 Gums TR 506-515).

Japan Agricultural Standard (JAS) for Organic Production

Xanthan gum is allowed in processed foods of animal origin limited to dairy or confectionary (2018 Gums TR 525-536).

International Federation of Organic Agriculture Movements (IFOAM)

Xanthan gum is allowed with no limitations on use (2018 Gums TR 538-541).

Ancillary Substances:

According to the 2016 TR (258-263), ancillary substances are not commonly added to commercial available forms of xanthan gum for use in foods. Through a search of publically available specification sheets a few exceptions were identified: glucose in a xanthan and guar gum blend and polysorbate 60 in GRINSTED®.

Background Information:

Xanthan gum has been used for decades globally in the food system, and subsequently has undergone numerous clinical trials and studies to look for impacts on human health in adults, children, infants, and animals (TR 637-742). Some studies have shown that xanthan gum is beneficial to human health; soluble fiber that may help improve colon health and reduce cholesterol (2018 TR 933, 963-976). In 2011 there was a recall of a xanthan gum product that was being fed to premature babies due to the lack of destruction of potentially harmful bacteria that may lead to necrotizing enterocolitis; no conclusions were made regarding the safety of xanthan gum thickeners for premature baby formulas (TR 678-711).

There was no mention of specific environmental issues regarding the production of xanthan gum.

Additional information requested by NOSB

1.) Is xanthan gum still considered essential to organic production?

Reference: 7 CFR §205.606

Gums: (Arabic, Guar, Locust bean , and Carob bean)

Reference: 205.606(k) Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean)
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published XX/XX/XX (XX FR XXXXX)
Sunset Date: 6/27/2017 (NOP renewal pending)

Commented [MOU2]: Need new 2018 Gums TR link once available

Material Use:

Gum Arabic, Locust/Carob bean gum, and Guar gum are high molecular-weight-polysaccharides extracted via water processing and then drying and milling (2018 TR 78-103). These gums are extracted from the endosperm of plants of the *Leguminosae*. The specific plants are guar, carob and locust bean. Gum Arabic is obtained from the exudate from the bark of the acacia tree and is one of the oldest known natural gums (TAP pg 8, 2018 TR 443). These gums are used in various food applications due to their ability to modify viscosity of products (hydrocolloid function) through the binding of water and generation of gelling effects (2018 TR 182-187). These properties are the primary function of gums and lend them to be common and popular thickeners and stabilizers in food products. Guar gum, gum Arabic and locust bean/carob bean gum are also thickening agents, which makes them useful since not all hydrocolloids function as thickening agents (2018 TR 189-192).

Despite having some similar characteristics, not all gums are interchangeable. Due to the structure of the gums, some behave differently in different temperatures, pH ranges, physical agitation, etc. (2018 TR 194-200). This variability requires formulations specific to the type of food product, intended shelf-life and product use. Many times these gums are used in combination to impart the correct properties in the finished goods (2018 TR 416). The table provided on line 285 in the 2018 Technical report distinguishes the different characteristics of common gums.

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		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
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Manufacture:

Gum Arabic is obtained from the exudate from dried sap collected from the stems and branches of the Acacia tree, both wild grown and cultivated. The gum is cleaned by mechanical sieves and graded, then milled to a powder. (2018 TR 566-573)

Locust/Carob bean gum is derived from the seeds of the carob tree, which are processed through a series of crushing, sifting, and grinding steps (2018 TR 594-595)

Guar gum is formed form the seeds of the guar bean plant. The endosperm is dehusked, milled and screened, and the gum is then clarified (2018 TR 584-586).

International Equivalency:

Gum Arabic, locust/carob bean gum and guar gum are all listed by the FDA as Generally Recognized as Safe (GRAS) (2018 TR 750-752).

Canadian Organic Regime's Canadian General Standards Board Permitted Substances List (Nov 2015 ed.) allows the use of Gum Arabic, Locust/Carob bean gum, and Guar gum as long as they are derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 TR 491-496).

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

Gum Arabic (414), Locust/Carob bean gum (410), and Guar gum (412) are allowed and the CODEX General Standard for Food Additives (GSFA) describes the compliant uses (2018 TR 498-504).

European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008

Gum Arabic, Locust/Carob bean gum, and Guar gum are allowed for use in processed organic foods as a

food additive in the preparation of foodstuffs of plant 508 or animal origin with no specific limitations (2018 TR 506-515).

Japan Agricultural Standard (JAS) for Organic Production

Arabian gum (INS 414) is limited to dairy products, edible fat, and oil and confectionary products (2018 TR 527).

Carob bean gum/locust bean gum (INS 410) is limited to dairy and processed meats. (2018 TR 529)

Guar gum (INS 412) can be used in processed foods of animal origin limited to dairy, canned meat or egg products. (2018 TR 531)

International Federation of Organic Agriculture Movements (IFOAM)

IFOAM allows locust bean gum (INS 410), guar gum (INS 412), tragacanth gum (INS 413), Arabic gum (INS 414) and xanthan gum (INS 415). There are no restrictions on how any of these items can be used (IFOAM, 2014). (2018 TR 539-541)

East African Organic Product Standard

Locust bean gum, guar gums are allowed with no restrictions. Arabic gum is allowed for milk products, fat products, confectionary, sweets and eggs (2018 TR 544-550).

Ancillary Substances:

According to the 2018 TR (434-438) no information was found indicating that any additional materials are generally added to commercially available forms of the gums. However, according to the 2016 TR on xanthan gum two exceptions were identified during a review of publically available specification sheets: glucose used to standardize a xanthan and guar gum blend, and polysorbate 60 in GRINSTED®.

Background Information:

No environmental or health concerns were noted in the manufacture or use of these gums in the general population. The EFSA (European Food Safety Authority) re-evaluated five gums in 2017 including arabic, guar, and locust. The panel concluded there wasn't adequate data available to assess the effects of locus bean and guar gum on infants and young children, and recommend that additional data be generated.

In 2015 these gums were unanimously voted by the NOSB to remain on 205.606(k).

Additional information requested by NOSB

1.) Are organic versions of Gum Arabic, Locust/Carob Bean Gum, and Guar gums available?

Tragacanth gum

Reference: 7 CFR 205.606(x) - As nonorganically produced agricultural product allowed as ingredient in or on processed products.

Technical Report: none

Commented [MOU3]: Link needed to new 2018 TR

Original Petition: 2007 Tragacanth Gum

Past NOSB Actions: 2008 Final Recommendation; 2014 sunset recommendation

Regulatory Background: Proposed rule (including justification) published 06/03/09 (74 FR 26591), Added to National List 12/13/2010 (75 FR 7751). Sunset renewal notice published 06/22/2015 (80 FR 35177)

Sunset Date: 06/22/20

Material Use:

Tragacanth gum is a polysaccharide that forms gels and can be used as a thickener and emulsifier. This material is effective at low pH and at many temperatures; its stability at low pH is noted as one of its distinguishing characteristics and is commonly used in high acid products like salad dressings (2018 TR 218-225, 337). The percentage in final formulations is usually low, below 1% of a total formula (2018 TR 338).

Manufacture:

Tragacanth gum is prepared from the sap of various species of legumes in the *Astragalus* species during July to September (2018 TR 576-581). Once collected it is dried and ground into powder and may, or may not, undergo a mitigation step to reduce the microbial load of the powder (2018 TR 578-581).

International Equivalency:

Tragacanth gum is listed as Generally Recognized as Safe by the FDA, 21 CFR 184.1351) (2018 TR 750-752).

Canadian Organic Regime's Canadian General Standards Board Permitted Substances List (Nov 2015 ed.) allows the use of tragacanth gum as long as its derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 TR 491-496).

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

Tragacanth gum (412) is allowed and the CODEX General Standard for Food Additives (GSFA) describes the compliant uses (2018 TR 498-504).

European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008

Tragacanth gum is allowed as a food additive in compliance with the General Standard for Food Additives Annex II and III of the Regulation (EC) No. 1333/2008 on food additives (2018 TR 506-515).

Japan Agricultural Standard (JAS) for Organic Production

Tragacanth gum is listed with no limitations (2018 TR 535).

International Federation of Organic Agriculture Movements (IFOAM)

IFOAM allows tragacanth gum (INS 413) with no restrictions on how any of this item can be used (IFOAM, 2014) (2018 TR 539-541).

East African Organic Product Standard

Tragacanth gum is allowed with no restrictions (2018 TR 547).

Ancillary Substances:

According to the 2018 TR (434-438) no information was found indicating that any additional materials are generally added to commercially available forms of the gums. However, according to the 2016 TR on xanthan gum two exceptions were identified during a review of publically available specification sheets: glucose used to standardize a xanthan and guar gum blend, and polysorbate 60 in GRINSTED®.

Environmental Issues:

Background Information:

No environmental or health concerns noted in the manufacture or use of this gum.

The NOSB Subcommittee noted in 2008 that due to limited growing regions (Turkey and Iran) and relevant trade embargoes, the supply of conventional tragacanth gum was fragile and limited. In October 2014 organic tragacanth gum was not known to be in production. The 2014 Subcommittee was unable to find evidence that tragacanth is available in organic form, and received testimony from a certifier and a producer who currently uses non-organic tragacanth.

Additional information requested by NOSB

1.) Is organic tragacanth now available?

Sunset 2020 Review Summary
Meeting 1 - Request for Public Comment
Handling Substances
April 2018

Note: With the exception of tragacanth and gellan gums, 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 205.605 *Nonagricultural* (Nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

§205.605(a) Nonsynthetics allowed:

Calcium carbonate
Flavors
Gellan Gum
Oxygen
Potassium chloride

§205.605(b) Synthetics allowed:

Alginates
Calcium hydroxide
Ethylene
Glycerides: mono and di
Magnesium stearate
Phosphoric acid
Potassium carbonate
Sulfur dioxide
Xanthan gum

Reference: 7 CFR §205.606

Fructooligosaccharides
Gums: Arabic Carob bean Guar Locust bean
Lecithin - de-oiled
Tragacanth gum

Flavors

Gellan gum

Reference: 7 CFR 205.605(a) – high acyl form only - As a nonagricultural (nonorganic) substance allowed as ingredient in or on processed products.

Technical Report: 2006 TAP, 2018 TR

Commented [JM1]: Need new TR link once available

Petition(s): 2004 Gellan gum

Past NOSB Actions: 2007 Formal Recommendation; 2014 sunset recommendation

Regulatory Background: Proposed rule (including justification) published 06/03/09 (74 FR 26591), Added to National List 12/13/2010 (75 FR 7751). Sunset renewal notice published 06/22/2015 (80 FR 35177)

Sunset Date: 6/22/20

Material Use:

Gellan gum is water soluble, heat stable, low pH stable, and is able to form thicker gels when positive ions (cations) are added to a solution (2006 TR 32-34, Petition pg 10). Gellan gum is considered a hydrocolloid and is very useful as a thickening and gelling agent in food products, including bakery fillings, confections, dairy products, dessert gels, frostings, icings, glazes, jams, and personal care items (2018 TR 182-187, 2006 TR 37-41, Petition pg 2). Typical use of gellan gum is at <0.5% of a finished product formula (Petition pg 2). The firmness of the gel can be enhanced by the additions of cationic materials such as potassium, calcium, etc. and this gives it numerous applications in different areas of food products.

Despite having some similar characteristics, not all gums are interchangeable. Due to the structure of the gums, some behave differently in different temperatures, pH ranges, physical agitation, etc. (2018 TR 194-200). This variability requires formulations specific to the type of food product, intended shelf-life and product use. Many times these gums are used in combination to impart the correct properties in the finished goods (2018 TR 416). The table provided on line 285 in the 2018 Technical report distinguishes the different characteristics of common gums.

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		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
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Manufacture:

Gellan gum is a high molecular weight polysaccharide gum produced through fermentation by the bacterium *Sphingomonas elodea*. This aerobic, gram-negative bacterium produces the material through fermentation and then separation of the gellan gum by isopropyl alcohol or ethanol (2006 TR 16-19, 66-70, 2018 TR 648-660). The 2018 Technical report notes that no known genetically modified strain of this bacteria exists (2018 TR 662-670). Isopropyl alcohol cannot be at greater than 0.075% in the finished materials as dictated by FDA (2006 TR 54-55). The firmness of the gellan gum can be adjusted by the removal of acetyl groups through addition of cations (e.g. potassium, calcium, magnesium); these deacylated forms are not approved on 205.605(a) (2006 TR 109-112). As a result, the generation of gellan gum approved for 205.605(a) is through a naturally-occurring biological process (2006 TR 107-117).

International Equivalency:

The material is FDA approved as a direct food additive in accordance with 21 CFR 172.665; it is also approved in many countries worldwide in food and non-food items. Gellan gum is listed by the World Health Organization Joint Expert Committee for Food Additives (Petition pg 5).

Canadian Organic Regime's Canadian General Standards Board Permitted Substances List (Nov 2015 ed.) allows the use of gellan gum as long as it is derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 TR 491-496).

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Gellan gum is allowed and the CODEX General Standard for Food Additives (GSFA) 502 describes the compliant uses (2018 TR 498-504).

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Ancillary Substances:

According to the 2018 TR (434-438) no information was found indicating that any additional materials are generally added to commercially available forms of the gums. However, according to the 2016 TR on xanthan gum two exceptions were identified during a review of publically available specification sheets: glucose used to standardize a xanthan and guar gum blend, and polysorbate 60 in GRINSTED®.

Background Information:

The two available TRs did not list any notable human health or environmental concerns regarding the use of gellan gum.

Public comment in 2014 supported the ongoing essentiality of this material.

Additional information requested by Subcommittee:

None

Xanthan gum

Reference: 205.605(b)

Technical Report: 1995 TAP; 2016 TR

Petition(s): N/A

Past NOSB Actions: 04/1995 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 renewal notice published XX/XX/XX (XX FR XXXXX)

Sunset Date: 06/27/2017 (NOP renewal pending)

Material Use:

Xanthan gum is used in numerous foods products as a hydrocolloid (i.e. substances that disperse water, giving a thickening or gelling effect) including but not limited to: baked goods, beverages, dairy products, dressings, nutritional supplements, frozen foods, etc. (TR 758-759, 135-137). The gum is used in small percentages of the finished products, usually at <0.5% by weight (TR 145-146). Xanthan gum is used along with other gums to achieve the desired viscosities and product structures for firmness, water binding, flavor delivery, etc. (TR 229-236); it is particularly effective in frozen and chilled products where it can impart thickness, freeze-thaw protection, and stability during processing and shelf-life (TR 251-256). Common synergistic gums used along with xanthan gum are locust bean gums, guar gums, carrageenan gums (TR 229-236).

Despite having some similar characteristics, not all gums are interchangeable. Due to the structure of the gums, some behave differently in different temperatures, pH ranges, physical agitation, etc. (2018 TR 194-200). This variability requires formulations specific to the type of food product, intended shelf-life and product use. Many times these gums are used in combination to impart the correct properties in the finished goods (2018 TR 416). The table provided on line 285 in the 2018 Technical report distinguishes the different characteristics of common gums.

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High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		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
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Manufacture:

Xanthan gum is a high-molecular weight polysaccharide produced though natural fermentation by *Xanthomonas campestris* and precipitation through addition of an alcohol; it subsequently is dewatered, possibly washed in a salt solution, dried and milled (TR 36-38, 90-97). The gum is water soluble, stable at numerous pH, salt and temperature ranges (including frozen temperatures) (TR 120-124). The side chains carry negative charges and will associate with positive cations to increase the firmness of the solution (TR 50-55). Overall, the structure of xanthan gum is such that it is a cellulose chain with trisaccharide side chains. In solution, the side chains wrap around the cellulose backbone and aid in the ability for xanthan gum to be stable in low pH and high salinity solutions (TR 48-50). In addition to its wide applicability under differing food mediums, it also has pseudo-plastic characteristics which under shear force make the solution less viscous and thus easier to move during processing. When the shear force is removed, the solution will again exhibit its characteristic thickness. Xanthan gum is not a gelling agent, and as a result it is often used in combination with other materials including locust bean gum, guar gum, starches, carrageenan and konjac glucomannan to increase viscosity (2018 Gums TR 424-432).

International Equivalency:

FDA has approved the use of xanthan gum as a food additive since 1969 without restrictions on quantity in finished applications (TR 162-163, 637-638); it must be isolated by isopropyl alcohol precipitation and made into a sodium, potassium, or calcium salt (TR 164-166). It is approved by FDA at 21 CFR 172.695 but is not GRAS; though three FDA notices for GRAS allow isolation of xanthan gum by ethanol and pyruvate, and in combination with konjac glucomannan and sodium alginate (TR 651-659).

Canadian Organic Regime's Canadian General Standards Board Permitted Substances List (Nov 2015 ed.) allows the use of xanthan gum as long as it is derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 Gums TR 491-496).

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

Xanthan gum is allowed and the CODEX General Standard for Food Additives (GSFA) 502 describes the compliant uses (2018 Gums TR 498-504).

European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008

Xanthan gum is allowed for use as compliant with General Standard for Food Additives Annex II and III in processed organic foods and as a food additive in the preparation of foodstuffs of plant or animal origin (2018 Gums TR 506-515).

Japan Agricultural Standard (JAS) for Organic Production

Xanthan gum is allowed in processed foods of animal origin limited to dairy or confectionary (2018 Gums TR 525-536).

International Federation of Organic Agriculture Movements (IFOAM)

Xanthan gum is allowed with no limitations on use (2018 Gums TR 538-541).

Ancillary Substances:

According to the 2016 TR (258-263), ancillary substances are not commonly added to commercially available forms of xanthan gum for use in foods. Through a search of publically available specification sheets a few exceptions were identified: glucose in a xanthan and guar gum blend and polysorbate 60 in GRINSTED®.

Background Information:

Xanthan gum has been used for decades globally in the food system, and subsequently has undergone numerous clinical trials and studies to look for impacts on human health in adults, children, infants, and animals (TR 637-742). Some studies have shown that xanthan gum is beneficial to human health; soluble fiber that may help improve colon health and reduce cholesterol (2018 TR 933, 963-976). In 2011 there was a recall of a xanthan gum product that was being fed to premature babies due to the lack of destruction of potentially harmful bacteria that may lead to necrotizing enterocolitis; no conclusions were made regarding the safety of xanthan gum thickeners for premature baby formulas (TR 678-711).

There was no mention of specific environmental issues regarding the production of xanthan gum.

Additional information requested by Subcommittee:

None

Gums: (Arabic, Guar, Locust bean , and Carob bean)

Reference: 205.606(k) Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean)
Technical Report: 1995 TAP 2018 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published XX/XX/XX (XX FR XXXXX)
Sunset Date: 6/27/2017 (NOP renewal pending)

Commented [MOU2]: Need new 2018 Gums TR link once available

Material Use:

Gum arabic, locust bean gum, carob bean gum, and guar gum are high molecular-weight-polysaccharides extracted via water processing and then drying and milling (2018 TR 78-103). These gums are extracted from the endosperm of plants of the *Leguminosae*. The specific plants are guar, carob and locust bean. Gum Arabic is obtained from the exudate from the bark of the acacia tree and is one of the oldest known natural gums (TAP pg 8, 2018 TR 443). These gums are used in various food applications due to their ability to modify viscosity of products (hydrocolloid function) through the binding of water and generation of gelling effects (2018 TR 182-187). These properties are the primary function of gums and lend them to be common and popular thickeners and stabilizers in food products. Guar gum, gum Arabic and locust bean/carob bean gum are also thickening agents, which makes them useful since not all hydrocolloids function as thickening agents (2018 TR 189-192).

Despite having some similar characteristics, not all gums are interchangeable. Due to the structure of the gums, some behave differently in different temperatures, pH ranges, physical agitation, etc. (2018 TR 194-200). This variability requires formulations specific to the type of food product, intended shelf-life and product use. Many times these gums are used in combination to impart the correct properties in the finished goods (2018 TR 416). The table provided on line 285 in the 2018 technical report distinguishes the different characteristics of common gums.

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		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
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Manufacture:

Gum arabic is obtained from the exudate from dried sap collected from the stems and branches of the Acacia tree, both wild grown and cultivated. The gum is cleaned by mechanical sieves and graded, then milled to a powder. (2018 TR 566-573)

Locust/carob bean gum is derived from the seeds of the carob tree, which are processed through a series of crushing, sifting, and grinding steps (2018 TR 594-595)

Guar gum is formed form the seeds of the guar bean plant. The endosperm is dehusked, milled and screened, and the gum is then clarified (2018 TR 584-586).

International Equivalency:

Gum arabic, locust/carob bean gum and guar gum are all listed by the FDA as Generally Recognized as Safe (GRAS) (2018 TR 750-752).

Canadian Organic Regime's Canadian General Standards Board Permitted Substances List (Nov 2015 ed.) allows the use of Gum Arabic, locust/carob bean gum, and guar gum as long as they are derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 TR 491-496).

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

Gum Arabic (414), locust/carob bean gum (410), and guar gum (412) are allowed and the CODEX General Standard for Food Additives (GSFA) describes the compliant uses (2018 TR 498-504).

European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008

Gum Arabic, locust/carob bean gum, and guar gum are allowed for use in processed organic foods as a

food additive in the preparation of foodstuffs of plant 508 or animal origin with no specific limitations (2018 TR 506-515).

Japan Agricultural Standard (JAS) for Organic Production

Arabian gum (INS 414) is limited to dairy products, edible fat, and oil and confectionary products (2018 TR 527).

Carob bean gum/locust bean gum (INS 410) is limited to dairy and processed meats. (2018 TR 529)

Guar gum (INS 412) can be used in processed foods of animal origin limited to dairy, canned meat or egg products. (2018 TR 531)

International Federation of Organic Agriculture Movements (IFOAM)

IFOAM allows locust bean gum (INS 410), guar gum (INS 412), tragacanth gum (INS 413), Arabic gum (INS 414) and xanthan gum (INS 415). There are no restrictions on how any of these items can be used (IFOAM, 2014). (2018 TR 539-541)

East African Organic Product Standard

Locust bean gum, guar gums are allowed with no restrictions. Arabic gum is allowed for milk products, fat products, confectionary, sweets and eggs (2018 TR 544-550).

Ancillary Substances:

According to the 2018 TR (434-438) no information was found indicating that any additional materials are generally added to commercially available forms of the gums. However, according to the 2016 TR on xanthan gum two exceptions were identified during a review of publically available specification sheets: glucose used to standardize a xanthan and guar gum blend, and polysorbate 60 in GRINSTED®.

Background Information:

No environmental or health concerns were noted in the manufacture or use of these gums in the general population. The EFSA (European Food Safety Authority) re-evaluated five gums in 2017 including arabic, guar, and locust. The panel concluded there wasn't adequate data available to assess the effects of locust bean and guar gum on infants and young children, and recommend that additional data be generated.

In 2015 these gums were unanimously voted by the NOSB to remain on 205.606(k).

Additional information requested by Subcommittee:

Are organic versions of gum arabic, locust/carob bean gum, and guar gums commercially available?

Tragacanth gum

Reference: 7 CFR 205.606(x) - As nonorganically produced agricultural product allowed as ingredient in or on processed products.

Technical Report: none

Commented [MOU3]: Link needed to new 2018 TR

Original Petition: 2007 Tragacanth Gum, 2018 TR

Past NOSB Actions: 2008 Final Recommendation; 2014 sunset recommendation

Regulatory Background: Proposed rule (including justification) published 06/03/09 (74 FR 26591), Added to National List 12/13/2010 (75 FR 7751). Sunset renewal notice published 06/22/2015 (80 FR 35177)

Sunset Date: 06/22/20

Material Use:

Tragacanth gum is a polysaccharide that forms gels and can be used as a thickener and emulsifier. This material is effective at low pH and at many temperatures; its stability at low pH is noted as one of its distinguishing characteristics and is commonly used in high acid products like salad dressings (2018 TR 218-225, 337). The percentage in final formulations is usually low, below 1% of a total formula (2018 TR 338).

Despite having some similar characteristics, not all gums are interchangeable. Due to the structure of the gums, some behave differently in different temperatures, pH ranges, physical agitation, etc. (2018 TR 194-200). This variability requires formulations specific to the type of food product, intended shelf-life and product use. Many times these gums are used in combination to impart the correct properties in the finished goods (2018 TR 416). The table provided on line 285 in the 2018 Technical report distinguishes the different characteristics of common gums.

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		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
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Manufacture:

Tragacanth gum is prepared from the sap of various species of legumes in the *Astragalus* species during July to September (2018 TR 576-581). Once collected it is dried and ground into powder and may, or may not, undergo a mitigation step to reduce the microbial load of the powder (2018 TR 578-581).

International Equivalency:

Tragacanth gum is listed as Generally Recognized as Safe (GRAS) by the FDA at 21 CFR 184.1351 (2018 TR 750-752).

Canadian Organic Regime's Canadian General Standards Board Permitted Substances List (Nov 2015 ed.) allows the use of tragacanth gum as long as it's derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 TR 491-496).

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

Tragacanth gum (412) is allowed and the CODEX General Standard for Food Additives (GSFA) describes the compliant uses (2018 TR 498-504).

European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008

Tragacanth gum is allowed as a food additive in compliance with the General Standard for Food Additives Annex II and III of the Regulation (EC) No. 1333/2008 on food additives (2018 TR 506-515).

Japan Agricultural Standard (JAS) for Organic Production

Tragacanth gum is listed with no limitations (2018 TR 535).

International Federation of Organic Agriculture Movements (IFOAM)

IFOAM allows tragacanth gum (INS 413) with no restrictions on how any of this item can be used (IFOAM, 2014) (2018 TR 539-541).

East African Organic Product Standard

Tragacanth gum is allowed with no restrictions (2018 TR 547).

Ancillary Substances:

According to the 2018 TR (434-438) no information was found indicating that any additional materials are generally added to commercially available forms of the gums. However, according to the 2016 TR on xanthan gum two exceptions were identified during a review of publically available specification sheets: glucose used to standardize a xanthan and guar gum blend, and polysorbate 60 in GRINSTED®.

Background Information:

No environmental or health concerns were noted in the manufacture or use of this gum.

The NOSB Subcommittee noted in 2008 that due to limited growing regions (Turkey and Iran) and relevant trade embargoes, the supply of conventional tragacanth gum was fragile and limited. In October 2014 organic tragacanth gum was not known to be in production. The 2014 Subcommittee was unable to find evidence that tragacanth is available in organic form, and received testimony from a certifier and a producer who currently uses non-organic tragacanth.

Additional information requested by Subcommittee:

Is organic tragacanth now commercially available?

Sunset 2020 Review
Meeting 1 - Request for Public Comment
Handling Substances
April 2018

Lecithin- de-oiled

Reference: 205.606(o) Lecithin—de-oiled.

Technical Report: 1995 TAP; 2009 TR

Petition(s): Lecithin, bleached (remove 2008)

Past NOSB Actions: 04/1995 minutes and vote; 05/2009 recommendation (remove from 605b); 05/2009 Recommendation (amend 606)

Recent Regulatory Background: Annotation change effective 03/15/2012 (77 FR 8089)

Sunset Date: 03/15/17

Background from Subcommittee:

(b)(5)

Use

Lecithin is the substance isolated as a gum following hydration of solvent-extracted soy, safflower or corn oils. Lecithin has a wide range of food application, which includes emulsification, release properties, wetting, dispersing, and texturization. The major applications for lecithin include margarine, chocolates, instantizing powders, release sprays, and baked goods. It is used as a natural surfactant between oil and water systems as seen in margarine products. Lecithin also helps modify chocolates for better enrobing and reduces crystallization of cocoa fat. In release applications, lecithin modifies the cooking surface to allow products to be more easily removed. As an instantizing agent, lecithin reduces the hydration properties of powders that would otherwise clump during dispersion in water and milk products. In baking, the lecithin provides a multifunction application by emulsifying the fat and water and as an anti-staling agent by inhibiting starch retrogradation. Lecithin improves water absorption in baked goods and dough, increasing volume and shelf life, and improving uniformity of the products. It is also used as a packaging aid and directly on processing equipment as a lubricant. In addition, lecithin is used in pharmaceuticals (as dietary supplements, emulsifying agent for intravenous injections, and dispersant for vitamins); in cosmetics (as emulsifier and emollient in hair and make-up preparations, creams, and oils); and in animal feeds (as a nutritional ingredient, emulsifier, and wetting aid in calf milk replacers, pet foods, and many other types of feeds required high fat and oil contents). Bleached lecithin is used in applications where a lighter color is deemed important. Unbleached fluid lecithin has a dark brown color which does not permit high use levels in white or very light colored products; however, in some formulations, brown fluid lecithin can be used effectively at low concentrations (Scocca, 1976). Dry lecithin is used in commercial applications of food systems where liquid lecithin is more difficult to handle and the powdered or granular lecithin is more easily incorporated.

Manufacture

Lecithin is the substance isolated as a gum following hydration of solvent-extracted soy, safflower or corn oils. Most commercial lecithin is made from crude soy oil extracted from soy flakes. The crude soy oil is then treated with water or steam to precipitate the lecithin as a gums. These wet gums isare

centrifuged, bleached (with hydrogen peroxide and/or benzoyl peroxide), and dried to become a bleached lecithin.

International

-The Joint FAO/WHO Expert Committee on Food Additives— Lecithin (INS1: 322) functional uses as antioxidant and emulsifier agent. Acceptable daily intake is not limited.

Canadian Organic Standards— Lecithin bleached form is allowed when unbleached form is not suitable from organic sources only. Lecithin is listed in the table of "Food Additives" of the "Non-organic Ingredients" section under permitted substances lists for processing and sanitation

The EU Organic Regulation No 2092/91— The use of lecithin as (1) a fungicide, listed in the section "Substances of crop or animal origin", for plant protections; and (2) a food additive, listed in the subsection "Food additives, including carriers" of the section "INGREDIENTS OF NON-AGRICULTURAL ORIGIN", for preparation of foodstuffs composed essentially of one or more ingredients of plant and/or animal origin.

The Codex Guidelines for Organically Produced Foods— Lecithin used for pest and disease control need recognized by the certification body or authority, e.g., volume, frequency of application, specific purpose, etc. In addition, lecithin (obtained without bleaches and organic solvents) as a food additive is permitted for use in foods of plant origin and certain foods of animal origin (such as dairy products and analogues, fats and oils, fat emulsions, emulsified sauces, and infant formulae and follow-on formula).

Commented [AM-A2]: ?

Environmental Health Issues

Lecithin is found in brain, nerve, liver, kidney, heart, blood, and other tissues. Because of its strong affinity for water, it facilitates the passage of fats in and out of the cells; and it probably plays a role in fat absorption from the intestine and transport of fats from the liver (Potter, 1973). No acute exposure studies were found for soybean–derived lecithin in humans. According to MSDS, the dust is predicated to be irritating to the eyes, skin, and respiratory tract from mechanical action. Inhalation of lecithin aerosols may cause pulmonary edema; it may cause occupational asthma from pulmonary sensitization. Acute ingestion may affect the liver (fatty liver degeneration). - Safety glasses, lab coat, dust respirator, and gloves are needed for personal protection.

Soy has also been recognized as one of the eight most common food allergens. During manufacture of lecithin derived from soy, most, but not all, of the soy protein is removed. Soy allergens, to the extent they are present in lecithin, would be found in the protein fraction of the ingredient. Accurately measuring lecithin's protein content presents challenges to current analytical methodology due to the ingredient's oily matrix and low levels of protein.

Discussion

During the ssunset rReview in October 2006, the NOSB recommended renewing lecithin-bleached under 7 CFR §205.605(b) Synthetics allowed. In the committee summary, the Bboard further recognized that there are "plentiful non-synthetic and organic alternatives to synthetic bleached lecithin in liquid form" but that there is currently no such alternative for "bleached lecithin in dry, de-oiled form". Because the Ssunset Rreview provided no opportunities to add annotations, the board saw no alternative but to recommend renewal of bleached lecithin. In its closing its summary, the Bboard invited a petition to restrict the use of bleached lecithin to dry forms only. Since then, the supply of organic lecithin has evolved to the point that there is now certified organic lecithin available to replace the need for non-organic bleached lecithin. But, there still remains a question of whether there is an organic lecithin that is in dry, de-oiled form.

During the May 2009 NOSB meeting, several experts and lecithin industry members provided informational presentations describing the types of lecithin available, and the methods of manufacture for each. It was explained that it is the "de-oiling" process, not the bleaching ~~process, which~~ process that ~~truly~~ differentiate~~sd~~ the types and functionality of lecithin, and dictate~~ds~~ in which products they could be used. At this time, there are now many forms of organic lecithin available, as well as organic and conventional non-synthetic gums, which make the use of this synthetic form of lecithin no longer essential in organic handling. The board voted to remove the "bleached" form of lecithin from 205.605(b), but in a separate vote, agreed to list "lecithin – de-oiled" in 205.606, making that form available to organic manufacturers who truly needed it, but subjecting its use to commercial availability scrutiny by certifiers. Both the petitioner and lecithin -using handlers present at the NOSB meeting were satisfied with this recommendation.

In 2009, t~~T~~he NOSB reviewed the arguments for and against renewal of lecithin. ~~points in favor of renewing the substance as well as those in favor of removal from the list.~~ Those in favor of renewing pointed out that there is was insufficient supply in an organic form, specifically from raw materials other than soy. Additionally other sources were not yet in production and were located in a country under political turmoil. Those in favor of removal argued the product was available in an organic form internationally. –The majority of the NOSB concluded that it meets the OFPA criteria ~~in OFPA~~, is not available in an organic form, and should be renewed.

Additional information requested by Subcommittee:

Are there commercially available organic forms of lecithin in de-oiled form?

National Organic Standards Board (NOSB)
Crops Subcommittee (CS) Meeting Notes
Tuesday April 3, 2018 2:00 pm ET

Present: Steve Ela, Chair (SE); Emily Oakley, Vice Chair (EO); Harriet Behar (HB); Dave Mortensen (DM); Jesse Buie (JB)
Absent: Asa Bradman (AB); Sue Baird (SB)
Staff: Michelle Arsenault (MA)

Work Agenda

Petitioned Substances					
Substance	**Con-tact**	**TR request?**	**Notes**	**Discussed, Voted**	**Meeting**
Polyoxin D Zinc salt 205.601 Petition Addendum #1 Petition Addendum #2	JB	Y	Petition sent to CS 06 16 16. Petition suff/TR request due 08 16 16. Petition found sufficient 08 16 16. Discuss need for Lmt'd scope TR. CS requested Lmt'd scope TR 10 04 16. TR sent to Subcommittee on 12 19 17. Response due 02 20 18. TR found sufficient 02 20 18.	Feb 6, Feb 20	Spr 2018
Allyl Isothiocyanate (AITC) Petition (2016) 205.601	JB	Y Lmt'd scope	Petition sent to CS 07 06 16. Petition suff/TR request due 09 06 16. Petition found suff 10 04 16. CS requested Lmt'd scope TR 10 04 16. TR in development. Expected Feb/Mar 2018. Lmtd scope TR sent to CS 02 16 18. Response due 04 18 18. TR found sufficient 03 06 18 • AITC Petition (2013) (PDF) • NOSB Subcommittee Proposal (2014) (PDF) • Technical Evaluation Report (2014) (PDF)	Mar 6	Fall 2018
Sodium Citrate 205.601	HB	Y	Petition sent to CS 07 27 16. Petition suff/TR request due 09 27 16. Petition was found sufficient 10 04 16. CS requested a TR 10 04 16. TR in development. TR - Handling, Citric acid and salts (2015). TR sent to CS 08 07 17. Response due 10 06 17. Found TR insufficient 09 19 17. HS sent additional questions to TR contractor 12 11 17. Revised TR sent to CS 12 20 17. Response due 02 19 18. TR found sufficient 02 06 18.	Sep 19, 2017, Feb 6, 2018 Mar 6 Apr 3	Fall 2018

Natamycin	HB	Y	Petition sent to CS 09 09 16. Petition suff/TR request due 11 08 16. Petition found sufficient 11 01 16, and CS requested TR 11 01 16. TR in development. Expected October 2017. TR sent to CS 11 3 17. Response due 01 12 18. TR found sufficient 12 5 17.	Dec 5, Mar 3	Fall 2018
Sulfur (as a molluscicide) 205.601	AB	N	Petition sent to CS 06 08 17. Petition suff/TR request due 09 05 17. Petition found sufficient 09 19 17. No TR request.	Sep 19 Feb 20	Spr 2018
Ammonium Citrate 205.601	EO/DM	Y	Petition sent to CS 10 25 17. Petition suff/TR request due 12 26 17. TR requested 11 21 17.	Nov 21	TBD
Ammonium Glycinate 205.601	EO/DM	Y	Petition sent to CS 10 25 17. Petition suff/TR request due 12 26 17. TR requested 11 21 17.	Nov 21	TBD
Calcium Acetate	SB	Y	Petition sent to CS 1 20 17. Petition suff/TR request due 01 17 17. Petition found suff 02 06 18. CS requested TR with specific questions 02 06 18.	Feb 6	TBD

Other Topics

Project	Con-tact	Doc type	Notes*	Discussed/ Voted	Meeting
(Manure treatments) Anaerobic Digestate - Food Waste 205.601(j) and other manure issues	EO/HB	Disc Doc	Petition sent to CS 04 08 15. Questions or request for TR due 06 09 15. Petition found sufficient 06 02 15. TR rqst sent to NOP 10 06 15. Petition withdrawn 10 14 15. CS moved project to "other topics" NOP sent memo to board 05 09 16 requesting review. TR request sent to NOP 07 05 16 (see anaerobic digestate above). Waiting for result of FDA's risk assessment.	Aug 1, Aug 15, 2017	Fall 2018
Biodegradable Biobased Mulch annotation change	HB/AB	Disc Doc	Limited scope TR request sent to NOP 08 02 16. TR sent to CS on 12 28 16. TR Suff due 02 27 17. CS found TR suff 01 03 17. Pending further research	Aug 1, 2017	TBD
Prohibition of NPEs in inerts - annotation change/ EPA List 4 Inerts annotation change	HB/EO/ DM/AB	Disc Doc/Prop	IWG recommended NOSB work on NPEs/TR requested July 2014. DD - April 2016. EPA List 4 inerts disc doc (originated from 2017 sunset review conducted in 2015). Pending EPA decision	TBD	Fall 2018

Marine materials (marine algae and extracts) on the National List	EO	Disc doc	NOP approved request 01 12 16. TR request sent to NOP 02 05 16. TR sent to HS 08 10 16. Referred back to CS at Spr 2017 meeting. Moved to MS 03 16 18.	Aug 15, Dec 5	TBD
Field and Greenhouse Container Production	JB, HB, FT and EO	TBD	On hold as per NOP Jan 2018.	TBD	TBD
Strengthen and clarify the requirements for use of organic seed (NOP 5029)	HB	Proposal	Originated in MS. Referred back to CS at Spr 2017 meeting. Referred back to CS at Fall 2017 meeting.	TBD	TBD
Research Priorities	All	NA	RPs due to MS Aug 2018	NA	Fall 2018

* Yellow highlight indicates Subcommittee action needed *Highlight indicates review completion

2020 Sunsets **TR Requests: July 2017, Summary: Spr 2018, Review: Fall 2018**						
Substance		**Contact**	**TR request?**	**Notes**	**Scheduled, Discussed**	**Meeting**
Alcohols: Ethanol Isopropanol	205.601(a)(1)(i), 205.601(a)(1)(ii)	JB	N	1995 TAP; 2014 TR - Ethanol; 2014 TR - Isopropanol	Feb 6	Summary: Spr 2018 Review: Fall 2018
Sodium carbonate peroxyhydrate	205.601(a)	EO	N	2006 TAP; 2014 TR	Dec 5	"
Newspaper or other recycled paper	205.601(b) and (c)	HB	N	2017 TR	Dec 5	"
Plastic mulch and covers	205.601(b)	HB	N	1995 TAP: TR for biodegradable mulch. Low priority	Dec 19, Jan 2	"
Aqueous potassium silicate	205.601(e), 205.601(i)	DM	N	2014 TR	Jan 2, Feb 6	"

Elemental sulfur	205.601(e)(5), 205.601(i)(10), 205.601(j)(2)	AB	Y	1995 TAP; 2017 TR for Livestock. TR requested 07 28 17. In contracting. TR sent to CS 01 10 18. TR sufficiency due 03 12 18. CS sent additional questions to the TR contractor. TR final draft expected April 2018.	Dec 19, Jan 2 Feb 20	"
Lime sulfur	205.601(e)(6), 205.601(i)(6)	SE	N	2014 TR	Dec 19	"
Sucrose octanoate esters	205.601(e)(10)	SB	N	2005 TR	Dec 19	"
Hydrated lime	205.601(i)(4)	DM	N	1995 TAP; 2001 TAP; 2002 TR for Calcium Hydroxide	Jan 2	"
Liquid fish products	205.601(j)	AB	N	1995 TAP; 2006 TR	Jan 16,	"
Sulfurous Acid	205.601(j)	SE	N	2010 TAP; 2014 TR	Dec 19	"
Ethylene	205.601(k)	EO	N	2000 Supplemental TAP; 2007 TAP; 2011 Supplemental TR	Dec 19	"
Microcrystalline cheesewax	205.601(o)	SB	Y	None. TR requested 07 28 17. In contracting. TR sent to CS 01 11 18. TR found sufficient 02 20 18.	Dec 19, Feb 20	"
Potassium chloride	205.602(e)	HB	N	1995 TAP. Low priority	Jan 16	"

Agenda

- Sodium Citrate (HB). Discuss and vote
- Assign leads to 2021 sunsets
- Natamycin (HB) - Discuss proposal
- Adjourn

Discussion

- **Sodium Citrate (HB).** HB forwarded an OMRI newsletter to the group that had an article about sodium citrate and "excipients". The group discussed the possibility of recommending that NOP publish guidance, or perhaps convene a task force. The CS asked the NOP to ask the petitioner about the history of this material and why they are petitioning it for addition to the list. The lead will write the draft proposal and the group will discuss it on a future call.
- **Assign leads to 2021 sunsets.** See table below
- **Natamycin (HB)**. Under the new materials classification guidance, this is potentially classified as a natural. The CS will move forward with a classification motion, and if found to be a "natural" will not need to be added to the list. The CS is interested in submitting a petition to add Natamycin to 205.602, as a prohibited natural.
- **The meeting was adjourned**

Previous CS Notes

Future Call Schedule (1st and 3rd Tuesdays 2:00 ET)

March 6, 2018
- Allyl Isothiocyanate (AITC) (JB) - TR sufficiency
- Sodium Citrate (HB) - Discuss proposal
- Natamycin (HB) - Discuss proposal

March 20, 2018 - cancelled call

April 3, 2018
- Sodium Citrate (HB). Discuss and vote
- Assign leads to 2021 sunsets
- Natamycin (HB) - Discuss proposal
- Discuss public comment

April 17, 2018 - NOSB public comment webinar

May 1, 2018 - cancelled

May 15, 2018
- Natamycin (HB) - Discuss proposal and vote
- Sodium Citrate (HB). Discuss proposal and vote
- Allyl Isothiocyanate (AITC) (JB) - Discuss proposal

June 5, 2018
- 2021 sunsets - Determine need for TRs

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**
Hydrogen peroxide	205.601(a), 205.601(i)	JB		2015 Hydrogen Peroxide (Crops) 2017 NOSB Recommendation		Summary: Spr 2019 Review: Fall 2019
Soaps, ammonium	205.601(d)	SB		1996 TAP 2017 NOSB Recommendation		"
Oils, horticultural (Narrow range oils)	205.601(e), 205.601(i)	SE		1995 TAP 2017 NOSB Recommendation		"
Pheromones	205.601(f)	SE		2012 TR 2017 NOSB Recommendation		"
Ferric phosphate	205.601(h)	SB		2012 TR 2016 NOSB Recommendation		"
Potassium bicarbonate	205.601(i)	EO		2015 TR 2017 NOSB Recommendation		"
Magnesium sulfate	205.601(j)	EO		2011 TR 2017 NOSB Recommendation		"
Hydrogen chloride	205.601(n)	AB		2014 Lmtd Scope TR 2016 NOSB Recommendation		"
Ash from manure burning	205.602(a)	HB		2016 sunset rec 2017 NOSB Recommendation		"
Sodium fluoaluminate	205.602(f)	HB		None. 2017 NOSB Recommendation		"

National Organic Standards Board (NOSB)
Handling Subcommittee (HS) Meeting Notes
Tuesday, April 3, 2018 1:00 pm ET

Present: Lisa de Lima (LD), Chair; Scott Rice, Vice Chair (SR); Steve Ela (SE); A-dae Briones (ARB); Tom Chapman (TC) ; Harriet Behar (HB) - observer
Absent: Asa Bradman (AB)
Staff: Michelle Arsenault (MA)

Work Agenda

Petitioned Substances						
Substance	**National List §**	**Contact**	**TR rqst?**	**Notes***	**Scheduled, Discussed, Voted**	**Meeting**
Sodium dodecylbenzene sulfonate (SDBS) Petition Addendum #1, SDBS (PDF)	205.605(b)	SR	Y	Petition sent to HS on 11 02 15. Response/request for TR due 01 04 16. Petition found suff 12 01 15. No new TR will be requested. Referred back to HS at Apr 2016 NOSB meeting. TR request sent 05 18 16. TR in development - Expected late Dec 2016/early Jan. TR delayed until Spring 2017. TR sent to HS 05 30 17. Response due 08 01 17. Petition addendum sent to HS 07 12 17. The HS found the petition addendum suff 08 01 17	Aug 1, Aug 15 Jan 2 Jan 16	Spr 2018
Sodium Chlorite for the generation of chlorine dioxide gas Petition, Addendum	205.605	SR	Y	Petition for chlorine dioxide dry gas sent to HS on 12 02 15. Response/request for TR due 02 02 16. HS sent request 03 17 16 for additional info from petitioner. Sodium chlorite addendum received 05 05 16. Suff due 07 05 16. Petition found sufficient 06 07 16. Sent back to Subcomm at Fall 2016 meeting. HS requested a TR 06 06 17. TR sent to HS 01 09 18. Response due 03 13 18. TR found sufficient 03 06 18.	May 16, Jun 6, Jan 16 Mar 6	Fall 2018

Petitioned Substances						
Substance	**National List §**	**Contact**	**TR rqst?**	**Notes***	**Scheduled, Discussed, Voted**	**Meeting**
Silver Dihydrogen Citrate Petition Addendum #1	205.605(b)	TC	Y	Petition sent to HS 01 24 17. Response/request for TR due 03 28 17. Petition found sufficient 03 07 17. HS requested TR 03 07 14. TR in development. Petition addendum sent to HS 08 03 17. TR sent to HS 10 19 17/ Suff due 12 19 17. HS sent additional questions to TR contractor 12 05 17. TR under revision. Revised TR sent to HS 02 21 18. Response due 04 23 18.	Mar 7, Dec 5 Mar 6	Fall 2018
Japones pepper	205.606	ARB	N	Petition sent to HS 02 09 17. Response/request for TR due 04 11 17. Petition found suff 04 04 17. No TR. HS requested additional info from petitioner 07 19 17 & 11 07 17	Apr 4, Jul 18 Oct 3 Nov 7	Fall 2018
Ethiopian pepper	205.606	ARB	N	Petition sent to HS 02 09 17. Response/request for TR due 04 11 17. Petition found suff 04 04 17. No TR. HS requested additional info from petitioner 07 19 17 & 11 07 17	Apr 4 Jul 18 Oct 3 Nov 7	Fall 2018
Tamarind Seed Gum Petition Addendum, August 22, 2017	205.606	SE		Petition sent to HS 02 15 17. Response/request for TR due 04 17 17. HS requested additional info from the petitioner 04 04 17. Petition addendum Rcvd 08 10 17. Response due 10 10 17. Updated petition addendum rcvd 08 22 17. TR requested 10 03 17. TR in development - expected March 2018. TR sent to HS 03 12 18. Suff due 05 11 18. TR found suff 04 03 18.	Apr 4 Sep 5, Oct 3 Apr 3	Fall 2018
Pullulan	205.605(a)	LD		Petition sent to HS 02 27 18/ Sufficiency due 04 30 18. Petition found suff 04 03 18. HS requested TR 04 03 18	Apr 3	TBD
Collagen Gel (casing)	§205.606			Petition sent to HS 03 23 18. Petition Sufficiency due 5 22 18		

2020 Sunsets TR Requests: July 2017, Summary: Spr 2018, Review: Fall 2018						
Name	**National List §**	**Contact**	**TAP/TR**	**Notes**	**Scheduled, Discussed**	**Review Meeting**
Calcium carbonate	205.605(a)	SR	Y	1995 TAP. TR requested 07 28 17. Low priority. TR sent to HS 01 29 18. Suff due 03 30 18. TR found suff 02 20 18	Feb 20	Summary: Spr 2018 Review: Fall 2018
Flavors	205.605(a)	TC	N	2005 TR	Jan 2	"
Gellan Gum	205.605(a)	LD	N	2006 TAP	Feb 20	"
Oxygen	205.605(a)	LD	N	1995 TAP. TR requested 07 28 17. Low priority	Dec 5	"
Potassium chloride	205.605(a)	ARB	N	1995 TAP; 2015 TR for Nutrient vitamins and minerals	Dec 5	"
Alginates	205.605(b)	SE	N	1995 TAP; 2015 TR	Dec 19	"
Calcium hydroxide	205.605(b)	ARB	N	1995 TAP. TR requested 07 28 17. Low priority	Dec 5	"
Ethylene	205.605(b)	AB	N	1995 TAP; 1999 TAP - Processing. TR requested 07 28 17. Contingent on request from other Subcomms	Dec 19, Jan 2	"
Glycerides: mono and di	205.605(b)	LD	N	1995 TAP; 2015 TR	Dec 5	"
Magnesium stearate	205.605(b)	AB	Y	1995 TAP. TR requested 07 28 17. Low priority. TR sent to HS 01 29 18. Suff due 03 30 18. TR found sufficient 02 20 18.	Feb 20	"
Phosphoric acid	205.605(b)	ARB	N	2003 TAP. TR requested 07 28 17. Contingent on request from other Subcomms	Dec 5	"
Potassium carbonate	205.605(b)	SR	N	1995 TAP. TR requested 07 28 17. Low priority.	Feb 20	"
Sulfur dioxide	205.605(b)	SE	N	1995 TAP; 2011 TR	Dec 19	"
Xanthan gum	205.605(b)	LD	N	1995 TAP; 2016 TR	Feb 20	"
Fructooligosaccharides (FOS)	205.606	TC	N	2006 TAP; 2015 TR	Jan 2	"
Gums: Arabic, Carob bean, Guar, Locust bean	205.606(k)	LD	Y	1995 TAP. TR requested 07 28 17. TR in contracting. TR sent to HS 01 30 18. Suff due 04 02 18. TR found sufficient 02 20 18.	Feb 20	"

Lecithin - de-oiled	205.606	ARB	N	1995 TAP; 2009 TR	Jan 16	"
Tragacanth gum	205.606	LD	Y	None. TR requested 07 28 17. TR in contracting. TR sent to HS 01 30 18. Suff due 04 02 18. TR found sufficient 02 20 18.	Feb 20	"

Other projects			
Name	**Contact**	**Notes***	**Meeting**
Packaging substances used in organic food handling - including BPA	LD/AB	Submitted briefing paper to NOP 01 12 14. Response memo from NOP sent to HS 11 19 14. TR in development, expected mid-Sep - delayed. TR received 9/30/16. In review by the program. TR sent to HS 10 19 16. TR sufficiency due 12 20 16. TR found insufficient 12 20 16. Vote: 02 21 17. New TR in development. Expected July 2017. TR received 07 10 17. Response due 09 08 17. TR found sufficient 08 01 17.	Discussion doc TBD
Nutrient Vitamins and Minerals - annotation change	TC	Pending NOP Approval. Approved 01 12 16. Proposal. On hold.	TBD
Marine materials (marine algae and extracts). Proposal	SR	Pending NOP approval. NOP approved request 01 12 16. TR request sent to NOP 02 05 16. TR expected Jul 2016. TR sent to HS 08 10 16. TR suff due 10 11 16. TR found sufficient 09 06 16. Voted 09 06 16. Proposal in development 12 06 16. Voted 01 17 17. Referred back to HS at Spr 2017 NOSB meeting. Moved to MS for completion 04 03 18.	TBD
Magnesium chloride reclassification 205.605(b)	LD	HS requested addition of this item and NOP approved 01 12 16; TR completed 11/30/16. Voted 02 06 18	Spr 2018
Research Priorities	TC/ALL	RPs due to MS Aug 2018	Fall 2018

*Highlight indicates committee action needed. *Highlight indicates review completion and/or vote

Agenda

- Approve March 6, 2018 notes?
- Tamarind Seed Gum (SE) - TR sufficiency
- Pullulan petition sufficiency (LD)
- Assign leads to 2021 Sunsets (All)
- Other items – marine materials moved to MS. LS and EO will be working on this within MS
- Adjourn

Discussion

- **Assign leads to 2021 Sunsets (All).** See table below

- **Tamarind Seed Gum.** The TR was found sufficient. The lead noted that it was well written, and answered all the questions that the HS had.
- **Pullulan petition sufficiency (LD**). Pullulan is a material that is already in use: in vegetarian capsules used in "made with organic" supplements. After classification guidance was published, it was deemed not agricultural anymore. If that is case then it needs to be on 605(a). The HS found the petition sufficient and will request a TR.
- **Other items.** Marine materials was moved to the Materials Subcommittee. LD and EO will be working on this within MS
- **The meeting was adjourned**

Previous HS Notes

Future Call Schedule (1st and 3rd Tuesdays 1:00 ET)

March 6, 2018
March 20, 2018 - cancelled
April 3, 2018
Tamarind seed gum (SE) - TR sufficiency
Pullulan (LD) - petition sufficiency
Sodium Chlorite for the generation of chlorine dioxide gas (SR) - discuss proposal
April 17, 2018 – cancelled. NOSB public comment webinar.
May 1, 2018 - cancelled
May 15, 2018
Silver dihydrogen citrate (SR) - discuss proposal, vote
Collagen gel - assign lead
Discuss requests for TRs for 2021 sunsets
Sodium chlorite for the generation of chlorine dioxide gas proposal discussion (SR) - discuss proposal
Tamarind seed gum (SE) - discuss proposal
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**
Alginic acid	205.605(a)	LD		2015 TR 2017 NOSB Recommendation		Summary: Spr 2019 Review: Fall 2019
Calcium chloride	205.605(a)	TC		1995 TAP 2017 NOSB Recommendation		"
Citric acid	205.605(a)	LD		2015 TR 2017 NOSB Recommendation		"
Dairy cultures	205.605(a)	SE		1995 TAP See TR for microorganisms		"
Enzymes	205.605(a)	SE		2015 TR 2017 NOSB Recommendation		"
Lactic acid	205.605(a)	LD		2015 TR 2017 NOSB Recommendation		"
L-Malic acid	205.605(a)	LD		2003 TAP 2015 NOSB Recommendation		"
Magnesium sulfate	205.605(a)	SR		2011 TR 2017 NOSB Recommendation		"
Microorganisms	205.605(a)	SE		2014 TR 2015 NOSB Recommendation		"
Perlite	205.605(a)	SR		1996 TAP 2017 NOSB Recommendation		"
Potassium iodide	205.605(a)	TC		2011 TR 2017 NOSB Recommendation		"
Yeast	205.605(a)	SE		2014 TR 2017 NOSB Recommendation		"
Activated charcoal	205.605(b)	SR		2002 TR 2015 NOSB Recommendation		"
Ascorbic acid	205.605(b)	LD		1995 TAP 2017 NOSB Recommendation		"
Calcium citrate	205.605(b)	LS		2015 TR 2017 NOSB Recommendation		"

Ferrous sulfate	205.605(b)	TC		1995 TR 2017 NOSB Recommendation		“
Hydrogen peroxide	205.605(b)	AB		2015 Hydrogen Peroxide (Crops) 2017 NOSB Recommendation		“
Nutrient vitamins and minerals	205.605(b)	TC		2015 TR 2017 NOSB Recommendation		“
Peracetic acid	205.605(b)	AB		2016 TR 2015 NOSB Recommendation		“
Potassium citrate	205.605(b)	LD		2015 TR 2017 NOSB Recommendation		“
Potassium phosphate	205.605(b)	TC		1995 TAP 2017 NOSB Recommendation		“
Sodium acid pyrophosphate	205.605(b)	SR		2001 TAP 2015 NOSB Recommendation		“
Sodium citrate	205.605(b)	LD		2015 TR 2017 NOSB Recommendation		“
Tocopherols	205.605(b)	AB		2015 TR 2017 NOSB Recommendation		“
Celery powder	205.606	AB		None 2017 NOSB Recommendation		“
Fish oil	205.606	TC		2015 TR 2017 NOSB Recommendation		“
Gelatin	205.606	ARB		2002 TAP 2017 NOSB Recommendation		“
Orange pulp, dried	205.606	ARB		None 2017 NOSB Recommendation		“
Seaweed, Pacific kombu	205.606	ARB		None. See TR for marine materials 2017 NOSB Recommendation		“
Seaweed, Wakame (Undaria pinnatifida)	205.606	ARB		None. See TR for marine materials 2017 NOSB Recommendation		“

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)
Compliance, Accreditation & Certification Subcommittee (CACS) Notes
Tuesday April 10, 2018, 3:00 pm ET

Attending: Scott Rice (SR), Chair; Emily Oakley (EO), Vice Chair; Ashley Swaffar (AS); Harriet Behar (HB); Lisa de Lima (LD); A-dae Romero-Briones (ARB)
Absent: Tom Chapman (TC)
Staff: Michelle Arsenault (MA)

Work Agenda

Project	Contact	Status	Discussion, Vote	Meeting
Inspector qualifications proposal	SR	Approved for addition to work agenda 04 21 16. Referred back to CACS at Spr 2017 meeting	Dec 12, Jan 9, Jan 23, Feb 13	Spr 2018
Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production proposal	HB	Approved for addition to work agenda 07 15 16. Verbal update Fall 2016. DD Spr 2017. Proposal Fall 2017. Referred back to CACS at Fall 2017 meeting	Nov 28, Jan 23, Feb 27	Spr 2018
Import Oversight	ALL	NOP Memo sent to NOSB 08 10 17.	Nov 28, Jan 9, Jan 23, Feb 13, Feb 27	Disc doc Spr 2018

***Discussed** ***Voted**

Agenda

- Import Panel - Questions/discussion points
- Discuss public comment
- Other items
- Adjourn

Discussion

- **Import Panel - Questions/discussion points.**
  - The CACS discussed various questions for the panelists and logistics for the import panel. The CACS will reformat the panels so that there is time at the end to bring all 9 of the panelists together for Q & A. In addition to the current list of questions, a member noted that she is interested in learning more about technology such as block chain.
  - SR will compile the questions and share them with the panelists ahead of time. He asked that members provide any additional questions by the end of the week.

- **Discuss public comment**
    - Members discussed public comments about the proposal on native ecosystems.
    - OEFFA contacted the CACS Chair regarding fracking and impacts to operations that they certify. The CACS has discussed this previously and it is on hold at the moment. The Chair encouraged OEFFA to consider the current administration's priorities, which are integrity and oversight.
- **Other items.** None
- **The meeting was adjourned**

Previous CACS Notes

Future Call Schedule (2nd Tuesday 3:00 ET)
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

Wednesday April 25	April 2018 NOSB Oral Comment In-Person Registration															Notes
Time	Serial	Submitted Time	First Name	Last Name	E-mail	Phone	Affiliation	Certi	Crop	Hand	Lives	Mate	Polic	Gene	Additional Information	
10 30	1	3/9/2018 14 54	Kelly	Damewood	kdamewood@ccof.org	8313466254	CCOF	X	X	X	X	X	X	X		
10 35	2	3/9/2018 14 55	Phil	LaRocca	pnell@ccof.org	8313466218	CCOF		X							
10 40	3	3/9/2018 14 56	Zea	Sonnabend	zea@well.com	8317613213	CCOF		X			X		X		
10 45	21	3/10/2018 12 49	Richard	Wallick	(b)(6)	(b)(6)	general public	X	X	X		X	X	X	Please provide me with the earliest morning slot available (b)(6) you!	
10 50	4	3/9/2018 15 56	Jenny	Cruse	jennycruse@accreditedcertifiers.org	8447837974	Accredited Certifiers Association	X							If I could give comments on Day 1 it would be great because I might not be there for the last part of the meeting.	
10 55	5	3/9/2018 16 24	Mark	Kastel	kastel@cornucopia.org	6086252042	The cornucopia Institute							X		
11 00	6	3/9/2018 16 25	Christopher	Pierce	chris@heritagepms.com	7178678366	Heritage Poultry Management Services, Inc.				X					
11 05	8	3/15/2018 14 28	Shannon	Helms	shannon.helms@cpkelco.com	(b)(6)	CP Kelco			X					I will be presenting with Wanda Jurlina and Jessica Knutzen. We would like to go in the following order if possible 1-Shannon Helms 2-Jessica Knutzen 3-Wanda Jurlina	
11 10	9	3/15/2018 14 32	Jessica	Knutzon	jessica.knutzon@cpkelco.com	6782477593	CP Kelco			X					Please place be after Shannon Helms and before Wanda Jurlina.	
11 15	10	3/9/2018 16 40	Wanda	Jurlina	wanda.jurlina@cpkelco.com	(b)(6)	general public, company name, organization,					X			Xanthan and Gellan Gum comments	
11 20	11	3/9/2018 16 51	Theojary	Crisantes	theo@wh.farm	(b)(6)	Wholesum Farms Arizona LLC		X							
11 25	12	3/9/2018 16 51	Zak	Wiegand	zak@tilth.org	5033780690	Oregon Tilth			X						
11 30	13	3/9/2018 16 52	Jackie	Sleeper	jackie@tilth.org	5033780690	Oregon Tilth		X		X	X				
11 35	14	3/9/2018 16 54	Emily	Lyons	elyons@idfa.org	2022203507	International Dairy Foods Association			X						
11 40	15	3/9/2018 18 01	Terry	Shistar	(b)(6)	7857480950	Beyond Pesticides	X	X	X		X	X	X		
11 45	16	3/9/2018 18 08	Deborah	Klein	deborah.klein@ecolab.com	3365088926	Ecolab			X					Sodium Dodecylbenzene Sulfonate.	
11 50	17	3/9/2018 18 17	Lynn	Coody	LynnCoody@cs.com	(b)(6)	Organic Produce Wholesalers Coalition	X	X	X					I will be at the entire meeting and can do my public comment at any time that is convenient for you.	
11 55	18	3/9/2018 19 32	Kiki	Hubbard	kristina@seedalliance.org	4065448946	Organic Seed Alliance		X			X				
12 00	19	3/9/2018 21 23	Abby	Youngblood	abby@nationalorganiccoalition.org	6465257165	National Organic Coalition	X	X			X		X		
12 05	7	3/9/2018 16 26	Margaret	Scoles	(b)(6)	4064362031	International Organic Inspectors Association	X							I can be scheduled any time at your convenience, as I intend to attend the entire meeting. I would prefer not to be early in the morning or late evening, as I am staying outside of Tucson about one hour from the venue. And I would prefer to speak no later than Day 2. But to accommodate other speakers, you can schedule me any time that really works for everyone.	mid day
12 10	20	3/10/2018 6 28	Jay	Feldman	jfeldman@beyondpesticides.org	2025435450	Beyond Pesticides							X	Thanks Michelle!	
12 15	22	3/10/2018 18 17	Jo Ann	Baumgartner	joannb@wildfarmalliance.org	8317618408	Wild Farm Alliance	X								
12 20	67	3/30/2018 17 58	Edward	Maltby	(b)(6)	(b)(6)	general public, company name, organization,				X				I am flying from the East coast and have a flight back on the Wednesday evening	early
12 25	23	3/10/2018 20 17	Garth	Kahl	(b)(6)	5414864400	Independent Organic Services, Inc.		X		X	X				
14 00	24	3/12/2018 8 13	Richard	Mathews	(b)(6)	7174570100	Western Organic Dairy Producers Alliance	X			X					
14 05	25	3/12/2018 9 00	Kyla	Smith	kyla@paorganic.org	(b)(6)	Pennsylvania Certified Organic (PCO)	X			X					
14 10	26	3/12/2018 9 07	Cameron	Harsh	charsh@centerforfoodsafety.org	2025479359	Center for Food Safety		X	X		X				
14 15	27	3/12/2018 9 30	Jennifer	Berkebile	jen@paorganic.org	8144220251	general public, company name, organization,		X	X	X	X				
14 20	28	3/12/2018 9 40	Sam	Welsch	sam@onecert.com	4024206080	OneCert, Inc.							X		
14 25	29	3/12/2018 9 55	Madison	Kempner	maddie@nofavt.org	8024344122	NOFA-VT	X	X					X	I have a noon flight on Thursday, so would like to request a slot on Wednesday or Thursday before 10am. Thank you!	
14 30	30	3/12/2018 10 13	Christie	Badger	(b)(6)	(b)(6)	National Organic Coalition							X	Thanks, Michelle!)	
14 35	31	3/12/2018 11 09	Gwendolyn	Wyard	gwyard@ota.com	5037983294	Organic Trade Association	X		X		X				
14 40	32	3/12/2018 11 20	Kenichiro	Takei	takei_ken-ichiro@kaken.co.jp	7033391117	Kaken Phramaceutical Co., Ltd.		X							
14 45	33	3/12/2018 11 22	Cynthia	Smith	cindy@connsmith.com	7033391117	Conn & Smith, Inc.		X							
14 50	34	3/12/2018 11 42	Johanna	Mirenda	johannam@omri.org	(b)(6)	OMRI							X		
14 55	35	3/12/2018 12 34	Amalie	Lipstreu	amalie@oeffa.org	(b)(6)	Ohio Ecological Food and Farm Associatioon							X		
15 00	36	3/12/2018 12 56	Alesia	Bock	alesia@agrisysintl.com	(b)(6)	general public, company name, organization,			X						
15 05	37	3/12/2018 15 08	Dana	Perls	dperls@foe.org	5109784425	Friends of the Earth					X				
15 10	38	3/12/2018 15 13	Alan	Lewis	(b)(6)	(b)(6)	Natural Grocers							X		

15 15	39	3/12/2018 15 40	Thomas	Harding	tom@lehighvalleyorganicgrowers.com	(b)(6)	LVOG, Inc.		X							NOP/NOSB Policy National Materials List Petition Process	
15 20	40	3/12/2018 17 46	Alexis	Randolph	randolph@qai-inc.com	(b)(6)	Quality Assurance International								X		
15 25	41	3/13/2018 13 01	Melody	Meyer	mmeyer@unfi.com	(b)(6)	UNFI								X		
15 30	42	3/13/2018 13 42	Hans	Dramm	hdramm@dramm.com	9206456422	Dramm Corporation		X							I would like to address the committee in support of Liquid Fish Products and to share our insights regarding pH measurement requirement as it relates to acids added for stability of liquid fish fertilizers. Thank you.	
15 35	43	3/13/2018 17 28	Jake	Lewin	ralvarez@ccof.org	8313466232	CCOF	X									
15 40	44	3/14/2018 19 28	Anne	Ross	ross@cornucopia.org	8432091732	The Cornucopia Institute	X								Hello, I plan to attend in-person and address the issue of import oversight.	
16 00	45	3/15/2018 11 26	Linley	Dixon	dixon@cornucopia.org	(b)(6)	The Cornucopia Institute		X							Prefer to comment on Thursday.	
16 05	46	3/15/2018 14 26	Julie	Weisman	julie@flavorganics.com	9733448014	Elan, Inc, and Flavorganics,LLC			X						I will be commenting on the Proposed Rule to change the annotation for the listing of Flavors, non-synthetic on section 205.605a of the National List. I can speak anytime on Wednesday, April 25.	
16 10	47	3/15/2018 15 40	Michael	Sligh	msligh@rafiusa.org	9196419341	RAFI								X	I would prefer the 25th, as I must depart on the 26th. thank you Michael	
16 15	48	3/19/2018 11 40	Marisol	Oviedo	oviedo@nwhort.org	15094533193	Northwest Horticultural Council		X	X							
16 20	49	3/20/2018 10 38	Jackie	DeMinter	jdeminter@mosaorganic.org	6086372526	MOSA - certifier				X	X					
16 25	50	3/21/2018 16 17	Nate	Lewis	nlewis@ota.com	5037983294	OTA	X	X		X						
16 30	52	3/21/2018 16 54	Patricia	Mayer	(b)(6)	(b)(6)	general public	X				X	X	X		I will be driving from Phoenix, and would like to drive down on Wednesday morning, so if I could have a late morning or any time in the afternoon, it would be much appreciated!	Later
16 35	53	3/22/2018 14 38	Jessica	Walden	walden@qai-inc.com	(b)(6)	certifier	X									
16 40	54	3/22/2018 19 31	Ruth	Watts	ruth.watts@basf.com	(b)(6)	BASF Corporation		X							Thank you, MIchelle, for all you do for the NOP and the NOSB. I will have my 3 minute presentation for my oral comments to provide you when I see you during the meeting. Thanks again.	
16 45	55	3/22/2018 20 23	Bill	Wolf	bwolf@organicspecialists.com	(b)(6)	Wolf, DiMatteo + Associates		X	X		X		X		I plan to have a short powerpoint to share. Thanks.	
16 50	56	3/22/2018 20 37	Michael	Menes	mmenes@true.ag	(b)(6)	general public, company name, organization,		X			X		X		I will be using a powerpoint.	
16 55	57	3/23/2018 15 00	Brian	Baker	(b)(6)	(b)(6)	IFOAM North America								X	Interested in the global impact of the NOSB's recommendations and NOP policy.	
17 00	58	3/23/2018 15 11	Jerry	Tyler	jerry@heartofnature.biz	(b)(6)	President, Heart Of Nature					X				I would like to speak in person , and am available both days. Any time is fine. I'm speaking on NOP acceptance of Elemental Sulfur versus naturally mined sulfur.	
17 05	59	3/24/2018 12 42	Gerald	Robertson	grobertson@berry.net	(b)(6)	Reiter Affiliated Companies		X								
17 10	60	3/25/2018 22 27	Isaura	Andaluz	info@c4puertas.org	(b)(6)	cuatro puertas								X	Seeds	
17 15	61	3/27/2018 18 31	Jean	Halloran	jhalloran@consumer.org	9143782457	Consumers Union	X			X	X	X				
17 20	62	3/28/2018 12 19	Richard	Conn	richard@connsmith.com	7033394199	Conn & Smith, Inc.		X								
17 25	63	3/28/2018 13 30	Kelly	Shea	kelly.shea@whitewave.com	3036354447	DanoneWave								X		
17 30	64	3/29/2018 9 14	Daniel	Martens	dan.martens@novamont.com	(b)(6)	Novamont North America		X							I will be coming in person and have a flexible schedule but if Thursday is free that would be better for me.	sent email 4/2/18
17 35	65	3/30/2018 1 55	ZEN	HONEYCUT	(b)(6)	(b)(6)	2005	X	X	X						I am planning on coming in and being there for the day. Please confirm if there is an availability of time for me to speak so I can make travel plans ahead of time. If my other travel plans do not work out nearby I may need to cancel my attendance and comment by webinar. Thank you very much.	sent email 4/2/18
17 40	66	3/30/2018 9 20	Nicole	Dehne	nicole@nofavt.org	8028643271	Vermont Organic Farmers (USDA Accredited								X	I would love to comment on Wednesday if possible.	
17 45	68	4/2/2018 9 25	Mary Agnes	Rawlings	(b)(6)	(b)(6)	Farm owner						X	X		I leave Tucson on Wed early evening so if there is a slot open earlier that would be better. Signed up for backup at webinar - unsure if she will come to Tucson. Waiting for NOC reply.	Waiting to hear back from NOC. early
17 50	51	3/21/2018 16 30	Laura	Batcha	lbatcha@ota.com	(b)(6)	OTA								X	Please schedule towards the end of the comment block.	Late
17 55	69	4/2/2018 11 12	Pat	Kerrigan	patrick@organicconsumers.org	(b)(6)	Organic Consumers Association								X		
18 00	70	4/2/2018 11 48	Sarah	Leibowitz	sarah.leibowitz@delaval.com	816.891.6960	DeLaval Mfgtg				X glycolic acid						
	WAITLIST																
	71	4/2/2018	Lee	Frankel	info@coalitionforsustainableorganics.org	619.587.4341	coalitionforsustainableorganics										
	72	4/3/2018	Marty	Mesh	Marty@foginfo.org	352.377.6345	FOG								X		
	73	4/3/2018 1650	Emily	Musgrave	Emily.Musgrave@driscolls.com	(b)(6)	Driscolls		X								
	74	4/3/2018 1741 phone	Ian	Justus	ian.justus@driscolls.com	(b)(6)	Driscolls		X								

	75	4/3/2018 1746	Albert	Straus	albert@strausmilk.com	707.776.2887	Strauss Family Creamery							X		
	76	4/3/2018 1746	Bob	McGee	Bob@strausmilk.com	707.776.2887	Strauss Family Creamery							X		
	77	4/3/2018 1857	Mike	Dill	mdill@organicgrown.com	503.907.3679	Organically Grown Company	X								
	78	4/4/2018 1153	John	Bobbe	(b)(6)	(b)(6)	OFARM	X								
	79	4/4/2018 1651 phone	John	Mesko	john@mosesorganic org	763.260.0209	MOSES				X					
		4/4/2018 18 14	Suzanne	McMillan	suzanne.mcmillan@aspca.org	(b)(6)	ASPCA				X				If possible, please also add me to the wait list for oral comments, and if a slot opens up, remove me from this webinar list. Thank you!	
	80	4/4/2018 2200 email	Beth	Rota	Beth@qcsinfo.org	(b)(6)	QCS									
		4/4/2018 22 11	john	schumacher	john@hallcrestvineyards.com	(b)(6)	Hallcrest Vineyards & The Organic Wine Works					X			this comment will specifically address the use of sulfites in wine. I would like to make this comment in person if I may. Please put me on the waiting list. Thank You, John Schumacher	
	81	4/5/2018 1657 email	Stephanie	Rose (Joliet)	Stephanie.Rose@pqcorp.com		PQ Corporation		X aqueous potassium silicate							

	April 2018 NOSB Oral Comment Webinar Registration															
Tuesday	Seria	Submitted Time	First Name	Last Name	E-mail	Phone	Affiliation	Cert	Crop	Hand	Lives	Mate	Polic	Gene	Additional Information	Date
13:10	1	1/24/2018 9:30	Alec	Caso	acaso@dclrs.com	(b)(6)	DCLRS		X							
13:15	2	1/24/2018 9:31	Laurie	Flanagan	lflanagan@dclrs.com	2028728440	DCLRS		X							
13:20	3	2/2/2018 6:10	prisca	lisanga	(b)(6)	(b)(6)	daydreamfarms		X							
13:25	4	3/9/2018 16:45	Robert	Landers	(b)(6)	(b)(6)	Seed of Inundation	X	X	X		X	X	X	(b)(6)	
13:30	5	3/10/2018 6:49	Charlotte	Vallaeys	charlotte.vallaeys@consumer.org	9783911240	Consumers Union, the advocacy division of Consumer							X		
13:35	6	3/10/2018 18:27	Sam	Earnshaw	hedgerows@baymoon.com	8317225556	Hedgerows Unlimited	X							I will be calling in from California.	
13:40	7	3/12/2018 9:27	julia	barton	julia@oeffa.org	6143593180	Ohio Ecological Food and Farm Association (OEFFA)							X		
13:45	8	3/12/2018 10:23	Steve	Etka	(b)(6)	7035197772	National Organic Coalition							X		
13 50	9	4/4/2018 11:42 00 AM	Harold	Austin	harolda@zirklefruit.com	509.697.0508	Past NOSB member		X			X		X		
13 55	10	3/12/2018 13 53	Peter	Nell	pnell@ccof.org	8313466218	CCOF	X	X	X	X	X	X	X		
14 00	11	3/13/2018 13 09	Casey	Schoenberge	cschoenberger@dramm.com	3603334044	Dramm Corporation		X						Speaking to address the myriad questions and concerns regarding Liquid Fish Products up for regular sunset review process.	
14 05	12	3/13/2018 19:36	Marie	Burcham	burcham@cornucopia.org	(b)(6)	The Cornucopia Institute							X		
14:10	13	3/18/2018 14:23	Domenico	Tassone	(b)(6)	3124924652	general public, company name, organization, associati							X		
14:15	14	3/19/2018 15 04	Shelly	Connor	shellyconnor@wildfarmalliance.org	(b)(6)	Wild Farm Alliance	X							I am calling in from Central Time Zone.	
14:20	15	3/21/2018 16:47	Dianah	Ngonyama	drn@iastate.edu	(b)(6)	Iowa State University	X	X		X				I will be calling into the Webinar, from Ames, Iowa (US Central time). Haven't commented before.	Not first
14:25	16	3/22/2018 11:25	Kim	Dietz	kim.dietz@jmsmucker.com	5308995058	The JM Smucker Company			X						
14:30	17	3/22/2018 17 57	Amber	Pool	amber@ccof.org	8313466214	general public, company na		X							
14:35	18	3/23/2018 12:42	Rhodes	Yepsen	exec.dir@bpiworld.org	6104016666	BPI		X						Soil Biodegradable Mulch Film	
14:40	19	3/26/2018 14:13	Patrick	Arndt	parndt@ccof.org	(b)(6)	CCOF			X					April 17 preferred	17
14:45	20	3/27/2018 12:11	Helen	Atthowe	(b)(6)	5418935001	WoodLeaf Farm	X							Pacific Time Zone	
14 50	21	3/27/2018 16:23	Sam	Raser	sam.raser@grainmillers.com	9529831311	Grain MIllers Inc			X						
14 55	22	3/28/2018 17:44	Stephen	Walker	spwalker@mosaorganic.org	6086372526	MOSA Certified Organic					X		X		
15 00	23	4/2/2018 14:44	Nathan	Brown	(b)(6)	4065796439	Organic Farmer Amaltheia C	X								
15 05	24	4/3/2018 9:06	Dave	Chapman	(b)(6)	8022997737	Real Organic Project		X		X					
15:10	25	4/3/2018 13:56	Alan	Schreiber	(b)(6)	5092664300	Washington Berry Commiss	X								
15:15	26	4/3/2018 15:05	Jessie	Bovay	jessie.bovay@mercaris.com	3124231877	Mercaris	X							Available at any date and time.	
15:20	27	4/3/2018 16:39	Jeff	Dean	(b)(6)	4196030664	Timberlane Farms	X								
15:25	28	3/26/2018 11:16	Sydney	Rosario	sydneyr@millerpoultry.com	(b)(6)	Miller Poultry				X				Prefer Tuesday, April 17th, later in the afternoon	17 later in afternoon
15:30	29	4/3/2018 16:40	Elijah	Dean	e-dean@onu.edu	(b)(6)	Timberlane Farms	X								
15:35	30	4/3/2018 17:02	Dean	McIlvaine	(b)(6)	3304662545	Twin Parks Farm	X								
15:40	31	4/4/2018 6:37	Jim	Gerritsen	jim@woodprairie.com	2074299765	Wood Prairie Family Farm							X	Maine, Eastern time zone.	
15:45	32	4/4/2018 10:58	Kenneth	Parker	Kenneth@Flastrawberry.com	(b)(6)	Fla Strawberry Growers Ass	X								
Thursday April 19																
13:10	33	4/4/2018 18:22	Edward	Field	ed@naturalmerchants.com	5305542333	Natural Merchants, Inc.					X			We are in Spain, a time zone that is 6 hours later than East Coast time. We would love to have a slot between 3am and 1pm EST on Thursday, April 19. Thank you for your consideration!	19 early
13:15	34	3/22/2018 19:24	Katharina	Schlegel	katharina.a.schlegel@basf.com	4.91734E+11	BASF Corporation		X						6 hours ahead. Please schedule me for one of the webinar dates. I live in Ludwigshafen, Germany.	19 EARLY in day
13:20	35	4/2/2018 17:43	Angela	Anandappa	angela.anandappa@unl.edu	8477780567	Alliance for Advanced T	X						X	I will be traveling during both days with flights overlapping some of these times, and would like to request time towards the early part of the 1pm East time on the 19th if possible. Thank you	19 early (near 1)
13:25	36	4/3/2018 11:05	Mary Agnes	Rawlings	(b)(6)	(b)(6)	Farm owner						X		**Signed up for backup at webinar - unsure if she will come to Tucson. Waiting for NOC reply. The sanctity of natural habitat and eco system survival is of ultimate importance. There is plenty of commercialized farm land that can be transitioned to organic farmer. As a farm owner in Central Illinois we know it can be done we did it... and without destroying habitat!**	19
13:30	37	3/13/2018 18:37	Angela	Wartes-Kahl	(b)(6)	5414864400	Independent Organic S	X			X				I am only available on April 19th for a webinar slot. Thank you! -angela	19
13:35	38	3/17/2018 14 04	Barry	Flamm	(b)(6)	4068832858	conservation consultar	X							I would like the April 19 slot. Any time is ok.	19
13:40	39	3/26/2018 10:26	Britt	Lundgren	blundgren@stonyfield.com	6034374040	Stonyfield	X		X					Hi - I am traveling on 4/17 and would strongly prefer an April 19 comment slot if possible.	19
13:45	40	3/23/2018 12:30	Katherine	DiMatteo	kdimatteo@organicspecialists.com	4136245569	Wolf, DiMatteo + Associates	X							I am available on Wednesday, the 18th or **Thursday after 10am ET.**	19
13 50	41	4/3/2018 18:31	Francis	Thicke	fthicke@iowatelecom.net	6419198554	Organic Farmers Association	X						X		
13 55	42	4/4/2018 11:28	Catherine	McDonnell-F	(b)(6)	(b)(6)	None						X	X	I support NOSB's motion to approve the two-part proposal to Eliminate the Incentive to Convert Native Ecosystems to Organic Production	
14 00	43	4/4/2018 12:40	Aviva	Glaser	glasera@nwf.org	2027976616	National Wildlife Feder	X								
14 05	44	4/4/2018 14:28	Thomas	Braun	(b)(6)	4808839591	N2E+ for Life							X	In Phoenix Az Thank you for the opportunity to voice my opinion on this topic. Thomas Braun RPh Advocate for a Health Lifestyle.	
14:10	45	4/4/2018 14:55	Megan	DeBates	mdebates@ota.com	2024038643	Organic Trade Associat	X								
14:15	46	4/4/2018 15:05	Elise	George	elise@oeffa.org	6149471615	OEFFA Certification (N	X							Discussion Document: Import Oversight	
14:20	47	4/4/2018 16:17	Carol	Goland	cgoland@oeffa.org	7403989099	Ohio Ecological Food and Farm Association							X		

14:25	48	4/4/2018 16:18	Noelle	Weber Straus	(b)(6)	(b)(6)	General public	X						X	I would love to call in and comment on the importance of having the highest standards for organic food. I live in Wisconsin.	
14:30	49	4/4/2018 16:27	Dave	Shively	(b)(6)	(b)(6)	Shively Farms; Preside	X								
14:35	50	4/4/2018 16:52	David	Marchant	(b)(6)	8028496853	Certified Organic Farmer in	X							Thursday 19th only	19
14:40	51	4/4/2018 18:14	Suzanne	McMillan	suzanne.mcmillan@aspca.org	(b)(6)	ASPCA				X				**If possible, please also add me to the wait list for oral comments, and if a slot opens up, remove me from this webinar list. Thank you!**	
14:45	52	4/4/2018 18:48	Michael	Jones	(b)(6)	(b)(6)	Sanctuary Farm	X								
14 50	53	4/4/2018 20:37	Michael	Stein	michael@ofrf.org	(b)(6)	Organic Farming Research Foundation							X	The Organic Farming Research Foundation will be providing comment on the Research Priorities of the National Organic Standards Board.	
14 55	54	4/4/2018 22:11	john	schumacher	john@hallcrestvineyards.com	(b)(6)	Hallcrest Vineyards & The Organic Wine Wo	X							this comment will specifically address the use of sulfites in wine. I would like to make this comment in person if I may. Please put me on the waiting list. Thank You, John Schumacher	
15 00	55	4/5/2018 1:08	Lois	Christie	lois@christieorganic.com	7604195056	Christie Organic Consultants	X							Sulfurous Acid: Used in water as a plant or soil amendment for soils that are alkaline or saline. Sunset June 22, 2020; in particular the use of sulfur burners to create on-farm sulfurous acid.	
15 05	56	4/5/2018 9:15	David	Bell	(b)(6)	(b)(6)	Paul Bell and Sons, LLC	X								
15:10	57	4/3/2018 4:50 00 PM	Emily	Musgrave	Emily.Musgrave@driscolls.com	(b)(6)	Driscolls		X							
15:15	58	4/4/2018 23:05 email	Andrew	Tomes	Andrew.Tomes@wiserg.com	(425) 526-6784	WISErg		X							
15:20	59	4/5/2018 9:05 email	Jeff	Bogusz	Jeff.Bogusz@ferrarausa.com	(b)(6)	Ferrara Candy Company			X?					April 19 only	19

Abby	Youngblood
Alan	Lew s
A an	Schreiber
Albe t	St aus
Alec	Caso
Ales a	Bock
Alex s	Randolph
Amal e	L pst eu
Amber	Pool
And ew	Tomes
Angela	Wartes-Kahl
Angela	Anandappa
Anne	Ross
Aviva	Glaser
Barry	Flamm
Beth	Nolta
B l	Wolf
Bob	McGee
B an	Bake
Britt	Lundgren
Came on	Ha sh
Carol	Goland
Casey	Schoenberger
Catherine	**McDonnell-Forney**
Catherine	**McDonnell-Forney**
Charlotte	Val aeys
Ch st e	Badge
Ch stophe	P e ce
Cynth a	Sm th
Dana	Pe ls
Dan el	Ma tens
Dave	Chapman
Dave	Shively
David	Marchant
David	Be l
Dean	McIlvaine
Debo ah	Kle n
Dianah	**Ngonyama**
Dianah	**Ngonyama**
Domenico	Tassone
Edwa d	Ma tby
Edward	Field
Elijah	Dean
Elise	George
Em ly	Lyons
Em ly	**Musgrave**
Em ly	**Musgrave**
Francis	**Thicke**
Francis	**Thicke**
Ga th	Kahl
Ge ald	Robe tson
Gwendolyn	Wya d
Hans	D amm
Harold	Austin
Helen	Atthowe
Ian	Justus
Isau a	Andaluz
Jack e	Sleepe
Jack e	DeM nte
Jake	Lew n
Jay	Feldman
Jean	Hallo an
Jeff	Dean
Jenn fe	Be keb le
Jenny	C use
Je y	Tyle
Jess ca	Knutzon
Jess ca	Walden
Jessie	Bovay
Jim	Gerritsen
Jo Ann	Baunga tne
Johanna	M enda
John	schumacher
John	Bobbe
John	Mesko
Ju ia	barton
Jul e	We sman
Katharina	Schlegel
Katherine	DiMatteo
Ke ly	Damewood
Ke ly	Shea
Ken ch o	Take
Kenneth	Parker
K k	Hubba d
K m	Dietz
Kyla	Sm th
Lau a	Batcha
Laurie	Flanagan
Lee	F ankel
L nley	D xon
Lois	Christie
Lynn	Coody
Mad son	Kempne
Ma ga et	Scoles
Marie	Burcham
Ma sol	Ov edo
Ma k	Kastel
Ma ty	Mesh
Mary Agn	**Rawlings**
Mary A	**Rawlings**
Megan	DeBates
Melody	Meye
M chael	Sl gh
M chael	Menes
Michael	Jones
Michael	Stein
M ke	D ll
Nate	Lew s
Nathan	Brown
N cole	Dehne
Noelle	Weber Strauss
Pat	Ke gan
Pat c a	Maye
Patrick	Arndt
Peter	Nell
Ph l	LaRocca
prisca	lisanga
Rhodes	Yepsen
R cha d	Wall ck
R cha d	Mathews
R cha d	Conn
Robert	Landers
Ruth	Watts
Sam	Welsch
Sam	Earnshaw
Sam	Raser
Sa ah	Le bow tz
Shannon	Helms
Shelly	Connor
Stephen	Walker
Steve	Etka
Suzanne	McMillan
Sydney	Rosario
Te y	Sh sta
Theoja y	C santes
Thomas	Ha d ng
Thomas	Braun
Wanda	Ju l na
Zak	W egand
Zea	Sonnabend
ZEN	HONEYCUTT

Wa tlist
Webinar
F2F

Oral Commenter Sign-in
National Organic Standards Board April 2018

Marriott Tucson University Park | Tucson, AZ

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WEDNESDAY APRIL 25, 2018		Time	First Name	Last Name	Affiliation	Subcommittee/topics	Initials
	1	10:30 AM	Kelly	Damewood	CCOF	All	
	2	10:35 AM	Phil	LaRocca	CCOF	Crops	
	3	10:40 AM	Zea	Sonnabend	CCOF	Crops, Materials, General	
	4	10:45 AM	Richard	Wallick	general public	All	
	5	10:50 AM	Jenny	Cruse	Accredited Certifiers Association	CACS	
	6	10:55 AM	Mark	Kastel	The cornucopia Institute	General	
	7	11:00 AM	Christopher	Pierce	Heritage Poultry Management Services, Inc.	Livestock	
	8	11:05 AM	Shannon	Helms	CP Kelco	Handling	
	9	11:10 AM	Jessica	Knutzon	CP Kelco	Handling	
	10	11:15 AM	Wanda	Jurlina	CP Kelco	Materials	
	11	11:20 AM	Theojary	Crisantes	Wholesum Farms Arizona LLC	Crops	
	12	11:25 AM	Zak	Wiegand	Oregon Tilth	Handling, Materials	
	13	11:30 AM	Ryan	Costello	Oregon Tilth	Crops	
	14	11:35 AM	Lee	Frankel	coalitionforsustainableorganics	Crops	
	15	11:40 AM	Terry	Shistar	Beyond Pesticides	Misc	
	16	11:45 AM	Deborah	Klein	Ecolab	Handling	

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National Organic Standards Board April 2018
Marriott Tucson University Park | Tucson, AZ
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		Time	First Name	Last Name	Affiliation	Subcommittee/topics	Initials
WEDNESDAY APRIL 25, 2018	17	11:50 AM	Lynn	Coody	Organic Produce Wholesalers Coalition	CACS, Crops, Handling	
	18	11:55 AM	Kiki	Hubbard	Organic Seed Alliance	Crops, Materials	
	19	12:00 PM	Abby	Youngblood	National Organic Coalition	Misc	
	20	12:05 PM	Margaret	Scoles	International Organic Inspectors Association	CACS	
	21	12:10 PM	Jay	Feldman	Beyond Pesticides	General	
	22	12:15 PM	Jo Ann	Baumgartner	Wild Farm Alliance	CACS	
	23	12:20 PM	Edward	Maltby	NODPA	Livestock	
	24	12:25 PM	Garth	Kahl	Independent Organic Services, Inc.	Crops, Livestock, Materials	
	LUNCH						
	25	2:00 PM	Richard	Mathews	Western Organic Dairy Producers Alliance (WODPA)	CACS, Livestock	
	26	2:05 PM	Kyla	Smith	Pennsylvania Certified Organic (PCO)	CACS, Livestock	
	27	2:10 PM	Cameron	Harsh	Center for Food Safety	Crops, Handling, Materials	
	28	2:15 PM	Jennifer	Berkebile	PCO	Crops, Handling, Livestock, Materials	
	29	2:20 PM	Sam	Welsch	OneCert, Inc.	General	
	30	2:25 PM	Madison	Kempner	NOFA-VT	CACS, Crops, General	

Oral Commenter Sign-in
National Organic Standards Board April 2018
Marriott Tucson University Park | Tucson, AZ
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WEDNESDAY APRIL 25, 2018		Time	First Name	Last Name	Affiliation	Subcommittee/topics	Initials
	31	2:30 PM	Christie	Badger	National Organic Coalition	General	
	32	2:35 PM	Gwendolyn	Wyard	Organic Trade Association	CACS, Handling, Materials	
	33	2:40 PM	Kenichiro	Takei	Kaken Pharmaceutical Co., Ltd.	Crops	
	34	2:45 PM	Cynthia	Smith	Conn & Smith, Inc.	Crops	
	35	2:50 PM	Johanna	Mirenda	OMRI	General	
	36	2:55 PM	Amalie	Lipstreu	Ohio Ecological Food and Farm Associatioon	General	
	37	3:00 PM	Alesia	Bock	general public, company name, organization, association, etc	Handling	
	38	3:05 PM	Dana	Perls	Friends of the Earth	Materials	
	39	3:10 PM	Alan	Lewis	Natural Grocers	General	
	40	3:15 PM	Thomas	Harding	LVOG, Inc.	Crops	
	41	3:20 PM	Alexis	Randolph	Quality Assurance International	General	
	42	3:25 PM	Melody	Meyer	UNFI	General	
	43	3:30 PM	Anne	Ross	The Cornucopia Institute	CACS	
	44	3:35 PM	Hans	Dramm	Dramm Corporation	Crops	
	45	3:40 PM	Jake	Lewin	CCOF	CACS	

Oral Commenter Sign-in
National Organic Standards Board April 2018
Marriott Tucson University Park | Tucson, AZ
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WEDNESDAY APRIL 25, 2018		Time	First Name	Last Name	Affiliation	Subcommittee/topics	Initials
	46	4:00 PM	Julie	Weisman	Elan, Inc, and Flavorganics,LLC	Handling	
	47	4:05 PM	Michael	Sligh	RAFI	General	
	48	4:10 PM	Marisol	Oviedo	Northwest Horticultural Council	Crops, Handling	
	49	4:15 PM	Linley	Dixon	The Cornucopia Institute	Crops	
	50	4:20 PM	Jackie	DeMinter	MOSA - certifier	Livestock, Materials	
	51	4:25 PM	Nate	Lewis	OTA	CACS, Crops, Livestock	
	52	4:30 PM	Patricia	Mayer	general public	Misc	
	53	4:35 PM	Jessica	Walden	certifier	CACS	
	54	4:40 PM	Ruth	Watts	BASF Corporation	Crops	
	55	4:45 PM	Bill	Wolf	Wolf, DiMatteo + Associates	Misc	
	56	4:50 PM	Michael	Menes	True Organic Products	Crops, Materials, General	
	57	4:55 PM	Brian	Baker	IFOAM North America	General	
	58	5:00 PM	Jerry	Tyler	President, Heart Of Nature	Materials	
	59	5:05 PM	Gerald	Robertson	Reiter Affiliated Companies	Crops	
	60	5:10 PM	Isaura	Andaluz	cuatro puertas	General	

Oral Commenter Sign-in
National Organic Standards Board April 2018
Marriott Tucson University Park | Tucson, AZ
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WEDNESDAY APRIL 25, 2018		Time	First Name	Last Name	Affiliation	Subcommittee/topics	Initials
	61	5:15 PM	Jean	Halloran	Consumers Union	Misc	
	62	5:20 PM	Richard	Conn	Conn & Smith, Inc.	Crops	
	63	5:25 PM	Kelly	Shea	DanoneWave	General	
	64	5:30 PM	Daniel	Martens	Novamont North America	Crops	
	65	5:35 PM	Zen	Honeycutt		CACS, Crops, Handling	
	66	5:40 PM	Nicole	Dehne	Vermont Organic Farmers (USDA Accredited Certification Body)	General	
	67	5:45 PM	Laura	Batcha	OTA	General	
	68	5:50 PM	Pat	Kerrigan	Organic Consumers Association	General	
	69	5:55 PM	Sarah	Leibowitz	DeLaval Mfgtg	Livestock – Glycolic Acid	

Oral Commenter Sign-in
National Organic Standards Board April 2018

Marriott Tucson University Park | Tucson, AZ

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WAITLIST

WAITLIST

	Time	First Name	Last Name	Affiliation	Subcommittee/topics	Initials
1		Marty	Mesh	FOG	General	
2		Emily	Musgrave	Driscolls	Crops	
3		Ian	Justus	Driscolls	Crops	
4		Albert	Straus	Straus Family Creamery	General	
5		Bob	McGee	Straus Family Creamery	General	
6		Mike	Dill	Organically Grown Company	CACS	
7		John	Bobbe	OFARM	CACS	
8		John	Mesko	MOSES	Livestock	
9		Suzanne	McMillan	ASPCA	Livestock	
10		Beth	Rota	QCS	CACS - Imports	
11		john	schumacher	Hallcrest Vineyards & The Organic Wine Works	Materials	
12		Javier	Zamora	CA farmer		
13						
14						

Oral Commenter Sign-in
National Organic Standards Board April 2018

Marriott Tucson University Park | Tucson, AZ

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WEDNESDAY APRIL 25, 2018	Power point	Time	First Name	Last Name	Affiliation	Subcommittee/topics	Initials
	1	10:30 AM	Kelly	Damewood	CCOF	All	
	2	10:35 AM	Phil	LaRocca	CCOF	Crops	
	3	10:40 AM	Zea	Sonnabend	CCOF	Crops, Materials, General	
	4	10:45 AM	Richard	Wallick	general public	All	
	5	10:50 AM	Jenny	Cruse	Accredited Certifiers Association	CACS	
	6	10:55 AM	Marty	Mesh	FOG	General	
	7	11:00 AM	Christopher	Pierce	Heritage Poultry Management Services, Inc.	Livestock	
	8	11:05 AM	Shannon	Helms	CP Kelco	Handling	
	9	11:10 AM	Jessica	Knutzon	CP Kelco	Handling	
	10	11:15 AM	Wanda	Jurlina	CP Kelco	Materials	
	11	11:20 AM	Theojary	Crisantes	Wholesum Farms Arizona LLC	Crops	
	12	11:25 AM	Zak	Wiegand	Oregon Tilth	Handling, Materials	
	13	11:30 AM	Ryan	Costello	Oregon Tilth	Crops	
	14	11:35 AM	Lee	Frankel	coalitionforsustainableorganics	Crops	
	15	11:40 AM	Terry	Shistar	Beyond Pesticides	Misc	
	16	11:45 AM	Deborah	Klein	Ecolab	Handling	

Oral Commenter Sign-in
National Organic Standards Board April 2018

Marriott Tucson University Park | Tucson, AZ

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WEDNESDAY APRIL 25, 2018		Time	First Name	Last Name	Affiliation	Subcommittee/topics	Initials
	17	11:50 AM	Lynn	Coody	Organic Produce Wholesalers Coalition	CACS, Crops, Handling	
	18	11:55 AM	Kiki	Hubbard	Organic Seed Alliance	Crops, Materials	
	19	12:00 PM	Abby	Youngblood	National Organic Coalition	Misc	
	20	12:05 PM	Margaret	Scoles	International Organic Inspectors Association	CACS	
	21	12:10 PM	Jay	Feldman	Beyond Pesticides	General	
	22	12:15 PM	Jo Ann	Baumgartner	Wild Farm Alliance	CACS	
	23	12:20 PM	Edward	Maltby	NODPA	Livestock	
	24	12:25 PM	Garth	Kahl	Independent Organic Services, Inc.	Crops, Livestock, Materials	
	LUNCH						
	25	2:00 PM	Richard	Mathews	Western Organic Dairy Producers Alliance (WODPA)	CACS, Livestock	
	26	2:05 PM	Albert	Straus	Straus Family Creamery	General	
	27	2:10 PM	Cameron	Harsh	Center for Food Safety	Crops, Handling, Materials	
	28	2:15 PM	Jennifer	Berkebile	PCO	Crops, Handling, Livestock, Materials	
	29	2:20 PM	Sam	Welsch	OneCert, Inc.	General	
	30	2:25 PM	Madison	Kempner	NOFA-VT	CACS, Crops, General	

Oral Commenter Sign-in
National Organic Standards Board April 2018
Marriott Tucson University Park | Tucson, AZ
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WEDNESDAY APRIL 25, 2018		Time	First Name	Last Name	Affiliation	Subcommittee/topics	Initials
	31	2:30 PM	Christie	Badger	National Organic Coalition	General	
	32	2:35 PM	Gwendolyn	Wyard	Organic Trade Association	CACS, Handling, Materials	
	33	2:40 PM	Kenichiro	Takei	Kaken Pharmaceutical Co., Ltd.	Crops	
	34	2:45 PM	Cynthia	Smith	Conn & Smith, Inc.	Crops	
	35	2:50 PM	Johanna	Mirenda	OMRI	General	
	36	2:55 PM	Amalie	Lipstreu	Ohio Ecological Food and Farm Associatioon	General	
	37	3:00 PM	Alesia	Bock	general public, company name, organization, association, etc	Handling	
	38	3:05 PM	Kendra	Klein	Friends of the Earth	Materials	
	39	3:10 PM	Alan	Lewis	Natural Grocers	General	
	40	3:15 PM	Thomas	Harding	LVOG, Inc.	Crops	
	41	3:20 PM	Alexis	Randolph	Quality Assurance International	General	
	42	3:25 PM	Melody	Meyer	UNFI	General	
	43	3:30 PM	Anne	Ross	The Cornucopia Institute	CACS	
	44	3:35 PM	Hans	Dramm	Dramm Corporation	Crops	
	45	3:40 PM	Jake	Lewin	CCOF	CACS	