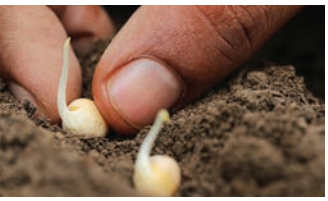



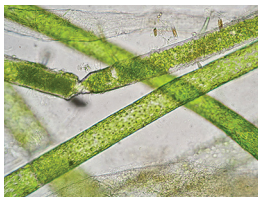

Comments to the National Organic Standards Board

Spring 2016 Meeting
April 25-27
Washington, DC

CORNUCOPIA
INSTITUTE

The Cornucopia Institute is engaged in research and educational activities supporting the ecological principles and economic wisdom underlying sustainable and organic agriculture. Through research and investigations on agricultural and food issues, The Cornucopia Institute provides needed information to family farmers, consumers, stakeholders involved in the good food movement, and the media.

The Cornucopia Institute wishes to thank the thousands of family farmers and their urban allies who fund our work with their generous donations.

The Cornucopia Institute
P.O. Box 126
Cornucopia, WI 54827
608-625-2000 voice
866-861-2214 fax
cultivate@cornucopia.org
www.cornucopia.org

Cover design: Draft Horse Studio | drafthorsestudio.com
Cover photos: iStock

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INTRODUCTION

The Cornucopia Institute is pleased to offer the National Organic Standards Board our formal analysis of, and recommendations on, issues and materials up for review at the Spring 2016 meeting.

Cornucopia adamantly believes that a thorough and appropriate review process needs to take place for all petitioned materials, and that all materials should conform with the Organic Foods Production Act of 1990 (OFPA) and the federal organic standards. We hope that the Board will benefit from Cornucopia's independent perspective in these comments.

The Cornucopia Institute is a 501(c)(3) public interest farm and food policy research organization. Cornucopia engages in educational activities, supporting the ecological principles and economic wisdom underlying sustainable and organic agriculture.

Through research and investigations on agricultural and food issues, The Cornucopia Institute provides educational information to farmers, consumers, other stakeholders involved in the good food movement, and the media.

We are proud to represent over 10,000 supporting members, including an impressive percentage of the nation's certified organic farmers.

We do not sell materials seeking approval for Sunset reauthorization, and we do not sell organic products that utilize any substances that might be petitioned.

We have no financial interest in the approval of any of the materials proposed for use in organic foods.

These formal comments follow the Spring 2016 Tentative Agenda released by the USDA National Organic Program, beginning with materials under review by the Materials Subcommittee and concluding with those under review by the Crops Subcommittee.

Likewise, each subcommittee section follows the Tentative Agenda, beginning with Sunset Materials, followed by Proposals and Discussion Documents.

MATERIALS SUBCOMMITTEE

PROPOSAL

Excluded Methods Terminology

SUMMARY

The definition of "excluded methods" in the USDA Organic Regulations (7 CFR 205.2; Terms Defined) is:

> *"A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture."* [1]

Since this definition was developed in 1995, a number of new technologies have emerged. These technologies are being quickly adopted, requiring a reworking as well as an expansion of the definition of "excluded methods" in order to address issues created by rapid advances in biotechnology. This update should occur regularly to account for the rapid development of new technologies.

These include:

- Genetically engineered vaccines for livestock;
- The use of cell fusion within plant families to create male sterility in brassica hybrids;
- The use of GMOs used to make biodegradable bioplastic mulches;
- The use of genetically mutated algae;
- Untraceable plant breeding techniques such as double haploid production, gene editing with no insertion of foreign DNA, irradiation, embryo rescue, gene silencing via RNAi pathway, and others; and,
- Synthetic biology, genetically engineered insects.

The first discussion document (2013) discussed terms in the above definition, defined and discussed other terms related to traditional breeding, and introduced new terms that could be considered to be genetic engineering and suggested that more work was needed to clarify what terms could be considered excluded methods.

The Second Discussion Document (9/2014 and 4/2015) summarized the public comments received in response to the first discussion document and proposed several options for an updated definition, as well as for principles and criteria for use when evaluating the various genetic modification issues. Additional terms were collected and the beginnings of some definitions were started. A structure was proposed, similar to the one in use by the research Institute of Organic Agriculture (FiBL) in Europe that involves an itemized chart with a "yes/no" column, where the specific techniques could be itemized and evaluated. A recommendation was informally made by the subcommittee, but not voted upon, that these revisions to the definition and structure for evaluating techniques be regulated through NOP guidance rather than additional rulemaking.

The NOSB acknowledged that there will be some unresolved issues that will need continued public discussion, because they pose enforcement challenges, are totally hidden from view, or not enough is known about them yet. Finally, the NOSB requested additional public comments to help clarify Excluded Methods Terminology for accredited certifiers and organic producers.

DISCUSSION

The Cornucopia Institute appreciates the work done by the Materials Subcommittee (MS) to develop the Excluded Methods Terminology Proposal. As stated by the MS, a concrete, flexible, and resilient regulatory framework is urgently needed, considering that current biotechnology discovery and innovation "is rapidly outpacing any regulatory structure."

Cornucopia agrees with an approach that would separate out technologies, terms, and issues on which no agreement has been reached yet, while moving forward where there is consensus. This underscores the importance of maintaining regulations that have broad support, yet are relatively simple, and addressing complex issues and new technologies via guidance. Cornucopia requests that the NOP posts proposed guidance for public comments.

There are 3 parts to this proposal:

1. A definitional framework for "excluded methods" that uses a process-based approach to add to and expand the original definition;

2. Criteria and principles for use in reviews based on the updated definition; and,

3. A terminology chart compiling those technologies that are clearly "excluded methods" based on the definition and criteria.

Definitional framework

Basic terms, to "be adopted by the NOSB as being Excluded Methods," are defined. Cornucopia agrees with the definitions developed by the MS; as stated by the subcommittee, "*[t]his series of definitions provide a better framework than solely the existing*

definition to further elaborate the various technologies that would be prohibited as well as those which would be allowed."

Criteria and principles for use in reviews based on the updated definition

This section of the proposal gives a solid foundation by starting with principles that define organic production, using both the NOSB Principles of Organic Production and Handling and IFOAM's Principles of Organic Agriculture as a foundation for criteria to review biotechnology processes. The developed criteria are based on process, rather than product, providing the needed flexibility to address the new technologies being developed at an ever increasing rate.

A terminology chart compiling technologies that are clearly "excluded methods"

This is a good start; it is **important to identify all of the terms related to biotechnology that fall under the definition of excluded methods**. This section should be a work in progress, as new technology is continuously being developed.

Excluded methods terminology proposal

Cornucopia agrees with Beyond Pesticides that the approach adopted to develop this proposal is sound and consistent with organic production practices. A systematic process-based approach needs to be clearly established and utilized in all regulatory schemes, not just organic. In fact, new biotech processes that "are very clearly genetic engineering techniques are not regulated by the current government structure because they do not involve DNA from a 'pest' under the USDA APHIS regulatory structure." This has generated a multitude of problems for organic producers and others. Relying on a product-based regulatory scheme, particularly one based on limited and outdated definitions (such as the definition of "pest"), was demonstrated to be unworkable.

Some technical corrections and additions, provided by others such as the Center for Food Safety, may be required, but Cornucopia supports the overall proposal and its expedited enactment.

DISCUSSION DOCUMENT

Excluded Methods Terminology

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

As stated above, Cornucopia agrees with an approach that would separate out technologies, terms, and issues on which no agreement has been reached yet, while moving forward where there is consensus. This allows for the gathering of the additional information and input on technologies, terms, and issues where consensus has not been reached yet.

Cornucopia comments address general principles and processes, leaving comments on scientific details to others.

DISCUSSION

The NOSB lists several areas for future discussion and work on this subject:

- Additional criteria for evaluating technologies that need to be considered.

Cornucopia supports the inclusion of the additional criteria from FiBL, the Research Institute for Organic Agriculture from Switzerland:[1]

- How to detect those technologies that are excluded but may not provide detectable genetically engineered DNA when tested.
- Enforcement of the excluded method provisions of the rule when they are not traceable and undetectable.

The issues of detection and enforcement are difficult to address within the organic rules and regulations. The issue is similar to the use of pesticides, some cause damages at presently undetectable levels or the knowledge is lacking as to what the impacts may be, or as to where to look for potential harmful effects. How to deal with such issues must be partly referred to those who allow such technologies use – for example, the USDA deregulating genetically engineered (GE) organisms. GE crops should not be allowed without a practical detection method and established safeguards to prevent unchecked environmental contamination by unforeseen gene transfer.

Materials Subcommittee action and vote

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

The MS would like public input on the following questions:

1. Are there any additional criteria for evaluating technologies that need to be considered?
2. Do you have any insights on how to detect those technologies that are excluded but may not provide detectable genetically engineered DNA?
3. Please offer any suggestions for enforcement of the excluded method provisions of the rule when they are not traceable or detectable.
4. Opinions are welcome on the terms in the chart above that may or may not be clearly prohibited as excluded methods.

Subcommittee vote
Motion to adopt the third discussion document on Excluded Methods
Motion by: Zea Sonnabend
Second: Emily Oakley
Yes: 6, No: 0, Absent: 0, Recuse: 0

CONCLUSION

The Cornucopia Institute recommends that:

- The additional criteria by the FiBL be included in the proposal;
- The NOSB call upon the Secretary of Agriculture to reverse its policy, allowing an increasing number of genetically engineered crops in conventional agriculture;
- And, the NOSB request and support legislation that would place liability for damages on the patent holder, providing a recourse for organic producers facing the genetic contamination of their crops.

Seed Purity – Next Steps

Organic seed is the foundation of organic agriculture and should be protected. The Cornucopia Institute appreciates the work done to develop the Discussion Document on Next Steps for Improving Seed Purity and the continued work in this important area of organic production. This issue threatens all of organics and needs to be dealt with by applying **the precautionary principle** first and foremost. Organic farmers should be relived of some of the financial burden caused by seed contamination.

DISCUSSION

Do you think that any of the suggestions above (A - D) are workable? What would you change to make them better?

A. The Cornucopia Institute agrees that more data regarding seed purity issues would help determine the best path to take in the long run. In general, it is advisable to support development of data-collection programs from sources other than the government, which may be a slow source of funding for this project. However, it is important to rely on data only from a reputable source and ensure that that source is named to encourage transparency.

In addition, any data collection involving testing of seed stocks should be done with PCR testing as oppose to strip testing. While strip testing is cheaper, it often inaccurate with the standard error and sensitivity level for each test varying by manufacturer.[2] Strip tests can accurately show when something is "hot" (i.e. contaminated), but because false negatives are common. A seed producer may rely on this inaccurate information and use those seeds in other growing programs or use those seeds for sale to organic farmers.[3] Inaccurate testing exacerbates the problem of contamination within organic seed. If a seed has even a small percentage of contamination, the organic farmer that grows that seed could find themselves over the legal limit and lose the ability to sell a resulting crop "organic." **This is a huge economic burden on organic farmers that should not be tolerated.**

While strip testing could be used for an initial screen, PCR testing should occur at the essential parts of the data collection analysis. Other organizations support this methodology, including

[2] "…strip tests are not as accurate as ELISA … or DNA PCR tests. Because they can be performed in the field, there is also a higher potential for human error. Furthermore, proteins are a product of the gene and have a tendency to vary in different environments. They are therefore not recommended as sufficient analysis for organic seed… Both ELISA and strip tests are further limited in the range of proteins detected. Different events require individual testing for their presence. For example, a corn sample cannot be tested for all GE traits simultaneously and the same sample cannot be reused with different tests." The Organic Farmer's Handbook to GE Avoidance and Testing (2014). Page 57. *Available at*: http://www.osgata.org/organic-seed-integrity/

[3] Conversation with Jim Gerritsen, President of the Organic Seed Growers and Trade Association (OSGATA) on April 12 & 13, 2016.

the Non-GMO Project.[4]

Cornucopia disagrees that implementation of protective methods should be delayed to wait for further data collection. While that data is being, collected we should err on the side of caution**.** This means quickly developing an interim guidance to deal with seed purity issues while more data is collected. This guidance should contain stopgap measures and lay out strategies for certifiers dealing with seed purity issues. Then, with adaptive management strategies, all affected parties can respond to the changing need for seed purity.

Some of the best sources for data will come from NGOs, organic seed producers, and organic farmers. Some non-government sources have already developed data that could be utilized. For example, the Organic Seed Growers and Trade Association produced a handbook titled "Protecting Organic Seed Integrity: The Organic Farmer's Handbook to GE Avoidance and Testing." [5] The document "Best Management Practices for Producers of GMO and Non-GMO Crops" also provides a succinct guide for protecting seed purity.[6]

Other subjects where data should be collected to move projects forward on seed purity include:

- Finding newer and cheaper lab work methods to verify seed purity that maintain the same accuracy standards as PCR testing.
- Determining specific land-use strategies that can help particularly sensitive crops (such as corn which, as a wind-pollinated crop, is particularly vulnerable to contamination).

B. Cornucopia would support a recommendation that the USDA establish a Seed Purity Advisory Task Force with certain qualifications. This task force should include environmental scientists, organic seed producers, seed biologists, and representatives of certifying agencies, at a minimum. However, anyone appointed to this task force must be **members of the organic community.** These experts are needed to help guide policy as seed purity issues evolve and assigning people from outside the organic industry has the potential to, due to conflicts of interest, undermine what the task force is intended to protect and study. In addition, **we recommend a faster timetable than 3-5 years, as these are issues that are playing out today that will impact the future of organic production.**

If created, some areas on which the task force should focus their work include:

- Determining the methods to spread the costs of seed contamination throughout the whole agricultural industry so organic producers to not carry the brunt of the burden.
- Working with Accredited Certifying Agents (ACAs) to pinpoint common areas of concern.

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[4] Non-GMO Project: Guidelines. *Available online at:* http://www.nongmoproject.org/product-verification/about-gmo-testing/guidelines/

5 The Organic Farmer's Handbook to GE Avoidance and Testing (2014). *Available at*: http://www.osgata.org/organic-seed-integrity/

[6] Best Management Practices for Producers of GMO and Non-GMO Crops, By Jim Riddle, Organic Outreach Coordinator. *Available online at*: http://www.demeter-usa.org/downloads/GMO-Contamination-Prevention.pdf

- Quickly releasing or work with the NOSB in releasing guidance(s) to help maintain seed purity while regulations are being modified.
- Soliciting public comment to shape guidance and the overall direction of the task force's projects.

C. Cornucopia would support the NOSB producing guidance's to help strengthen organic seed provisions in the regulations. However, this should be one tactic of many and not the only step taken with respect to seed purity.

The NOP should formally recognize that the burden of genetic contamination should fall on the polluters and incorporate that into any regulations and guidance. The NOP and USDA should develop both guidance and regulations to bring conventional agriculture into the conversation. Even outside the question of organics, it benefits agriculture in general to have many pure lines of seeds. As environmental pressures from climate change and overpopulation increase, our food system will become more insecure. Relying on monoculture increases the risk of agricultural collapse. In this respect, organic production encourages the development and purity of non-GM seeds and contributes to future food security for all agricultural sectors.

With respect to the specific items listed under this section, Cornucopia **supports** the recommendation that the **"***NOP should provide meaningful training to ACAs annually on how to monitor progress in complying with the need for continuing improvement in seed sourcing*" in particular. The NOP need to help the ACAs help organic operators and take the burden of outside pollution off organic producers who are already doing all they can to protect their own crops from contamination and having to work within the limitations of the organic seed market.

D. Soybeans could provide a valuable test, because it is an easier crop to control. **However, the need to develop seed purity protocols for at-risk crops is *urgent* and should not be delayed with endless testing on crops that are less at-risk.**

Do you have a new suggestion to add under letter "E"?

- Cornucopia believes that ensuring the purity of seeds used for organic production is especially important when organic growers use conventional seed.[7] As of yet, **this area has not been subjected to the same oversight as the use of organic seed**. This oversight should be rectified in the guidance.
- Cornucopia maintains that the focus should be on conventional, not organic, seed. As detailed in Cornucopia's comments on the NOP seed guidance in March of 2013, adding another test or protocol to test organic seed increases the costs for certifiers and producers. If regulations or guidance is only applied to organic seed, this will increase the overall costs of that seed and hurts the organic market. Because of this

[7] Conventional seed can be used in specific circumstances according to §205.204(a)(1) which states that "Nonorganically produced, untreated seeds and planting stock may be used to produce an organic crop when an equivalent organically produced variety is not commercially available…"

harmful disincentive, any seed purity standard **should apply to *both* conventional and organic seed.** This means that any conventional seed used in organic agriculture should also maintain a 0% threshold.

- The expense for testing for seed contamination should **fall on the polluters.** Nowhere else in our legal system does a property owner have to pay out of their own pockets for the trespass of another onto their property – but that is what is happening in organic agriculture. The current system is unbalanced, corrupt, and causes economic harm to organic farmers. Organic producers should not have to pay the expense of confirming their crops are free from contamination, and economic loss if it is proven to be contaminated, as they are an innocent victim. Instead, manufacturers of GE crops should contribute to a fund which organic farmers can draw from for PCR testing. The USDA and APHIS should mandate this funding through their regulation of genetically engineered crops.

If you think that A is workable how and where would you suggest for the testing data to be collected and compiled?

These questions are already being actively addressed by organic seed producers. Cornucopia supports testing using PCR methods, as relying on inaccurate tests (such as strip tests) can destroy an organic farmer's viability.

If you think that C should be taken up by the NOSB, are there other portions of the Seed Guidance that should be strengthened?

As pointed out by many stakeholders, the NOP seed guidance issued in March, 2013 failed to address many of the public comments or the NOSB recommendations of the time. Many of these comments were well-researched and should be utilized by the NOP in the future to strengthen the Seed Guidance.

In addition to these issues, the seed purity standard should be based on a ***zero tolerance system*.** That means that organic seeds should test as having no genetically engineered constituents. Conventional seed used for organic agriculture meet the same zero tolerance requirement.

LIVESTOCK SUBCOMMITTEE

PROPOSALS

Hypochlorous Acid

Comments listed on pages 114-120

Lidocaine & Procaine Annotation

SUMMARY

The Cornucopia Institute **supports the changes recommended by the Livestock Subcommittee regarding** lidocaine & procaine on the National List under §205.603 synthetic substances allowed for use in organic livestock. The suggested changes are to reduce the withholding period for meat and dairy from treated animals.

Rationale:

- Lidocaine & Procaine are relatively safe, effective, widely available, local anesthetics used to reduce pain in an animal during veterinary surgical procedures or during dehorning.
- Lidocaine is predominantly used by veterinarians because it is faster acting and longer lasting, as well as being approved for veterinary use.
- Potential toxicity is minimal when used appropriately.
- Safe and effective non-synthetic alternatives are not available.
- The current 90-day withholding periods seem excessive and may discourage producers from using these anesthetics.
- Shorter withholding periods are supported by research. However, some research does indicate the proposed 8-day withholding period may not be long enough to remove toxic metabolites. However, a 15-day withholding period for milk and a 28-day withholding period for meat appear be sufficient to reduce any residues to safe levels.

DISCUSSION

The synthetic drugs lidocaine and procaine were first approved for use in organic livestock production in 1995. Procaine was developed for commercial use in 1905, while lidocaine has been in commercial use since 1949. While the compounds share some similarity in their mode of action, lidocaine is quicker acting, and more effective, than procaine.[8] Additionally, it is the only anesthetic actually approved for use on cattle by the FDA.[9] As such, lidocaine has become the mostly commonly used local anesthetic in veterinary medicine in the U.S.[10]

Lidocaine hydrochloride is a water-soluble injectable drug which acts quickly to numb an injection site to reduce the feeling of pain. It is regularly used for minimizing pain during surgery or dehorning, for treating painful wounds, or as an epidural. While the local

[8] Opinion of the Scientific Committee of the Norwegian Scientific Committee for Food Safety 10 June 2005: Risk assessment of lidocaine residues in food products from cattle, swine, sheep and goats: withdrawal periods for meat and milk. www.vkm.no/dav/8b9b95e522.pdf

[9] Geof Smith, DVM, MS, PhD, "Extralabel Use of Anesthetic and Analgesic Compounds in Cattle" Vet Clin Food Anim 29 (2013) 29–45 http://dx.doi.org/10.1016/j.cvfa.2012.11.003

[10] https://instruction.cvhs.okstate.edu/.../pdf/14LocalAnesthesia2006b.pdf

synthetic anesthetic procaine can also be used, its action is slower to take effect and it does not last as long. Thus, it offers no advantages as an alternative to lidocaine for organic producers.

In a recent survey The Cornucopia Institute conducted with certified organic livestock producers (excluding poultry), 10 farmers out of 28 respondents, thus far, mentioned that they used the 2% lidocaine hydrochloride on one of their animals for pain relief. This probably demonstrates that it is a commonly used drug.

While it is possible to overdose, when lidocaine is used as directed it is considered safe, and non-addictive. It is not a drug that is in demand for illicit use. Two percent lidocaine hydrochloride is only available for use by a licensed veterinarian or under the direct supervision of a licensed veterinarian.

Concerns about withholding interval

For organic livestock use, the current withholding period after administering lidocaine is seven days for milk and 90 days for meat. It's questionable as to whether such a long withholding period is necessary for meat animals. A very real concern is that the excessively long withholding period may discourage livestock producers from using lidocaine to reduce pain when it would be in the best interest of the animal's welfare to use the drug.

Livestock producers face increasing scrutiny by the general public and media over their care of animals. When a wound, injury, or procedure is likely to cause an animal pain, livestock producers should be encouraged to provide treatment for that pain, as the humane treatment of livestock is a priority for both producers and consumers. Therefore, there should not be an unsubstantiated barrier to treating livestock for pain, such as an excessive withholding period for a commonly used, relatively safe drug, such as lidocaine hydrochloride.

Drug residues in meat and milk are a concern in modern livestock production, as residues can cause potential health hazards to humans. Withholding periods are set to reduce the risk of any potential hazards. Additionally, the NOP has **typically adopted withholding periods that are double the standard withholding periods for conventional livestock** production, based on consumer perception of the extra precautions taken in organic agriculture. The **90-day withholding requirement for meat animals in organic production seems excessive** and is not supported by research.[11] The current FARAD recommended withdrawal periods for lidocaine and procaine for conventional meat and dairy is 24 hours.

[11] Opinion of the Scientific Committee of the Norwegian Scientific Committee for Food Safety
10 June 2005: Risk assessment of lidocaine residues in food products from cattle, swine, sheep and goats: withdrawal periods for meat and milk. www.vkm.no/dav/8b9b95e522.pdf

However, a 24-hour withdrawal time might be insufficient. A 2015 review by European Medicines Agency's Committee for Medicinal Products for Veterinary Use (CVMP) suggests that a 28-day withholding period is sufficient for meat, and a 15-day withholding period is sufficient for dairy products, to reduce potential genotoxicity to a level below any concern.[12]

Research in dogs, cats, sheep, horses, and rats demonstrates rapid elimination of lidocaine and its metabolites, usually within several days of administration.[13] Research available from cattle suggests that half-lives of drugs are typically shorter in cattle than in dogs and cats or humans.[14] A study completed in 2009 on Holstein dairy cattle demonstrated almost total clearance and low-detectable residues in the milk within 36 hours of lidocaine administered as an injected epidural. This study is widely used to support the standard withholding periods of four days for meat and 72 hours for dairy.[15]

Yet, the CVMP review mentioned above supports longer withholding periods, because one of the metabolites of lidocaine called is a genotoxic carcinogen in rats and research has not established a level of exposure required for carcinogenicity. The CVMP set a threshold for consumption at 0.15 µg for 2,6 xylidine residue in meat and milk. Based on the expected half-life analysis from a maximum dose of lidocaine, a withdrawal period of 15 days for milk and 28 days for meat brings the residue levels well below that threshold.[5]

In the case of lidocaine and procaine, the recommended change to a withholding period of eight days for meat and six days for milk may be a rational compromise until there is further evidence for either shortening or lengthening the withdrawal period. This withdrawal period would allow for practical use of lidocaine and procaine and still likely minimize any issues with residues in meat and dairy production.

NOSB Livestock Subcommittee action

May 19, 2015
Lidocaine was evaluated against the OFPA criteria and found to satisfy them all.

Subcommittee vote
Motion to remove from §205.603
Yes: 0, No: 6.
The lead board member in the discussion of this material indicated that she would develop a proposal to modify/reduce the withdrawal period.

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[12] CVMP Assessment Report Regarding the Request for an Opinion Under Article 30(3) of Regulation (EC) No 726/2004. Committee for Medicinal Products for Veterinary Use. European Medicines Agency. EMA/CVMP/118717/2015. April 10, 2015.
[13] Ibid.
[14] Baggott JD. The Physiological Basis of Veterinary Clinical Pharmacology. Oxford: Blackwell, 2001
[15] Sellers, G., Lin, H. C., Riddell, M. G., Ravis, W. R., Duran, S. H. and Givens, M. D. 2009, Pharmacokinetics of lidocaine in serum and milk of mature Holstein cows. Journal of Veterinary Pharmacology and Therapeutics, 32: 446–450.

July 21, 2015
Lidocaine and Procaine - Annotation Change. The LS voted previously against removing lidocaine and procaine as part of Sunset review, but is developing a separate proposal to change the annotations. The LS proposed questions about a reduced withholding time and commenters, including several producers and organizations, were supportive of the step down. The lead indicated that there is strong science behind this idea. The lead made some modifications to the draft document based on the discussion.

Subcommittee vote:
Motion to change annotations for lidocaine and procaine on §205.603
Lidocaine - as a local anesthetic. Use requires a withdrawal period of 5 days after administering to livestock. Procaine—as a local anesthetic, use requires a withdrawal period of 5 days after administering to livestock.
Vote: Yes: 4, No: 0

August 4, 2015 LS notes
Lidocaine and procaine. Both of the documents proposing annotation changes were revised and will be put forth as discussion docs instead of proposals. In light of the revisions, the LS chose to revote on the 2017 Sunset proposal to remove procaine. The original vote was conducted on May 19. The LS does not feel that they need a revote on lidocaine, as these changes will not affect the outcome of that vote.

Subcommittee revote:
Additional Discussion: Yes: 4, No: 2
Lidocaine/Procaine annotation change discussion document. The LS added specific questions for both lidocaine and procaine for which they are seeking public comment.
Motion to accept the Lidocaine/Procaine annotation change discussion document.
Additional Discussion: none Yes: 6, No: 0

January 19, 2016
To amend §205.603(b) As topical treatment, external parasiticide or local anesthetic, as applicable. Lidocaine—as a local anesthetic. Use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals Procaine —as a local anesthetic. Use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals.

Subcommittee votes:
Motion #1. That the deleted language be removed and underlined language added at: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable. Lidocaine—as a local anesthetic. Use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals.
Yes: 6, No: 0, Abstain: 0, Absent: 0, Recuse: 0

Motion #2. That the deleted language be removed and underlined language added at: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable. (7) Procaine —as a local anesthetic. Use requires a withdrawal period of ~~90 days~~ 8 days after administering to livestock intended for slaughter and ~~7 days~~ 6 days after administering to dairy animals**.** Yes: 6, No: 0, Abstain: 0, Absent: 0, Recuse: 0

CONCLUSION

Lidocaine is a widely used, readily available, and relatively safe local anesthetic with no better alternatives. The Cornucopia Institute **supports the recommendations of the Livestock Subcommittee to shorten the withholding periods for meat and dairy animals after treatment with** lidocaine or procaine.

Annotation Changes Parasiticides

Ivermectin

SUMMARY

The Cornucopia Institute opposes the recommended changes made by the Livestock Subcommittee as they apply to Ivermectin. Instead, The Cornucopia Institute is in agreement with Livestock Subcommittee's 5:1 vote to remove Ivermectin on June 2, 2015. However, since delisting cannot be done at this meeting, The Cornucopia Institute recommends that Ivermectin be sent back to the LS for review.

Rationale:

- Ivermectin is harmful to the environment, as its residue in manure, from treated livestock, is lethal to dung beetles, and can poison aquatic species.
- Ivermectin has lost its effectiveness against many types of internal parasites due to its overuse in livestock production, and related resistance.

DISCUSSION

Since its introduction in 1981, as an anthelmetic/dewormer for livestock, Ivermectin has become the predominant parasiticide due to its low cost, its broad spectrum of effectiveness and variety of treatment methods in which it can be used.[16] Ivermectin is part of a class of chemical compounds called the "macrocyclic lactones." Ivermectin is in the macrocyclic lactone subgroup of **avermectins.** They are obtained in fermentation processes using *Streptomyces* and subsequent purification and/or chemical modification of the fermentation products. Ivermectin stimulates the release of gamma amino butyric acid (GABA) from nerve endings and enhances binding of GABA to special receptors at nerve junctions. This suppresses nerve impulses, leading to paralysis and, eventually, death of the parasite. The mode of action is similar for both nematodes and arthropods. Ivermectin is a broad-spectrum parasiticide and displays **antimicrobial activity, which has led some sources to consider it an "antibiotic."**

If Ivermectin is considered an antibiotic, it is difficult to reconcile its use, given the categorical prohibition on antibiotics for use in organic systems.

Parasiticide use has been tolerated in organic livestock production on a limited basis to alleviate animal suffering. To let an animal die because of an extensive parasite infection is

[16] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3043740/

inhumane and also not compatible with a system of organic agriculture. However, the parasiticide Fendbendazole is effective and much more environmentally benign.[17]
At the NOSB Spring meeting in 2015, Dr. Hubert Karreman recommended in his comments that Ivermectin be Sunsetted. "*This was the original intent when we voted to allow Fenbendazole while I was Livestock Chair of the NOSB. The transcripts of that meeting clearly reflect that intent. Ivermectin is toxic to dung beetles, which are an integral part of pastureland ecology*."

Environmental concerns

The avermectins, of which Ivermectin is a part, are **extremely broad-spectrum biocidal agents and are variably categorized as parasiticide, anthelmintics, acaricides, insecticides, or macrolide antibiotics**.

Free Ivermectin will bind to the soil. Once in the soil, as well as in the feces, Ivermectin has been linked to the **killing of dung beetles**.[18] The same study showed that Fenbendazole did not have the same toxic effects on dung beetles. Another study from Ohio State University confirmed that fecal concentrations of cattle given Ivermectin were lethal or sub-lethal to many dung breeding invertebrates beneficial to the ecosystem. This result was replicated in subsequent studies.[19]

A 2002 study showed that six commonly used veterinary medications (including both Ivermectin and Fenbendazole) caused livestock manure to more slowly decay, which likely indicates a negative effect on dung beetles or on the decaying microorganisms that normally would break down the manure in a matter of a few months.[20] **If livestock manure breaks down more slowly, not only can it harbor more parasites and fly larvae but this also prevents the recycling of nutrients that is so essential for good manure management**. Vegetation also does not grow well under intact manure which, over time, means a degradation of pasture health.

The 2015 Technical Report on Parasiticides, **compiled by USDA/AMS Agriculture Analytics Division [authors unknown]**, fully documents the studies mentioned above, that demonstrate Ivermectin's toxicity to dung beetles, and the consequential negative effects on the environment.[21]

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[17] Wall, R. and L. Strong. (1987). Environmental Consequences of Treating Cattle with the Antiparasitic Drug Ivermectin. *Nature* 327: 418-421.
[18] Ibid.
[19] Madsen, M. (1990). Treating cattle with Ivermectin: Effects on the Fauna and decomposition of dung pats. *Journal of Applied Ecology*. 27: 1-15.
[20] Sommer, C. and B.M. Bibby. (2002). The influence of veterinary medicines on the decomposition of dung organic matter in soil. *European Journal of Soil Biology*. 38(2): 155-159.
[21] Technical Report on Parasiticides. (2015). Compiled by USDA, AMS, Agricultural Analytics Division for the USDA National Organic Program

Human and livestock health concerns

Because many macrocyclic lactones are lipophilic (meaning they have an affinity to fats and do not dissolve well in water), **substantial concentrations will be found in edible tissues of the livestock**. As much as 5% of the administered drug can be secreted in the animals' milk. For this reason, Ivermectin is not approved for use on dairy animals (but topical Moxidectin, another macrocyclic lactone, is allowed).[22]

Essentiality and alternatives

All three of these parasiticides described in these comments have shown some problems with variable levels of resistance development by some parasites. The research is not really conclusive; what works on one farm or one flock/herd of animals may not work on another. Because of this, it is important to first identify which parasites are present and at what levels. If the levels of parasitism require intervention and all other methods have failed, then a farmer must pick the parasiticide most effective against that particular parasite. If a wormer used by a producer doesn't appear to offer the desired control, a different one may have to be tried. This is one reason why it is important to have a few choices of anthelmintics in case the parasites are showing resistance to one of the wormers.

There are also many alternatives to using synthetic parasiticides and restricted use requirements should favor these. As with all livestock diseases, organic farmers should implement a variety of *preventative* practices to avoid having parasite issues. Some alternatives include: selection of disease-resistant breeds and breeding stock, culling susceptible animals (roughly 10%-15% of a herd will shed 80% of the parasite eggs), rotational grazing, preventing overgrazing (in which the livestock is forced to eat lower on the plants where the larvae tend to accumulate), planting of naturally anthelmintic plants in the pastures (*Sericea lespedeza*, chicory, and plantain are a few examples), and other management approaches. Natural remedies once an animal has parasites may include garlic, wormwood, psyllium, quassia, pumpkin seed meal, papaya seeds, diatomaceous earth, activated charcoal, and other methods, although their efficacy is unconvincing.[23],[24] Jackson-O'Brien's research showed that a pumpkin seed meal oral drench showed some promise, but that garlic, ginger, and papaya seeds show no efficacy.

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[22] Baynes, R.E., M. Payne, T.M. Jimenez, A.R. Abdullah, K.L. Anderson, A.I. Webb, A. Craigmill, J.E. Riviere. (2000). Extralabel use of Ivermectin and Moxidectin in food animals. *Veterinary Medicine Today: FARAD Digest*. 217(5): 668-671.

[23] Allen, J., M. Boal, P. Doherty. (1998). Identifying and Testing Alternative Parasiticides for Use in the Production of Organic Lamb. *Organic Farming Research Foundation Final Report* 98-03.

[24] Jackson-O'Brien, D.(2012). Efficacy of Natural Dewormers in the Control of Gastrointestinal Nematodes of Small Ruminants. *Sustainable Agriculture Research and Education (SARE)*. Northeast SARE 2012 Final Report

Preliminary Results of Cornucopia's Certified Organic Livestock Producer Survey

In our latest survey of certified organic livestock producers, 32% said that they used at least one of these three synthetic wormers on occasion, the most common being Ivermectin (7 out of 28 respondents).

Alternatives to utilizing chemical wormers that were mentioned by survey respondents include (by order of frequency): diatomaceous earth (7), pumpkins or pumpkin seeds (2), Pyganic (1), rotational grazing (1), keeping a closed herd (1), homeopathy (1), copper boluses (1), garlic (1), herbs (1), and Neem-a-tox (1). Several mentioned that much more research needs to go into alternatives to synthetic wormers, as parasites are an ongoing issue for almost every livestock producer, regardless of how well they farm. There will always be some level of parasite colonization in livestock.

Compatibility with organic agriculture

In light of the NOSB's other policies on animal health, use of such materials would not be considered compatible with a system of organic agriculture. The administration of any synthetic anthelmintics would result in the loss of organic status of the animal. However, the long withdrawal periods required in the annotations (90 days for dairy animals, last third of gestation for breeding stock, prohibited in slaughter stock completely) are believed by some to be a reasonable compromise instead of a complete loss of the organic status for the animals. In any case, just as in the administration of therapeutic antibiotics, producers should not withhold treatment from infested animals to have them considered organic. Such animals must be treated and diverted to the conventional market if necessary.

Compatibility with a system of sustainable agriculture must be evaluated on several levels. One is the welfare of the animals being raised. In addition to alleviating animal suffering related to itching and a failure to thrive, parasites can have more serious consequences for the animals themselves. Internal parasitism is a common cause of anemia in small ruminants.[25] In fact, a frequent reason for using anthelmintics in small ruminants is salvage (i.e., treatment to save the life of the animal), not just parasite control.[26] Also, a very infected, wormy animal will often be condemned by USDA inspectors at slaughter, so there is an additional economic loss from parasitism.

Yet, sustainability of synthetic parasiticides will always be compromised by interdependent factors, such as the under-dosing of animals by owners treating their own livestock (or worming the entire herd whether needed or not), leading to an increase in anthelmintic resistance, environmental contamination, and resulting in greater use of anthelmintics with lower control achieved. Therefore, the NOSB should not concern itself with whether or not

[25] Waldridge, BM (1998) Weight Loss and lethargy: diagnostic challenge. *Veterinary Forum* (May): 72-73.
[26] Luginbuhl JM (1997) Roundworms in goat herds. Livestock Newsletter. http://jackson.ces.stat.nc.us/newsletters/livestock/jan-feb97

infected animals should be treated; the consensus is that they should. The real question is what to do with treated animals and what to do with operations that regularly use synthetic parasiticides prophylactically on a large portion of their herds. Again, the annotations prohibit routine use, so this should not be an issue for certified organic operations.

Is the use of synthetic parasiticides, even with the restrictive annotation, compatible with the principles and practice of organic agriculture? This is an especially poignant question, as some experts view this material as an "antibiotic." However, from an animal welfare perspective, when parasiticides such as Ivermectin are used, as a last resort to save the life of an animal, they are certainly necessary. The question is should that animal be forced to be diverted from organic production as is in the case after administration of therapeutic antibiotics. In regards to the use of Ivermectin, the answer is yes.

NOSB Livestock Subcommittee action

On June 2nd, 2015 the Livestock Subcommittee found that Ivermectin failed to meet the OFPA criteria regarding environmental impacts, because it is harmful to dung beetles and the soil.

Subcommittee vote:
Motion to remove Ivermectin from §205.603
Yes: 5, No: 1, Absent: 2
However, the NOSB relisted all parasiticides, including Ivermectin at the 2015 Fall NOSB meeting.

January 19, 2016: The Livestock Subcommittee (LS) has, as requested by commenters during the Sunset consideration of these materials, reconsidered the listing of all three and makes these proposals:

Motion #1. To amend §205.238(b)(2) as follows: Dairy stock animals - cows, when used a minimum of 90 days after use of Ivermectin, or 2 days after use of Fenbenzadole or Moxidectin, prior to the production of milk or milk products that are to be sold, labeled, or represented as organic. AND Motion to amend §205.603(a)(18) as follows: Milk or milk products from a treated animal cow cannot be labeled as provided for in subpart D of this part for 90 days, following treatment with Ivermectin, or 2 days following treatment with Fenbenzadole or Moxidectin, prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.
Motion: JR
Second: FT
Additional discussion: none
Yes: 6, No: 0, Abstain: 0, Recuse: 0, Absent: 0

Motion #2. To add §205.238(b)(3) as follows: Dairy animals-goats/sheep when used a minimum of 90 days after use of Ivermectin, or 36 days after use of Fenbenzadole or

Moxidectin. AND Motion to amend §205.603(a)(18) as follows: "…Milk or milk products from a treated animal goat/sheep cannot be labeled as provided for in subpart D of this part for 90 days following treatment with Ivermectin, or 36 days following treatment with Fenbenzadole or Moxidectin.
Motion: JR
Second: FT
Additional discussion: none
Yes: 6, No: 0, Abstain: 0, Recuse: 0, Absent: 0

CONCLUSION

The Cornucopia Institute **opposes the listing of Ivermectin** on §205.603 as a restricted parasiticide and encourages the NOSB to send this material back to the LS for review. Ivermectin is harmful to dung beetles and soil life, can act as an antibiotic, and is not consistent with OFPA criteria.

Moxidectin

SUMMARY

The Cornucopia Institute **supports the recommended changes suggested by the Livestock Subcommittee as they apply to Moxidectin**:

> ***Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.***

NOSB Livestock Subcommittee action

June 2, 2015: The subcommittee motion to remove **Moxidectin** from §205.603 as a treatment for livestock was Yes: 4, No: 2. However, the NOSB relisted all parasiticides, including Moxidectin at the 2015 Fall NOSB meeting.

Subcommittee votes
January 19, 2016:
Motion #1. To amend §205.238(b)(2) as follows: Dairy stock animals - cows, when used a minimum of 90 days after use of Ivermectin, or 2 days after use of Fenbenzadole or Moxidectin, prior to the production of milk or milk products that are to be sold, labeled, or represented as organic. And, Motion to amend §205.603(a)(18) as follows: Milk or milk products from a treated animal cow cannot be labeled as provided for in subpart D of this part for 90 days following treatment with Ivermectin, or 2 days following treatment with Fenbenzadole or Moxidectin, prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.
Motion: JR Second: FT Additional discussion: none
Yes: 6, No: 0, Abstain: 0, Recuse: 0, Absent: 0

Motion #2. To add §205.238(b)(3) as follows: Dairy animals-goats/sheep when used a minimum of 90 days after use of Ivermectin, or 36 days after use of Fenbenzadole or Moxidectin. AND Motion to amend §205.603(a)(18) as follows: "…Milk or milk products from a treated animal goat/sheep cannot be labeled as provided for in subpart D of this part for 90 days following treatment with Ivermectin, or 36 days following treatment with Fenbenzadole or Moxidectin.
Motion: JR Second: FT Additional discussion: none
Yes: 6, No: 0, Abstain: 0, Recuse: 0, Absent: 0

Motion #3. To amend §205.603(a)(18)(iii) as follows: Moxidectin (CAS #113507-06-5)—for control of internal parasites only.
Motion: JR Second: TF Further discussion: none
Yes: 6, No: 0, Abstain: 0, Recuse: 0, Absent: 0

Motion #4. To amend §205.238(b)(4) to add (3) Fiber bearing animals, when used a minimum of 90 days prior to production of fleece or wool that is to be sold, labeled or represented as organic. AND Motion to amend §205.603(a)(18) to add- Allowed for fiber bearing animals when used a minimum of 90 days prior to production of fleece or wool that is to be sold, labeled or represented as organic.
Motion: JR Second: TF Additional discussion: none
Yes: 6, No: 0, Abstain: 0, Recuse: 0, Absent: 0

Fenbendazole

SUMMARY

The Cornucopia Institute **supports the recommended changes suggested by the Livestock Subcommittee as they apply to Fenbendazole**:

> *"Prohibited in slaughter stock. May only be used 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 represented as organic, either as "100% organic" or as contributing organic ingredients in a "95% organic" or "made with organic" product 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 of breeding stock. Only for use by or on the lawful written order of a licensed veterinarian. Synthetic parasiticides must not be administered on a routine basis."*

NOSB Livestock Subcommittee action

June 2, 2015 Fendbendazole was found to satisfy all OFPA criteria. The NOSB relisted all parasiticides, including Fendbendazole, at the 2015 Fall NOSB meeting.

Subcommittee votes:
Motion #1. To remove Fendbendazole from §205.603
Yes: 0, No: 6.

August 18, 2015 LS notes. Paraciticides. (Ivermectin, Moxidectin, and Fendbendazole). The LS developed a discussion document in an effort to clarify the annotations. The LS also feels that the withholding periods for these materials are excessive, and will suggest changes. The Subcommittee will include several questions for public comment.

January 19th, 2016
Motion #2. To amend §205.238(b)(2) as follows: Dairy stock animals - cows, when used a minimum of 90 days after use of Ivermectin, or 2 days after use of Fenbenzadole or Moxidectin, prior to the production of milk or milk products that are to be sold, labeled, or represented as organic. AND Motion to amend §205.603(a)(18) as follows: Milk or milk products from a treated animal cow cannot be labeled as provided for in subpart D of this part for 90 days following treatment with Ivermectin, or 2 days following treatment with Fenbenzadole or Moxidectin, prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.
Motion: JR, Second: FT, Additional discussion: none
Yes: 6, No: 0, Abstain: 0, Recuse: 0, Absent: 0

Motion #3. To add §205.238(b)(3) as follows: Dairy animals-goats/sheep when used a minimum of 90 days after use of Ivermectin, or 36 days after use of Fenbenzadole or Moxidectin. And, Motion to amend §205.603(a)(18) as follows: "…Milk or milk products from a treated animal goat/sheep cannot be labeled as provided for in subpart D of this part for 90 days following treatment with Ivermectin, or 36 days following treatment with Fenbenzadole or Moxidectin.
Motion: JR, Second: FT, Additional discussion: none
Yes: 6, No: 0, Abstain: 0, Recuse: 0, Absent: 0

Motion #4. To amend §205.603(a)(18)(i) as follows: Fenbendazole (CAS #43210-67-9) only for use by or on the lawful written order of a licensed veterinarian
Motion: JR Second: FT Additional discussion: none
Yes: 6, No: 0, Abstain: 0, Recuse: 0, Absent: 0

Motion #5. To amend §205.238(b)(4) to add (3) fiber bearing animals, when used a minimum of 90 days prior to production of fleece or wool that is to be sold, labeled or represented as organic. AND Motion to amend §205.603(a)(18) to add- Allowed for fiber bearing animals when used a minimum of 90 days prior to production of fleece or wool that is to be sold, labeled or represented as organic.
Motion: JR Second: TF Additional discussion: none
Yes: 6, No: 0, Abstain: 0, Recuse: 0, Absent: 0

POLICY DEVELOPMENT SUBCOMMITTEE

PROPOSAL

Policy and Procedures Manual Revisions

Refer to supplemental document.

DISCUSSION DOCUMENT

Sunset Timeline Reorganization

The Cornucopia Institute generally supports any recommendation for Sunset reorganization that does not impede public comment, the time given for the NOSB to review comments, or violates OFPA. We recognize that having an unbalanced number of material reviews from one year to another leads to a frantic workload in some years and a more manageable workload other in others. Efficiency should be an important part of NOSB administration, so long as it does not impact the quality of the reviews.

However, because some materials may be reviewed earlier than they would have been under the old system, it is important that there is a mechanism to allow new information to be introduced in the intervening years. Otherwise, a material reviewed earlier than its five-year Sunset date could miss new research, comments, or other information necessary to the decision-making process.

We recommend that there is a system in place for ongoing comment on any NOSB material. In the past the NOSB, supported by the organic community, has asked the NOP to set up an open docket so that open communications could take place between meetings.

The current 30-day comment period after the NOSB meeting agenda and materials are released is **not enough time to thoroughly review each agenda item**. In addition, there is not enough time between when comments are submitted to regulations.gov and the time the NOSB meeting begins. Board members cannot properly read and interpret all comments submitted without exorbitant time commitments.

SPECIAL COMMENT

CACS: Eliminating the Incentive to Convert Natural Ecosystems into Organic Production

BACKGROUND

In May, 2009 the National Organic Standards Board (NOSB) made some specific recommendations asking the NOP to establish standards for biodiversity, including biodiversity standards for accreditation and certifier audits.[27]

In December, 2014, the NOP published the **5020 Draft Guidance Natural Resources and Biodiversity Conservation for Certified Operations** in the *Federal Register,* requesting public comment. The final guidance was completed, after consideration of public comment, in January, 2016.[28] The NOP acknowledged they were only addressing a couple of the NOSB's 2009 recommendations. They set aside the recommendations to incorporate biodiversity standards into the procedures for accreditation and certifier audits; and the recommendation for use of materials evaluation criteria that foster consideration of biodiversity conservation when adding or deleting materials from the National List of Allowed and Prohibited Substances.

In February, 2015 the Wild Farm Alliance (WFA) released a comment on the NOP's 5020 Draft Guidance. In general, WFA considered the guidance a positive step toward addressing issues of biodiversity and conservation within organics. **However, they also had some valid concerns regarding the NOP policy.** Chief among these concerns was the practical effect of the NOP's policy to waive the three-year waiting period for transitioning to organic production from land that has never had chemical applications. While WFA acknowledged that this transitioning policy serves a critical purpose and should be retained, they also pointed out that **an unintended consequence of this transition policy is to incentivize the conversion of native ecosystems to organic production**. WFA ultimately made some recommendations to develop regulatory or guidance language to discourage such conversion.

The Cornucopia Institute agrees with WFA that supporting conservation practices, addressing natural resource issues, and supporting biodiversity conservation within agriculture is essential. The conversion of native ecosystems in particular is a serious

[27] Formal Recommendation by the National organic Standards Board to the National Organic Program [PDF]. Subject: Biodiversity Conservation. May 6, 2009. *Available online: https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20Biodiversity.pdf*

[28] Guidance Natural Resources and Biodiversity Conservation [PDF]. NOP 5020. Agricultural Marketing Service. Effective Date: 1/15/16. *Available online: h*ttps://www.ams.usda.gov/sites/default/files/media/NOP%205020%20Biodiversity%20Guidance%20Rev01%20%28Final%29.pdf

problem that *must* be dealt with in a timely manner. When untouched native ecosystems are destroyed, there is no way to get them back to a pristine character. Habitat loss is the single most pervasive threat to wildlife and native plant life. Finally, incentivizing the conversion of native ecosystems is contrary to standing organic policy and hurts the integrity of the organic label.

DISCUSSION

Biodiversity loss is a global crisis

As the NOP states in its guide for organic crop producers: "*Sustainability can be defined as meeting the needs of the present without compromising the ability of future generations to meet their own needs.*"[29] **The loss of native ecosystems compromises the ability of future generations to meet their needs.**

- **Plant and animal biodiversity is an indicator of environmental health.**[30]
- Biodiversity is greatest in undisturbed environments, like native ecosystems. These areas serve as vital habitat for plants and animals, and may be vital to the survival of some species. **Biodiversity forms the foundation of the vast array of ecosystem services that critically contribute to human well-being.** [31]
- Agriculture is one of the primary causes of ecosystem and biodiversity loss.[32] In the intervening decade, there has been an increase in land used for agriculture (including organic production) and that pressure continues today. [33]
- Agricultural practices effect how farming impacts biodiversity more than any other factor. A 2010 report on global diversity found that, despite recent efforts, the decline in biodiversity has not slowed. The report called for strengthening efforts to protect biodiversity "…by reversing detrimental policies, fully integrating biodiversity into broad-scale land-use planning… [and] funding and implementing policies that tackle biodiversity loss…" [34] **Changing organic policy so that there is**

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[29] *Guide For Organic Crop Producers*, By Pamela Coleman National Center for Appropriate Technology (NCAT) Agriculture Specialist. November 2012. *Available online:* https://www.ams.usda.gov/sites/default/files/media/Guide-OrganicCropProducers.pdf

[30] Article 2. Use of Terms (Definitions). Convention on Biological Diversity. *Last accessed online 3/31/2016 at:* https://www.cbd.int/convention/articles/default.shtml?a=cbd-02

[31] Millennium Ecosystem Assessment, 2005. Ecosystems and Human Well-being: Biodiversity Synthesis. World Resources Institute, Washington, DC. Chapter 1, p.18. *Available online at:* http://www.millenniumassessment.org/documents/document.354.aspx.pdf

[32] Tomorrow's Approach: Food Production and Ecosystem Conservation in a Changing Climate, by Janet Ranganathan and Craig Hanson, World Resources Institute. *Last accessed online 3/30/2016 at:* http://www.wri.org/our-work/project/world-resources-report/tomorrows-approach-food-production-and-ecosystem

[33] Habitat Loss. National Wildlife Federation. *Last accessed online 3/31/2016 at:* https://www.nwf.org/Wildlife/Threats-to-Wildlife/Habitat-Loss.aspx

[34] Global Biodiversity: Indicators of Recent Declines. Stuart H. M. Butchart, *et al.* Science 328, 1164 (2010); DOI: 10.1126/science.1187512. *Available online:* https://www.researchgate.net/profile/Marc_Hockings/publication/43354916_Global_Biodiversity_Indicators_of_Recent_Declines/links/0fcfd50646704ecf9b000000.pdf

no incentive to convert native ecosystems is a vital step in protecting biodiversity.

The question of **whether something "has a positive impact on biodiversity" should be asked for every stage of organic production.** These questions can be answered with assistance from WFA and other public interest organizations. For example, WFA produced a valuable guide regarding Biodiversity Conservation in Organic Agriculture Systems in April, 2012.[35] This guide is comprehensive in its review of how organic regulations and guidance documents require that biodiversity be considered throughout every facet of organic production.

Consumers expect their organic food to come from a source that is ecologically sound. This means that, at a minimum, the methods of organic production should ***do no harm*** to biodiversity and ecological systems. Or, as the 2001 NOSB Principles of Organic Production and Handling state: "*Organic agriculture is an **ecological production management system that promotes and enhances biodiversity** [emphasis added], biological cycles, and soil biological activity.*"[36]

Native ecosystems provide valuable ecosystem services

As defined by the National Wildlife Federation, an **"An ecosystem service is any positive benefit that wildlife or ecosystems provide to people."** [37] The conversion of native ecosystems also causes the loss of these valuable ecosystem services, which serve humanity by cleaning air and water, preventing flooding, mitigating climate change, and offering a myriad of other benefits. [38]

Restoration of native ecosystems is a valuable tool that should be encouraged, but preservation of already-existing ecosystems should be a higher priority.

Organic regulations do not explicitly protect native ecosystems from being converted to organic production

In the current organic regulations, it is required that lands being converted to new organic farms "*[h]ave had no prohibited substances, as listed in § 205.105, applied to it for a period of 3 years immediately preceding harvest of the crop…*"[39] This means that, for products to qualify for the organic label, no prohibited materials can be applied for a period of three years. Because native ecosystems are considered "pristine" (i.e. free from agrochemicals already), this requirement provides a perverse incentive to convert native ecosystem to

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[35] Biodiversity Conservation Draft Guidance - Wild Farm Alliance [PDF]. *Available at: http://www.wildfarmalliance.org/resources/NOP_WFA_BDGuidance.pdf*

[36] NOSB Principles of Organic Production and Handling. Adopted October 17, 2001. Article 1.1.

[37] *Ecosystem Services*. National Wildlife Federation. *Last accessed online 3/28/2016:* https://www.nwf.org/Wildlife/Wildlife-Conservation/Ecosystem-Services.aspx

[38] Climate Change Impacts – Ecosystems Impacts. U.S. Environmental protection Agency. *Last accessed 4/4/2016 at:* https://www3.epa.gov/climatechange/impacts/ecosystems.html

[39] 7 CFR §205.202(b)

organic production. Farmers can immediately "plow up" native grassland, forest, scrubland, and riparian zones and start farming them organically right away to overcome this three-year waiting period.

As detailed by the WFA document, this conversion is occurring throughout the U.S. as an unintended consequence of the three-year requirement.

RECOMMENDATIONS

The Certification, Accreditation, and Compliance Subcommittee and National Organic Standards Board should tackle this issue

In August, 2015, the NOSB's Compliance, Accreditation & Certification Subcommittee (CACS) reviewed the Wild Farm Alliance document "Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production." They came to the conclusion that "conversion of native ecosystems into organic crop production is a serious problem, but that it is too large in scope for the CACS or NOSB to take up." [40] **The Cornucopia Institute disagrees with this sentiment**: the NOSB is specifically assigned to tackle problems with organic agriculture and make recommendations about organics to the Secretary.

CACS should approach the problem of de-incentivizing the conversion of native ecosystems because they are positioned to do exactly this kind of analysis within the NOSB. This issue is one of certification and compliance, and therefore falls firmly in CACS' wheelhouse.[41] In addition, biodiversity conservation was a topic of discussion at the May 2008 NOSB meeting and resulted in the full Board directing a Joint Crops and Compliance, Accreditation, & Certification Committee to review implementation of standards and, as necessary, prepare further guidance for Board consideration.[42] As already discussed, biological biodiversity is a key part of this issue.

CACS does not need to solve these issues in a vacuum – the science behind conserving native ecosystems is well established. The Food and Agriculture Organization (FAO) of the United Nations developed a guide to help deal with the competing challenges of conserving biodiversity and sensitive areas while also providing the basis for the social and economic development of local residents.[43] This outlook is sensible and takes into account both sustainability and the economic incentives farmers face. In addition, FAO recommends that

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[40] https://www.ams.usda.gov/sites/default/files/media/CACS%20Notes%202015.pdf

[41] Certification, Accreditation, & Compliance Subcommittee. Agricultural Marketing Service. *Available online:* https://www.ams.usda.gov/rules-regulations/organic/nosb/subcommittees/certification-accreditation-and-compliance

[42] *See details in the* Formal Recommendation by the National Organic Standards Board to the National Organic Program [PDF]. Subject: Biodiversity Conservation. May 6, 2009. *Available online: https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20Biodiversity.pdf*

[43] The Scope of Organic Agriculture, Sustainable Forest Management and Ecoforestry. Produced by: Natural Resources Management and Environment Department. *Available online:* http://www.fao.org/docrep/007/y5558e/y5558e03.htm

the development of organic standards continue acknowledging the important part voluntary labeling systems have in consumer choice and awareness.

Wild Farm Alliance's recommendations

In their comment on the NOP's 5020 Draft Guidance Natural Resources and Biodiversity Conservation for Certified Operations, WFA made several recommendations as to how to improve the guidance document. Ultimately, the WFA noted that the "the National Organic Program should have barriers that discourage the conversion of intact, biodiverse ecosystems to agricultural cropland within five years from the date of application for certification." In general, the Cornucopia Institute supports all of WFA's recommendations on the issue of "Eliminating the Incentive to Convert Natural Ecosystems into Organic Production," with a few clarifications and additions.

First, WFA made the following recommendations (shown in part; please see WFA's piece for the full text):

> *In the "Role of Certified Organic Operations" section, these new bullets elements should be added:*
>
> - *Certified operations should not have cleared, burned, drained, cultivated, or otherwise irrevocably altered established, diverse and abundant ecosystems such as, but not limited to, forests, woodlands, shrublands, grasslands, riparian habitats, or wetland areas, for organic agricultural crop production, in the five years preceding the date of application for certification of a parcel... This restriction does not stop operations from harvesting wild crops or from managing production systems that sustain the diversity and abundance found in these ecosystems, such as mechanical collection of native seeds or low impact grazing. Organic operations must not convert ecologically at risk ecosystems to organic agricultural production…*

The Cornucopia Institute supports this language from WFA with the following edits: **"…**for organic agricultural crop production **or organic livestock production**, in the five years preceding the date of application for certification of a parcel." We recommend this addition because *intensive livestock operations* can irrevocably damage native ecosystems. While it is possible that low-intensity grazing that mimics the behavior of native herbivores can retain native ecosystems in a vital state, leaving the option open to all livestock operations could be a fatal loophole. As WFA states later in this addition, "low impact grazing" could be allowed, but this should be differentiated from other methods of livestock production that are utilized in organic agriculture. Cornucopia supports the rest of WFA's addition above without comment.

WFA continued with their recommendations, stating that a new bullet should be added to the "Role of Certifiers" in the 5020 Guidance document:

- *"Certifiers must ensure that an operation has not cleared, burned, drained, cultivated, or otherwise irrevocably altered established, diverse and abundant ecosystems such as, but not limited to, forests, woodlands, shrublands, grasslands, riparian habitats, or wetland areas, for organic agricultural crop production in the five years preceding the date of application for certification of a parcel (for a parcel coming out of Conservation Reserve Program, see comment #7 below). This restriction does not stop operations from harvesting wild crops or from managing production systems that sustain the diversity and abundance found in these ecosystems, such as mechanical collection of native seeds or low impact grazing. Organic operations must not convert ecologically at risk ecosystems to organic agricultural production."*

- *"The certifiers' OSP forms must collect sufficient information for the certifier to assess the conservation value of each parcel covered by the certification application…"*

Cornucopia supports the above WFA recommendation regarding certification with the following comments and suggestions:

1. The language "Organic operations must not convert ecologically at risk ecosystems to organic agricultural production," should be emphasized over anything else. Some ecosystems are so rare that every effort should be made to preserve them. While Cornucopia supports ending the incentive to convert native ecosystems, it should be **prohibited outright to convert ecosystems to organic agriculture that are known to be sensitive, imperiled, or unique**.

2. As a minimum bar, a native ecosystem should be considered sensitive, imperiled, or unique whenever it is considered habitat for endangered or threatened species, or species under consideration for listing, or the ecosystem itself provides an essential ecosystem service that cannot be duplicated at a local level.

3. A recommendation for what should be included in the certifiers' OSP forms regarding conserving native ecosystems should be developed to assist certifiers in their duties. Certifier education should come from a source knowledgeable in spotting sensitive and native ecosystems, and prepared to communicate with operators about conserving this land.

4. CACS should either develop or recommend the NOP commission the development of teaching documents for certifiers and operators which should include information on identifying native ecosystems and incentivizing their preservation.

CONCLUSION

Protecting sensitive habitats from degradation or conversion to other uses is critical for conserving the increasingly at risk biodiversity of the planet. Native ecosystems provide habitat that is essential for biodiversity, ecosystem services, and long term sustainability.

While the NOP's three-year waiting period for transitioning to organic production is critical in maintaining organic integrity, in and of itself, the consequence of this practice flies in the face of biodiversity conservation. Without removing the waiting period requirement, CACS and the NOSB as a whole can help protect biodiversity by discouraging the conversion of native ecosystems. To this end, they should develop and recommend regulatory or guidance language to that effect.

The NOSB has stated that "*Organic production and handling systems strive to achieve agro-ecosystems that are ecologically, socially, and economically sustainable.*"[44] As stated in a World Resources Institute article, **"**[f]uture approaches to conserving ecosystems must tackle the three interlinked challenges of climate change, ecosystem services degradation and rising demand for food."[45]

Organic production can either be part of the solution or part of the problem. Without action on the incentive to convert native ecosystems, organic agriculture is contributing to the loss of vital ecosystems, the services they provide, and global biodiversity. Organic regulations ***must prevent*** the incentive to convert pristine ecosystems to organic production.

[44] NOSB Principles of Organic Production and Handling. Adopted October 17, 2001. Article 1.5.
[45] Tomorrow's Approach: Food Production and Ecosystem Conservation in a Changing Climate, by Janet Ranganathan and Craig Hanson, World Resources Institute. *Last accessed online 3/30/2016 at:* http://www.wri.org/our-work/project/world-resources-report/tomorrows-approach-food-production-and-ecosystem

HANDLING SUBCOMMITTEE

2018 SUNSET MATERIALS

Agar-Agar

SUMMARY

The Cornucopia Institute is neutral toward the relisting of agar-agar under §205.605(a) as a nonorganic substance allowed as ingredients in or on processed products labeled as "organic" or "made with organic." The Cornucopia Institute would **support** relisting agar-agar if an annotation is added stating "*from Gelidium species only, processed without alkaline treatment and sourced from areas managed for sustainability."*

A new Limited Scope Technical Review should be prepared. The 2011 Technical Review did not take into account **sustainability concerns** associated with overharvest and climate change. In addition, the Federal Drug Administration **(*FDA) has some open questions about the effect of agar-agar on human health*** that should be investigated further.

Rationale:

- ***Gelidium* is the algae species** (often called seaweed) first used for agar-agar production, while the other species highlighted in the Technical Review, *Gracilaria,* **must be treated with chemicals** to be commercially viable. This process creates alkali wastewater.
- The wild harvest of red algae **disrupts native marine ecosystems** when it is overharvested and not managed appropriately.
- The **health effects of agar-agar have not been deeply explored**, but there are some concerns that should be explored further.
- There are several alternatives to agar-agar. Some of these are likely more dangerous for human consumption (like carrageenan) or may not meet the demand for a vegan or non-pork product.

DISCUSSION

Agar-agar is a product derived from red marine algae that is widely used as an additive in food as a thickener, texturizer, emulsifier, flavor enhancer, and other qualities. The main uses of red seaweeds are as food agar and carrageenan. The highest quality agar comes from the red algae found in the family *Gelidiaceae* (of which the species *Gelidium* is a part).

The lower quality agars are found in the *Gracilariaceae* family.[46] Agar-agar is often used as a vegetarian substitute for animal gelatin and has many of the same uses.

The red algae used for agar-agar production can be either cultivated or harvested in the natural environment.[47] Much of the natural harvest comes from gathering the algae that is untethered from its growing base by storms. This is done by nets of suction tubes. Harvest can also be done by divers who pluck the seaweeds from where they are anchored to marine rocks.

The cultivation of red algae has not always been economically viable. *Gelidium*, in particular, has historically not been economically viable when cultivated because it grows slowly.[48] However *Gracilaria* cultivation is widespread and more economically viable when cultivated.

The Technical Reviews

The original 1995 Technical Advisory Panel (TAP) review was compiled by Steve Taylor and Dr. Rich Theuer (a former agribusiness executive and consultant to the industry). In this TAP, the food additive safety information was only compiled for the *Gelidium* variety of seaweed. *Gracilaria,* and the issues with processing that variety to obtain agar-agar, were not explored in the TAP. In addition, they emphasized that the amount of agar-agar used in food is self-limiting because it is expensive. Since 1995 the use of agar-agar has increased as consumers reject the use of gelatin in processed foods.

The most recent Technical Review for agar-agar was compiled by ICF International for the USDA National Organic Program (the names of the author(s) were withheld). As pointed out in Cornucopia's Spring 2012 comments, this 2011 Technical Review was unclear about how *Gracilaria* has to be processed before it is commercially viable.[49] To make agar-agar *Gracilaria always* has to be **treated with an alkali solution and undergoes a chemical change** during this process. Agar-agar products derived from *Gracilaria* species are therefore synthetic and should not be listed under §205.605(a).

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[46] Agars, The Seaweed Site: information on marine algae. *Available online:* http://www.seaweed.ie/uses_general/agars.php

[47] Seaweeds used as a source of agar (2003). Produced by: Fisheries and Aquaculture Department, Food and Agriculture Organization of the United Nations. *Available online:* http://www.fao.org/docrep/006/y4765e/y4765e05.htm

[48] Seaweeds used as a source of agar (2003). Produced by: Fisheries and Aquaculture Department, Food and Agriculture Organization of the United Nations. *Available online:* http://www.fao.org/docrep/006/y4765e/y4765e05.htm

[49] The Cornucopia Institute's Comments to the National Organic Standards Board. Spring 2012 meeting, Albuquerque, NM. Submitted May 3, 2012. Pp. 8. *Available online at:* http://www.cornucopia.org/wp-content/uploads/2012/11/CORNUCOPIA-Comment-NOSB-May-2012.pdf

Essentiality and alternatives

As listed in the 2011 Technical Review, there are multiple alternatives to agar-agar currently on the market. Agar-agar is a flavorless gelling agent and can be replaced by gelatin, pectin, guar gum (or other gums), xanthan gum (derived from corn), and other thickeners or emulsifiers including arrowroot or potato starch. **Some of these alternatives are either already available in organic form** or are on the National List for these uses. Carrageenan is often cited as an alternative to agar-agar. However carrageenan's health concerns associated with its ingestion are severe (and well-documented by a plethora of publicly-funded research). This substance should not be considered as a viable substitute. Considering the number of listed alternatives to agar-agar products, it appears agar-agar is not essential for organic handling.

Human and environmental health

Agar-agar is considered GRAS by the FDA due to its long history as a food additive.[50] FDA also noted that some studies **have shown death in lab animals** with high rates of consumption. In addition, the FDA acknowledged that seaweeds can uptake harmful levels of **heavy metals like mercury** and that, while the expected rate of consumption of agar-agar should not be harmful, they do not know what the effect of an increased dietary intake would mean. **The increasing use of agar-agar in vegan food may have unexplored effects on human health**.

As acknowledged in the 2011 Technical Review, the major environmental concerns with agar-agar production are associated with the alkaline wastewater and overharvesting in marine environments.

The harvest of red algae for agar-agar poses a risk to sensitive marine ecosystems. Seaweed is a "keystone" species, which provides nutrients and energy for animals and act as a filter for seawater.[51] Studies on seaweed harvest in general show that the biodiversity and resilience of the marine ecosystems is harmed by the harvest of red algae.[52]

CONCLUSION

Cornucopia is **neutral** towards the relisting of agar-agar due to the open-ended listing that allows *Gracilaria* as a source of agar. In addition, there are sustainability concerns associated with red algae harvest that should be addressed if agar-agar is relisted; this is why The Cornucopia Institute recommends the addition of an annotation stating "*from*

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50 Select Committee on GRAS Substances (SCOGS) Opinion: Agar-agar. *Available at:* http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/SCOGS/ucm260847.htm

51 How vegan demand for agar is killing Morocco's red seaweed, by Linda Pappagallo. October, 2014. *Last accessed online 4/8/2016 at:* www.greenprophet.com/2014/10/how-vegans-demand-for-red-gold-algae-is-killing-moroccan-ecosystem/

52 Doriane Stagnol D, Renaud M, Davoult D. "Effects of commercial harvesting of intertidal macroalgae on ecosystem biodiversity and functioning." March, 2013. *Available online: h*ttp://www.sciencedirect.com/science/article/pii/S0272771413001121

Gelidium species only, processed without alkaline treatment and sourced from areas managed for sustainability."

Animal Enzymes

SUMMARY

The Cornucopia Institute **supports** the relisting of animal enzymes as non-agricultural, nonorganic substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic" under 7 CFR §205.605(a). Animal enzymes are a necessary processing medium for some organic foods and there is limited availability of organic animal enzymes. Other than enzymes derived from a genetically engineered source, no other products have the exact qualities needed for making certain types of cheese and cultured products.

In conjunction with a recommendation to relist animal enzymes, The Cornucopia Institute requests that **any ancillary substances used together with animal enzymes be labeled on product packaging**. The public will also benefit from having the source of any added enzymes in a product (whether it is microbial, vegetable, or animal-derived), labeled clearly on the packaging. In addition, The Cornucopia Institute supports the development of **a Technical Review investigating the current availability of organic alternatives** to animal enzymes (such as vegetable sources possessing the same properties) and a survey of the potential availability of animal enzymes derived from organically certified livestock.

Rationale:

- The use of animal enzymes is widespread and they are an essential non-synthetic material for the production of organic cheese and sour cream.
- Some alternatives do exist, including microbial rennet and vegetable rennet. However, these enzymes may give a different (often bitter) character to a finished food product that is undesirable. Certain cheese varieties depend exclusively on animal-based rennet.
- Ancillary substances are added to preserve, or otherwise affect animal enzymes in some way.
- Product labels are not required to identify the source of the enzyme used which can be frustrating or even dangerous to consumers with specific dietary needs.

DISCUSSION

Enzymes are proteins. The animal enzymes included on the National List as non-agricultural, nonorganic substances allowed as ingredients in the processing of organic products are rennet, catalase, animal lipase, pancreatin, pepsin, and trypsin.[53] Most enzymes in use in organic production today are digestive enzymes that are extracted and refined from the stomachs of ruminants and hogs. Rennet is usually used as the prime example of an animal enzyme. The other enzymes utilized in organic production are extracted from other parts of livestock animals. For example, catalase is extracted from

[53] 7 CFR §205.605(a). Animal enzymes.

bovine liver, pancreatin is extracted from animal pancreases, and "animal lipases" are extracted from ruminant and hog pancreatic glands and the pre-gastric juices of young ruminants.[54] Animal enzymes are primarily used to **curdle milk for the production of cheese and sour cream.[55]**

All animal enzymes included on the National List have been previously classified as non-synthetic under 7 CFR §523 205.605(a). There were no synthetic versions of animal-derived enzymes identified in the Technical Reviews or original Technical Advisory Panel (TAP), which was completed in 2000. Enzymes derived from edible, non-toxic plants, nonpathogenic fungi, or nonpathogenic bacteria are also allowed in organic products.[56]

Past NOSB deliberations

The Board first considered the use of animal enzymes for organic processing and as ingredients in November 2000. The 2000 TAP review prepared by the Organic Materials Review Institute was presented at this meeting (authors: identities withheld by USDA). The Processing Committee considered proposed annotations from the TAP review that restricted additives and preservatives used in enzyme preparations. Though there was information on six other enzymes, animal-derived rennet was the model and featured as the primary point of the discussion. Rennet is the blanket term for several of the enzymes listed and animal-derived rennet includes several types of enzymes. Ultimately, the Board decided to list 6 specific animal enzymes as allowed, without annotation.

In November, 2007 the Handling Committee initially issued a recommendation against relisting of animal enzymes (along with other substances including carrageenan) due to a lack of public comment in support of relisting. Once this recommendation was released, public comments came in, universally supporting the continued listing of animal enzymes. With this new information, the committee determined that there was a demonstrated need for continued use in handling and because an organic substitute was unavailable at the time. The Handling Committee reconsidered its earlier vote and animal enzymes were relisted.

A full Technical Report compiled by ICF International on animal enzymes is available from 2011 (authors: identities withheld by USDA). The focus of the discussion was on animal-derived rennet. The 2011 Technical Report also discussed the most widely used substitute for animal-derived rennet today: enzymes produced from genetically modified organisms. Genetic Engineering is an "excluded method", thus GMO enzymes are not allowed in organic production.

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[54] Enzyme Preparations Used in Food (Partial List). Federal Drug Administration. Last Updated: 08/14/2015. *Available online:* http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/EnzymePreparations/default.htm

[55] Enzymes – A Primer on Use and Benefits. Enzyme Technical Association. June 2001. *Available Online:* http://www.enzymeassociation.org/wp-content/uploads/2013/09/benefits_paper.pdf

[56] 7 CFR §205.605(a).

The most recent evaluation was completed in 2015 by the Organic Materials Review Institute (authors: identities withheld by the USDA). This Technical Report was limited in its scope, only dealing with the ancillary substances used in conjunction with enzymes. This supplemental discussion was requested per the 2014 NOP Memo on Ancillary Substances Review. These ancillary substances include a long list of stabilizers, diluents or carriers, preservatives, buffers, coatings, and enzyme inhibitors. In fact, additives can make up the majority of an enzyme formulation. The conclusion of this report was that the ancillary substances are "generally recognized as safe" (GRAS). The report also concluded that there are organic alternatives for all the common ancillary substances.

In 2011 the Handling Committee recommended that animal enzymes remain listed as allowed as non-synthetic.

Subcommittee vote:
Motion to relist Animal Enzymes to the National List section §205.605(a) in 2011.
Yes: 14, No: 0, Absent: No, Abstentions: 0, Recusals: 0

For the current Sunset review period, the NOSB requested additional information on items that were addressed but unanswered in the 2000 TAP. Specifically, these were:

1. Are any animal derived enzymes currently being produced from organic livestock? If yes, on what scale?

2. In the 2011 TR on Animal Enzymes, manufacture of the substance is focused on rennet. Please submit information if the manufacture of other types of animal enzymes differ from rennet.

Essentiality and alternatives

Alternatives to animal enzymes do exist as **rennet can be produced from vegetables and microorganisms**. The key is to find an enzyme with properties similar to that of animal-derived digestive enzymes. **There are already diverse rennet substitutes in use**, partly because of the high demand and lack of supply of animal enzymes.

Some vegetables have coagulating properties that can serve the same purpose as animal enzymes in cheese making. Conceivably, these vegetable enzymes could be derived from certified organic sources (for example, nettle and fig bark extracts have similar properties when refined). There are at least some organic vegetable rennet currently on the market, though much of the rennet marketed as "vegetable-derived" it is actually produced from molds and should fall under the category of microbial rennet.[57],[58] Microbial rennet is typically derived from fermentation using specific mold species.

[57] *Cultures for Health, SM.* Product listing. *Last accessed online 3/23/2016 at:* http://www.culturesforhealth.com/organic-vegetable-rennet.html?gclid=CjwKEAjw_ci3BRDSvfjortr--DQSJADU8f2j6ecLmyFg_x8TId__1EUWczrSj_ZYPK6Ji8upXFT52hoCe-Dw_wcB

Despite their similar properties, both vegetable and microbial enzymes may not provide the same end product when compared to animal enzymes. A certain "bitter" quality is associated with cheese made from vegetable or microbial enzymes,[59] making animal-derived enzymes a preferred choice among many cheesemakers. The bitterness of the product often increases the longer a cheese is aged, so while soft cheeses may do well with a vegetable or microbial enzyme, many varieties of hard aged cheese currently require the use of animal enzymes to maintain the same product standards.

It is unknown as to whether or not these alternatives could meet the enormous demand by organic cheese producers nationally, but it would likely be a difficult transition. As it stands, there is an insufficient animal-derived rennet supply to meet demand, so rennet produced from genetically engineered organisms is now the main source for the nonorganic market.[60] The most widely available animal enzyme is not suitable for organic production, because it is the result of genetic engineering.

Organic animal enzymes are already available, but the market availability appears very limited.[61] It is possible this market could be developed over time, but for the present, no true organic alternatives exist.

Environmental concerns

In general terms, there are no known environmental concerns related to the use of animal enzymes. Enzymes are proteins found in all vertebrates and they break down quickly in the environment. In addition, animal enzymes are water soluble and are quickly diluted in the environment.

Unfortunately, because many of the animal enzymes utilized today are often derived from conventional agriculture, their production involves the use of pesticides. In addition, conventional animals that are the source of enzymes are usually fed genetically engineered crops. These issues can have wide ranging environmental and human health consequences and are incompatible with organic agriculture. **For the above reasons, encouraging the development of organically sourced animal enzymes should be a priority.**

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[58] *New England Cheese Making Supply Co*. Product listing. *Last accessed online 3/23/2016 at:* http://www.cheesemaking.com/shop/organic-vegetable-rennet.html

[59] Agboola S, Chen S, and Zhao J. 2004. "Formation of bitter peptides during ripening of ovine milk cheese made with different coagulants". Charles Sturt University, Бэтхерст, New South Wales, Australia. Dairy Science & Technology (Impact Factor: 1.6). 11/2004; 84(6). DOI: 10.1051/lait:2004032. *Available online:* https://www.researchgate.net/publication/46089920_Formation_of_bitter_peptides_during_ripening_of_ovine_milk_cheese_made_with_different_coagulants

[60] *Chymosin*. GMO Compass. *Last accessed online 3/30/2016 at:* http://www.gmo-ompass.org/eng/database/enzymes/83.chymosin.html

[61] See product example: *New England Cheese Making Supply Co*. Product listing. *Last accessed online 3/23/2016 at:* http://www.cheesemaking.com/shop/animal-rennet-tablets-20-tablets.html

Human health concerns

According to the FDA, animal enzymes are GRAS based on their common use in food for a significant stretch of human history.[62,63,64] The amount of enzyme remaining in a finished food product is usually a trace amount, in part, because enzymes are "used up" in the process of making cheese.

Despite the recognition that these products are safe, **increasing allergies and food sensitivities make it important that all components (including ancillary ingredients) are listed on product packaging.** Comprehensive labeling is an important part of maintaining transparency and organic producers should be willing to identify both the enzymes and their source as well as any ancillary substances used in their enzyme preparations. While allergens other than the major food allergens are not subject to **Food Allergen Labeling and Consumer Protection Act of 2004** labeling requirements, it is always better to err on the side of caution with allergens as food allergies and sensitivities are becoming more common in the United States and in developed countries worldwide.[65,66]

Consumers may choose organic food, because they feel they are safer than the alternative, and it is important to maintain this trust for the organic label as a whole.
While the risk is low, from an occupational perspective, animal enzymes can cause skin and eye irritation.[67] Allergies toward enzymes can also develop, though this is usually more of a concern with enzymes used in industrial setting rather than through exposure in food.

CONCLUSION

The Cornucopia Institute **supports** the relisting of the 2018 Sunset material animal enzymes at 7 CFR §205.605(a). Animal enzymes do not pose a serious risk to human health or the environment and are essential for organic production of some varieties of cheese

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[62] Enzyme Preparations. U.S. Food and Drug Administration. *Available online:* http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/EnzymePreparations/default.htm
[63] 21 CFR 184.1685
[64] Guidance for Industry: Frequently Asked Questions About GRAS. U.S. Food and Drug Administration. December 2004. *Available online:* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm061846.htm#Q1
[65] Guidance for Industry: A Food Labeling Guide (6. Ingredient Lists). Federal Drug Administration. January 2013. *Available online:* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064880.htm#label
[66] About Food Allergy – Facts and Statistics. Food Allergy Research & Education. *Available online:* https://www.foodallergy.org/facts-and-stats
[67] Working Safely With Enzymes. Enzyme Technical Association. *Available online at:* http://www.enzymeassociation.org/wp-content/uploads/2013/09/Working-Safely-With-Enzymes-English.pdf

and other foods. As of yet, there are no direct alternatives to the use of animal enzymes, though **organic alternatives to animal and vegetable enzymes should be explored more fully before the next Sunset review**. **Requiring clear and honest labeling from organic producers will maintain consumer trust and protect individuals with food allergies and sensitivities.**

Calcium Sulfate - Mined

SUMMARY

The Cornucopia Institute is **neutral** as to the relisting of Calcium sulfate (mined) as a non-agricultural, nonorganic substance allowed as ingredients in or on processed products labeled as "organic" or "made with organic" under §205.605(a).[68] Given the potential environmental and human health effects associated with mining, The Cornucopia Institute **recommends that a new Technical Report be prepared to fully evaluate and discuss these concerns before the relisting proceeds.**

In addition, the relisting for Calcium sulfate (mined) should include an **annotation requiring that Calcium sulfate used as ingredients or in processed products come from sources with a low potential for environmental and human harm, based on the findings of a new Technical Report.**

Rationale:

- The use of Calcium sulfate is widespread and has a long history of being used in food products as a firming or coagulating agent and calcium supplement.
- Some alternatives may exist, but it is possible they will not result in a product consumers will accept. Calcium sulfate may be essential for producing particular tofu products.
- The environmental concerns associated with mining can be extensive and were not fully explored by the Handling Subcommittee.

DISCUSSION

Calcium sulfate, also known as **gypsum**, can come from a natural source or through chemical synthesis as an industrial byproduct. The listing currently up for Sunset restricts Calcium sulfate to *mined* sources. Naturally occurring deposits of gypsum are the primary source of mined Calcium sulfate; the United States has large deposits of gypsum which can be utilized for this purpose.

Gypsum is used in food products as a coagulant (particularly tofu), and in baking as a leavening and anti-foaming agent. It is also utilized as a source of dietary calcium in some foods. The FDA describes Calcium sulfate as an agent with many properties, including purposes as a firming agent (as for canned fruits and vegetables), anticaking, and as a stabilizer and thickener.[69] Gypsum's other uses are as a soil amendment, and as the main

[68] 7 CFR §205.605(a) *Non-synthetics allowed.*
[69] US Food And Drug Administration, Code of Federal Regulations Title 21: Calcium Sulfate, Revised April 1, 2009, US Food and Drug Administration. *Available online at*: http://www.befoodsmart.com/ingredients/calcium-sulfate.php#sthash.VfIxxFG9.dpuf

component in several types of building plaster and similar materials.[70] It is widely used in the manufacturing industry.

After mining, crude gypsum is ground and separated. During processing, any impurities are usually removed. Calcium sulfate is also produced as a by-product of other industrial processing applications. The National Toxicology Program released a review of Calcium sulfate in 2006.[71]

Past NOSB deliberations

The current Handling Subcommittee relied on TAPs from 1996 and 2001 to make their current recommendation to relist Calcium sulfate (mined). The Handing Subcommittee acknowledged that they were relying on information from the petition and the 2001 TAP review, both of which show that Calcium sulfate is consistent with organic criteria.
In the 1996 Technical Report, William A. Zimmer, DVM, was the primary reviewer of the material. In this review, he listed the uses as a soil amendment and as an animal feed. Calcium sulfate's use in food was discussed in relation to it being synthetic, noting that synthetic manufacture of the substance is required for its use in food in order to remove its impurities. The final recommendation of this 1996 report was to list Calcium sulfate as an **allowed synthetic.**

The 2001 TAP for Calcium sulfate was compiled by the Organic Materials Review Institute (authors: identities withheld by USDA). It focused on Calcium sulfate's use in tofu processing since that was the petitioner's described use. **This TAP is sorely out of date.** For example, the TAP states that there was no information on toxicology studies for Calcium sulfate from the National Toxicology Program. However, just such a report was produced in 2006.

The report explored in depth the effect of gypsum for different exposure mechanisms. Though this report deals primarily with non-dietary exposure to Calcium sulfate, the information contained is applicable to the risks to human health experienced in mining operations. This new information was not considered by the Handling Subcommittee.

The 2001 TAP review also discussed the cost-effectiveness of mining gypsum, when compared to getting the material from another source. Naturally occurring gypsum is an abundant mineral, but it is still a non-renewable resource in nature. If Calcium sulfate is essential to the production of some organic products, it would benefit the industry as a whole to keep apprised as to how Calcium sulfate is produced as a by-product and whether that by-product can serve as a food grade substitute to mined Calcium sulfate. Now, in 2016, the cost-effectiveness of mining versus using a by-product should be re-examined.

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[70] Gypsum (fact sheet). Mineral Education Coalition. *Last accessed online 3/24/2016:* https://www.mineraleducationcoalition.org/minerals/gypsum

[71] Chemical Information Review Document for Synthetic and Naturally Mined Gypsum (Calcium Sulfate Dihydrate). National Toxicology Program. CAS No. 13397-24-5. *Available online: http://ntp.niehs.nih.gov/ntp/htdocs/chem_background/pubnomsupport/gypsum1_508.pdf*

Although a different source of Calcium sulfate may not align with organic principles of handling, there may be options available now or in the future that pose less risk to environmental and human health. In particular, mining may no longer be the most sustainable approach. **A new TR is warranted: these options need to be explored.**

At the last Sunset review of Calcium sulfate in 2012, the NOSB stated that the "[*r]eview of the original recommendation, the 2001 TAP review, historical documents, the 2007 Sunset recommendation, and public comments do not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of this material.*" [72] In 2012 the NOSB voted to relist Calcium sulfate in §205.605(a) as follows: Calcium sulfate—mined. The final 2012 votes was: 15 yes, 0 no.

Ultimately, the current Handling Subcommittee recommended that the material be renewed unless they received new information from the public about human or environmental issues associated with Calcium sulfate. **There is enough new information available about the environmental and human health risks of Calcium sulfate that a new Technical Report should be prepared to comprehensively explore and evaluate the potential impact of using this material.**

Essentiality and alternatives

Some alternatives may exist to the use of Calcium sulfate in tofu and other organic products. These alternatives include, but are not limited to: vinegars, lemon juice, epsom salts (Magnesium sulfate), nigari (Magnesium chloride), and Glucono deltalactone.[73] Some of these alternatives are available in organic form.

However, Calcium sulfate is the most versatile coagulant for soy milk, producing a tenderer tofu. Other coagulants may impart a bitter flavor or undesirable texture to the end product that may discourage consumers. **For some products, Calcium sulfate may be an essential additive.**

Information on alternatives should be updated before Calcium sulfate is relisted. In the intervening years since the 2001, TAP new alternatives or processes comparable to the use of Calcium sulfate in tofu may have arisen. In addition, alternate sources of Calcium sulfate may be a viable or even preferable source of this product and this option needs to be explored.

[72] Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP). May 25, 2012. Calcium Sulfate: Listing at § 205.605(a) for Sunset 2013.
[73] For examples see: Tofu Coagulant Guide: What to buy and where to find it. Viet World Kitchen. October, 2012. *Last accessed online 3/25/2016:* http://www.vietworldkitchen.com/blog/2012/10/tofu-coagulant-guide.html

Environmental concerns

There are environmental concerns associated with the mining and refining of Calcium sulfate. ***Gypsum*** is produced commercially mainly from surfacing mining, as it is a sedimentary soft rock.[74] Some mining does occur in pit mines. Food-grade gypsum is usually taken from high quality deposits, but it can also be a refined by-product of industrial processes.

The potential environmental harm from mining operation can be extensive and were poorly explored in the 2001 TAP, and should be considered in more depth.

All mining operations generate waste. This waste must be discarded in some form, but is often deposited as tailings or as landfill. Depending on the content and treatment of the "leftovers" from mining operations, there are different environmental risks. Generally, mining waste causes problems with water pollution and, because gypsum is highly soluble, it mixes with water and washes away easily. For gypsum tailings, the most common risk is the salination of runoff, which can have catastrophic impacts on downstream ecology. [75] Sediments and dust from mine waste can also wash into waterways and disrupt sensitive riparian ecosystems. The Handling Subcommittee did not consider these issues when it reviewed mined Calcium sulfate.

Surface mining is also associated with habitat destruction and displacement of wildlife. Noise pollution and fugitive dust drift from drilling and blasting can extend the area of environmental effect far away from any mine. In addition, mining can lead to subsidence and ground collapse, which perpetuates the environmental damage long after mining in an area has ended.

There are environmental risks related to the processing of gypsum as well. The EPA noted that the processing of raw gypsum does release pollutants, mostly in the form of particulate matter released from the machinery used to refine the substance.[76] There are also emissions associated with gypsum mining from drilling and blasting.

Many of these environmental dangers associated with gypsum mining can be minimized by strict management. Rehabilitation of mines after mineral extraction can help return the preexisting ecosystems to a more natural state. Careful management of water resources and waste products is necessary to prevent serious environmental damage. However, **none of these protective measures are mentioned in the listing of Calcium sulfate.**

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[74] Gypsum (fact sheet). Mineral Education Coalition. *Last accessed online 3/24/2016:* https://www.mineralseducationcoalition.org/minerals/gypsum

[75] Mine wastes: characterization, treatment and environmental impacts, by Bernd Lottermoser. Springer Science & Business Media, Jul 9, 2010. *See* p. 74-88, 178.

[76] AP-42, CH 11.16: Gypsum Manufacturing. US Environmental Protection Agency. *Available online:* https://www3.epa.gov/ttnchie1/ap42/ch11/final/c11s16.pdf

Human health concerns and benefits

In the amounts typically found in food and supplements, Calcium sulfate isn't likely to cause adverse effects and is "generally regarded as safe" by the U.S. Food and Drug Administration.[77] In part, this is due to the extensive historical use of calcium sulfate in tofu and other coagulated foods.

The National Toxicology Program identified adverse health effects from gypsum when it is inhaled or makes contact with the skin or mucous membranes.[78] These risks apply to the workforce in gypsum mines where workers can inhale or otherwise be exposed to gypsum dust kicked up from drilling activity. Other harms associated with mining include injuries from blasting and drilling. The long-term human health effects include catastrophic subsidence of the ground above or surrounding old mines, which can cause fatalities and property damage. **All these human health risks from gypsum mining should be seriously and carefully considered before Calcium sulfate is relisted.**

Despite the risks of mining to human health, Calcium sulfate may play an important role in vegan and vegetarian diets. The addition of Calcium sulfate to foods including tofu provides a source of calcium for people that choose not to eat meat.[79] While there are many other plant-based sources of calcium that are highly digestible, consuming tofu is an easy way for vegans and vegetarians to meet this important nutritional requirement.

CONCLUSION

The Cornucopia Institute stands **neutral** on the relisting of Calcium sulfate (mined) because of environmental concerns that were not fully explored or updated in the Handling Subcommittee's review. We recommend that a new TR be requested in order to fully consider the environmental and human health risks of gypsum mining before Calcium sulfate is relisted.

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[77] 21 CFR §184.1230

[78] Chemical Information Review Document for Synthetic and Naturally Mined Gypsum (Calcium Sulfate Dihydrate). National Toxicology Program.) CAS No. 13397-24-5. *Available online: http://ntp.niehs.nih.gov/ntp/htdocs/chem_background/pubnomsupport/gypsum1_508.pdf*

[79] Calcium in the Vegan Diet, by Reed Mangels, PhD, RD. From *Simply Vegan*, 5th Edition. *Last accessed online at*:
http://www.vrg.org/nutrition/calcium.php

Carrageenan

Please refer to supplemental document.

Glucono Delta-Lactone

SUMMARY

The Cornucopia Institute **opposes** the relisting of Glucono delta-lactone (GDL) under §205.605(a) as an allowed *non-synthetic. This listing would be more compatible with organic principles of handling with* ***an annotation change including*** **the phrase "from a non-genetically modified source and method of production**."

In addition, Cornucopia suggests that ingredients labeling for GDL include a reference to the original source of the product. This makes it easier for those with food allergies to identify potentially allergenic ingredients and would increase trust in organic foods.

Rationale:

- GDL is a useful product in acidifying foods and is often used to impart desired qualities in silken tofu.
- Other coagulants are more readily available and work as well, if not better, in tofu including Calcium sulfate, Magnesium sulfate, nigari, and lemon juice. Calcium sulfate also imparts a silken texture rendering **GDL not essential**.
- GDL is a product of fermentation from sugars that are typically derived from corn or rice. **These sources could be products of genetic engineering**.
- Increasing prevalence of food allergies makes it important that the carbohydrate source of GDL and similar ingredients are listed on any packaging. This can be as simple as "Glucono delta-lactone (corn derived)" in a list.

DISCUSSION

GDL is currently a "Non-agricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic…"[80] The current annotation for Glucono delta-lactone reads: "Glucono delta-lactone—production by the oxidation of D-glucose with bromine water is prohibited."

[80] 7 CFR 205.605(a)

As the 2016 Technical Review states, GDL is primarily used in the production of tofu in the organic market. It is also used as an acidifying agent and preservative, leavening agent, and sequestrant.

GDL is created when gluconic acid is crystalized. Gluconic acid is naturally occurring in plants, fruits and other foods including grape juice and wine.[81] For commercial uses, GDL is usually prepared by microbial fermentation of a carbohydrate source. Corn is the major commercial source though rice is used as well.[82] **Because of this sourcing, it is likely that GDL is obtained from sugars or starches derived from genetically engineered crops.**

Technical Reviews

GDL was petitioned in 2002. **The 2002 TAP was compiled by OMRI (the names of the specific author(s) were withheld**).[83] One of the reviewers in this TAP noted that GDL should be derived from a non-GMO source and produced by fermentation with a microorganism. The final annotation did not incorporate the suggestion that the GDL be sourced from a non-GMO carbohydrate (for example, no glucose from GMO corn). At the time, there was little information about whether a market already existed for non-GMO sources of corn or rice, but because there are non-GMO varieties of corn and rice, development of this market was considered possible.

In 2016 another Technical Review was prepared by OMRI (the names of the specific author(s) were withheld). This Technical Review went into more detail about the alternatives available for silken tofu and GDL's other uses in organic food. This technical Review also acknowledged that "t*he starting materials, such as cornstarch or molasses that are necessary for production of Gluconic acid are agricultural products.*" These materials could come from a GMO source.

Additional information requested by NOSB:

1. *Is GDL being used in applications other than tofu production for organic processed foods?*
2. *If GDL was removed from the national list, are alternative tofu coagulants such as calcium and sulfate salts sufficient to produce all forms of tofu?*
   - Research shows that GDL is actually utilized more for how it imparts a certain texture to tofu than as a coagulant. As stated in the Technical Review, **other coagulants are more readily available and work the same if not better for that purpose in tofu.**

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[81] Glucono-delta-Lactone (GdL) A natural way of leavening. Jungbunzlauer. October/November 2008. *Available online:* http://www.jungbunzlauer.com/fileadmin/content/_PDF/GdL_-_A_natural_way_of_leavening_Oct08.pdf

[82] Glucono Delta Lactone Is an All-Vegetable Ingredient. October 01, 2010. *Last accessed 4/10/2016 at:* http://www.vrg.org/blog/2010/10/01/glucono-delta-lactone-is-an-all-vegetable-ingredient/

[83] Glucono Delta-Lactone. NOSB TAP Materials Database Compiled by OMRI. *Available online at:* https://www.ams.usda.gov/sites/default/files/media/Glucono%20Delta%20Lactone%20TR.pdf

3. Should GDL produced from enzymes be prohibited or further restricted due to concerns around GMOs?

- **Yes, GDL produced from enzymes should be prohibited due to concerns about the use of microorganisms obtained by excluded methods** (genetically engineered).

Human health

GDL is generally considered safe by the FDA.[84] Since GDL occurs naturally in some foods (such as fruit juice), it is likely that this substance is not harmful to human health. In toxicology studies, GDL was found to have no effect on human health, though long-term effects of its consumption were not studied.[85]

Essentiality and alternatives

As a coagulant for tofu, there are many alternatives available on the market, including calcium sulfate, magnesium sulfate, nigari, and even lemon juice. However, while GDL is listed for its qualities as a coagulant in tofu, the focus is on how it imparts a softer texture to silken tofu. Apparently, this texture makes the silken tofu easier to work with and it is the primary reason GDL is used in these varieties of tofu. **However, some tofu "experts" note that Calcium sulfate is preferred, even for silken tofu, as GDL gives the tofu a Jello-like quality and does not impart the same flavor profile.[86] For these reason, GDL is non-essential.**

CONCLUSION

Cornucopia **opposes** the relisting Glucono delta-lactone (GDL) under §205.605(a) as an allowed *non-synthetic because, while it appears safe for human consumption and may impart desired qualities in some foods, it is* ***likely produced from a genetically engineered source product and it is not essential. A change to the annotation excluding GMO products would help*** *this problem and make GDL more compatible with the organic label if other commenters successfully show that GDL is essential. Finally, the carbohydrate sourcing of GDL should be identified so consumers with food allergies or sensitivities can easily identify possible triggers.*

[84] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=184.1318
[85] FAO Nutrition Meetings. Report Series No. 40A,B,C. WHO/Food Add./67.29. *Available online at:* http://www.inchem.org/documents/jecfa/jecmono/40abcj42.htm
[86] All About Silken Tofu: *An Interview with Andrea Nguyen. Accessed online 4/10/2016:* http://www.thekitchn.com/silken-tofu-an-interview-with-andrea-nguyenexpert-interview-171294

Tartaric acid

SUMMARY

The Cornucopia Institute **supports** the relisting of Tartaric acid under §205.605(a) *Non-synthetics allowed.* However, because this listing may discourage the use of organic Tartaric acid from organic grape wine, The Cornucopia Institute **strongly recommends the addition of an annotation specifying that the nonorganic form of Tartaric acid can only be used when the product is not commercially available in organic form.** This annotation would create an incentive for the utilization of Tartaric acid from organic grape wine, and would increase the commercial availability of natural Tartaric acid from organic sources (e.g.; organic grape wine) as well as provide an additional source of income to organic vintners.

Rationale:

- The current listing does not promote the use of Tartaric acid derived from organic grape wine.
- The current listing does not motivate the commercial production of Tartaric acid derived from organic grape wine or from other organic sources**.**
- The development of a sufficient commercial supply of Tartaric acid from an organic source would result in the delisting of Tartaric acid, the ultimate purpose of the National List.

DISCUSSION

Tartaric acid is a natural organic acid that is present in many plants, particularly in grapes, bananas, and tamarinds. It is also one of the main acids found in wine. Tartaric acid is used to create several different salts, including tartar emetic (Antimony potassium tartrate), cream of tartar (Potassium hydrogen tartrate), and Rochelle salt (Potassium sodium tartrate). The primary uses associated with Tartaric acid relate to its salts.[87]

Tartaric acid and its salts have a very wide variety of applications, such as acidulant, pH control agent, preservative, emulsifier, chelating agent, flavor enhancer and modifier, stabilizer, anti-caking agent and firming agent. It has been used in the preparation of baked goods and confections, dairy products, edible oils and fats, tinned fruits and vegetables, seafood products, meat and poultry products, juice beverages and soft drinks, sugar preserves, chewing gum, cocoa powder, and alcoholic drinks.[88]

Tartaric acid and related salts are particularly useful in baking. Tartaric acid is one of the ingredients, along with baking soda (Sodium bicarbonate), in baking powder. In a wet environment, as in a batter, Tartaric acid reacts with Sodium bicarbonate, producing

[87] https://www.thechemco.com/chemical/tartaric-acid/
[88] 2011 TR. Tartaric acid, lines 58-63.

Carbon dioxide and causing various baking products to rise without the use of yeast. This action alters the texture of many foods, and as such Tartaric acid is used in pancakes, cookies, and cakes mixes. Cream of tartar is used to make cake frosting and candies.[89] There are no sound alternatives to Tartaric acid in many baking applications.[90]

In the winemaking process, Tartaric acid is used to alter acidity. Tartaric acid is a natural component of grapes, which are commonly used in the production of wine. However, Tartaric acid is used to correct natural acid deficiencies in grape juice and wine and to stabilize the wine color by lowering the pH. In addition, Tartaric acid is used to enhance the flavor and mouthfeel of the wine. It is also used as a preservative, due to its antimicrobial properties. Furthermore, there are other wines, not made with grapes, which will need the addition of Tartaric acid to increase the acidity of the beverage.[91]

Tartaric acid is a critical component in winemaking and cannot, presently, be replaced with an organic alternative.[92]

Human and environmental health concerns

Non-synthetic Tartaric acid and its salts (i.e. Potassium acid tartrate, Sodium potassium tartrate acid) are classified as Generally Recognized as Safe (GRAS) by the US Food and Drug Administration (FDA).[93]

There are no known hazards to human health associated with the normal use of Tartaric acid. The effects (some irritation), due to acute accidental occupational exposure, are listed in Materials Safety Data Sheets (MSDS).

If disposed properly, it is unlikely that Tartaric acid would cause environmental damages. As an organic acid, accidental release of large amounts in the environment could alter the pH of aquatic and soil environments. However, Tartaric acid degrades rapidly (95% after 3 days) and is considered readily biodegradable and does not bioaccumulate.

Technical Reports and past NOSB deliberations

The 2011 technical review for Tartaric acid was compiled by **ICF International for the USDA National Organic Program (NOP). [the author(s) of the review were not disclosed]**

For the current Sunset review period, the NOSB has requested additional information:

1. The Handling Subcommittee requests public comment on the use of Tartaric acid

[89] 2011 TR. Tartaric acid, lines 69-74.
[90] 2011 TR. Tartaric acid, lines 429-431.
[91] 2011 TR. Tartaric acid, lines 76-82.
[92] 2011 TR. Tartaric acid, lines 437-440.
[93] 2011 TR. Tartaric acid, lines 307-310.

and its essentiality in organic processing.

CONCLUSION

The Cornucopia Institute **supports** the relisting of Tartaric acid under §205.605(a) *Non-synthetics allowed.*

However, because this listing may discourage the commercial development and use of Tartaric acid from organic grape wine, The Cornucopia Institute **strongly recommends** the addition of an annotation specifying that the nonorganic form of Tartaric acid can only be used when the product is not commercially available in organic form.

Cellulose

SUMMARY

The Cornucopia Institute is **neutral** on the relisting of cellulose under §205.605(b) (synthetics allowed) due to the non-specificity of the current annotation. The current annotation reads: "*Cellulose—for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.*" This annotation does not rule out the use of types of cellulose that have not been thoroughly investigated in Technical Reviews. Cornucopia **would support relisting if the annotation were changed to limit the types of cellulose used in organic handling to "amorphous powdered cellulose and inedible cellulose casing."** It is also essential that cellulose is refined from a sustainable source such as seed hulls or through recycling.

Rationale:

- Cellulose is the "woody" part of plant cells and has many uses in food processing. Some of these uses are essential for certain organic products such as organic juice, shredded cheese, and vegetarian processed meat products.
- The listing does not differentiate between the types of cellulose allowed in organic handling, leaving the use of the highly processed **microcrystalline cellulose available for use by handlers.**
- The sourcing of wood pulp for food grade cellulose may incentivize deforestation and planting pulp trees in what could be native habitat.
- Agricultural "waste" products (such as corn cobs and seed hulls) provide another source of food-grade cellulose which may be more sustainable than wood pulp and may be available from organic sources. Obviously, GMO sourcing would have to be explicitly excluded.

DISCUSSION

Cellulose is the fibrous casing around the cells of all plants. Food-grade cellulose is typically derived from wood pulp harvested for that purpose, though cellulose can come from almost any plant source, including "waste" products like corn cobs and soybean hulls. Cellulose is considered a synthetic material, because it must be refined through processing. The methods for refining cellulose are varied, but require some chemical inputs to separate and refine the cellulose from its source. The woody products are typically treated with strong acids or alkali substances to break the bonds between the cellulose and other plant constituents that bind them together.[94] Some forms of cellulose require more processing than others. The cellulose fibers are then removed and refined for various uses.

[94] Cellulose Products. University of California, Riverside. *Last accessed 4/6/2016 at:* http://www.faculty.ucr.edu/~legneref/botany/sugcellu.htm

The current annotation for cellulose in organic handling under §205.605(b) specifies particular *uses* allowed in organic handling. Food-grade cellulose is used in organic food, mostly to filter juices, as an anti-caking ingredient in shredded cheese, and to help form peel-able processed meat casings. Its uses outside of organic food are as a fiber "filler" to bulk up foods in place of fat and to add fiber for marketing purposes.

With respect to its uses in organic handling, there are few, if any, alternatives to cellulose. Alternatives that might exist (such as potato starch), do not provide the same qualities and may not be as innocuous toward human and environmental health. Combined with aids like diatomaceous earth, cellulose provides an effective and biodegradable filter. As for its use as an anti-caking agent, it appears to be essential for packaged shredded cheeses and is commonly used for that purpose.[95]

Microcrystalline cellulose is a chemically modified form of cellulose that has a structural change from its native form that differentiates it from other types of cellulose products.[96] **This form of cellulose can be used as an anti-caking component and so would not be prohibited from organic handling.**

Technical Reports and past NOSB deliberations

The first Technical Review for cellulose was completed in 2001. This review was prepared by OMRI **(the authors of the review were undisclosed).** The reviewers in the 2001 report made a specific recommendation regarding microcrystalline cellulose, a cellulose differentiated from other forms by its processing**:**

> *Incorporation of any form of microcrystalline cellulose into organic products should be prohibited. It is clearly a chemically modified form of naturally occurring cellulose. Microcrystalline cellulose has undergone additional hydrolysis with additional breakage of covalent Beta-1,4 bonds causing a complete structural and functional change from its native form. Therefore, it should be classified as a synthetic prohibited food additive.*

In 2001 the NOSB voted to list cellulose as a synthetic material approved for use in organic processing with the annotation it currently holds. No distinction was made between the source of the cellulose or how the cellulose was processed, including microcrystalline cellulose.

In May, 2012 the NOSB recommended that the annotation to cellulose be modified to read: "*Cellulose—for use in regenerative casings,* ***powdered cellulose*** *[emphasis added] as an*

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[95] From McDonald's To Organic Valley, You're Probably Eating Wood Pulp, by Allison Aubrey. National Public Radio, Morning Edition. July 10, 2014. *Available at:* http://www.npr.org/sections/thesalt/2014/07/10/329767647/from-mcdonalds-to-organic-valley-youre-probably-eating-wood-pulp

[96] Microcrystalline cellulose. Food and Agriculture Organization of the U.N.. *Available at:* http://www.fao.org/docrep/w6355e/w6355e0l.htm

anticaking agent (non-chlorine bleached) and filtering aid." [97] The USDA rejected this proposed annotation change for cellulose in 2013 without explanation.

In 2012 the NOSB also recommended that the NOP "*prohibit the microcrystalline form of this substance by specifying the forms that are allowed.*" [98] However, this recommendation was rejected by the USDA, despite several commenters supporting the NOSB's recommendation. The USDA stated that they needed to confirm that microcrystalline cellulose was not in use in organic processed products and would consider a restriction on its use for future rulemaking.

The second Technical Review was completed recently in 2016. This review was also prepared by OMRI. **The authors of the 2016 review were undisclosed.**

The 2016 TR only considered *two forms* that are currently permitted for use in organic processing and handling: amorphous powdered cellulose and inedible cellulose casing. The 2016 TR reviewers stated that microcrystalline cellulose was beyond the scope of the review. However, there is **no indication in the listing that microcrystalline cellulose is not allowed in organic handling.**

The Handling Subcommittee stated at the Spring 2012 NOSB meeting that certifiers and handlers provided information to show that the microcrystalline form was not used in organic handling and that, per conversations with the NOP, it was also determined that this form of cellulose was not allowed for use in organic handling. Despite these assurances, the annotation for cellulose does not put any restriction on the type of cellulose allowed in organic handling. **To avoid confusion among certifiers, handlers, and the public, the NOSB should recommend, once again, that the annotation specify the forms of cellulose that are allowed before re-listing.**

For the current Sunset review period, the NOSB requested additional information. Specifically:

1. Have there been any new sources for either a non-synthetic or an organic form of cellulose identified during this current Sunset cycle? If so please provide the NOSB with information on this source.
2. Are there any new or potential uses not covered by the current annotation that should be brought to the NOSB's attention? If so please explain.
3. Have there been any possible alternatives to any of the allowed uses for cellulose identified during this current Sunset cycle, and if so please provide the NOSB with their names and how they compare to the use of cellulose for the specific use.
4. What impact would the inclusion of the word "powdered" as part of the annotation have on your handling process? Should the NOSB consider bringing forth a separate proposal to make this change to the cellulose annotation?

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[97] Cellulose: Listing at § 205.605(a) for Sunset 2013. NOSB recommendation May, 2012. *Available at:* https://www.ams.usda.gov/sites/default/files/media/Cellulose%20Rec.pdf

[98] 78 FR 61154. Sunset renewal notice effective 11/03/13. Pp. 61158. *Available at:* https://www.gpo.gov/fdsys/pkg/FR-2013-10-03/pdf/2013-24208.pdf

- The term "powdered" would not prevent the use of microcrystalline cellulose or other forms not investigated in the reviews.

5. Could you help us to identify any ancillary substances that might be used with cellulose in organic handling or processing? The new Technical Evaluation Report mentions several potential ones for both powdered and the inedible form used in regenerative casings. Are any of these currently being used in organic handling and processing?

Human and environmental health concerns

While the FDA has not listed cellulose and its many iterations as GRAS, it is not considered a risk to the public. Cellulose is generally regarded as an inert component in food that is indigestible by humans.[99] This quality makes cellulose function like other fiber in the diet, and it is often added to foods to "bulk up" the product. While cellulose may not be toxic, it is not nutritive either.

The primary environmental concern for the use of cellulose is its sourcing. As the 2016 TR acknowledged there are issues with the harvest of trees for wood pulp. While the Handling Subcommittee states that recycling and the use of alternative crops will help to mitigate the impact, there is **no incentive within the regulations to rely on sources of cellulose that do not rely on logging.**

A more sustainable approach will be to obtain cellulose from cotton linters[100] or other agricultural sources, including corn cobs and soybean and oat hulls. Cotton is mostly cellulose and can be easily purified for this purpose. However, because cotton is such a high-value crop it is not usually utilized in food, but is, instead, used for textile purposes. Other agricultural sources could be considered a form of recycling, as grain and legume hulls and corn cobs are often considered a waste product (though they can be utilized as a filler in livestock feed or in other agricultural applications). The use of these agricultural products should always be the preference over wood pulp – especially where those waste products come from organic sources.

CONCLUSION

The Cornucopia Institute is **neutral** toward the relisting of cellulose due to the non-specificity of the current annotation which could allow for the use of **microcrystalline cellulose**. The NOSB, Technical Reviewers, and the public have requested that **microcrystalline cellulose not be allowed in organic handling and Cornucopia agrees.** The Cornucopia Institute would support relisting if the annotation were changed to limit the types of cellulose used in organic handling to "amorphous powdered cellulose and

[99] Select Committee on GRAS Substances (SCOGS) Opinion: Methylcellulose. Federal Drug Administration. *Available online:* http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/SCOGS/ucm260473.htm
[100] Sczostak A. "Cotton Linters: An Alternative Cellulosic Raw Material." JUN 30, 2009. DOI: 10.1002/masy.200950606. *Available at:* http://onlinelibrary.wiley.com/doi/10.1002/masy.200950606/abstract

inedible cellulose casing" and to add a preference that cellulose come from sustainable agricultural or recycled sources.

Potassium Hydroxide

SUMMARY

The Cornucopia Institute **supports** the relisting of Potassium hydroxide under §205.605(b) *Synthetics Allowed.*

However, **The Cornucopia Institute suggests that the NOSB include an annotation with a 5-year term limit on the use of Potassium hydroxide to peel peaches.**

This suggestion is made in consideration that one of the overarching principles of organic processing is the development of new, environmentally sensitive and functionally appropriate technologies to replace the ubiquitous use of synthetic food-grade chemicals in our food supply.[101]

It should also be noted that, in the past, prohibitions on products and processes were motivations for the organic industry to drive innovation and invention in order to replace the environmentally harmful practices often found on conventional farms and in processing facilities.[102]

Rationale:

- For certain applications, such as lye peeling of peaches, Potassium hydroxide is currently essential.
- There are several alternative approaches to peel peaches that are being developed; only one of them is now available commercially.

DISCUSSION

Potassium hydroxide (KOH) is currently allowed for use in in organic handling and processing as a synthetic non-agricultural (nonorganic) substance listed under §205.605(b) for use as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" with the following annotation: "prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches."

It is used as a direct food additive, formulation aid (i.e.; soap making), pH adjuster, cleaning agent, stabilizer, thickener, and poultry scald agent. The main food processing applications of Potassium hydroxide include uses as a pH adjuster, cleaning agent, stabilizer, thickener, fruit and vegetable peeling agent, and poultry scald agent. It is used in dairy products, baked goods, cocoa, fruits, vegetables, soft drinks, and poultry. The main foods processed

[101] 2001 TR. Potassium hydroxide. Lines 440-443.
[102] 2001 TR. Potassium hydroxide. Lines 404-406.

with Potassium hydroxide are chicken, cocoa, coloring agents, ice cream, and black olives. It is also used in the manufacturing of soap.

Human and environmental health concerns

Uses of Potassium hydroxide that are Generally Recognized as Safe (GRAS) by the US Food and Drug Administration (FDA) include use as a formulation aid, pH control agent, processing aid, stabilizer, and thickener.[103]

However, as summarized in the 2001 TAP review, this chemical is quite hazardous to human health:[104]

> The substance is highly corrosive and can cause severe burns of eyes, skin, and mucous membranes. Generally, studies and surveys regarding the toxicity of Potassium hydroxide are included with studies of Sodium hydroxide, and they are collectively known as 'caustics' or 'lye'. Lye poisoning results in numerous deaths annually, generally as accidents involving cleaners. Lyes are particularly penetrating and corrosive with tissue. This is due to the solubilizing reactions with protein, saponification of fats, and dehydration of tissue.

When Potassium hydroxide was first reviewed for inclusion on the National List in 1995, the NOSB recommended that it be prohibited for use in lye peeling of fruits and vegetables. At the time, the **main concerns regarding lye peeling related to the environmental effects of the effluent and other waste products**, as well as the belief that mechanical or non-chemical alternatives were available for most fruits and vegetables.[105]

A lye-peeling processing method **generates large amounts of potentially toxic waste** to be handled. Peach processing plants using lye peeling are generally restricted by state and local waste water treatment requirements, which has resulted in a limited number of plants and sites being operated.[106]

However, the environmental impact of the use of caustics in chemical peeling can be mitigated through careful waste water management practices. Documentation provided by the petitioner and corroborated by the local water treatment agency seem to indicate that this petitioner had developed an environmentally benign process that results in a potassium-rich, pH-neutral, treated effluent that is being returned to cropland with no negative impact on the local hydrology.[107]

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[103] https://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol3/xml/CFR-2011-title21-vol3-sec184-1631.xml
[104] 2001 TR. Potassium hydroxide. Lines 118-122.
[105] 2016 TR. Potassium hydroxide. Lines 129-137
[106] 2001 TR. Potassium hydroxide. Lines 165-172.
[107] 2001 TR. Potassium hydroxide. Lines 528-530.

Furthermore, **mitigation of the adverse environmental impacts of lye peeling and research on alternatives have become priorities for the food processing industry because of the adverse effects of caustic substances released into the environment.**[108]

Essentiality and Alternatives

The original 2001 TAP review indicated clearly that there were no viable alternatives to lye peeling of peaches, the 2016 TR does not add much to the information provided by the TAP review, but states:

> *"Other physical methods that are being explored include infrared, ohmic heating, and physical ultrasonics. While these are promising alternatives that may address the various problems caused by lye peeling, they are not yet considered commercially viable."*

Infrared dry peeling of peach is now commercially available[109], while enzymatic peeling of stone fruits is a promising approach currently being developed.[110]

Sodium hydroxide, listed at §205.605(b) with the annotation: "*prohibited for the use in lye peeling of fruits and vegetables, is a substitute for many uses of Potassium hydroxide."* Although more expensive than Sodium hydroxide, Potassium hydroxide is used in applications where sodium levels need to be restricted, and does not create salinity problems associated with excess sodium.

For specific applications, such as the peeling of peaches, the manufacturing of soaps, as a cleaning agent, formulation aid, black olive curing, poultry scald agent, and other applications where sodium is undesirable, Potassium hydroxide is currently still essential.

Technical Reports and Past NOSB Deliberations

Both the 2001 Technical Advisory Panel (TAP) review and the 2016 TR were compiled by OMRI; however. [the specific author(s) were not identified]

History

In 1995 the NOSB approved the addition of Potassium hydroxide to §205.605(b), with an annotation prohibiting its use in the lye peeling of fruits and vegetables. This restriction was based on concerns about the environmental effects of the waste products of the lye peeling process, and the fact that mechanical and non-chemical alternatives were available for most fruits and vegetables.

In 2001 a petitioner sought to expand the use of Potassium hydroxide by amending the annotation to read — "*prohibited for use in lye peeling of fruits and vegetables except when*

[108] 2016 TR. Potassium hydroxide. Lines 360-362
[109] http://www.catalyticdrying.com/application02.html
[110] Enzymatic peeling of apricots, nectarines and peaches. Lebensmittel-Wissenschaft und-Technologie. 36(2):215-221. Feb. 2003.

used for peeling peaches during the Individually Quick Frozen (IQF) production process." The 2001 TAP review for that expansion noted that: "T*he stone fruit (peaches, nectarines, and apricots) do not appear to currently have alternative methods available on a commercial scale to achieve peeling without the use of caustic substances.*"

The 2001 TAP review also noted that the environmental effects, which had originally resulted in the restrictive annotation, could be mitigated with the use of good wastewater management practices. Peach processing plants are generally restricted by state and local wastewater treatment requirements, and the natural acidity of the fruit and additional pH adjustments buffer the alkalinity of the wastewater.

Because no commercially viable alternatives are available, and processing practice mitigates the potential environmental effects, the NOSB approved the expanded annotation.

A new petition from the same petitioner was filed in 2011, seeking to expand the annotation again to allow the use of Potassium hydroxide to peel fresh peaches before canning. The petition confirms the lack of commercially viable alternatives for this use, and the mitigation of potential environmental impact. The processing of peaches for canning and freezing is identical up until the freezing or canning step.

Based on the petition, the 2001 TAP review, and the rationale of the 2001 NOSB, the Handling Committee supported the expansion of this annotation to allow Potassium hydroxide's use in the peeling of both IQF and canned peaches.

Accordingly, since canning and freezing are the primary processing methods commercially used for peaches, the NOSB full board favored removing the language regarding IQF methods so that the exception to the prohibition on lye peeling applies to all peach peeling.[111]

For the current Sunset review period, the NOSB has requested additional information:

1. The Handling Subcommittee requests public comment on the use of Potassium hydroxide and its essentiality in organic processing.

CONCLUSION

The Cornucopia Institute **supports** the relisting of Potassium hydroxide under §205.605(b) *Synthetics Allowed.* However, The Cornucopia Institute **suggests** that the NOSB put a 5-year term limit on the use of Potassium hydroxide to peel peaches, in order to motivate innovation by the organic fruit industry to find a viable alternative to lye peeling.

[111] All proposals. NOSB April 2016. https://www.ams.usda.gov/sites/default/files/media/ALL%20Proposals%20NOSB%20April%202016_0.pdf

Silicon Dioxide

SUMMARY

The Cornucopia Institute **supports the relisting of Silicon dioxide–Permitted as a defoamer. Allowed for other uses *when organic rice hulls are not commercially available*** under §205.605(b) *Synthetic allowed*. Silicon dioxide is primarily used as a defoamer and when organic rice hulls are not available, as an anti-caking agent, a filtering and tableting aid, as well as a processing aid for wine and beer, fruit and vegetable processing, and gelatin production.[112]

However, The Cornucopia Institute **strongly recommends that the annotation be changed** to the language originally passed by the National Organic Standard Board (NOSB): "**Permitted as a defoamer. Allowed for other uses when an organic substitute is not commercially available.**"

Rationale:

- The production of organic biogenic silica products from alternative sources has not been thoroughly investigated.
- The commercial availability of alternative organic biogenic silica products has not been thoroughly investigated and should be encouraged.

DISCUSSION

Silicon dioxide was originally listed owing to its unique properties, its overall safety profile, limited environmental concerns, and the lack of biogenic alternatives, whether organic or not.

In 2010 a petition was submitted to the National Organic Program (NOP) to remove the listing on §205.605(b), stating that a viable, non-synthetic, certified organic substitute to Silicon dioxide, derived from rice-hull material, was now commercially available. This alternative product possesses similar functional properties to Silicon dioxide as it is produced from rice hulls which naturally contain a high concentration of silica.[113]

This petition addressed concerns noted by the Handling Subcommittee (HS) during the 2010 Sunset review process as to whether or not "*applicable* alternatives exist for sufficient uses and applications of Silicon dioxide in organic handling."[114]

Nevertheless, the HS felt that the information provided by the petition was "still limited, not published from a third party source, and does not conclusively demonstrate its

[112] 2010 TR – Silicon dioxide. Lines 124-158
[113] https://www.ams.usda.gov/sites/default/files/media/Silicon%20dioxide.pdf
[114] https://www.ams.usda.gov/sites/default/files/media/Silicon%20D%20proposal.pdf

applicability in all products and processes."[115] Even though the petition was deemed insufficient to justify the removal of Silicon dioxide from 205.605(b), the HS wanted to acknowledge the availability of a natural alternative.

In 2011, the NOSB voted to annotate the listing of Silicon dioxide in order to recognize and encourage the use of organic rice hulls (and other non-synthetic substances) as an alternative for most uses of Silicon dioxide. The NOSB recommended the following annotation: "*Allowed for use as a defoamer. May be used in other applications when non-synthetic alternatives are not commercially available.*''

Instead, the NOP proposed and put into regulation the following annotation: "Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available."

The NOP justified this change as follows:

> *AMS understands that the intent of the NOSB's recommendation is to allow the continued use of Silicon dioxide as a defoamer and to require the use of a non-synthetic substance instead of Silicon dioxide when possible. To ensure clarity and consistency within the USDA organic regulations, AMS is proposing a modification to the NOSB's recommendation.*

The annotation in the final rule is less restrictive than the NOSB recommendation, and therefore allows the use of the synthetic Silicon dioxide in cases where there is a non-synthetic alternative other than organic rice hulls. This is contrary to OFPA §6517(d)(2).[116]

According to the 2010 Technical Review (TR), which was compiled by the Technical Services Branch for the NOP **[no author(s) listed]**, other plant materials could be utilized in the production of biogenic silica products.[117]

Handling Subcommittee Deliberations

The 2010 TR did not find the manufacture or use of Silicon dioxide to be harmful to people or the environment. The subcommittee questions whether silicone dioxide should remain on the list due to §205.600:

In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:

- The substance cannot be produced from a natural source and there are no organic substitutes.

[115] https://www.ams.usda.gov/sites/default/files/media/Silicon%20D%20recommendation.pdf
[116] "The Secretary may not include exemptions for the use of specific synthetic substances in the National List other than those exemptions contained in the Proposed National List or Proposed Amendments to the National List."
[117] 2010 TR – Silicon dioxide. Lines 438-448.

Additional information requested by NOSB:

1. Are there instances where due to lack of availability of organic alternatives, you must use Silicon dioxide?
2. Are there instances where the organic alternative does not perform the needed function and, therefore, you must use Silicon dioxide? If so, what are those functions? And, what has been the undesired result when Silicon dioxide was tried?

CONCLUSION

The Cornucopia Institute **supports the relisting of Silicon dioxide** in §205.605(b), with the recommendation that the availability of organic biogenic sources of silica products be further investigated.

In addition, the Cornucopia Institute strongly recommends that the annotation be changed in order to encourage the development and commercialization of alternative organic biogenic silica products: **Silicon dioxide – Permitted as a defoamer. Allowed for other uses when an organic substitute is not commercially available.**

Colors: β-Carotene Extract Color

SUMMARY

The Cornucopia Institute **opposes** the relisting of β-carotene extract color under §205.606(d)(2) derived from carrots or algae (pigment CAS# 7235-40-7).

Rationale:

- The Handling Subcommittee, based on the public comments made during the Spring 2015 NOSB meeting, recommended for the Fall 2015 NOSB meeting that Carrot Juice color be **removed from the National List because a sufficient commercial supply of organic carrot was believed to be available**.
- **Organic alternatives exist: the yellow to red carotenoid pigments from organic annatto could be used to replace beta-carotene extract color. Sufficient supplies of organic annatto are commercially available.**
- The solvents, vegetable oil, or ethanol, used to extract beta-carotene from carrots or algae are obtained from crops produced from **chemically intensive agriculture and are likely GMO**, both excluded methods in organic production.
- A form of nonorganic beta-carotene is derived from carrots grown using chemically intensive conventional agriculture.
- Past NOSB recommendations have not taken into account the impacts of chemically intensive agriculture.
- The beta-carotene pigment is a **highly concentrated extract,** from the root, which is **likely to contain high levels of pesticides residues** — Current research is lacking to determine possible impact on human health.
- Consumers expect organic food to be unadulterated – that is, without having its essential characteristics manipulated with the addition of nonorganic ingredients, whether to enhance flavors or colors.
- These materials are prohibited by the organic rules under §205.600(b)(4) – preservative, flavor and color enhancement, and creation of texture—therefore, they should be allowed to Sunset.

DISCUSSION

Colors in food products serve various purposes: to enhance appearance and attractiveness of the food, to ensure uniformity of color, to replace color that was lost during processing, to accentuate existing colors, to preserve flavor and protect light-sensitive vitamins.

The people who choose to eat organic food do so because organic production is supposed to guarantee that, in addition to producing more healthy food products, it minimizes impacts on farmworkers and the environment, including soil and water resources, wildlife, and beneficial insects.

Beta-carotene from carrots

In its August 2010 recommendation for § 205.606 Sunset review of Colors Derived from Agricultural Products, the NOSB stated:

> *"A review of the original petitions and recommendations, historical documents, and public comments does not reveal unacceptable risks to the environment, human or animal health as a result of the use or manufacture of these colors. There is no new information contradicting the original recommendation which were the basis for the previous NOSB decisions to list these colors. As §205.606 listed materials, all are subject to commercial availability scrutiny for use in organic products*."

Despite the NOSB's findings with respect to these colors, the Beta-carotene extract color is derived from carrots grown with conventional agriculture, **a chemically intensive** approach. Conventional agriculture uses many pesticides[118] and herbicides, toxic chemical compounds that negatively impact the greater environment, the farmworkers, the customers, due to residues, as well as **poison** and deplete the soil, affecting its ability to produce food over the long-term and threatening the survival of the human species.

In spite of the fact that the use of such substances is not compatible with a system of sustainable agriculture [§6518 m.7]**,** past recommendations have not taken into account the impacts of chemically intensive agriculture from which these materials are derived.

Beta-carotene extract color from algae

Beta-carotene is extracted from algae with hot vegetable oil or ethanol. It can also be extracted using carbon dioxide by supercritical fluid extraction (SFE), together with ethanol.[119] Both ethanol and vegetable oil are derived from crops (corn: sugar beet or soybean, canola: cotton) grown using chemically intensive agriculture, and which are likely to be GMO. Extraction with volatile solvents (such as ethanol) is a *prohibited method* in the organic regulations.

Human and environmental health concerns

Fruits and vegetables conventionally grown may contain pesticides, which are limited by pesticide tolerances for food products, as regulated by the EPA.[120] The FDA routinely monitors for pesticides residues on fruits and vegetables to ensure that food products (domestic or imported) comply with pesticide tolerance.[121] Whether or not the currently established pesticide tolerances reflect the recent advances in residue analysis

[118] http://www.beyondpesticides.org/organicfood/conscience/navigation.php .
[119] Colors – 2015 TR, pp 480-492
[120] Colors – 2015 TR, pp 689-690
[121] U.S. EPA. 2014. Pesticide Tolerances. Office of Pesticide Programs, U.S. Environmental Protection Agency. Available: http://www.epa.gov/pesticides/regulating/tolerances.htm

instrumentation, or provide an adequate protection to the public, is left for another discussion.

Beyond Pesticides' database shows that, while carrots grown with toxic chemicals show low pesticide residues on the finished commodity, there are 42 pesticides with established tolerances for carrots, 17 are acutely toxic creating a hazardous environment for farmworkers (35 California farmworker poisonings over an 18-year period), 38 are linked to chronic health problems (such as cancer), 13 contaminate streams or groundwater, and 42 are poisonous to wildlife.[122]

The 2007 Petition by the manufacturers of the conventionally grown colorants states that "***Because natural colorants are concentrated and very strong, they are used in organic food and beverage products at very low levels…"***[123]

This would imply, for example, that in order to extract color from carrot pulp, it would take a large amount of carrots to produce a small amount of colorant, thus the pesticide residues would become very concentrated.

The 2011 TR, compiled by the USDA Technical Services Branch **[no author(s) specified]** for the NOP, mentions the 1993 WHO toxicological monograph, in which the committee states that no toxicological data on vegetable extracts were available and concluded that there was no objection to the use of vegetable extracts as coloring agents, provided that the level of use did not exceed the level normally present in vegetables. The report further stated that "*implicit in this conclusion is that the extracts* ***should not be made toxic by virtue of the concentration of toxic compounds*** *(including toxicants naturally occurring in the vegetables) nor by the generation of reaction products or* ***residues*** *of a nature or* ***in such amounts as to be toxicologically significant****.*"

This is quite an interesting statement, yet the TR not only does not further expand on the possibility of toxic amounts of pesticides residues in vegetable extracts, nor does it discuss the possibility of the presence of pesticides residues in extracts from carrots grown by pesticide intensive agriculture.

It appears the NOSB has never considered the implication of concentrating extracts obtained from plants grown using a chemically intensive approach.

The 2015 TR, compiled by ICF International **[no author(s) specified]** for the NOP, mentions the possibility of finding pesticides residues on the fruits and vegetables used as sources of colors, **but does not address the possibility of high pesticide residue levels in concentrated fruit or vegetable extracts.** This is a logical and fairly straightforward

[122] http://www.beyondpesticides.org/resources/eating-with-a-conscience/choose-a-crop?foodid=10
[123] Petition for the Addition of NonOrganic Agricultural Substance to the National List Pursuant to Section 205.606. Page 3 – January 15, 2007.
http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5057458

consideration, fully supported by the industry's own admission as to the concentration of natural colorants.

The technical challenge posed by the presence of concentrated pigments has limited extensive testing. A search of the scientific literature suggested that natural **pigments interfere with pesticide residue analysis** and need to be separated/removed during the analysis process.[124] Therefore, the high levels of pigments in concentrated juice or vegetable extracts would likely create a significant interference and challenge to the analysis of pesticides residues. Perhaps this is why no-one seems to have undertaken such a project, in addition to the fact that the use of "natural" colors is still very limited, but actively growing.[125]

The main point is that no one seems to have looked at the potential accumulation and resulting high levels of pesticide residues in concentrated fruit and vegetable extracts and, thus, it would make sense to err on the side of caution until this possibility is further investigated and allow beta-carotene in §205.606 to Sunset.

Essentiality and alternatives

1. Is-there a need for "**organic enhanced food**" – that is food with added colors or flavors, which are manufactured "natural" derivatives of nonorganic crops?

§205.600(b)(4) states: "*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*." Natural colors are often destroyed or muted during processing of food, so colors, such as beta-carotene, are added to replace and improve the lost colors.

The TR states that "*colorants are added to consumable products for the sole purpose of enhancing the visual appeal.*"[126] This purpose is clearly not allowed under the organic regulations.

Consumers expect that organic food or its essential characteristics will not be modified with nonorganic ingredients (otherwise prohibited) added for non-essential purposes, such as enhancing appearance (color) or intensifying flavors**.** If consumers demand colors added to their organic food, these colors should be derived from organic fruits or vegetables.

2. Is the current supply of organic fruits and vegetables sufficient to provide the amounts of colorants needed by the industry?

[124] http://www.sciencedirect.com/science/article/pii/S0021967303005399
[125] http://naturesflavors.com/baking/organic-baking/organic-food-colors
[126] β-Carotene – 2011 TR, pp 438-445

Beta-carotene was petitioned by color manufacturers in 2007. No TAP was requested. The NOSB Handling Subcommittee rejected the petition to add this material to §205.606 stating: "*the petitioner did not provide credible information regarding the lack of supply of organic raw material, and the ability to process them as organic.*"[127] However, at the March 2007 NOSB meeting, the material was approved.

There were already questions as to the lack of supply of organic raw material in 2007 and, since then, the organic industry has grown steadily every year over the last 7 yearswhich has likely increased the supply of organic carrots.[128, 129] **A quick web search found that several sources of organic carrot extracts – used to obtain beta-carotene extract color – are readily available as organic vegetable juice concentrates**.[130,131] This demonstrates that organic agriculture can now fulfill some, if not all, the demand for beta-carotene.

Other sources of organic beta-carotene exist; the 2011 TR lists several vegetable resources rich in beta-carotene, such as the fruit of the oil palm. [132] The carotenes are extracted from the oil which contains beta-carotene, along with several other carotenes. Organic palm oil is commercially available.[133] Among the other potential sources of beta-carotene is sweet potato, commercially available in organic form.[134]

Alternatively, the yellow to red carotenoid pigments from organic annatto could be used to replace β-carotene extract color.[135] Sufficient supplies of organic annatto are commercially available and, as such, nonorganic annatto was removed from the National List in 2013.[136]

Materials should be removed from §205.606 if they can be supplied organically. And, of course, if these materials are allowed to Sunset, whether the organic production may or may not be sufficient, the demand will create a supply, a process stimulating growth and benefiting the organic industry and the economy.

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[127] https://www.ams.usda.gov/sites/default/files/media/Color%20Beta%20Carotene%202007%20Committee%20Rec.pdf
[128] http://www.ers.usda.gov/data-products/chart-gallery/detail.aspx?chartId=35003
[129] https://www.ota.com/what-ota-does/market-analysis
[130] http://www.fruitjuiceconcentrate.org/organic-carrot-juice-concentrate
[131] http://www.ariza.nl/products/concentrated-juices/organic-carrot-concentrate/
[132] β-Carotene – 2011 TR, pp 362-367
[133] Colors – 2015 TR, pp 786-791
[134] http://www.thepacker.com/fruit-vegetable-news/special-sections/Organics-try-to-carve-niche-in-NC-sweet-potato-business-282285571.html
[135] Colors – 2015 TR, pp 793-796
[136] USDA. 2011. Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP). Petition to Remove Annatto extract color. National Organic Program, Agricultural Marketing Service, U.S. Department of Agriculture. Available at: https://www.ams.usda.gov/sites/default/files/media/Color%20Annatto%20Extract%20Formal%20Rec.pdf

Handling subcommittee deliberation and vote

After discussing the history of beta-carotene, which was approved at the March, 2007 NOSB meeting, it was noted that the NOSB is in the process of reviewing the use of all marine plants currently on the National List, and will be requesting a limited Technical Report. Marine plants will be discussed as a separate item at the Fall 2016 meeting.

The NOSB is requesting additional information about beta-carotene:

1. Has there been any change in the ability of manufacturers to produce beta-carotene color from carrots using NOP compliant extraction methods?
2. Is this color necessary for organic processors?
3. Which species of algae are used and from where are they harvested?
4. If the typical species used are from the genus Dunaliella (as cited in the TR) is harvesting of these species of micro algae from the wild, certified wildcrafted, or cultivated?
5. When used as a color, is this material also a source of Vitamin A?

The Handling Subcommittee, based on the public comments made during the Spring 2015 NOSB meeting, recommended for the Fall 2015 NOSB meeting that carrot juice color be removed from the National List, because a sufficient commercial supply of organic carrots was believed to be available.

CONCLUSION

The Cornucopia Institute **rejects** the relisting of β-carotene extract color under §205.606(d)(2) derived from carrots or algae on the National List under §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

The Cornucopia Institute questions the essentiality of using a color from a nonorganic agricultural source, considering that colors from nonorganic fruit or vegetable sources **may contain significant amount of pesticide residues**, a human health threat. In addition, there appears to be **a sufficient commercial supply of organic sources of beta-carotene color** and of an organic alternative to beta-carotene color to justify the removal of beta-carotene from §205.606(d)(2).

PETITIONED MATERIALS

Lactates, Sodium and Potassium

SUMMARY

The Cornucopia Institute **opposes** the listing of sodium and potassium lactates on the National List under §205.605(b) *Synthetics allowed,* because they are not essential and more appropriate alternatives exist. In addition, their petitioned use is as synthetic preservatives and for color and flavor enhancement, a purpose prohibited by organic regulations under *§205.600(b)(4): The substance primary use is not as a preservative, color and flavor enhancement, and creation of texture.*

Rationale:

- The petitioned uses for these materials are prohibited by §205.600(b)(4) – preservative, flavor and color enhancement, and creation of texture—therefore they should not be added to the National List.
- A large percentage of the agricultural feedstock (corn or beet sugar) that is fermented to produce lactic acid may be **from conventional, GMO sources**, and the fermenting microorganisms may be genetically modified.

DISCUSSION

Sodium lactate and potassium lactate were petitioned for inclusion on the National List under §205.605 on January 5, 2004. On January 22, 2004 the NOP notified the petitioner (Applegate Farms) that the petitions were not necessary since the materials were combinations of materials already on the National List (i.e., lactic acid combined with Sodium hydroxide and lactic acid combined with Potassium hydroxide). Since the NOP's letter to the petitioner was released, both sodium lactate and potassium lactate have been allowed for use in organic processing. **It is not clear whether certifiers have allowed it just for meat production or for other applications as well.**

On June 25, 2014 the NOP issued a memorandum to the NOSB regarding the regulatory statuses of sodium lactate and potassium lactate. In that memorandum, the NOP acknowledged that the interpretation published on January 22, 2004, was not consistent with previous NOSB recommendations on classification of materials, and they requested that the NOSB take up the petitions for these two substances for consideration for inclusion on the National List (McEvoy 2014)[137].

Sodium lactate and potassium lactate are **produced by reacting natural (fermented) lactic acid with Sodium hydroxide, Sodium carbonate or Potassium hydroxide**,

[137] McEvoy, M. "USDA Agricultural Marketing Service." *National Organic Program.* January 25, 2014. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5108095

respectively. A reaction between an acid and a hydroxide is a **synthetic reaction** and the resulting compounds are **synthetics**. The literature does not suggest the existence of any non-synthetic forms of sodium lactate or potassium lactate.[138]

Sodium lactate and potassium lactate are often used to improve or enhance flavors and textures of food products. However, they are primarily used in meat products (including cured meats) due to their antimicrobial activity.[139]

They were petitioned for use as a **pathogen inhibitor** in processed meat. Sodium and potassium lactates are some of the few antimicrobial compounds accepted by the FDA that can replace nitrates/nitrites in meat products and are GRAS.[140]

§205.600(b)(4) states: "*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*." The inhibition of pathogens is a property displayed by preservatives. This indicates very clearly that the petitioned purpose for sodium and potassium lactate should not be allowed under the organic regulations.

Human and environmental health concerns

Lactate salts are GRAS, and pose low potential risk to human health. Their use in some applications can actually be beneficial to human health by reducing the risk of foodborne pathogens.[141]

Environmental hazards due to the manufacture or use of lactic acid or its salts are considered low. However, the conventional fermentation-based process creates a surplus of Calcium sulfate (gypsum) waste, the disposal of which can be problematic. Some of the current commercial uses for gypsum are in the manufacture of plasterboards and as a soil amendment, for which it is marketed by some of the manufacturers of lactic acid. Other lactic acid production processes are currently being investigated to enhance efficiency and productivity while diminishing waste production. [142]

Essentiality and alternatives

Sodium lactate and potassium lactate are mainly used as preservatives in meat products (primarily cured meats) for food safety reasons as they are important factors in the control of *Listeria monocytogenes, Clostridium botulinum, Salmonella, E. coli O157:H7* and other microorganisms[143] responsible for food-borne illness. Nitrates and nitrites are other preservatives commonly used in nonorganic cured meats, mainly for the control of *Clostridium botulinum* and to assist in the control of *Listeria monocytogenes* but are not

[138] 2015 TR – Lactic acid and lactates. Page 13, lines 611-615
[139] 2015 TR – Lactic acid and lactates. Page 14, lines 670-671
[140] 2015 TR – Lactic acid and lactates. Page 5, lines 171-179
[141] 2015 TR – Lactic acid and lactates. Page 17, lines 848-850
[142] 2015 TR – Lactic acid and lactates. Page 16-17, lines 770-805
[143] 2015 TR – Lactic acid and lactates. Page 17, lines 848-850

allowed in organic products (other than high nitrate-celery juice powder, obtained from specialized, conventionally grown varieties of celery plants specifically bred to handle high applications of synthetic nitrogen during their production).

However, **there are a variety of allowed natural products and organic products that could be used instead of lactates.** These include various organic acids, listed under 205.605(a), bacteriophages (listed under microorganisms) which are utilized as an antimicrobial to control bacteria during food processing. And, there are also some lactic acid cultures that have the ability to reduce naturally occurring nitrates to nitrites and have been used for over 100 years to cure meat, especially dry sausage. These cultures are used together with the aforementioned celery juice powder, a pseudo "natural" source of nitrates, to effectively control *Clostridium botulinum* and *Listeria monocytogenes*. Celery powder is available in organic form, although nitrate levels are typically lower in organic celery powder.[144]

Vinegar powder as well as other fruits powders (lime, lemon, cranberry, and cherry) and essential oils are all agricultural products available in organic forms that can be effective antimicrobials or can modify pH and are being actively investigated.[145]

Handling Subcommittee discussion and vote

A Technical Report (TR) for lactic acid and its salt was requested by the subcommittee in August, 2014 and was received in February, 2015. The TR was contracted to OMRI. **The identity of the author(s) is not specified in the TR and is unknown**.

The history and the use of sodium and potassium lactate was reviewed, and it was noted that the original petitioned use for these materials was in ready-to-eat meat and poultry products as a pathogen inhibitor, especially for use in controlling *Listeria monocytogenes*.

The subcommittee noted that The USDA Food Standards and Labeling Policy Book states:

> *It should be noted that meat products that contain sodium and potassium lactates can no longer be labeled as "natural" without a case-by-case assessment of what function these materials are serving in the product, and at what levels (USDA FSIS 2005).*

This is because the lactates are likely to be used as "chemical preservatives," rather than as flavors.

And finally, the Handling Subcommittee would like to know from organic handlers currently using these materials whether the proposed annotation would capture current use pattern, assuming that these two materials were added to the National List. The Handling Subcommittee is requesting an explanation as to why these substances would be preferred over currently used alternative materials or practices.

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[144] 2015 TR – Lactic acid and lactates. Page 18-21, lines 901-1032
[145] 2015 TR – Lactic acid and lactates. Page 21-24, lines 1041-1197

Subcommittee action and vote

Subcommittee votes
Motion #1. To classify both Sodium Lactate and Potassium Lactate as synthetic.
Motion by: Harold Austin
Seconded by: Ashley Swaffar
Yes: 7, No: 0, Absent: 0, Abstain: 0, Recuse: 0

Listing Motion:
Motion #2. To list Sodium Lactate and Potassium Lactate on section 205.605(b) with the following annotation: for use as an antimicrobial agent and pH regulator only.
Motion by: Harold Austin
Seconded by: Ashley Swaffar
Yes: 4, No: 1, Abstain: 2, Absent: 0, Recuse: 0

CONCLUSION

The Cornucopia Institute opposes the listing of sodium and potassium lactates on the National List under §205.605(b) *Synthetics allowed* for the petitioned purpose.

There are many alternatives to these substances, some natural and some organic agricultural as listed in the TR[146]; therefore these alternatives should be carefully considered by the NOSB when evaluating the listing of sodium and potassium lactates on the National List under §205.605(b) *Synthetics allowed*.

In addition, these compounds are used specifically for flavor enhancement and the preservation of meat, which is prohibited under §205.600(b)(4). [147]

[146] 2015 TR – Lactic acid and lactates. Page 21-24, lines 1041-1197
[147] 2015 TR – Lactic acid and lactates. Page 15, lines 720-732

Oat Beta-Glucan

SUMMARY

The Cornucopia Institute **opposes** the listing of Oat beta glucan to the National List for handling under §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Rationale:

- **Essentiality has not been demonstrated** by the petitioner.
- Its **production is not compatible with organic production** and handling.
- Oats, from which this substance is derived, are available in organic form in sufficient supply.
- Conventional oats are grown using chemically intensive agriculture. It is important for the NOSB to take into account the environmental and human health impacts of chemically intensive agriculture.

DISCUSSION

Oat beta glucan is being petitioned by manufacturer Tate & Lyle for addition on the National List at §205.606. It will be used to supplement fiber content in processed foods such as biscuits, cakes, breads, cereals, bars, soups, and smoothies.

Human and environmental health concerns

Conventional oats are grown by a chemically intensive agriculture, which was noted by the Handling Subcommittee in its discussion[148]:

> *The petition points out that oat beta glucan is used in handling, not crop production and thereby concludes that it has no effect on soil, crops, or livestock. The subcommittee however would like to point out that according to the USDA pesticide data program there are 7 pesticide residues found on conventionally grown oats.*

Beyond Pesticides' "Eating with a Conscience" database shows that oats grown with toxic chemicals show low pesticide residues on the finished commodity. There are 56 pesticides with established tolerances for oats, 20 are acutely toxic creating a hazardous environment for farmworkers, 52 are linked to chronic health problems (such as cancer), 14 contaminate streams or groundwater, and 48 are poisonous to wildlife.

[148] NOSB. April 2016. Proposals & Discussion Documents. https://www.ams.usda.gov/sites/default/files/media/ALL%20Proposals%20NOSB%20April%202016_0.pdf

Pollinator Impacts: In addition to habitat loss due to the expansion of agricultural and urban areas, the database shows that there are 19 pesticides used on oats that are considered **toxic to honey bees** and other insect pollinators. Although oats are not dependent on pollinators or foraged by pollinators, pesticides applied to the crop affect pollinators foraging on weeds in the field and plants surrounding the field.[149]

Essentiality and alternatives

The Cornucopia Institute believes that the petition fails in its discussion of oat beta glucan in regard to its essentiality to organic production and handling and because it could be manufactured from organic oats.

There is no demand for oat beta glucan, particularly grown using chemically intensive agriculture. In fact, oat beta glucan could be manufactured just as easily with organic oats, for which an international supply exists. The HS states[150]:

> *…the manufacturer Garuda International used to produce organic oat beta glucan but stopped doing so due to low demand.*

Oat beta glucan is incompatible with organic production and handling

It is unnecessary to add dietary fiber to a processed food if natural fiber is not removed. It follows that the use of oat beta glucan is contrary to §205.600(b)(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.*" This regulation codifies the expectations of organic consumers: the food they are buying is healthful because it is whole food grown in accordance with organic principles.

Handling Subcommittee deliberations and vote

The subcommittee sees no reason why oat beta glucan could not be manufactured organically.

Substance Fails Criteria Category: 2- Essentiality and Availability.
Comments: The Subcommittee felt that there were alternatives currently available and alternative sources for which these petitioned needs could be met.

Subcommittee Action & Vote, including classification proposal (state actual motion):

Subcommittee votes
Motion #1. To classify Oat Beta Glucan as agricultural
Motion by: Lisa de Lima

[149] http://www.beyondpesticides.org/resources/eating-with-a-conscience/choose-a-crop?foodid=85
[150] NOSB. April 2016. Proposals & Discussion Documents.
https://www.ams.usda.gov/sites/default/files/media/ALL%20Proposals%20NOSB%20April%202016_0.pdf

Seconded by: Ashley Swaffar
Yes: 4, No: 0, Abstain: 0, Absent: 2, Recuse: 0

Motion #2. To list Oat Beta Glucan at §205.606 of the National List
Motion by: Lisa de Lima
Seconded by: Jean Richardson
Yes: 0, No: 4, Abstain: 0, Absent: 2, Recuse: 0

CONCLUSION

The Cornucopia Institute **opposes the listing of Oat beta glucan on §205.606** because it appears non-essential, its use is not compatible with organic practices, and its production does not meet the criteria under OFPA of being free from health and environmental harm.

Hypochlorous Acid

Comments listed on pages 114-120

Sodium Dodecylbenzene Sulfonate

SUMMARY

The Cornucopia Institute **opposes** the listing of Sodium dodecylbenzene sulfonate (SDBS) at §205.605(b) as an allowed synthetic. This substance is **not necessary** for organic production and there are **unanswered questions about its safety for humans and the environment**.

Rationale:

- Essentiality has not been demonstrated by the petitioner and there are alternatives already permitted in organic handling.
- There needs to be more research as to SDBS's potential harm to human health and the environment before this material is added to the National List.

DISCUSSION

The petition was submitted by Ecolab, Inc. SDBS is being petitioned for use as an active ingredient (one of the active ingredients, the other is lactic acid) in **an antimicrobial** formulation. The specific application envisioned by the petitioner would be **for "treating fruits and vegetables** in the premises of organic food retail establishments." This use would essentially put SDBS **in the wash water for produce**.

The petitioner asserts that antimicrobial substances already allowed in organic handling, normally used for processing, do not fill the needs at the food retail level for raw and ready to eat fruits and vegetables.

Human and environmental health concerns

SDBS is not generally recognized as safe and more data is needed as to its potential impact on human health.[151] There is very little data available for either human health endpoints or exposure. As the Handling Subcommittee stated, it is known as a potential skin irritant, exposure may result in eye damages and inhalation exposure can result in irritation of the nose, throat, and lungs. SBDS can also contain contaminants.

[151] http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices

While the predicted use of SDBS is not *expected* to cause serious harm to the environment, some information exists regarding its potential toxicity to aquatic organisms.[152] Even if SDBS degrades quickly in the environment, aquatic organisms are particularly sensitive, and only a few hours of exposure can harm delicate aquatic species. In addition, SDBS is an antimicrobial agent and as such will always have an impact on the surrounding environment because it is intended to kill microbes.

Cornucopia agrees with Beyond Pesticides' sentiment that ***"[t]o the extent that organic producers must use antimicrobials, the choice must be made in favor of those that have fewer negative health impacts on workers and consumers, degrade quickly to non-toxic products, and do not pose environmental hazards throughout their life cycle."***

Essentiality and alternatives

There are many available sanitizing and disinfecting agents available for use in organic production, some of which are non-synthetic (including ethanol, l-lactic acid, Citric acid, and essential oils). These substances are considered among the "least hazardous" antimicrobial agents by the EPA and have been more thoroughly studied than SDBS.[153]

Handling Subcommittee deliberations and vote

The Handling Subcommittee determined that the substance fails the "Essentiality and Availability" criteria, one of the standards that a material must meet in order to be considered for addition to the National List.

Subcommittee votes:
Motion #1. To classify Sodium dodecylbenzene sulfonate as synthetic.
Motion by: Harold V. Austin IV, Seconded by: Ashley Swaffar
Yes: 7, No: 0, Abstain: 0, Absent: 1, Recuse: 0

Motion #2. To list Sodium dodecylbenzene sulfonate at §205.605 – Non-agricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" of the National List. Motion by: Harold V. Austin IV, Seconded by: Tom Chapman
Yes: 1, No: 5, Abstain: 1, Absent: 1, Recuse: 0

[152] Pesticide Action Network database Sodium dodecylbenzene sulfonate. *Available online at:* http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC33286
[153] Design for the Environment Antimicrobial Pesticide Pilot Project: Moving Toward the Green End of the Pesticide Spectrum. EPA. *Available online at:* http://www.epa.gov/pesticides/regulating/labels/design-dfe-pilot.html

CONCLUSION

The Cornucopia Institute **opposes** the listing of Sodium dodecylbenzene sulfonate at §205.605(b) as an allowed synthetic because it appears non-essential, as there are alternatives already on the National List, is potentially harmful to human and environmental health, and there is not enough data to determine if its use is compatible with organic practices.

Ancillary Substances Procedure

SUMMARY

The Cornucopia Institute **opposes** the Ancillary Substance Procedure proposal and maintains that ancillary substances must be reviewed and approved for each particular use. **Ancillary substances should only be allowed if they meet OFPA criteria.** In addition, Cornucopia agrees that defining terms for any policy document is needed. Cornucopia wholeheartedly **supports Beyond Pesticide's comments** and rationale on this issue.

Rationale:

- A definition section is needed to properly communicate any policy document.
- OFPA appears to demand that ancillary substances must gain approval for their use in organic products by requiring their listing on the National List of Allowed and Prohibited Substances (National List).

Background

Ancillary substances are those "other ingredients" added to materials found in organic foods to achieve some effect in those ingredients. They are added as preservatives, moisture adjusters, and even to control pests. In 2013 the NOSB adopted a policy recommending that all ancillary substances should be reviewed according to OFPA criteria.[154] The NOP supported these recommendations in general, agreeing that the individual ancillary substances did not have to be separately listed on the National List.[155] **Despite this decision, the Handling Subcommittee (HS) has simply been listing those ancillary substances known to be in use when they release material reviews.**

Now the HS is proposing to modify the policy, framing it as an additional set of criteria and procedures for Accredited Certifying Agents (ACAs) and suppliers of ingredients. The HS states that "*[i]f these are adopted and followed, there will not be a need for a separate ancillary substance proposal for each listing on the National List.*"

The proposal includes:

1. A definition of Ancillary Substance.
2. Criteria used to review ancillary substances that can be used by both the NOSB in initial review and ACAs in subsequent verifications.
3. Procedures for the NOSB to follow for those materials that may have ancillary substances to be reviewed.
4. (optional) Example of a standardized template for ACAs to determine compliance.

[154] https://www.ams.usda.gov/sites/default/files/media/NOP%20Handling%20Final%20Rec%20Ancillary%20Substances.pdf

[155] https://www.ams.usda.gov/sites/default/files/media/NOSB%20Memo%20Trial%20Process%20for%20Ancillary%20Substance%20Review.pdf

Handling Subcommittee vote

Motion #1. To adopt the proposal as stated above for the definition, criteria for compliance, and procedure for the review of ancillary substances was as follows:
Motion by: Zea Sonnabend, Seconded by: Jean Richardson
Yes: 6, No: 0, Abstain: 0, Absent: 2, Recuse: 0

DISCUSSION

The Cornucopia Institute's position on the HS's proposal is as follows:

Definitions

Cornucopia agrees that definitions are needed. In order for any new policy to be useful to those it affects, it must define the terms it uses. Cornucopia supports Beyond Pesticides' suggestions for definitions.

Ancillary substance review

With respect to the criteria used to review ancillary substances, **each ancillary substance must be approved for each particular use.** When the NOSB made its initial recommendation in 2013 it seemed to have good intentions. Though the NOSB did not take the preferred approach of listing ancillary substances on the National List, its recommendation, which required all ancillary substances to be reviewed according to OFPA criteria, was the next best thing. The HS proposal does not base the approval of ancillary substances according to the OFPA criteria and for that reason, the majority of this proposal should be rejected.

Particular problems with the HS proposal include:

- The proposal would allow new chemicals without review if they fall within particular "functional classes." This is contrary to the legal requirements, and in direct contradiction to the previous recommendation by the NOSB. Furthermore, its implementation would likely harm the integrity of the organic label. **The NOSB must not allow substances that have not been reviewed, even if they belong to a particular functional class.**
- The proposal would essentially grandfather all known existing ancillary substances into the same "functional categories" as unknown materials. Grouping materials in the same functional categories without complete reviews would disincentivize the production of ingredients compatible with the organic label.
- The proposal would promote the practice of "rubber stamping" ancillary substances that are currently in use.

CONCLUSION

Cornucopia **opposes** the wholesale adoption of the Ancillary Substances Procedure. The HS should reconsider the 2013 NOSB ancillary substances policy recommendation before adopting a new policy. All ancillary substances should go through review in order to determine whether or not they meet the OFPA criteria before they are approved.

ANNOTATION CHANGE – DISCUSSION DOCUMENT

Nutrient Vitamins and Minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.

SUMMARY

The Cornucopia Institute **supports** the annotation change for Nutrient Vitamins and Minerals under §205.605(b), **as suggested by the Handling Subcommittee (HS) discussion document under option #1 with respect to synthetic vitamins and minerals**. However, The Cornucopia Institute believes that non-synthetic vitamins and minerals should be subject to the same restrictions as synthetic ones.

Consequently, the Cornucopia Institute **opposes** option #2, the alternate annotation change also proposed in the HS discussion document that would allow non-synthetic and synthetic vitamins and minerals in products labeled "made with organic" or "organic".

Rationale:

- One of the reasons consumers choose organic products is that they expect their food to contain a full complement of vitamins and minerals and other isolated nutrients, as a result of organic agricultural production practices, not through supplementation.
- Non-synthetic vitamins and minerals may be extracted, from conventional feedstock, with synthetic solvents and may include synthetic ancillary substances.
- Any supplement, whether it is from non-synthetic or synthetic sources may consist of substances not naturally occurring in any food.
- Any supplement, whether it is from non-synthetic or synthetic sources may consist of substances not naturally occurring in a particular food.
- Supplementation with substances naturally occurring in specific food might be added at artificially high levels.
- Applying the same restrictions to non-synthetic and synthetic vitamins and minerals will ease ACAs regulatory burden in determining what label is appropriate for a given formulation.

DISCUSSION

Option 1 is a complex option. In order to clarify their meanings, annotations 1, 2, and 3 are summarized below. Option 1 would allow the following:

- **In food labeled "organic"**: **Synthetic** vitamins, minerals, and other isolated nutrients only when their use is required by law or to meet an FDA standard of

identity in which they are incorporated. **Non-synthetic** minerals (including trace elements) and vitamins identified as essential in 21 CFR 101.9.

- **In food labeled "made with organic":** Synthetic vitamins, minerals, and other isolated nutrients when their use is required by law or to meet an FDA standard of identity in which they are incorporated, **or identified as essential in §101.9**. Non-synthetic minerals (including trace elements) and vitamins identified as essential in §101.9.

- **In infant formula labeled "organic"**: **Synthetic vitamins, minerals, or other isolated nutrients** are not allowed. Non-synthetic vitamins and minerals as required by law as per 21 CFR 107.100 or §107.10.

- **In infant formula labeled "made with organic":** Synthetic **or** non-synthetic vitamins and minerals as required by §107.100 or §107.10.

Option 2 would allow synthetic vitamins and minerals, whether they are classified as essential in 21 CFR §101.9 or required as per §107.100 or §107.10, in both "made with organic" and "organic" food. Synthetic vitamins and minerals required as per §107.100 or §107.10 would be allowed in both "made with organic" and "organic" infant formula.

It is important to note that nutrients identified as "essential" in 21 CFR 101.9 are not required by law to be added to processed food. As stated, they have been identified as essential components of a healthy and complete diet, and should normally be provided by nutritious food, such as food produced by organic agricultural production practices.

In many instances, these materials are being added to processed food as a marketing strategy to enhance the perceived desirability of the so fortified product.

The current listing and annotation for "Nutrient Vitamins and Minerals" on the National List has resulted in the indiscriminate addition of synthetic nutrients to organic foods. For years manufacturers of processed conventional and organic food have actively promoted, with various health claims, supplementation with both synthetic and non-synthetic nutrients vitamins and minerals. In organic offerings the supplementation has been claimed to be legal because of their classification as "essential" as per §101.9.

However, only synthetic and non-synthetic nutrient additives that are required by the FDA to be added to a specific food should be considered necessary in the production of an organic version of that food.

Nutrient vitamins and minerals in food

The HS' proposed Annotation #1 [§205.605(b) Vitamins and Minerals, Synthetic. For Food – Mineral (including trace elements), vitamins and similar isolated ingredients a**re allowed only when their use is required by law or to meet an FDA standard of identity in which they are incorporated [emphasis added]** corresponds to the original NOSB intent

and to organic consumers expectations and perception that foods labeled as "organic" are more nutritious and contain fewer synthetic chemicals, such as synthetic vitamins and minerals.[156]

As stated by some members of the HS, allowing other uses of "essential" synthetic vitamins and minerals is a suitable use of the "made with organic" label. **However, this reasoning should also be applied to non-synthetic vitamins and minerals.** Organic consumers expect their food to be nutritionally complete, containing the necessary vitamins and minerals as a result of organic agricultural production practices (rather than supplementation). Applying the same rule to the addition of synthetic and non-synthetic vitamins and minerals would ensure that the only supplementation allowed in processed food labeled "organic" is required by law. In addition, this would simplify determination by the ACA as to whether the label is appropriate for a given formulation.

Nutrient vitamins and minerals in infant formula

Option 1 is unlikely to allow any infant formula to be labeled "organic," considering the requirements of §107.100 and given the difficulty of sourcing non-synthetic forms of some vitamins and minerals.[157] Therefore, the specification that non-synthetic forms of these substances can only be allowed in foods and formulas labeled "made with organic" seems appropriate.

In contrast with other foods, infant formula is an imitation product. Making formula involves attempts to render cow's milk or milk substitutes similar to breast milk. This requires adding nutrients that are potentially not optimal, adequate, or sufficient compared to human breast milk. This is a complex issue, as the making of such products is fundamentally not aligned with "organic" principles. Formula manufacturers have promoted, often irresponsibly (e.g.; Nestlé, resulting in a boycott), formula feeding over breastfeeding, which has led to conflicts with the pediatric community and other advocates of breastfeeding. [158]

Accepting as a tenet that infant formula is an artificial product, the principle that organic food derives its nutrients from organic production methods and processes does not necessarily apply. It may be argued that supplementation by vitamins and minerals as required by §107.100 is acceptable, since infant formula is intrinsically artificial. However, it certainly would not be appropriate to allow substances that are prohibited in other organic foods in organic infant formula.

Consequently, the adoption of option 1, or option 1 combined with the restriction that non-synthetic vitamins and minerals required by §107.100 or §107.10 be prohibited in "organic" food, would result in premium infant formulas being labeled as "made with organic". This does not prevent infant formulas from containing organic ingredients, it just

[156] 2015 TR, lines 814-816.
[157] 2015 TR, lines 442-459.
[158] https://en.wikipedia.org/wiki/Nestlé_boycott

prevents infant formulas containing any synthetic ingredients from being labeled “organic”.

This is important to note since, although recognizing its superiority, some women are not physically able to breast feed and need the best possible alternative options, while others sometimes do not have the social support system needed to make breast feeding feasible. The continued availability of infant formula produced with organic ingredients is imperative.

CONCLUSION

The Cornucopia Institute **supports** the annotation change for **Nutrient Vitamins and Minerals** under §205.605(b), as suggested by the HS discussion document under option #1 with respect to synthetic vitamins and minerals, **excepting** that non-synthetic vitamins and minerals should be subject, in so far as it is required by law, to the same restrictions as synthetic ones, because, when not required by law, supplementation of organic food, whether with synthetic or non-synthetic nutrients, should not be necessary, needed or “essential.”

Furthermore, the Cornucopia Institute **opposes** option #2, the alternate annotation change also proposed in the HS discussion document, which would allow everything in option #1 that is specific to food labeled “made with organic” in both food labeled “made with organic” and food labeled “organic.”

CROPS SUBCOMMITTEE

2018 SUNSET MATERIALS

Copper Sulfate

SUMMARY

The Cornucopia Institute **opposes** the relisting of Copper sulfate to §205.601 under the following listings:

§205.601(a)(3) Copper sulfate—for use as an algaecide 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.

§205.601(e)(4) 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.

Rationale:

- Copper sulfate contains arsenic, which rice accumulates.[159]
- Copper sulfate is toxic to aquatic animals, many of which provide biological control for algae, including Pacific tree frog tadpoles and bullfrog tadpoles.[160]
- Current Copper sulfate application rates on rice paddies harm other beneficial organisms, such as fish that eat mosquitos, pond snails, and Western toad tadpoles.
- Wetlands wildlife found in rice paddies are sensitive to copper. From the "Principles of Organic Production and Handling," adopted by the NOSB in 2001: **"Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity."** Copper sulfate is a broad-spectrum herbicide and pesticide that is not target specific. Its use for these purposes is not in line with OFPA.
- Alternative rice production systems include dryland drilling seed and transplanting seedlings. Both these methods are promoted by the National Academy of Sciences, ATTRA, and the International Rice Research Institute (IRRI) and would make algae and shrimp control unnecessary.

[159] http://agr.wa.gov/pestfert/fertilizers/FertDB/Product1.aspx
[160] EPA, 2007. *Aquatic Life Ambient Freshwater Criteria—Copper*, Office of Water. EPA-822-R-07-001

- Growers may be using the two 24-month annotations to apply Copper sulfate every year by alternating its use as an algaecide with its use as a pesticide.

DISCUSSION

In 2001 a petition was submitted to the NOP to expand the use of Copper sulfate in rice production as an herbicide to control algae and pesticide for tadpole shrimp control.[161]

Copper sulfate and fixed coppers used for plant disease control (§205.601(i)(2) and §205.601(i)(3)) were recently reviewed and relisted for Sunset 2017. The listings under review now are for copper used in aquatic rice production to control algae or tadpole shrimp (§205.601(a)(3) and §205.601(e)(4), respectively). Because Copper sulfate is used in aquatic systems, the current annotations include specific requirements for application rates.

Application as a pesticide can be timed with the lifecycle of the pest: tadpole shrimp. Tadpole shrimp are crustaceans, but they are similar to tadpoles in size, shape, color, and mobility. Adult shrimp deposit eggs individually on soil or at the base of plants. Eggs resist drying and remain viable for several years in unflooded soil, but require flooding to hatch. Most of the eggs hatch 1 to 3 days after spring flooding of the rice fields, but hatching may continue for 1 to 2 weeks. The young resemble the adults in less than 24 hours and develop rapidly through series of molts.

Tadpole shrimp feed on a variety of small animals and plants as they grow and molt. They cause losses in seedling rice stands by chewing off the coleoptiles, roots, and leaves of the seedling, and uproot seedlings with their digging and feeding activity. Tadpole shrimp also muddy the water when they dig to lay eggs, reducing light penetration and slowing the growth of submerged rice seedlings. Tadpole shrimp cause no injury once the rice leaves have reached the water surface and the roots are well established in the soil.

Copper sulfate affects the functioning of the surface-layer (epithelia) on tadpole shrimp and, as an algaecide, it disrupts peroxidase enzymes in plants. Many copper compounds may be used without additional synthetic inert ingredients. However, some formulated pesticide products may contain inert ingredients, in addition to copper as the active ingredient.[162]

Nine to eleven million pounds of elemental copper, in the form of Copper sulfate pentahydrate, are applied each year solely for algae and weed control.[163] Applied Biochemists Company estimates that 300,000 pounds of elemental copper in various forms

[161] McElroy B. 2001. Petition for copper sulfate in crop production – To add another annotation. California Certified Organic Farmers.
http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5067032&acct=nopgeninfo
[162] RED-Cu. 2009. Reregistration eligibility decision (RED) for coppers. U.S. EPA, May 2009.
http://nepis.epa.gov - enter search terms: RED Copper 2009
[163] CSTF: In support of the agricultural uses of copper, the 17-member Copper Sulfate Task Force (CSTF) was formed in 1986 to represent the interest of several registrants.

of complexed copper compounds are applied annually for algae and weed control.[164] The largest applications are for oranges, walnuts, grapefruit, almonds, tomatoes, and grapes. Non-agricultural uses of copper sulfate are many and include uses in the leather industry, petroleum industry, steel manufacturing, as a germicide, textile mordant, pigment production, electric batteries, electroplating coatings, copper salts, reagent in analytical chemistry, medicine, wood preservative, process engraving and lithography, ore flotation, synthetic rubber, and treatment of natural asphalts.

The Washington State Department of Agriculture fertilizer database reports that arsenic is found in many Copper sulfate products:[165]

Copper Sulfate Listing	Copper Content (%)	Arsenic Content (ppm)
Copper sulfate crystals Product #:0871-0001	25.0	3
Copper sulfate pentahydrate Product #:1815-0003	24.3	7.2
Copper sulfate pentahydrate Product #:1755-0006	25.0	100.0
Copper sulfate pentahydrate granular (organic) Product #:1665-0018	25.0	10.0

NOSB actions and deliberations

The most recent TR was completed in 2011 by the Technical Services Branch for the USDA National Organic Program. **Authors of this TR were not disclosed.** The TR did not discuss the potential for Copper sulfate to contain arsenic, or the volumes of research on upland rice production that does not require rice-field flooding.

Additional information requested by NOSB for the 2018 Sunset include:

1. Has there been any new information regarding the viability of alternatives to these uses of copper?
   - **There is new information available.** The NOSB should review the scientific studies done on the sustainability of upland rice production.[166,167,168,169,170]

[164] RED-Cu. 2009. Reregistration eligibility decision (RED) for coppers. U.S. EPA, May 2009. http://nepis.epa.gov - enter search terms: RED Copper 2009
[165] http://agr.wa.gov/pestfert/fertilizers/FertDB/Product1.aspx
[166] http://www.fao.org/fileadmin/user_upload/ivc/docs/uplandrice.pdf
[167] https://www.washingtonpost.com/lifestyle/food/rice-grown-in-maryland-farmer-sees-a-future-that-doesnt-involve-flooding/2013/12/16/e4b6ccee-523a-11e3-9e2c-e1d01116fd98_story.html
[168] http://diaryofatomato.com/2014/04/08/4-7-14-growing-duborskian-upland-rice-in-maine/
[169] http://www.sherckseeds.com/pages/2013/good-yields-for-rice-here-in-northern-indiana/

2. Have ACAs noticed any increase in baseline soil test values for copper and done anything about it?

CONCLUSION

The Cornucopia Institute **opposes** the relisting of Copper sulfate to §205.601 for use as an algaecide and for tadpole shrimp control, because application harms natural biological control and wildlife. Copper sulfate formulations are contaminated with arsenic which accumulates in rice, and alternative production practices prevent the need.

[170] http://irri.org/resources/publications/books/item/upland-rice-household-food-security-and-commercialization-of-upland-agriculture-in-vietnam

Ozone Gas

SUMMARY

The Cornucopia Institute **opposes** the listing of ozone to §205.601(a)(5) as a synthetic substance allowed for use in organic crop production. Cornucopia would **support relisting** if a new Technical Report were prepared that would convincingly establish that the use of ozone gas in irrigation systems is safe for environmental and human health, and that existing alternatives are less compatible with the tenets of organic production.

Rationale:

- Ozone is toxic to humans even in small concentrations.
- Ground-level ozone is considered a dangerous pollutant by the Environmental Protection Agency (EPA).
- There are alternatives available, though more research would need to be done to determine what materials are most compatible with organic agriculture.

DISCUSSION

Ozone is a gas composed of three atoms of oxygen. Ozone occurs both in the Earth's upper atmosphere and at ground level. **Ground level ozone is considered by the EPA to be a pollutant and health hazard**, and is usually created through chemical reactions. The EPA updated the ozone standards in 2015, but the 2008 standards are still in effect.[171] These standards set the maximum allowed concentration limits for ozone in outdoor air.
The Cornucopia Institute recommends the preparation of a new Technical Report to compare farmers' current methods of sanitizing drip lines with allowed synthetic materials for their overall compatibility with organic guidelines.[172] This new technical report should comprehensively cover all disinfectants/sanitizers by 1) determining which uses are required by law including those on the National List as restricted-use materials limited to those particular applications, and (2) reviewing more organically compatible methods for all other uses.

The Technical Advisory Panel review and NOSB action

The sole Technical Advisory Panel (TAP) for ozone gas for this use was **prepared in 2002 by OMRI [the names of the specific author(s) were withheld]**. In general, the TAP discusses how ozone is a powerful oxidizing agent and that ozone has the potential to react with many different substances. Ozone oxidizes pesticides, organic matter, and reacts with iron and most other materials.

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[171] Environmental Protection Agency: Setting and Reviewing Standards to Control Ozone Pollution. *Available online at:* https://www.epa.gov/ozone-pollution/setting-and-reviewing-standards-control-ozone-pollution#technical
[172] 7 U.S.C. 6517(c)(1) National List – Guidelines for prohibitions or exemptions.

The original petition was for the use of ozone as a weed control agent, but that use was rejected because it was determined that ozone would likely be released into the atmosphere. The NOSB recommended to list ozone gas with the annotation: "f**or use as an irrigation system cleaner only.**" [173] It was hoped that this annotation would address reviewers' concerns about the unknown effects ozone gas could have on farmworkers and ecologies downwind of ozone application, and the unknown effect ozone might have on beneficial microorganisms. However, a new Technical Report would investigate, among other things, how much ozone is released from typical irrigation treatment systems. What the 2002 TAP fails to discuss is whether alternative synthetic substances are superior to ozone gas with respect to their appropriateness in organic farming.

The Crops Subcommittee requests some additional information from the public. The Crops Subcommittee would like to know if ozone is currently in use for irrigation system cleaning. The subcommittee also asks certifiers, inspectors, and producers to provide feedback on whether or not ozone is listed on organic system plans and used in organic crop production, to help evaluate if it is still necessary for ozone to remain on the National List.

Essentiality and alternatives

The list of other sanitizers that could serve as alternatives to ozone gas includes: alcohols, chlorine materials, Copper sulfate, Hydrogen peroxide, Peracetic acid, soap-based algaecides/demossers, and Sodium carbonate peroxyhydrate (use prohibited in food crops).[174]

The Board should consider the comparative effects of these materials on human and environmental health, their essentiality in organic farming, the unavailability of wholly natural substitutes, and whether their use is consistent with organic farming ideals.[175]

Human and environmental health concerns

The EPA has determined that breathing ozone can trigger a variety of health problems, particularly for sensitive populations like children, the elderly, and people of all ages who have lung diseases including asthma.[176] Concentrations above 0.1 mg/L averaged over an 8 hour period may cause nausea, chest pain, reduced visual acuity, and pulmonary edema. An exposure to a concentration of greater than 20 mg/L of ozone for at least an hour may be fatal. In terms of chronic effects, ozone exposure may have deleterious impacts on the lungs and result in respiratory diseases. These effects are serious and the Crops Subcommittee should consider whether the use of ozone in the prescribed manner poses an acceptable hazard to farm workers.

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[173] 7 CFR § 205.601(a)(5)
[174] 7 CFR § 205.601(a)
[175] 7 U.S.C. 6517(c)(1) National List – Guidelines for prohibitions or exemptions
[176] Environmental Protection Agency: Ozone Pollution. *Available online at:* https://www.epa.gov/ozone-pollution

With respect to the environmental issues, ground level ozone can be harmful to sensitive vegetation and ecosystems.[177] Even though it disappears quickly in the surrounding environment, its oxidizing properties will change the chemical composition of most things it touches.

CONCLUSION

Cornucopia **opposes** the relisting of ozone to the National List at §205.601(a)(5). Before ozone gas is relisted a new Technical Review should be prepared to answer concerns regarding the potential impact of ozone on human and environmental health, to ensure its use is compatible with the tenets of organic production and to evaluate the possibility of safer alternatives.

[177] Environmental Protection Agency: Ozone Pollution. *Available online at:* https://www.epa.gov/ozone-pollution

Peracetic Acid

SUMMARY

The Cornucopia Institute **supports** the relisting of Peracetic acid under §205.601(a)(6)—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.

205.601(i)(8) 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.

However, The Cornucopia Institute recommends that **the NOSB subcommittees commission a TR** that (1) determines what disinfectant/sanitizer uses are required by law, and (2) comprehensively reviews the most organically compatible methods and materials to determine which disinfectants/sanitizers are best for specific purposes. If there are uses for which specific disinfectant/sanitizer materials are necessary, then the NOSB should include them on the National List, as restricted-use materials, and limit them to those particular applications.

Rationale:

- Peracetic acid is currently allowed under NOP regulations for use in crop production, livestock production, and organic handling. Recently, Peracetic acid was voted to be relisted for both the 2017 Sunset Review for the **livestock listing**, and the 2016 Sunset Review for the **handling listing**.
- Disinfection of equipment, seed, and asexually propagated planting material is a critical step in preventing cross-contamination of crops with bacterial and other pathogens. Peracetic acid is a safer alternative for this use than chlorine materials.
- The current annotation seems to indicate that Peracetic acid is an "inert" ingredient, but it is not listed in EPA's Inert Finder database.[178]
- The March, 2016 Technical Report by OMRI **[individual authors not disclosed]** did not incorporate information from recent EPA reviews.[179,180]
- EPA has efficacy data for Peracetic acid products that indicate strong effectiveness on hard surfaces questioning the need for chlorine compounds.[181]
- In its summary of human health effects, data for the peroxy compounds EPA finds:

[178] http://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:7:::NO:1,3,31,7,12,25:P3_XCHEMICAL_ID:2278

[179] http://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:7:::NO:1,3,31,7,12,25:P3_XCHEMICAL_ID:2278

[180] Summary of Human Health Effects Data for the Peroxy Compounds Registration Review Decision Document. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0546-0003

[181] http://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:7:::NO:1,3,31,7,12,25:P3_XCHEMICAL_ID:2278

"High concentrations of peroxy compounds [including peracetic acid and hydrogen peroxide] are … corrosive and can be acutely toxic and/or extremely irritating to the lungs and skin," therefore specific uses and use rates should always be annotated.[182]

- A new Technical Review was published after the Crops Subcommittee completed its preliminary review. It reveals that there are several distinct substances called "Peracetic acid," and that not all are permitted under NOP regulations.[183]
- The NOSB needs to take a comprehensive look at all sanitizers, their needs, and evaluate whether all needs can be met with materials that have low impacts on human health and the environment.
- Is Peracetic acid effective for all uses of chlorine? If Peracetic acid remains on the National List, can chlorine be eliminated from use in organic production?

DISCUSSION

Peracetic acid in organic crop production is used to disinfect equipment, seeds, asexually propagated plant materials, potting soil, and irrigation and pruning equipment. It is also used in Hydrogen peroxide formulations for fire blight control on the tree canopy. It is used in washing water as a bactericide and fungicide, specifically to help decrease *E. coli* O157:H7 and to treat harvested fruits and vegetables to reduce spoilage. Interest in the use of Peracetic acid for control of fire blight has increased with the recent removal of two antibiotics previously allowed to control the diseases on tree fruit.

Chemically, the term "peracetic acid" describes two substances. "Pure" Peracetic acid, described in the Merck Index, has the chemical formula $C_2H_4O_3$ (alternatively written CH_3CO_3H). In contrast, solutions of peracetic acid used as sanitizers are created by combining aqueous mixtures of Acetic acid (the acid in vinegar) and Hydrogen peroxide to form **an equilibrium solution containing Peracetic acid, Acetic acid and Hydrogen peroxide**. This equilibrium solution is the substance sold commercially as the sanitizer "peracetic acid." Adding a mineral acid catalyst accelerates the reaction. Peracetic acid is an unstable oxidizing agent, which is why it is such an effective sanitizer. **Most commercial peracetic acid solutions contain a synthetic stabilizer and chelating agent such as HEDP (1-hydroxyethylidene-1,1-diphosphonic acid) or dipicolinic acid (2,6-dicarboxypyridine) to slow the rate of oxidation or decomposition.**

Technical Reports and past NOSB deliberations

The Crops Subcommittee requested a new Technical Report for Peracetic acid, but it did not arrive before they submitted their comments for the Spring 2016 meeting. However, the new TR has been released, dated March 3, 2016. **Both the 2000 Technical Advisory Panel (TAP) review and the 2016 TR were compiled by OMRI; however. [the specific author(s) were not identified].**

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[182] Summary of Human Health Effects Data for the Peroxy Compounds Registration Review Decision Document. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0546-0003

[183] 2016 Peracetic Acid TR Crops. Lines 236-260 and Table 5.

Recently, Peracetic acid was voted to be relisted for both the 2017 Sunset review for the **livestock listing**, and the 2016 Sunset review for the **handling listing**.

In the December 2, 2011 NOSB recommendation for the 2013 Sunset review of Peracetic acid for the 2 Crops listings at §205.601(a)(6) and §205.601(i)(8), the Board clarified the annotation change from the 2009 recommendation and supported it. The original recommended annotation change was: §205.601(a)(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material. Permitted in Hydrogen peroxide formulations at concentration of no more than 5%. §205.601(i)(8) Peracetic acid—for use to control fire blight bacteria. Permitted in Hydrogen peroxide formulations at concentrations of no more than 5%. This annotation was later implemented by the NOP, but changed to a 6% limit, based on information provided during public comment stating the recommended 5% limit was too low compared to percentages in use at the time.

Additional information requested by NOSB:

1. Can organic crop producers or certifiers provide the full committee with any information that can explain why this material (or one of the alternative materials) is a better option for use, in organic crop production, for the listed allowed uses?

2. Has anything changed during the current Sunset cycle that would make this material no longer necessary for its intended uses for organic crop production? If so, please help to explain.

3. It would help the NOSB in the review of this material if we could get feedback as to whether the current annotation (at a concentration of no more than 6%) presents any unforeseen problems for organic stakeholders, certifiers, or for product formulation. Also, could you provide input as to whether or not this annotation is even necessary?

Human and environmental health concerns

Sensory irritation appears to be the most serious health concern.[184] The American Conference of Governmental Industrial Hygienists (ACGIH) has set new occupational exposure limits for Peracetic acid.[185] The National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL Committee) has established even more stringent limits.[186] A review from Ecolab, a member of the PCTF and manufacturer of

[184] Pechacek, N., Osorio, M., Caudill, J., & Peterson, B. (2015). Evaluation of the toxicity data for peracetic acid in deriving occupational exposure limits: A minireview. *Toxicology letters*, *233*(1), 45-57.
[185] http://potentcompoundsafety.com/2014/02/acgih-occupational-exposure-limit-peracetic-acid.html
[186] National Research Council (US) Committee on Acute Exposure Guideline Levels. Acute Exposure Guideline Levels for Selected Airborne Chemicals: Volume 8. Washington (DC): National Academies Press (US); 2010. 7, Peracetic Acid Acute Exposure Guideline Levels. Available from: http://www.ncbi.nlm.nih.gov/books/NBK220001/

Peracetic acid products, has come up with similar limits.[187] The review also stated: "Overall, there are notable deficiencies in the PAA toxicological dataset, particularly in regards to information gaps concerning chronic toxicity (e.g., carcinogenicity, mutagenicity/genotoxicity, reproductive/developmental toxicity, repeat-dose toxicity) and the fact that a large number of toxicity studies did not follow conventional testing methodology." Of note as well, anhydrous peracetic acid explodes violently upon heating.

Essentiality and alternatives

Non-synthetic alternatives to Peracetic acid sanitizers include vinegar, natural alcohols, citric acid, lactic acid and sodium bicarbonate. Unlike Peracetic acid, vinegar and alcohol are expected to have low efficacy in the presence of organic materials, but both have greater efficacy as a disinfectant than lemon juice (citric acid) and baking soda (sodium bicarbonate).[188,189] Alcohol is fast acting and effective against *S. aureus*, *Salmonella*, *Streptococcus,* and *Leptospira* and leaves no residuals.

There are also a number of synthetic substances allowed in the NOP regulations for use as disinfectants or sanitizers. These are synthetic alcohols (ethanol and isopropanol), chlorine materials (including Calcium hypochlorite, Chlorine dioxide and Sodium hypochlorite, electrolyzed water), Hydrogen peroxide, copper, ozone, and Sodium carbonate peroxyhydrate.

Another permitted use of Peracetic acid is in the control of the plant disease fire blight caused by *Erwinia amylovora*. Further research is needed to explore the potential role of Peracetic acid in fire blight control programs. In 2011 the USDA awarded federal funding to support the development of viable alternatives to antibiotics for fire blight control. Much research has been done to identify other controls for the disease that are both effective and compatible with organic regulations.

One possible biological control agent is a phage tail-like bacteriocin produced by *Serratia plymiticum*, called Serratine-P.[190] A company called AmebaGone supplies strains of amoebae that consume the fire blight pathogen, *E. amylovora*.[191] Other substances used for fire blight control are lime sulfur and fish oil, followed by the use of biological controls such as *Aureobasidium pullulans* and *Pantoea agglomerans.*[192] A webinar was recorded on March

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[187] Pechacek, N., Osorio, M., Caudill, J., & Peterson, B. (2015). Evaluation of the toxicity data for peracetic acid in deriving occupational exposure limits: A minireview. *Toxicology letters*, *233*(1), 45-57.
[188] Perry K and Caveney L (2011) "Chemical Disinfectants." In Veterinary Infection Prevention and Control, by Caveney, Jones, and Ellis, 129-143. John Wiley & Sons.
[189] Olson W, Vesley D, Bode M, Dubbel P, and Bauer T (1994) "Hard Surface Cleaning Performance of Six Alternative Household Cleaners Under Laboratory Conditions." *Journal of Environmental Health* 56(6): 27-31.
[190] Schoofs H, et al. (2002) Bacteriocin Serratine-P as a biological tool in the control of fire blight *Erwinia amylovora*. *Meded Rijksuniv Gent Fak Landbouwkd Toegep Biol Wet* 67(2) 2002:361-368.
[191] AmebaGone. AmebaGone; Pioneering Amoebic Biocontrol (2015) http://amebagone.com/about.php
[192] Johnson K and Temple TN (2015) Evaluation of non-antibiotic programs for control of apple fire blight. Department of Botany and Plant Pathology, University of Oregon.

17, 2015, discussing fire blight control options using several alternatives at specific stages during the fruit production cycle.[193]

Additional practices that can help minimize the spread of plant pathogenic diseases include disease resistant varieties, compost, crop rotations, and appropriate management of soil nutrients and water. Enhancing the diversity of soil microbial populations through the application of organic matter is known to provide competition to effectively suppress pathogen populations. Plant disease control practices must be tailored to the specific needs of the operation and monitoring climate and soil conditions as well as understanding the life cycle of the pathogen.

CONCLUSION

The Cornucopia Institute **supports** the relisting of Peracetic acid under §205.601(b) *Synthetics Allowed.* However, The Cornucopia Institute recommends that **the NOSB subcommittees commission a TR** that (1) determines what disinfectant/sanitizer uses are required by law, and (2) comprehensively reviews the most organically compatible methods and materials to determine which disinfectants/sanitizers are best for specific purposes. If there are uses for which specific disinfectant/sanitizer materials are necessary, then the NOSB should include them on the National List, as restricted-use materials, and limit them to those particular applications.

[193] Johnson K, Elkins R, and Smith T. "E-Organic." Non-Antibiotic Control of Fire Blight. March 17, 2015. https://articles.extension.org/pages/72567/non-antibiotic-control-of-fire-blight:-what-works-as-we-head-into-a-new-era

EPA List 3 – Inerts of Unknown Toxicity

"INERTS" LIST 3 SUNSET, NPE DISCUSSION DOCUMENT, LIST 4 UPDATE

The Cornucopia Institute supports the detailed testimony submitted to the NOSB by Beyond Pesticides that discusses the Sunset of List 3 "Inerts," the NPE discussion document, and the List 4 update.

In particular, Cornucopia urges the NOSB to:

- Move as expeditiously as possible in recommending an end to the use of endocrine-disrupting Alkylphenol ethoxylates (APEs), also known as Nonylphenol ethoxylates (NPEs). There are available alternatives.

- Fully and specifically review synthetic materials identified as "inert" or as other ingredients. This is a responsibility of the NOSB, not a responsibility that can be given to another agency lacking guidance for what materials meet OFPA criteria.

- Delist the List 3 "inerts". The NOSB previously voted in 2012 to place an expiration date of December 31, 2015 on these substances and this recommendation should be followed. Should the NOP continue to refuse to follow this motion, then the NOSB should be involved with a timely and initial review of these chemicals and any subsequent Sunset review of these chemicals.

Calcium Chloride

SUMMARY

The Cornucopia Institute **supports** the relisting of non-synthetic (natural) Calcium chloride on 205.602(c), **"**brine process is natural and **prohibited for use except as a foliar spray** to treat a physiological disorder associated with calcium uptake" because direct soil applications cause high chloride and high solubility concerns [emphasis added].

Rationale:

- Brine processed Calcium chloride is a mined natural substance of high solubility. Potential overuse could result in subsoil, surface water and ground water contamination with chloride, therefore the limitation on its use should be continued.

- As mentioned in §205.203(d)(3) Soil fertility and crop nutrient management practice standard. "*A producer may manage crop nutrients … in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients…*"

- In addition, the prohibition is necessary because natural sources of food-grade Calcium chloride should not be allowed as a postharvest dip due to chloride contamination of food.[194,195]

DISCUSSION

The Sunset of Calcium chloride is for its prohibition as a natural (non-synthetic) substance, and for its continued use as a foliar spray to treat a physiological disorder associated with calcium uptake.

This prohibition is in line with OFPA, in §205.601(j): "(*6) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or* ***chlorides are not allowed****. Soil deficiency must be documented by testing.*"

An updated TR was requested on Calcium chloride by the NOSB in 2011, but never received. The most recent TAP Review was completed by OMRI in 2001. **Names of individual scientists were not disclosed**, although in these older TAP Reviews, the reviewer's job titles and geographic locations were identified, but **not** the individual names (current TRs do not reveal the author's names or positions). **The Cornucopia Institute believes it is imperative that the names of the TR scientists are disclosed to identify**

[194] Hussain PR, Meena RS, Dar MA, and Wani AM (2012) Effect of post-harvest calcium chloride dip treatment and gamma irradiation on storage quality and shelf-life extension of Red delicious apple. *Journal of Food Science Technology* 49(4):415-426.
[195] Luna-Guzman I, Cantwell M, Barrett DM (1999) Fresh-cut cantaloupe: effects of $CaCl_2$ dips and heat treatments on firmness and metabolic activity. *Postharvest Biology and Technology* 17:201-213.

possible conflicts of interest and hold reviewers accountable for accuracy, as is the standard for all scientific publications.

All three 2001 TAP Reviewers stated that Calcium chloride is inappropriate for soil application given the high chloride content and high solubility. Two of the three reviewers suggested prohibiting all production uses except for foliar applications to correct nutritional deficiencies.

TAP Reviewer 2 did not see supporting evidence that the use of Calcium chloride as a foliar spray for calcium deficiencies was compatible with OFPA stating, "It appears that one of the reasons that calcium is deficient in the organs of certain fruits is that breeds of crops have been introduce to maximize fruit yield. If the deficiency is dependent on variety of fruit, would it behoove us to promote the use of varieties that do not exhibit the deficiencies?" (lines 423-425)

A petition was submitted in 2005 and again in 2015 to remove Calcium chloride from 205.602 with the following arguments:

1. Its allowance as a foliar spray is overly prescriptive. Modest application rates applied with the proper methods in irrigation water can supply calcium nutrients without significant soil or water contamination and with less salt burn to the crop foliage, particularly in sensitive vegetable and greenhouse crops.

2. The current annotation does not address the fact that chloride is an essential plant nutrient and can be deficient in some situations. In addition, some irrigation waters have almost no dissolved minerals (including chlorides and calcium), which can cause poor soil infiltration rates. Small amounts of calcium chloride added to irrigation water would be a very appropriate management choice to provide nutrients and improve the infiltration rate.

3. The limitations on Calcium chloride use are much more restrictive than the other mined natural chloride materials allowed in organic farming. The Potassium chloride annotation reads "*unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil*". Magnesium and Sodium chloride are not on the prohibited non-synthetic list, though they are also high solubility mined substances. Some consistency is needed in how these materials are listed.

As a result of the latest 2015 petition, the Crops Subcommittee has asked the following questions:

1. Is there any evidence that the prohibition is inappropriate?
   Yes, all three TAP reviewers stated that Calcium chloride is inappropriate for soil application given the high chloride content and high solubility.

2. What are the alternatives to the use "as a foliar spray to treat a physiological disorder associated with calcium uptake"?
   Calcium deficiencies are most frequently caused by a product of low transpiration of the whole plant because of water shortages. Plants are susceptible to such localized calcium deficiencies in dry periods because calcium is not transported in the phloem due to irregular irrigation. Slow transport of calcium throughout the plant can be due to poor uptake of calcium through the stem, or too much nitrogen in the soil. Adding organic matter to soils can help regulate soil moisture. Ensuring proper soil pH also helps calcium be available in a form the plant can uptake.

Essentiality and alternatives

In organic systems, nutrients are provided by the soil, and the farmer feeds the soil through natural organic and mineral materials. If additional nutrients are to be applied, it must be in concert with soil building practices that restore the soil balance naturally. These additives should be slow-release nutrients that do not contaminate soils or waterways with nutrients or added salts. Natural substitutes include limestone, gypsum, rock phosphate and bone meal.

Production practices can often eliminate calcium deficiencies. Acidic, sandy, or coarse soils often contain less calcium, but uneven soil moisture and over application of nitrogen and phosphorous can cause calcium deficiencies. In some cases, even with sufficient calcium in the soil, it is in an insoluble form and, therefore, unusable by the plant. Soils containing high phosphorus are particularly susceptible to creating insoluble forms of calcium.

Calcium deficiencies can often be rectified by adding lime to acidic soils (aiming at a pH of 6.5) and maintaining even soil moisture. Because of poor transport of calcium to low transpiring tissues, the problem cannot usually be cured by the addition of calcium to the roots.[196] Organic matter should be added to the soil to improve its moisture-retaining capacity.

There are currently 20 registered OMRI products and 10 WSDA registered products containing Calcium chloride for use as a foliar spray.

NOSB actions and deliberations

Non-synthetic Calcium chloride was originally not included on §205.601 or §205.602. The NOSB originally voted to allow Calcium chloride for use to control bitter pit in apples and as an emergency defoliant for cotton. Calcium chloride was subsequently petitioned and added to National List §205.602, as a non-synthetic substance prohibited for use in organic

[196] Bangerth F (1979) Calcium-Related Physiological Disorders of Plants. *Annual Review of Phytopathology* 17:97-122.

crop production with the annotation: “brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.”

Calcium chloride has historically not been allowed for direct soil applications due to high chloride and high solubility concerns, however 2005 and 2015 petitions for removal of the prohibition contests these concerns. In 2011 the NOSB voted Yes:14 No:0 in favor of keeping the prohibition and annotation due to potential overuse of Calcium chloride and resultant subsoil, surface water and ground water contamination. The recommendation was to retain Calcium chloride on §205.602(c).

CONCLUSION

The Cornucopia Institute **supports** the relisting of Calcium chloride to §205.602(c)**,** brine process is natural and **prohibited for use except as a foliar spray** to treat a physiological disorder associated with calcium uptake because Calcium chloride is inappropriate for soil application given the high chloride content and high solubility. All three TAP Reviewers agreed Calcium chloride should be prohibited for soil application.

PETITIONED MATERIALS

Ash from Manure Burning

SUMMARY

The Cornucopia Institute **opposes** the petition to annotate ash from manure burning at §205.602 (non-synthetic substances prohibited for use in organic crop production), with the annotation, "*except where the combustion reaction does not involve the use of synthetic additives and is controlled to separate and preserve nutrients*" because burning manure is incompatible with OFPA.

Rationale:

- According to the petition, poultry manure is sourced from concentrated animal feeding operations (CAFOs).
- Burning manure is not an appropriate method for recycling organic wastes, because the majority of the carbon goes into the atmosphere. This contributes to climate change and prevents the carbon from restoring soil with organic matter.

DISCUSSION

EnergyWorks BioPower, LLC submitted a petition to revise 7 CFR §205.602 (non-synthetic substances prohibited for use in organic crop production) (a), Ash from Manure Burning, to include the following annotation: "except where the combustion reaction does not involve the use of synthetic additives and is controlled to separate and preserve nutrients."

The petition states that EnergyWorks, "uses a staged thermochemical reactor to extract over 30 tons of minerals from 240 tons of egg-layer poultry manure each day." The petition also states that annotation approval will provide the following benefits:

1. Generate renewable electricity
2. Prevent excess nutrients in the environment
3. Increase development of similar commercial processing facilities in the US.

The facility sources poultry manure from CAFOs, dries it, and exposes it to heat and oxygen to achieve proper conversion of organic material into combustible biogas (where the primary goal of the process is denitrification). The mineral ash is then removed, cooled, tested, and sold.

Burning a material that is central to maintaining soil fertility and tilth in organic soils would be incompatible with organic production systems. Organic practices incorporate carbon in the soil. The petitioner's process destroys high-energy carbon molecules that are essential for feeding the soil microbiology. The petitioner does not consider carbon a "nutrient," and therefore devalues its presence in manure. While carbon may not be a plant

"nutrient," incorporating it back into the soil provides food for microbes, is essential to organic soils as humus, and helps combat climate change.

NOSB actions and deliberations

The Crops Subcommittee voted 5-0 against approving the petition to relist ash from manure burning during the 2017 Sunset review process based on the following rational:

> *Ash from manure burning was placed on §205.602 based on its incompatibility with organic production: "Burning these materials is not an appropriate method to use to recycle organic wastes and would not be considered a proper method in a manuring program because burning removes the carbon from these wastes and thereby destroys the value of the materials for restoring soil organic content."*

We agree with the Crops Subcommittee statement, "*Utilizing ash from manure burning in order to assist CAFOs in their reduction of environmental and human health contamination is not a compelling argument for consideration for addition to the National List.*"

The Crops Subcommittee did not request a TR, having determined that the continued blanket prohibition of ash from manure burning aligns with previous board recommendations. All past board recommendations have supported the prohibition of ash from manure burning.

The Crops Subcommittee determined that the annotation amendment fails the OFPA criteria and should not be added to the National List.

Subcommittee vote
Motion by: Carmela Beck
Seconded by: Colehour Bondera
Yes: 0, No: 5, Abstain: 0, Absent: 0, Recuse: 0

The motion failed, thus the Subcommittee supports retaining the existing prohibition of manure ash in organic crop production without the petitioned annotation.

CONCLUSION

The Cornucopia Institute **opposes** the petition to annotate ash from manure burning at §205.602 because burning manure is incompatible with OFPA.

Squid and Squid Byproducts

SUMMARY

The Cornucopia Institute **opposes** the petition to add "Squid and Squid Byproducts" as petitioned to §205.601(j) as plant or soil amendments, **but would support adding "Squid Byproducts" to the National List.** Squid byproducts are roughly 50% of squid catch and most organic farmers need added nutrients for growing starts. However, as the petition is listed, squid should not be included, as it allows for and encourages the additional harvest of whole squid for fertilizer.

Rationale:

- Considerable amounts of fish and squid processing byproducts are discarded each year.[197]
- Only "Squid Byproduct" should be allowed as fertilizer, because it is a waste product, whereas "Squid" may not be.
- Adding "Squid" to the National List encourages the additional wild harvest of squid for fertilizer.
- Canada, the EU, and IFOAM permit the use of fish **products** from sustainable fisheries in organic production. Japan permits the use of fish and squid **by-products** in organic production. Semantics are important here; we do not want to encourage the additional harvest of whole squid for fertilizer. Instead, recycling the waste product should be the only allowed use.

DISCUSSION

Shoreside Organics, LLC submitted a petition in April, 2015 to add "Squid and Squid Byproducts" to §205.601(j) As plant or soil amendments under (7) 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.for use as a fertilizer. The petitioner would like acid-adjusted "Squid and Squid Byproducts" to be categorized as fish products for use in organic production.

Squid and squid byproducts have been traditionally preserved by drying for both food and fertilizer use, dating back to the 1800's, when squid was shipped from California fisheries to Asian countries for calamari and fertilizer.[198] Squid byproducts make up 52% of the total body weight and include the squid ink, pen, skin, milt, liver, and viscera and are typically discarded as waste. Uses for these byproducts include food, medicine, fertilizer, and feed in aquaculture.[199]

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[197] Kristinsson HG and Rasco BA (2010) Fish Protein Hydrolysates: Production, Biochemical, and Functional Properties. *Critical Reviews in Food Science and Nutrition* 40(1):43-81.
[198] TR lines 62-65.
[199] Lian P, Lee CM, Park E (2005) Characterization of squid-Processing Byproduct Hydrolysate and Its Potential as Aquaculture Feed Ingredient. *Journal of Agriculture and Food Chemistry* 53(14):5587-92.

Squid byproducts are the starting ingredients in the production of enzymatically produced hydrolysates which have been used both as foliar sprays and soil amendments for propagating plants. In general, squid byproducts are chopped, heated, digested with natural enzymes, and stabilized with an acid such as Phosphoric, Sulfuric or Citric acid to prevent microbial growth.

Squid are commercially harvested using nets directly above spawning grounds during mating season. These harvests are primarily used for calamari. Fisherman target spawning squid because they die shortly after reproduction. There are several squid fisheries throughout the world and two main squid fisheries in the U.S., including the Atlantic coast for long finned squid and the Pacific coast for market squid. The U.S. Pacific squid fishery is managed by the CA Department of Fish and Game, the National Oceanographic and Atmospheric Administration (NOAA) Fisheries, and the Pacific Fishery Management Council. Atlantic squid are managed in federal waters by NOAA Fisheries, in conjunction with the Mid-Atlantic Fishery Management Council. Management includes seasonal catch limits, timed fishery closures, administration of permit issuance, and limitations on using lights to attract squid to ensure uninterrupted spawning.

Squid are littoral invertebrates classified into the phylum Mollusca, class Cephalopoda and order Loligo (later renamed Doryteuthis). There are an estimated 300 squid species known throughout the world. Common to the northeastern Atlantic coast is the longfin squid, species *Doryteuthis (Loligo) pealli*. Common to the U.S. west coast is the market squid, species *Doryteuthis (Loligo) opalescens*.

The Canadian Organic Standard allows for the use of squid under "fish products" because in Canadian fisheries, the definition of fish includes marine invertebrates such as squid. The EU Organic Standard allows the use of molluscan (squid) products from sustainable fisheries and may be used in organic production of feeds for non-herbivores. The Japanese Organic Standard permits the use of food industry byproducts of "fish origin" if they are derived from natural sources; mollusks (squid) are included in Japanese fisheries. IFOAM permits the use of fish and shell products and food processing of animal origin.

Harm to the environment

While some liquid squid products are made from squid waste, others are made from whole squid.[200] Squid that do not have commercial value may have ecological value.[201] Use of discarded squid parts as fertilizer may also remove food from marine ecosystems.[202] According to the Technical Review completed by the Agricultural Analytics Division of USDA's AMS **[authors unknown]**.[203]

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[200] Petition, #B.5.
[201] http://discovermagazine.com/2001/sep/featfish/?searchterm=menhaden.
[202] http://www.scotsman.com/news/environment/ban-on-fishing-discards-may-damage-ecosystem-1-3408818.
[203] TR lines 727-733.

Illegal, unreported, and unregulated (IUU) fishing is a significant problem that affects the marine ecosystem and those who depend on it for survival. Illegal and unreported catches represented 20–32% by weight of wild-caught seafood imported to the U.S. in 2011. The value is between $1.3 and $2.1 billion of $16.5 billion total for 2.3 million tons of edible seafood imports, including farmed products. An estimated 10-15% of squid caught by fisherman from China, 10-20% from Chile, 15-30% from Thailand, and 20-35% from India are illegal and unreported.

Liquid fish products are acidic, and too strong a solution can burn plants.[204] Squid products may also contain persistent, bio-accumulative toxic chemicals that can affect crops and livestock over the long term.[205]

Essentiality and alternatives

Other natural materials that could substitute for synthetic squid products are manure, compost, aquatic plant products, blood meal, bone meal, compost, feather meal, kelp meal, guano, and other non-synthetic animal or plant products.[206] Other practices include cover crops, crop rotations, and the application of plant and animal materials.[207] However, organic fertilization of transplants currently heavily depends on fish products.

In organic systems, nutrients are provided by the soil, and the farmer feeds the soil through natural organic and mineral materials. If synthetic nutrients are to be used at all, it must be as an exception and in concert with soil building practices that restore the soil balance naturally. From the TR:[208]

> *"Fertilizers produced with squid and squid byproducts and acidified with phosphoric acid are effective in providing essential nutrients to soils when compared to synthetic commercial fertilizers. However, it has been observed that they are no more environmentally friendly than other organic fertilizers or synthetic fertilizers, rather they have been found to have a similar risk of NO^3—N and PO—P leaching to that of liquid or granular synthetic fertilizers applied at rates up to 292 kilograms per hectare per year. Leaching of PO^4—P can promote eutrophication, toxic algal blooms, loss of dissolved oxygen and fish kills in aquatic ecosystems. NO^3—N leaching into groundwater subsequently used as drinking water has been linked with thyroid disease, blue baby syndrome, and nitrosamine production (which can cause cancer)."*

[204] TR lines 660-663.
[205] TR lines 500-506; 531-536.
[206] TR lines 738-750.
[207] TR lines 779-781.
[208] TR lines 685-693.

NOSB actions and deliberations

The subcommittee recommends amending the current listing to read: Liquid fish and squid 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.

Classification Motion: Move to classify Squid & Squid Byproducts as synthetic. Motion by: Carmela Beck Seconded by: Zea Sonnabend Yes: 6 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Listing Motion: Move to list Squid & Squid Byproducts at §205.601(j) of the National List – with the annotation – 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. Motion by: Carmela Beck; Seconded by: Zea Sonnabend Yes: 6 No: 0 Absent: 1 Abstain: 0 Recuse: 0

CONCLUSION

The Cornucopia Institute **opposes** the petition to add "Squid and Squid Byproducts" as petitioned to §205.601(j) as plant or soil amendments, **but would support adding "Squid Byproducts" to the NL.** Squid byproducts are roughly 50% of squid catch and most organic farmers need added nutrients for growing starts. However, as the petition is listed, squid should not be included, because it allows for and encourages the additional harvest of whole squid for fertilizer.

Hypochlorous Acid

SUMMARY

The Cornucopia Institute remains **neutral** in the petition to list Hypochlorous acid at §205.601, 603, and 605. The petition states that this material is essentially already allowed because, **the already listed chlorine materials,** in the dilute aqueous form in which they are used, exist in solution as Hypochlorous acid. Therefore, the petitioner requests that the current listings for chlorine materials (Calcium hypochlorite, Sodium hypochlorite, Chlorine dioxide) be amended to include Hypochlorous acid**. Hypochlorous acid is also formed by the electrolysis of a Sodium chloride solution to make electrolyzed water, used for sterilization.** Electrolysis units sold for industrial and institutional disinfectant use and for municipal water-treatment are known as chlorine *generators*. These avoid the need to ship and store chlorine solutions.

The current listings for chlorine materials which generate Hypochlorous acid are Calcium hypochlorite, Sodium hypochlorite, and Chlorine dioxide for use as algaecides, disinfectants, and sanitizers, including cleaning irrigation systems. Chlorine materials are also listed for pre-harvest use, where residual chlorine levels in the water must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.[209]

We believe the NOSB and NOP should investigate **the potential elimination of the use of chlorine-based materials** and develop guidance for the adoption and appropriate usage of alternative materials and practices. **The NOSB subcommittees should commission a TR** that (1) determines what disinfectant/sanitizer uses are required by law, and (2) comprehensively reviews more organically compatible methods and materials to determine whether chlorine-based materials are actually needed for any specific purposes. If there are uses for which chlorine materials are necessary, then the NOSB should include them on the National List, as restricted-use materials, and limit them to those particular applications.

Although Hypochlorous acid is already allowed to be used under the current chlorine listings due to the chemistry involved, we ask that the **NOSB delay recommending the petitioned change until it performs a thorough review of all sanitizers/disinfectants and their uses**.

Rationale:

- Electrolyzed water produces Hypochlorous acid **and** Sodium hydroxide. **How is the sodium hydroxide currently used/disposed?**
- There are methods for manufacturing Hypochlorous acid in addition to electrolyzed water, including Sodium hypochlorite, Calcium hypochlorite, and other materials

[209] EPA. 2009. List of Contaminants & their MCLs. Available at: http://water.epa.gov/drink/contaminants/index.cfm#List.

not on the NL. **How will this listing ensure which forms of Hypochlorous acid are allowed?** For this reason, we recommend listing electrolyzed water instead of Hypochlorous acid.

- Hypochlorous acid from electrolyzed water has shown to be effective as plant disease control. It is unclear whether listing electrolyzed water as "Hypochlorous acid" will allow for this potential use or not and whether this use is in line with OFPA.
- Electrolyzed water has the potential to be an alternative to iodine teat dips, but the allowance for chlorine products in livestock production does not permit their use as a teat dip. Should electrolyzed water be used for teat dips?
- Chlorine materials are harmful to the environment. Disinfection with chlorine, hypochlorite, or chloramines results in the formation of carcinogenic trihalomethanes, haloacetic acids, and other toxic byproducts. Disinfection with chlorine dioxide produces undesirable inorganic byproducts, chlorite and chlorate. Calcium hypochlorite and Sodium hypochlorite are highly caustic and are a concern for occupational exposures. Chlorine dioxide is a severe respiratory and eye irritant, and inhalation of Chlorine dioxide can cause nose, throat, and lung irritation. **Electrolyzed water appears not to have these toxic byproducts associated with it.** Can these other chlorine materials be removed given electrolyzed water is a safer alternative?
- Potentially safer disinfectants exist including Citric acid, Hydrogen peroxide, L-lactic acid, ethanol, isopropanol, Peracetic acid, and ozone. The safest of these, Lactic acid and Citric acid, are both considered non-synthetic and are listed on §205.605(a) with no restrictions as to their use. **A TR is desperately needed to assess the best disinfectants in organic production and handling.**
- Certifiers should be cautious of the fact that electrolyzed water is often used as a base disinfectant solution and then "blended with a portfolio of proprietary additive formulas to create application-specific products for numerous on-farm applications including animal and premise hygiene and water purification." [210]

DISCUSSION

The electrolyzed water obtained after the electrolyze process contains Hypochlorous acid, hypochloride ions, melted oxygen, ozone, and super oxyde radicals and has a relatively strong oxidation potential with high antimicrobial activity. [211] This electrolyzed water has shown to kill bacteria, virus, fungi, and parasites quickly and can be used to disinfect surfaces and the water systems. But the effects of electrolyzed water on microbes is not long and depends on the half-life of metabolites, especially chloride. Presence of organic matter reduces efficacy as an antimicrobial. Therefore, stronger concentrations, longer

[210] Timms L (2013) Evaluation of Chlorine Stability in a Novel Teat Dip Disinfectant System. *Animal Industry Report* As 659:ASLR2801. Available at: http://lib.dr.iastate.edu/ans_air/vol659/iss1/52

[211] Yanik et al. (2015) An investigation into the in-vitro effectiveness of electrolyzed water against various microorganisms. *Int J Clin Exp Med* 8(7):11463-11469.

contact time, and combination with other substances that make it more effective are often considered.[212]

In May, 2015 the NOSB received a petition by Botanical Food Company Pty Ltd. to add Hypochlorous acid to the NL at §205.601, 603, and 605. Hypochlorous acid is being petitioned for use in the following areas:

1. On Farm
    a. As a post-harvest sanitizer for raw herb and spice material <60 ppm
    b. As an equipment and cold room sanitizer <200 ppm
2. In Processing plants
    a. As a post-harvest, pre-process sanitizer for herbs and spices <200 ppm
    b. As a microbial rinse for herbs and spices <60ppm
    c. As an equipment and room sanitizer <200 ppm

The petition was submitted in response to a policy memo issued by the NOP on June 9, 2014: 14-3 Electrolyzed Water (EW). The memo stated that any allowance of EW by a certifier or a material evaluation program was based on an incorrect interpretation of the allowance for chlorine materials on the National List. The NOP requested that certifiers ensure that the use of EW was not allowed in organic handling or production and that any party wishing for further consideration of EW for use in organic handling or production, should submit a petition to get it added to the National List.

The 2015 Technical Review was completed by USDA/AMS Agricultural Analytics Division [**authors were not disclosed].** Electrolyzed water is the product of the electrolysis of a dilute Sodium chloride solution in an electrolysis cell containing a semi-permeable membrane that physically separates the anode and cathode, but permits specific ions to pass through. In the process, **Hypochlorous acid**, **hypochlorite ion**, and **Hydrochloric acid** are formed at the anode, and **Sodium hydroxide** is formed at the cathode. The solution formed on the anode side is acidic EW (pH 2 to 6), and the solution formed on the cathode side is basic EW (pH 7.5 to 13). Neutral EW, with a pH of 6 to 7.5 is produced by mixing the anodic solution with hydroxide, or by using a single-cell chamber for electrolysis.[213]

The effectiveness of Hypochlorous acid as a sanitizing agent is determined, in large part, by the solution pH. Hypochlorous acid exists interchangeably with other chlorine species, including chlorine, Hydrogen chloride (aqueous and gaseous) and hypochlorite. In a controlled pH environment, Hypochlorous acid will exist as the dominant chlorine species under pH conditions ranging from 2 to 7.[214] At a pH of 6.0-7.5 (neutral), EW contains primarily Hypochlorous acid, hypochlorite ion and trace amounts of chlorine.[215] At pH <4.0,

[212] Yanik et al. (2015) An investigation into the in-vitro effectiveness of electrolyzed water against various microorganisms. *Int J Clin Exp Med* 8(7):11463-11469.
[213] TR lines 48-68.
[214] TR lines 84-89.
[215] TR lines 118-119.

dissolved chlorine gas is rapidly lost due to volatilization, decreasing the biocidal effectiveness of the solution over time, and also creating human health and safety issues.[216] Therefore it is important that neutral EW be used for sanitizing, not acidic EW.

Electrolyzed water has received recent attention as an alternative to other chlorine disinfectants and sanitizers. A number of studies have demonstrated the strong antibacterial activity of EW water against foodborne pathogens on raw agricultural products and food contact surfaces.[217] Applications of EW as a disinfectant for reducing microbial contamination have been reported for fresh fruits and vegetables, poultry carcasses, shell eggs, cutting boards, and food processing surfaces.

The TR states that some advantages of using EW water are: (1) EW is as effective as any chlorine treatment, (2) it is not necessary to handle potentially dangerous chemicals, e.g. chlorine gas, Chlorine dioxide, bleach, (3) the apparatus to produce EW is relative inexpensive and easy to operate, (4) because only water and Sodium chloride are used, EW production is environmentally friendly, and (5) the properties of the EW can be controlled at the preparation site.[218]

The concentration of chlorine present in electrolyzed water is usually over ten thousand times less than household bleach. Hypochlorous acid is the same active sanitizing ingredient that is present in Sodium hypochlorite and Calcium hypochlorite. The reason Hypochlorous acid can be ten thousand times less concentrated than sodium and calcium hypochlorite solutions and still be an effective sanitizer is that sodium and calcium hypochlorite solutions (bleach) have a high pH. When the pH is high, the Hypochlorous acid/hypochlorite chemical equilibrium strongly shifts towards the presence of hypochlorite, whereas at neutral pH the chemical equilibrium shifts towards the presence of Hypochlorous acid, the effective sanitizing compound. Therefore, the petitioner argues that Hypochlorous acid is a safer product, for the environment and for human health, than chlorine sanitizer materials currently on the National List.

Essentiality and alternatives

The NOSB should be looking at non-chlorine alternative disinfectants (other than the residual level in finished drinking water). Alternative materials that could potentially be substituted for chlorine materials include Citric acid, Hydrogen peroxide, L-lactic acid, ethanol, isopropanol, Peracetic acid, Copper sulfate, and ozone. Alternative practices include steam sterilization and UV radiation.

EPA's Design for the Environment (DfE) program has been investigating alternative disinfectants. A DfE label on a disinfectant means that the product meets the following criteria:

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[216] TR lines 150-152.
[217] Al-Haq MM, Sugiyama LJ, and Isobe S (2005) Applications of electrolyzed water in agriculture and food industries, *Food Sci Technol Res* 11(2):135-150.
[218] TR lines 99-108.

- It is in the least-hazardous classes (i.e., III and IV) of EPA's acute toxicity category hierarchy;
- It is unlikely to have carcinogenic or endocrine disruptor properties;
- It is unlikely to cause developmental, reproductive, mutagenic, or neurotoxicity issues;
- It has no outstanding "conditional registration" data issues;
- EPA has reviewed and accepted mixtures, including inert ingredients;
- It does not require the use of agency-mandated personal protective equipment;
- It has no unresolved or unreasonable adverse effects reported;
- It has no unresolved efficacy failures (associated with the Antimicrobial Testing Program, or otherwise);
- It has no unresolved compliance or enforcement actions associated with it;
- And, it has the identical formulation as the one identified in the DfE application reviewed by EPA.[219]

The EPA has approved the following for use as DfE disinfectant products: Citric acid, Hydrogen peroxide, L-lactic acid, ethanol, and isopropanol. DfE disinfectant product formulations and "inert" ingredients must also meet the DfE standard for safer cleaning products.[220] **All of the approved DfE disinfectant active ingredients are on the National List.** Citric and Lactic acids are considered non-synthetic, are listed under §205.605(a), and do not need to be listed in order to be used in crop or livestock production. In addition, the need for clean equipment must be distinguished from the need for disinfection, and disinfection is difficult to accomplish if a surface is not clean.[221]

Technical Reviews on chlorine have identified the following alternative materials: ethanol and isopropanol; Copper sulfate; Peracetic acid, for use in disinfecting equipment, seed, and asexually propagated planting material; soap-based algaecide/demossers; Phosphoric acid; and ozone. The TRs also identified two alternative practices: steam sterilization and UV radiation.[222]

Results of Cornucopia's certified organic livestock producer survey

In our latest survey of certified organic livestock producers, conducted in 2015, 39% said that they used Sodium hypochlorite on occasion to disinfect equipment and just one producer (out of 28 respondents) said they utilized Chlorine dioxide. **No one mentioned using Calcium hypochlorite.**

Of concern is whether or not certain livestock producers, namely dairy farmers, are required to use chlorine-based disinfectants in order to meet their milk buyers' requirements or state or federal laws (such as the FDA's pasteurized milk ordinance). Four

[219] http://www.epa.gov/pesticides/regulating/labels/design-dfe-pilot.html
[220] http://www.epa.gov/dfe/pubs/projects/formulat/dfe_criteria_for_cleaning_products_10_09.pdf
[221] Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf
[222] 2011 Crops TR and 2006 Livestock TR.

producers out of 28 (14.3%) mentioned that they were required to use bleach to disinfect their milking equipment. In at least one case state regulators specified they keep Clorox brand bleach in the milk house at all times.

Alternatives used by survey respondents include 2 using Peracetic acid, 1 using hot water pressure washing, and 1 using Super San peroxide-based disinfectant.

Previous subcommittee discussions and vote

In 2011, the Crops Subcommittee made a recommendation to relist chlorine compounds, with a change to the annotation of the following chlorine materials (Calcium hypochlorite, Chlorine dioxide, and Sodium hypochlorite): 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. For disinfecting or sanitizing equipment or tools or in edible sprout production, chlorine products may be used up to maximum labeled rates.

While there were concerns about the relisting of chlorine materials for 2017 Sunset, there are also specific requirements to use chlorine above the 4ppm SDWA limit in several commodity specific industries. For example, The Pasteurized Milk Ordinance states that the product-contact surfaces of all multi-use containers, equipment, and utensils used in the handling, storage, or transportation of milk shall be sanitized before each usage.

In 2016, the handling, crops, and livestock subcommittees all voted in favor of the petition to add Hypochlorous acid to the National List.

Subcommittee votes:
Motion #1. To list Hypochlorous acid at §205.605(b), chlorine materials.
Motion by: Ashley Swaffar, Seconded by: Jean Richardson
Yes: 6, No: 0, Abstain: 0, Absent: 2, Recuse: 0

Motion #2. To list Hypochlorous acid as petitioned at §205.603 of the National List (a) As disinfectants, sanitizer, and medical treatments as applicable. (7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act. (iv) Hypochlorous acid.
Motion by: Francis Thicke, Seconded by: Jesse Buie
Yes: 7, No: 0, Abstain: 1, Absent: 0, Recuse: 0

Motion #3. To list Hypochlorous acid at §205.601 of the National List: Synthetic substances allowed for use in organic crop production. §205.605(a) As algaecide, disinfectants, and sanitizer (2) chlorine materials (iv) Hypochlorous acid.
Motion by: Harold V. Austin IV, Seconded by: Emily Oakley
Yes: 7, No: 0, Absent: 0, Abstain: 0, Recuse: 0

CONCLUSION

The Cornucopia Institute remains **neutral** on the petition to list Hypochlorous acid at §205.601, 603, and 605 as an allowed synthetic substance until the NOSB commissions a TR that (1) determines what disinfectant/sanitizer uses are required by law, and (2) comprehensively reviews more organically compatible methods and materials to determine whether chlorine-based materials, including Hypochlorous acid are actually needed for any specific purposes. The NOSB and NOP should investigate the potential elimination of the use of chlorine-based materials and develop guidance for the adoption and appropriate usage of alternative materials and practices. The subcommittees must take into consideration the widespread environmental impacts and threats to human health posed by the manufacture, use, and disposal of chlorine. **Limitations on the use of chlorine should be clarified.**

Soy Wax

SUMMARY

The Cornucopia Institute **supports** the petition to add soy wax to §205.601 (o) as production aids, with the annotation, "must be made from non-GMO soybeans," and with **a 5-year expiration date** to encourage the production of organic soy wax.

Rationale:

- Soy wax, for use in mushroom culture, is more compatible with organic production than microcrystalline cheesewax, a petroleum-based product.
- Nature's Gifts International, LLC, a company that currently makes soy wax for this purpose, claims that it is made from domestically grown, non-GMO soybeans, but they are not USDA certified organic.
- The removal of microcrystalline cheesewax from the National List will be possible should there prove to be sufficient quantities of soy wax available.
- Soy wax should have an expiration date, because the current company that manufactures this material does not use organic soybeans and the process for making wax is synthetic (involving a chemical change). This is likely to change if there is market demand to do so.

DISCUSSION

Soy Wax was petitioned by Beyond Pesticides, a national grassroots, membership organization, to provide organic mushroom growers with a non-petroleum derived alternative to microcrystalline cheesewax for sealing inoculation sites. Mushrooms may be grown on logs without sealant, but the use of a sealant increases the chances of success by reducing parasites, competitors, and drying. The purpose of a wax sealant is to provide a physical barrier that preserves moisture and excludes competing fungi and other organisms from colonizing cut ends and holes in mushroom logs. Vegetable oils have been tested and found to be biodegradable. Beeswax is environmentally better, but it cracks in cold weather and attracts some insects and rodents.

The current synthetic alternative on the National List for this purpose is listed as:

> *Microcrystalline cheesewax -for use in log grown mushroom production. Must be made without either ethylene-propylene co-polymer or synthetic colors, listed at §205.601 (o) As production aids.*

The petitioned alternative, soy wax, is synthetic because it is made by hydrogenating soy oil (making it a solid at room temperature). Hydrogenation is the process whereby poly- and mono-unsaturated oils are solidified in order to increase viscosity, the same process used to make margarine. Soybean oil is heated to (140-225^{o} C) in the presence of a nickel

catalyst. Since hydrogenation causes a chemical change not produced naturally, soy wax is a synthetic substance.

Currently, soy wax is sold by Fungi Perfecti that is represented as being made from non-GMO, domestically produced soybeans; however, all soy wax is not necessarily non-GMO, so the suggested annotation "must be made from non-GMO soybeans" is necessary.

Soy wax is more compatible with organic and sustainable production than microcrystalline cheesewax and should be allowed to be used in organic mushroom culture. Should sufficient quantities of soy wax prove to be available, microcrystalline cheesewax should be removed from the NL.

A 5-year expiration date on soy wax would allow this listing to be further annotated in the future to require the use of organic soybeans, or to be removed in favor of a non-synthetic alternative. Because the NOSB's revised Sunset policy prohibits annotation at Sunset, these improvements are only possible with an expiration date. Under NOP's revised Sunset policy a full review at Sunset does not necessarily occur because the subcommittee may choose not to produce a delisting motion that would subject the material to full board review, and the material does not require a decisive vote in order to be relisted.

Given that the soy wax currently available comes from conventional soybeans and the process for making wax is synthetic, this material should not remain on the list indefinitely, as is likely under the revised NOP Sunset policy. Organic production operates on the premise of continual improvement, therefore this conventional soy-based material should receive comprehensive review in five years, according to OFPA criteria and standards.

NOSB actions and deliberations

Subcommittee Vote
Proposed Annotation: Must be made from non-GMO soybean oil.
Motion by: Francis Thicke
Seconded by: Colehour Bondera
Yes: 4, No: 0, Abstain: 0, Absent: 1, Recuse: 0

CONCLUSION

The Cornucopia Institute **supports** the petition to add soy wax to §205.601 (o) as production aids, with the annotation, "must be made from non-GMO soybeans," and with **a 5-year expiration date** to encourage the production of organic soy wax.

DISCUSSION DOCUMENT

Prohibition of Nonyl Phenol Ethoxylates (NPEs) in Inerts Annotation Change

Included in comments on page 103.

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