



**National Organic Standards Board Meeting
Virtual**

April 20 & 22 (Comment webinars), and April 28 - 30, 2021 (NOSB meeting)

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National Organic Standards Board
Compliance, Accreditation & Certification Subcommittee Proposal
Human Capital: Strategy for Recruitment and Talent Management - Organic Inspectors and Reviewers
January 12, 2021

Background

In order to advance dialogue on the qualifications and training of organic inspection and reviewers, the National Organic Program (NOP) issued a July 31, 2020 Memorandum to the National Organic Standards Board regarding Human Capital Strategy for Organic Inspectors and Reviewers. Subsequently, the NOSB posted a Fall 2020 Discussion Document on Human Capital Strategy for Organic Inspectors and Reviewers to invite public comments and suggestions on this topic.

Discussion

During the Fall 2020 NOSB meeting, the board received valuable feedback from the International Organic Inspectors Association (IOIA), certifiers, inspectors, reviewers, and other stakeholders on strategies for recruiting and maintaining competent highly trained inspector and reviewer teams. It was universally acknowledged by IOIA, certifiers, and experienced inspectors that there is a decreasing number of qualified individuals who desire to be organic inspectors and reviewers, leading to a potential crisis in the inspection/reviewer pool of qualified individuals. After the Fall 2020 meeting, the CACS subcommittee reached out to IOIA, several certifiers, and to individual inspectors and reviewers to obtain further clarification about their perceptions of decreasing numbers of qualified inspectors from the organic certification industry and suggestions for addressing the expressed concerns. Effort was made to contact both large scale and small-scale certifiers, and experienced and new inspectors and/or reviewers.

Contact was made with currently employed and contract inspectors as well as some who had recently left organic inspection work. All were asked the following:

1. What made you choose to become an organic inspector and/or reviewer; and
2. To those who have left the profession, why did you leave, or are contemplating leaving the profession?

The answers were aggregated to protect the identity of those who answered the questions.

I. The Challenge

Several reasons for the decline in inspectors/reviewers were identified as:

- **Constant Travel Time**
 - Younger beginning inspectors stated that the constant travel to be successful inspectors is their number one reason for leaving, or contemplating leaving active inspection work. They stated that the valuable time lost with their young children is not worth the money gained from the inspection work. One inspector stated that to make a “living” at doing organic inspections, there must be a commitment to traveling a minimum of 60% of their time, leaving little time for family and friends.
 - Older, more experienced inspectors stated that the wear and tear on their bodies from the constant travel is beginning to be too much to tolerate. Older inspectors are moving to doing more reviews or higher paid consultant positions.

- **Professionalism**
 - Inspectors stated that the organic inspection industry is not viewed as being “professional.” Some inspectors stated that there is a vast difference in how they are treated when doing organic inspections as opposed to doing other related types of inspections, e.g. food safety inspections, non-GMO ID inspections, and gluten-free inspections. This feeling is not only conveyed to the inspectors by the inspected entities, but some also express that the certifiers of other standards are much more respectful than organic certifiers.
 - That same feeling of non-professionalism is evident in the amount of pay the inspector receives for doing organic inspections versus doing the other types of inspections. One inspector recently left the organic inspection industry to exclusively do food safety audits. She stated that she can make double and sometimes triple the money for the same amount of work for food safety audits. Another inspector/reviewer is leaving organic inspection/review work to become a reviewer for a gluten-free certifier. She stated that the work is much simpler with less headaches than doing organic reviews, while receiving significantly more pay.
 - Inspectors feel they are not valued as part of the certification team. This feeling was expressed by contract inspectors, but not so often heard from employee inspectors. Contract inspectors stated a feeling of poor communication and feedback from the certifiers and reviewers.
 - A positive note was shared by one inspector who stated that it is not mandatory for an otherwise qualified inspector to enter the industry with a college degree. The requirement of a college degree by some is a limiting factor as there are plenty of individuals with “common sense” and agricultural background who can be easily trained to complete crops and/or livestock organic inspections.
 - This inspector further noted however, that threats to professionalism exist when inspectors with a lack of specific skill sets are allowed and sometimes encouraged by a certifier needing a particular inspection completed, to start conducting complex multi-ingredient processing operations without the real knowledge needed to assess critical contamination or commingling issues. Threats to human capital exist when the same individuals with poor skill sets are allowed to continue conducting the inspections for which they have no real training or understanding of the industry, thus bringing down the credibility to the organic industry as a whole and to other inspectors operating at a higher level of certification.
- **Compensation for Experience**
 - There is little to no difference in pay for an inspector that has many years of inspector experience than what is paid to a new beginning inspector. Experienced inspectors sometimes receive the same pay that they received ten-fifteen years ago. If an experienced inspector tries to increase their hourly rate, they find that their inspection numbers are negatively affected as the newer inspectors are assigned or awarded the inspections at a lower hourly rate.
 - Inspectors noted going through a bid process requiring them to pre-determine rates of pay and travel expenses on a contract basis. One inspector said, “I feel that I consistently have to underbid my own worth as I know that I am bidding against other less experienced inspectors who are more willing to take a lessor rate of pay.”

- **Continuing Education**
 - There is no reimbursement available to new and beginning inspectors who make the effort to increase their organic inspection knowledge. To become an organic inspector, it costs a significant amount of money for the initial training and credentialing to make the first call to a certifier. Trainings are currently offered by only one recognized entity in the US which generally offers the trainings only twice per year. Trainings are not guaranteed if the classes are not filled. Most of trainings are conducted in the upper Midwest or on the West coast, adding additional travel expenses for trainees outside of these regions. After completing training, the potential new inspector is expected to go through an apprenticeship period under an experienced inspector prior to being hired.
 - Some certifiers of other standards offset the costs for the inspector who will also conduct organic inspections, but in doing so, they require a commitment from the inspector to work for them for a set amount of time.
 - One inspector noted that after they completed a 5-day per scope training with the organic training entity, they had a good understanding the NOP regulations, but still felt unprepared for the critical thinking and risk assessment skills needed to accurately perform inspections independently.
 - Experienced contract inspectors are expected to continue their organic certification education, again at their own expenses. In contrast, professional individuals in other fields have the Continuing Education Units (CEU)'s paid by their employer so that their knowledge is current. This concern was not cited by employee inspector/reviewers as their certifier employer will often pay for them to take continued training classes.
 - Many expressed the need for a strong one-on-one field mentorship program whereby experienced inspectors share their years of inspection expertise to beginning inspectors. Other inspectors acknowledged the need for mentoring new inspectors but stated that they were unwilling to become mentors because of the number of hours required to provide the one-on-one, uncompensated mentorship.
- **Cost of Insurances (Personal and Family Medical, Vehicle and Professional Liability, and Errors and Omissions)**
 - The cost of personal and family medical insurance, increased vehicle and professional liability insurance, and the cost of errors and omissions insurance is often prohibitive to new and experienced inspectors. One inspector interviewed stated that the cost for errors and omissions insurance is over \$1000 annually. Another stated that they were required to obtain a \$1 million car insurance policy when the agency they work for learned the number of miles required to be driven to conduct organic inspections. The cost of medical insurance is terribly expensive when buying it without a group plan. The cost of offering an employee benefits package for new inspector employees prevents many certifiers from adding new inspector employees to their staff.
- **Lack of Consistency between expectations of certifiers**
 - Some respondents noted there is a real weakness generated in the inspection field when each certifier creates its own versions of an inspection report. The diversity in report requirements is astounding. Some certifiers require the inspector to merely check yes or no boxes, others require detailed reporting on observations and paper documentation to be obtained while on site, and others require a hybrid between the two formats in reporting. Some certifiers require photos taken at the location, but most do not. As a result, inspectors are required to learn each type of inspection reporting details for each certifier.

II. Proposed Strategies

The CACS Subcommittee asked stakeholders for proposed strategies to alleviate the potential crisis of a shortage of organic inspectors and reviewers. Some responses follow:

- Develop working groups between organic industry leaders, such as the Accredited Certifiers Association, IOIA, Organic Trade Association and other trade associations. These working groups could develop collaborative strategies to increase the trained inspector pool.
- Collaborate with secondary education and other governmental entities to provide organic inspector training and apprenticeship programs. Tracks could be generated within colleges offering organic and sustainable agriculture to highlight inspection careers. An inspector track could offer classes in organic laws and regulations and how to interpret these in practical settings, instruct on process controls and mass balance, agronomic inputs, and stocking rates, and a host of other skills and knowledge essential to the trade.
- Funding for inspector training potentially could be tapped from the federal Workforce Innovation and Opportunity Act (WIOA) to provide the trainings to displaced workers, discharged veterans, and other socially disadvantaged individuals.
- Make use of virtual organic trainings using ZOOM and/or other web-based platforms to teach the basics of organic inspections. Some noted that this is an effective way to teach the basic regulations and theory but questioned the lack of hands-on experience gained from shadowing experienced inspectors in the field to develop the “inspector eye” for determining organic compliance.
- One-on-one mentoring programs are essential for developing a well-trained inspector. Some suggested that additional funding from NOP or industry leaders could be sourced to reimburse the mentor for the time spent mentoring new inspectors to develop the necessary skills needed to become successful inspectors.
- Several commented that the organic industry needs a greater awareness of the value of experienced inspectors. If/when the organic industry understands the value of the organic inspector to organic integrity throughout the supply chain, the industry might be willing to provide a wage reflective of organic inspectors’ essential role in the trade. This would alleviate much of the expressed frustrations from so many inspectors: lack of respect from industry and certifiers, compensation comparable to what they receive from other inspection work, ability to obtain quality insurances, etc. Perhaps this education could be coordinated by industry groups such as the Organic Trade Association (OTA), National Organic Program (NOP), National Organic Coalition (NOC), Organic Consumers Association (OCA), Accredited Certifying Association (ACA), and others.

Questions for Stakeholders

1. What have you experienced or witnessed that contributes to the shortage of organic inspectors/reviewers?
2. What are some additional strategies that can be employed to increase the numbers of organic inspectors and reviewers?
3. Are there appropriate ways for the National Organic Program to assist with the financial burdens of?:
 - a. Initial cost of becoming a trained organic inspector.
 - b. Costs of continuing education for existing experienced inspectors, and
 - c. Compensation for organizations and/or experienced inspectors to provide qualified one-on-one mentorships to beginning inspector/reviewers.

Vote in Subcommittee:

Motion to accept the proposal on Human Capital: Strategies for Recruitment and Talent Management-
Organic Inspectors and Reviewers

Motion by: Sue Baird

Seconded by: Kyla Smith

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Nate Powell-Palm, Subcommittee Chair, to transmit to NOSB January 12, 2021

National Organic Standards Board
Compliance, Accreditation & Certification Subcommittee Discussion Document
Supporting the Work of the NOSB
January 12, 2021

Background

In order to advance dialogue on the qualifications and training of organic inspection and reviewers, the National Organic Program (NOP) issued a July 31, 2020 [Memorandum to the National Organic Standards Board regarding Human Capital Strategy for Organic Inspectors and Reviewers](#). Subsequently, the NOSB posted a [Fall 2020 Discussion Document on Human Capital Strategy for Organic Inspectors and Reviewers](#) to invite public comments and suggestions on this topic.

Discussion

The board received valuable feedback on the areas addressed in the NOP's memo, particularly: Strategic Workforce Planning; Talent Management: Pipeline Development; Talent Management: Recruitment and Matching; Performance Management and Evaluation; and Professional Support and Educational Infrastructure.

In response to the questions posed by the NOP Memo under "Talent Management: Pipeline Development", the board received the following remark by a public commenter:

In addition to those fields noted in the memo, other expertise such as those in chemistry, ecology, biological sciences, plant pathology, and biological engineering would be particularly helpful, especially when considering many of the topics discussed and debated by the NOSB. We have long wondered what it would look like if each NOSB member had a research assistant (a co-op position for a graduate student, for example) to help conduct and provide literature reviews, write drafts, and otherwise support the work of NOSB members. What better way to expose young people to the organic community than through service to its leadership board!?

The level of work involved for NOSB members has been cited by some as a discouragement towards serving on the board. The Board has discussed previously if there might be ways to obtain outside assistance in its work without compromising the integrity of the process or the independent nature of the production and deliberation of its proposals. The Board appreciates that this is a sensitive topic.

Related References

- [The Policy and Procedures Manual](#) allows for the Advisory Committee Specialist to "Ensur[e] NOSB members have all necessary materials and information to provide informed, structured and timely recommendations to the NOP".
- The [NOSB Charter](#) provides that: "The National Organic Program shall provide administrative support to the NOSB through the work of an Advisory Committee Specialist, who is a staff member within the NOP. The NOP may also provide technical support to the NOSB based on need and available resources."
- [§6518. National Organic Standards Board \(j\) Other terms and conditions](#) states: "The Secretary shall authorize the Board to hire a staff director and shall detail staff of the Department of Agriculture or allow for the hiring of staff and may, subject to necessary appropriations, pay necessary expenses incurred by such Board in carrying out the provisions of this chapter, as determined appropriate by the Secretary."

Questions for Stakeholders

1. Please provide any general comments on the remark above.
2. Is the organic community comfortable with the Board getting support to “to help conduct and provide literature reviews, write drafts, and otherwise support the work of NOSB members”?
3. If so, what areas are appropriate for the Board to get support?
4. For which areas should the Board not use outside support?

Vote in Subcommittee

Motion to accept the Supporting the Work of the NOSB discussion document

Motion by: Emily Oakley

Seconded by: Nate Powell-Palm

Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Nate Powell-Palm, Subcommittee Chair, to transmit to NOSB January 12, 2021.

**National Organic Standards Board
Crops Subcommittee Petitioned Material Proposal
Paper Based Crop Planting Aids
January 19, 2021**

Summary of Petition and Petition Addendum for Paper (Plant Pots and Containers)

The NOSB received a petition in August 2018 for the addition of paper planting pots to the National List: **§ 205.601(o) production aids- Plant pot or growing container-hemp or other paper, without glossy or colored inks.**

This material has not been petitioned for inclusion on the National List in the past. However, paper chain pots have historically been allowed for the past 12 years by some organic certification agencies, under the allowance for “Newspaper or Other Recycled Paper as a mulch or compost feedstock”.

In February 2018, the NOP notified all certifiers that paper chain pots are not allowed in organic systems. However, because some certifiers had previously approved their use, NOP allowed a phase-out period until the end of the 2018 crop season. The NOP’s decision on this material was based primarily on the presence of an unapproved synthetic adhesive in the product and the use of virgin paper. Further, the current allowance for paper on the National List does not extend to the use associated with paper pots. At the October 2018 and April 2019 NOSB meetings, there were numerous oral and written public comments requesting a longer time period allowing use of these paper pots while the NOSB reviewed the petition. The NOSB also formally requested this extension in November 2018. The NOP agreed to allow the use of paper pots in organic agriculture in late Fall 2018, with no time restriction, to give the NOSB time to go through the review process of this material.

Paper pots are used by small scale farming operations to efficiently transplant using a non-motorized machine transplanting system. More information on this transplanting method can be found on these websites: <http://paper-pot.com/> and <http://www.smallfarmworks.com/>. This equipment, along with the paper pots, is imported from a manufacturer in Japan. According to the petition, the Nitten paper pot chain system uses paper, produced from a non-bleached Kraft pulp, and adhesives. Non-paper synthetic fibers have been used in small quantities (15%) in the paper pots, but these fibers are proposed to be replaced by a natural hemp fiber. The petitioner and public comment at the Spring and Fall 2018 NOSB meetings stated this system is unique and essential for smaller scale growers. The only alternative would be the much slower and more costly hand planting of individual plants. The system is used for closely spaced crops such as onions, beets, baby salad, etc. The petition states that, like newspaper, these pots decompose in the soil readily. At the time of this proposal, the first trial replacing the synthetic fibers with hemp fibers was not successful, and a second trial was in process.

In addition to the paper pots indicated in the petition, there are numerous other paper pot systems, both to be used to transplant single plants as well as in chains. In addition to paper, these other paper pot systems have various percentages of non-paper synthetic fibers, which may or may not be biobased. Paper pots can also include other ingredients, such as cow manure, synthetic antimicrobials, fungicides, and fertilizers. Public comment from another manufacturer based in Denmark, Ellepot (<https://www.ellepot.com/>), provided further information on non-chain paper pots for a variety of uses from fast maturing annuals to long term woody perennial crops. The percentage of cellulose based synthetic fibers in their paper pots can be 20-100%. Synthetic adhesives are currently the only synthetic material used in the Ellepots other than the paper itself.

The petition states that, in addition to information on paper, the TR on newspaper addresses the presence of adhesives and synthetic fibers in recycled newspaper as well. The three adhesives in the Nitten paper chain pots are vinyl-acetate resin (water soluble and stated to be leached from the pots before transplanting), ethylene-vinyl-acetate resin, and acrylic acid ester copolymer.

It should be noted that paper itself is a synthetic fiber due to the manufacturing process. However, for the purposes of this discussion, a distinction is made between synthetic paper fibers and synthetic fibers that are not strictly paper. These non-paper synthetic fibers can be biobased and made from cellulose or they can be non-biobased and made from several other materials such as petroleum-based plastics. Additionally, some synthetic cellulose-based materials may not be biodegradable. In general, many of the biobased, cellulose derived synthetic fibers used in paper pots are expected to biodegrade whereas the same might not be true of other petroleum-based fibers. Thus, it can be important to distinguish not only between synthetic paper fibers and other non-paper synthetic fibers but also between whether fibers from any source are biodegradable (as referenced to some recognized standard) or might persist in the soil.

The Crops Subcommittee has viewed paper pots, used as a crop production aid, as another use of paper beyond compost feedstocks and mulch, which are allowed under the NOP regulation. However, in order to do due diligence, the Crops Subcommittee requested a Technical Review (TR) to help identify the adhesives and synthetic fibers used in paper pots and identify if there are any that would not be present in the already allowed paper used in compost and mulch. Pots, compost, and mulch all degrade into the soil, and the Subcommittee believes if the fibers and adhesives are allowed in the other listings for paper, then their use in pots should be allowed as well.

The Technical Review clarified that the adhesives and non-paper synthetic fibers found in a variety of paper pots are also found in newspaper and recycled paper that are allowed for compost feedstock and mulch. Other possible adhesives and synthetic fibers for paper pots that were not mentioned in the petition are described in the TR.

Summary of Public Comment:

Many users of the paper pot chain system provided written and verbal comment to the NOSB at the Fall 2018 through Fall 2020 public meetings. They spoke in favor of its use due to its efficiency in transplanting at a small-scale level. Some certifiers spoke in favor of this material and noted that if the paper was torn off the pot before transplanting, it would then be allowed as a mulch or as a compost feedstock under our current regulation. Certifiers who had not allowed the use of these paper pots still supported the extended allowance for use while the NOSB performed its review.

There is more than one supplier of paper pots beyond the supplier noted in the petition. Approval of this material will open the door for other manufacturers to produce these pots once there is clarity on what would be allowed under the organic regulations. Paper pots can be made with all-natural fibers or with a mixture of synthetic and natural fibers. The pots with higher non-paper, synthetic fiber contents are more typically used in the nursery trade where perennial plants may be in the pots for 9-12 months before transplanting into the field. Natural fiber pots can, at times, be sufficient for use in transplanting annual vegetable and flower plants, depending on the time frame from planting into the pot to planting in the field and if the pots need extra strength for a “chain of pots” planting system. All the paper pots contain some type of synthetic adhesive, but these same adhesives are also found on recycled paper which is already allowed in organic agriculture.

Numerous commenters mentioned that all uses of paper as production aids should be included when the NOSB does its review for paper pots. Cloches or hot caps, seed tape, and cutworm prevention collars are other examples of production aids made from paper and typical paper adhesives.

There were also a number of comments about whether the listing for paper pots should be expanded to include additional distinct uses of paper as a production aid. Many commenters favored a listing that extended beyond only paper pots to include, but not be limited to, items such as seed tape, and other materials with direct soil contact. However, commenters also wanted to make sure that there was a differentiation between paper materials being used that are later incorporated into the soil versus paper materials that are intended to be removed after use. The Crops Subcommittee has narrowed the use from a “production aid” to a “planting aid” to limit the use of this paper to that period of the crop production, and to those aids that would be incorporated into the soil.

Comments submitted during both Spring and Fall 2020 meetings asked for further refinement of the definition and annotation for paper planting aids. These comments included the inclusion of nutrient and pesticide limitations, restricting the potential use of biodegradable biobased mulch under this definition, clarification of the makeup of the 40% of the products that are not cellulose based and who would qualify as a third party reviewer for biobased or cellulose based content.

Specific Uses of the Substance:

Paper pots are either single or in chains to allow for “mechanical” transplanting, either with a hand driven machine or with a tractor implement. The paper pots decompose into the soil and lessen transplant shock since the roots are not exposed to the air before transplanting like plants being removed from plastic pots. The use of paper pots can contribute to less use of plastic in the produce industry. Growers can also use soil blocks, which are compressed soil without any container, to grow transplants.

Other paper crop production aids include: cloches (a temporary covering used to protect newly transplanted plants), seed tape (where individual seed is spaced correctly on a paper tape which lessens the need for thinning), and collars to prevent cutworm damage to plants at the soil line. There could be other uses of paper currently used as crop production aids or there may be other uses developed over time. The composition of the paper allowed in paper pots and other planting aids, as well as the adhesives approved, would meet the manufacturer needs of these other paper planting aids.

Approved Legal Uses of the Substance:

Newspaper and recycled paper are allowed under the organic regulations in these two references:

Reference: 205.601(b) As herbicides, weed barriers, as applicable. (2) Mulches. (i) newspapers or other recycled paper, without glossy or colored inks.

Reference: 205.601(c) - As compost feedstocks - Newspapers or other recycled paper, without glossy or colored inks.

There have been three technical reports (TRs) for Newspaper, in 1995, 2006 and 2017, which can be found here: <https://www.ams.usda.gov/rules-regulations/organic/national-list/n>.

NOP guidance 5034-1 “Materials for Organic Crop Production” from December 2016 excludes virgin paper from the “newspaper or other recycled paper” allowance for mulch or compost feed stocks. The

guidance states: *“Includes newspaper and other recycled paper such as cardboard, without glossy or colored inks. Does not include paper that is not recycled (i.e., virgin paper).”*

The July 2019 Technical Review of Paper Pots and Containers, detailing the specific possible synthetic and natural fibers as well as synthetic adhesives found in paper pots currently commercially available, provided more clarity for the NOSB.

Manufacture:

Paper can be made from various plant sources including wood, trees, straw, hemp, bamboo, reeds, kenaf, sisal, jute, sugarcane bagasse, sunflower stalks as well as recycled sources of pulp. Cellulose sources are typically mechanically ground and then chemically “cooked” using an alkali or sulfite process. Newspaper and recycled papers can also have a variety of inks, although colored ink and glossy paper are not allowed as compost feedstocks or mulch under the organic rule. The paper used as a planting aid could include the typical adhesives found in newspaper and recycled paper.

Subcommittee Discussion:

The Crops Subcommittee has reviewed the petition, technical reviews, and public comments and has developed a listing and annotation that we believe meets the needs of producers while addressing environmental concerns that might be associated with some types of paper. When discussing the possible allowance for paper used as a planting aid, the Subcommittee also considered the fact that currently there is an allowance for “newspaper or other recycled paper” as weed control or as compost feed stocks and there are very few differences between the currently allowed paper and the paper as a planting aid under review, with the exception of paper pots that have a very high percentage of non-cellulose synthetic fibers. Requiring 60% cellulose fiber prevents the planting aids from being completely made of biobased, non-degradable plastics and yet allows current products on the market. It is hoped that this percentage can increase over time. Requiring 80% biobased content prevents the use of planting aids made primarily from petroleum sources and also allows the products currently on the market. Again, it is hoped that this percentage can be increased over time and that future Boards will be able to modify this annotation to reflect manufacturing technological advances that incorporate more natural materials and additional cellulose and biobased content. These future reviews should also encompass the biodegradability of both fibers and adhesives.

Small changes have been made to the annotation to reflect concerns from stakeholders.

- There was concern that the annotation specifically notes that allowed paper planting aids are not limited to those listed and that the materials will be incorporated into the soil (without reference of intent to biodegrade).
- As pointed out in public comment, the wording that allows the use of newspaper “without colored or glossy inks” was intended to prevent use of glossy paper and colored inks and the wording for paper planting aids is changed to prevent the use of glossy paper or colored inks.
- Stakeholders had asked for language regarding nutrient and pesticide inclusions in the paper planting aids to prevent the use of materials not allowed on the National List. However, later comments noted that the inclusion of pesticide language runs counter to the legal use of pesticides, so that language was removed.
- Concern was expressed by stakeholders about substances that might be included in the 40% non-cellulose portion of the paper planting aids. They suggested language limiting those materials and specifying what their uses might be. That language has been added to the definition.

- For clarity in listing, language needs modified in §205.601: *In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production: Provided, That, use of such substances do not contribute to contamination of crops, soil, or water. Substances allowed by this section, except disinfectants and sanitizers in paragraph (a) and those substances in paragraphs (c), (j), (k) (l), (n),(o) and (p) of this section, may only be used when the provisions set forth in §205.206(a) through (d) prove insufficient to prevent or control the target pest.*

The Board acknowledges that the percentage specificities in this listing should be reviewed by future Boards as technology and materials change. It seems likely that there will continue to be advances in fiber types that can be used in these paper planting aids. If so, the percentage of cellulose or biobased materials could be increased. It is hoped that at some point in the future this listing could be changed to 100% biobased, biodegradable fiber content as well as examining adhesives to address biodegradability.

Category 1: Classification

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

Due to the paper pulping production process and use of synthetic adhesives, this material is considered to be synthetic.

2. **For CROPS: Reference to appropriate OFPA category:**
Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

This material is considered a crop planting aid and is not a pesticide. Although some paper pots available on the market might have prohibited pesticides (insecticides, antimicrobials, fungicides etc.) embedded in the fiber, these would not be allowed in organic production. To be explicit, the annotation states that any added nutrients must conform to the National List or be allowed under OFPA. Additionally, the non-cellulose based content is expressly limited to non-synthetic materials, other permitted synthetic ingredients at §205.601(j), or synthetic strengthening fibers, adhesives, or resins.

Category 2: Adverse Impacts

1. **What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]**
Most of the paper used as a crop planting aid is functionally identical to newspaper and recycled paper. The current listing of newspaper and recycled paper has been found to have no detrimental interactions with other materials in organic agriculture.

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]

No toxicity or negative mode of action has been found in the breakdown of paper (cellulose) in the environment. No colored inks or glossy paper would be allowed for paper as a crop planting aid, similar to paper as it is currently annotated as a compost feedstock and/or mulch. The 2019 TR found many of the adhesives and synthetic fibers biodegraded with no negative impacts. There were some that were not as environmentally neutral as others, but all were also present in newspaper. The percentage of adhesives in the paper pots is very small. There could be an issue with paper used as a planting aid, containing large percentages of synthetic fibers that would not biodegrade readily.

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

There could be contaminants released into the environment during the manufacture of paper, and environmental degradation caused by harvest of cellulose, but no more than newspaper or recycled paper, which historically have been approved for use in organic agriculture. A difference between this paper and the previously approved newspaper is that we are not restricting it to the use of only recycled paper products. The annotation will allow virgin stocks of cellulose to be used in the paper used as a planting aid in organic agriculture. There are negative environmental impacts from harvesting trees to make paper such as road building, soil erosion, degraded water quality, and loss of habitat, but there are forestry best management practices that can mitigate some of these negative effects. Furthermore, there are non-tree cellulose sources that could be utilized in the future. The synthetic fibers that could be used in paper are manufactured in a wide range of production systems. These were not specifically addressed in the TR.

4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].

Paper, depending on the percentage of cellulose and type of synthetic fibers/materials used, is biodegradable and has no negative effects on human health. The 2019 TR did not find any evidence of harmful effects to human health.

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

Paper, depending on the percentage of cellulose and type of synthetic fibers/materials used, is not harmful to the environment. The 2019 TR did not find any evidence of harmful effects to environmental health.

6. Are there any adverse impacts on biodiversity? (§205.200)

Paper planting aids with high percentages of synthetic fibers that do not biodegrade readily could leave residues that would be harmful to terrestrial, avian, and aquatic wildlife if

consumed. Use of synthetic pesticides embedded in the pots could also have adverse impacts on biodiversity, but only organically allowable nutrients would be allowed in the paper used as a planting aid and there is a restriction on the types of materials allowed in the 40% non-cellulose based portion of the planting aids.

Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

There are biodegradable pots made from composted cow manure (<https://cowpots.com/>) but these have never been petitioned for use in organic agriculture. We do not know if they could be approved or not. The manufacturer states the pots contain post-consumer newsprint and are 100% biodegradable. In addition, they state they are not approved for Certified Organic operations as of January 2020. It is unclear if there are adhesives or synthetic fibers as well and what they are.

There are also tools to help growers roll up newspaper into a pot. The paper chain pots offer greater efficiency for small scale transplanting, although mechanical or hand transplanting operations can be used in both small- and large-scale operations with other types of pots or soil blocks.

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

The Crops Subcommittee has developed the definition and annotation described in the motion below to both meet the OFPA criteria and to provide a practical and achievable material for manufacturers to produce and for organic farmers to use. The material is a planting aid and the intent is to limit the use of this material to activities around planting of seeds or plants.

While hand planting, machine planting, and other methods may provide some alternatives to paper planting aids, testimony provided to the Board indicates that the use of paper planting aids is critical for a segment of organic growers.

The annotation of no less than 60% cellulose-based fiber content meets the needs of current manufacturers with the possibility that hemp or other natural cellulose fibers, capable of providing the strength needed to meet this annotation, could be used in the future. The 80% biobased requirement ensures that materials beyond the cellulose base are derived from biological sources. Both the 60% cellulose based fiber content and 80% biobased content requirements could be made more stringent by future Boards through an annotation change. As the technology of these planting aids advances it is possible manufacturers will be able to use more natural and biobased materials to strengthen the planting aids. Continuing the prohibition on glossy paper and colored inks prevents the incorporation into organic soil of the worst contaminants. It is understood that there would be a small percentage of adhesives and coatings and the Technical Reviews on paper and paper pots described how these are already allowed in paper as mulch or compost feedstocks.

The allowance for virgin paper allows for special papers to be developed that meet the specific crop planting needs for a variety of uses, and the amount of paper produced from virgin sources for these planting aids would be very small compared to the amount of paper manufactured for

all uses. Added fungicides, antimicrobials, insecticides, or other synthetic items not typically found in paper would not be allowed under the current annotation unless they were on the National List for that purpose or otherwise compliant with the OFPA. Genetically modified materials are prohibited under the organic regulation and would not be allowed as ingredients in paper-based crop planting aids. With the recommended annotation, paper-based crop planting aids are compatible with a sustainable system of agriculture.

The Crops Subcommittee did not include a biodegradability standard in this proposal due to the time and cost needed for testing to that standard. The Subcommittee would like to see continued innovation to move to 100% biobased as well as an increase in the natural fiber content of these planting aids. Additionally, the Subcommittee wants to make sure that these materials are promptly and economically available to growers of all sizes. The Subcommittee would like to encourage testing and trials of increased natural and/or biobased contents and believe that manufacturers would be less likely to provide small innovations of these new products to organic farmers if this testing were required.

Subcommittee Vote:

Classification Motion:

Motion to classify paper-based crop planting aid as a synthetic substance.

Motion by: Steve Ela

Seconded by: Jerry D'Amore

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

National List Motions:

Motion to add to 205.2 Terms Defined:

Paper-based crop planting aid. A material that is comprised of at least 60% cellulose-based fiber by weight, including, but not limited to, pots, seed tape, and collars that are placed in or on the soil and later incorporated into the soil, excluding biodegradable mulch film. Up to 40% of the ingredients can be non-synthetic, other permitted synthetic ingredients at §205.601(j), or synthetic strengthening fibers, adhesives, or resins. Contains no less than 80% biobased content as verified by a qualified third-party assessment (e.g. laboratory test using ASTM D6866 or composition review by qualified personnel).

Added nutrients must comply with §205.105, 205.203, and 205.206.

Motion by: Steve Ela

Seconded by: Rick Greenwood

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Motion to add to 205.601 (p) Production Aids:

Paper-based crop planting aids as defined in 205.2. Virgin or recycled paper without glossy paper or colored inks.

Motion by: Steve Ela

Seconded by: Emily Oakley

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Rick Greenwood, Crop Subcommittee Chair, to transmit to NOP January 19, 2021.

**National Organic Standards Board
Crops Subcommittee Proposal
Biodegradable Biobased Mulch Film
February 16, 2021**

I. Summary of biodegradable biobased mulch film

The NOP rescinded policy memorandum 15-1 in October 2019, stating that it was redundant with current regulations. The requirement for 100% biobased feedstocks is articulated in the preamble of the final rule and the status quo remains. Removal of the policy memorandum provides an opportunity for the NOSB to revise the current definition (§ 205.2) to reduce the biobased content requirement. The Crops Subcommittee is now planning to vote on an annotation at the Spring 2021 meeting addressing biodegradable mulch (BDM) film that is not 100% biobased.

II. Discussion:

Biodegradable biobased mulch film has been on the National List of approved synthetic substances since September 30, 2014, based on an October 2012 NOSB recommendation. Historical information on this material is as follows:

Reference on the National List: § 205.601(b) As herbicides, weed barriers, as applicable (2) Mulches (iii) Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods.

Technical Report: [2012 TR](#); [2015 Report](#); [NOP Policy Memorandum 15-1](#); [Supplemental Technical Evaluation Report 2016](#)

Petition(s): [2012](#)

Past NOSB Actions: [10/2012 NOSB Recommendation](#); [Memo to the NOSB with Report on Biodegradable Biobased Mulch Films in Organic Crop Production \(Michigan State University, September 2019\) \(pdf\)](#).

Recent Regulatory Background: Final Rule published 09/30/14 ([79 FR 58655](#)); Sunset renewal notice published 10/08/2019, [84 FR 53577](#)

Background from Subcommittee: Biodegradable biobased mulch films were approved for placement on the National List of approved synthetics (Biodegradable Mulch Film Made from Bioplastics) without detailing if non-biobased content would be allowed. Most mulch films in this category contain 20% or less of biobased materials (i.e., they are ~80% petroleum derived), with the remainder consisting of polymers, colorings, and other synthetic materials. There are some products that might meet the biobased aspect of this material's definition on at §205.2 but are either not biodegradable or are not used in production due to brittleness or other production issues.

In January 2015, the National Organic Program issued Policy Memorandum 15-1, to clarify that biodegradable biobased mulch film must not contain any non-biobased synthetic polymer feedstocks. The NOSB requested a limited scope technical report (TR) in 2016. The questions asked for this limited scope TR from 2016 were as follows:

1. What is the effect on overall soil health, including soil biology, when this material biodegrades?
2. What is the cumulative effect of the continued use of this biodegradable biobased mulch film, on soil nutrient balance, soil biological life, and soil tilth, when used in the same area of the field for 3-5-10 years?

3. What effect does the breakdown of these polymers have on soil and plant life as well as livestock that would graze either crop residues or forages grown the subsequent year after this mulch film was used?
4. Are there different cropping systems, climate, soil types or other factors that affect the decomposition rate (Examples would be long cold winters, or exceptionally dry conditions, such as found in a desert)?
5. Are there metabolites of these mulches that do not fully decompose, and if so, is there an effect upon soil health or biological life?

The TR focused on biobased biodegradable mulches that contain polymers and the soil and crop health effects they may have as they biodegrade. This supplemental TR was inconclusive, since research on these materials is currently limited, and the questions above were not answered to the NOSB crop subcommittee's satisfaction.

An argument can be made that even though the non-biobased polymers degrading into the soil originate from petroleum (a nonrenewable fossil fuel), the use of this product could be considered environmentally friendly because:

- Many organic production systems rely on enormous amounts of plastic, mostly polyethylene (PE) films, to produce organic crops;
- PE films likely shed micro plastics and leach chemicals into organic soil over the growing season;
- Before and during removal, PE films can tear and breakdown, leaving plastic in the soils or migrating off-site into aquatic habitats;
- PE films are generally not recyclable due to contamination by soils or the lack of recycling infrastructure;
- Plastic used in annual production systems end up in landfills;
- Biodegradable mulches potentially save labor and time, since the mulch does not have to be removed from the field and transported for disposal;

The current listing of biodegradable mulch on the National List is aspirational: there are no products on the market that are commercially viable made from 100% biobased carbon sources (i.e., no petroleum). In fact, some public commenters have recommended that BDM films be taken off the National List since the 100% biobased requirement essentially prohibits use of these materials. However, the NOSB reviewed this material for its five-year sunset renewal in 2017, and decided to relist it as written, with understanding that there were no products on the market that were commercially viable made from 100% biobased (no petroleum) materials. The crops subcommittee needed more information that addressed the key questions above to consider a change to the annotation. If it remained on the National List, the Board also hoped manufacturers would be able to develop a product that met that requirement of 100% biobased "ingredients", which was the preferred outcome.

The National Organic Program also reached out to Dr. Ramani Narayan, a researcher with the Department of Chemical Engineering and Materials Science at Michigan State University to provide more information beyond the technical review, which was completed in 2016, to the NOSB. The focus of Dr. Narayan's report is the biodegradability of both biobased and petroleum-based mulch films with limited research on the effect of these products degrading into the soil over time. Section 2.7 of the report states:

Environmental studies have not shown any adverse impacts associated with the incorporation of biodegradable mulch films (BDMs) into the soil to date. More research is needed to monitor any

potential formation of terrestrial micro and nanoplastics from biodegradable mulch films and ensure that there is no residual soil ecotoxicity. There is need for tuning the physicochemical properties of the biodegradable mulch films with the needs of specific cropping systems and climates. The biodegradable mulch films could provide additional environmental benefits by formulating them to deliver macro and micronutrients to the crop as they biodegrade in soil, or deliver pesticides directly into the soil. Sintim et al. showed that there was no significant effect on soil health over two years of monitoring and that the soil microbial communities did not differ much either. They found significant enrichment in bacterial and fungal gene copies under BDM treatments over 2 years, but no significant change under PE and no mulch. Another important observation was that repeated tillage of BDMs into the soil across 4 years did not impact crop yield significantly and had no major effect on crop quality.

While this section points out possible negative issues with some polymers used in the biodegradable mulch, most of the report focused on the positive aspects when the mulch does biodegrade. The report also discussed current regulations that protect organic integrity and would not allow the use of excluded methods (some of the polymers are extracted from petroleum through the use of bacteria created through excluded methods) and do not allow materials to be used that “contribute to contamination crops, soil or water.” Organic producers in the European Union are allowed to use petroleum based biodegradable mulch with no requirement on the percentage of bio-based ingredients. The EU will be reviewing these mulches in 2024 with possible changes to their annotation.

Key concerns of current and past NOSB members include the possibility of soil, aquatic, and other environmental contamination by partially decomposed BDM films even if the materials pass ASTM laboratory-based standards. Of particular concern to NOSB members is the possibility that BDM films will not decompose thoroughly in dry or cold environments where there is less biological activity in soils. A related concern is that BDM films ploughed into soils may be out of reach of peak biological activity to break it down. For example, most soil biological activity occurs in the top 4-6 inches, with only a small fraction below that level. If ploughing results in BDM film plastic mixed into soil 7-10 inches deep, there may be fewer microbiotic fauna available to consume BDM carbon sources.

Extensive public comments and up-to-date scientific reviews have been submitted to the NOSB, and in some cases submitters note sampling and/or other analytic methods are not yet developed enough to answer all questions about potential residues in soil.

The Board has also weighed the merits of comparing the risk to soils and the environment from BDM films versus risk from PE films. Board members are torn on this issue. Current use of plastic in organic production is increasing rapidly. Some small- and large-scale growing systems, such as organic “plasticulture” strawberry production, are highly dependent on PE films, with thousands of acres of plastic used annually across the industry. Board members are also concerned about the precedent of allowing petroleum-derived products to be added directly to soils. The comparative risk of the two production aids leaves some organic community members uncomfortable. In essence, the thinking is “I don’t think the reason to add a new material to the National List should be because we’re trying to mitigate the harms caused by another NL material.”

Precedents of Allowing the Addition of Petroleum Products to Soil

The National List currently allows the use of horticultural oils in crop production, including mineral oils refined from petroleum. Mineral oils are closer in chemistry to petroleum jellies and paraffin, versus other more volatile and toxic petroleum constituents. However, these materials pose some environmental and health risks, and their use on crops results in direct entry into soil ecosystems.

At this meeting (April 2021), the NOSB is also proposing allowance of paper pots as planting aids, with the listing to read as follows

Paper-based crop planting aid. A material that is comprised of at least 60% cellulose-based fiber by weight, including, but not limited to, pots, seed tape, and collars that are placed in or on the soil and later incorporated into the soil, excluding biodegradable mulch film. Up to 40% of the ingredients can be non-synthetic, other permitted synthetic ingredients at §205.601(j), or synthetic strengthening fibers, adhesives, or resins. Contains no less than 80% biobased content as verified by a qualified third-party assessment (e.g. laboratory test using ASTM D6866 or composition review by qualified personnel). Added nutrients must comply with §205.105, 205.203, and 205.206.

This proposal requires 80% biobased content **but allows 20% of the material to be non-biobased**, potentially including nylon and other *non-biodegradable* plastics in the paper pots. The paper-pot proposal is notable because it allows the direct application of non-biodegradable plastics to soil, although the long-term hope is that future products will be 100% biobased. Paper-pot production aids are generally used by small farmers and their contribution to soil plastics is likely to be small compared to the thousands of acres of soil covered by PE films and their possible future BDM film replacements.

Possible Use Restrictions

The Board has considered several options to guide use of BDM films if they are approved with less than 100% biobased content. Specifically:

1. Allow BDM film use followed by ploughing into soil (with some consideration for off-site transport), with monitoring and assessment to determine whether there are adverse impacts;
2. Restrict BDM film use based on soil types and climates where the BDM film may not biodegrade rapidly;
3. Allow BDM film use but require that it be gathered up at the end of the season followed by on-farm or off-farm composting.

In response to public comments, the Crops Subcommittee has concluded that Option 1, above, is the only reasonable option on which to vote. Soil types and climate are complex, and it is not possible to pre-identify regions and growing practices where use of the BDM films may or may not work (Option 2). Finally, Option 3 does not work because the films become brittle toward the end of the season and cannot be removed intact for later composting.

III. Proposal

Weighing the risks and benefits of using PE and BDM films, the Crops Subcommittee proposes to allow BDM films that are at least 80% biobased by weight, with the remaining 20% by weight consisting of materials that meet one of the following composting standards: ASTM D6400, ASTM D6868, EN 13432, EN 14995, or ISO 17088 (all incorporated by reference; see [§ 205.3](#)). The CS understands that this recommendation is still aspirational in the sense that no current BDM films meet the 80% biobased content criteria. However, several manufacturers have reported that producing 80% biobased film may be feasible, and this proposal sets a realistic goal. The CS also recommends that use of >80% biobased material be required if and when these materials become available.

The CS proposes the following annotation change for biodegradable biobased mulch film:

§205.601 Synthetic substances allowed for use in organic crop production.

(iii) Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods. ***When 100% biobased biodegradable plastic films become available, producers are required to use 100% biobased content BDM plastic films.***

§205.2.

Biodegradable biobased mulch film. A synthetic mulch film that meets the following criteria:

- (1) Meets the compostability specifications of one of the following standards: ASTM D6400, ASTM D6868, EN 13432, EN 14995, or ISO 17088 (all incorporated by reference; see § 205.3);
- (2) Demonstrates at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, according to one of the following test methods: ISO 17556 or ASTM D5988 (both incorporated by reference; see § 205.3); and
- (3) ***Biodegradable plastic mulch films must be at least 80%*** biobased with content determined using ASTM D6866 (incorporated by reference; see § 205.3).

III. Vote in Crops Subcommittee

Motion to accept the proposal on biodegradable biobased mulch film.

Motion by: Asa Bradman

Seconded by: Rick Greenwood

Yes: 5 No: 1 Abstain: 0 Absent: 2 Recuse: 0

Approved by Rick Greenwood, Crop Subcommittee Chair, to transmit to NOP February 19, 2021.

Sunset 2023
Meeting 1 - Request for Public Comment
Crops Substances § 205.601 & § 205.602
April 2021

Introduction

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

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2021 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2021 public meeting. Comments should be provided via Regulations.gov at www.regulations.gov on or before April 5, 2021, as explained in the meeting notice published in the Federal Register.

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

Public comments should clearly indicate the commentor's position on the allowance or prohibition of substances on the National List and explain the reasons for the position. Public comments should focus on providing relevant new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance (*e.g.*, scientific, environmental, manufacturing, industry impact information, etc.). Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

For Comments that Support the Continued Use of § 205.601 Substances in Organic Production:

If you provide comments supporting the allowance of a substance at § 205.601, you should provide information demonstrating that the substance is:

1. not harmful to human health or the environment;
2. necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
3. consistent with organic crop production.

For Comments that Do Not Support the Continued Use of § 205.601 Substances in Organic Production:

If you provide comments that do not support a substance at § 205.601, you should provide reasons why the use of the substance should no longer be allowed in organic production. Specifically, comments that

support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

1. harmful to human health or the environment;
2. unnecessary because of the availability of alternatives; and/or
3. inconsistent with organic crop production.

For Comments that Support the Continued Prohibition of § 205.602 Substances in Organic Production:

If you provide comments supporting the prohibition of a substance on the §205.602 section of the National List, you should provide information demonstrating that the substance is:

1. harmful to human health or the environment; and
2. inconsistent with organic crop production.

For Comments that Do Not Support the Continued Prohibition of § 205.602 Substances in Organic Production:

If you provide comments that do not support the prohibition of a substance at § 205.602, you should provide reasons why the use of the substance should no longer be prohibited in organic production. Specifically, comments that support the removal of a substance from the § 205.602 section of the National List should provide new information since its last NOSB review to demonstrate that the substance is:

1. not harmful to human health or the environment; and/or
2. consistent with organic crop production.

For Comments Addressing the Availability of Alternatives:

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

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

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

Written public comments will be accepted through April 5, 2021, via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

§205.601 Sunsets: Synthetic substances allowed for use in organic crop production:

- [Copper sulfate \(§205.601\(a\)\(3\) & §205.601\(e\)\(4\)\)](#)
- [Ozone gas](#)
- [Peracetic acid \(§205.601\(a\)\(6\) & §205.601\(i\)\(8\)\)](#)
- [EPA List 3 - Inerts of unknown toxicity](#)
- Chlorine materials
 - [\(i\) Calcium hypochlorite](#)
 - [\(ii\) Chlorine dioxide](#)
 - [\(iii\) Hypochlorous acid - generated from electrolyzed water](#)
 - [\(iv\) Sodium hypochlorite](#)
- [Magnesium oxide](#)

§205.602 Sunsets: Nonsynthetic substances prohibited for use in organic crop production:

- [Calcium chloride](#)
- [Rotenone \(CAS # 83-79-4\)](#)

Copper sulfate

Reference: §205.601(a)(3) Copper sulfate - for use as an algicide in aquatic rice systems, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent; and,

§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.

Technical Report: [1995 TAP \(Copper Sulfate and Other Coppers\)](#); [2001 TAP](#); [2011 TR](#)

Petition(s): [2001](#)

Past NOSB Actions: [10/2001 meeting minutes and vote](#); [11/2007 recommendation](#); [04/2011 recommendation](#); [10/2016 sunset recommendation](#); [11/2017 sunset recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987](#)); Sunset renewal notice effective 11/03/2013 ([78 FR 61154](#)); Sunset renewal notice effective 11/03/2013; Sunset renewal notice effective 5/29/2018 ([83 FR 14347](#))

Sunset Date: 5/29/2023

Subcommittee Review

Use

Copper sulfate is used as an algicide for rice crops, as the growth of algal matting in flooded fields can dislodge young seedlings. It is broadcast aerially into the flooded rice fields by plane. Rice farmers also spray copper sulfate to control a freshwater invertebrate, *Triops longicaudatus*, otherwise known as tadpole shrimp. Tadpole shrimp are also only detrimental to very young seedlings, as their burrowing activities can disrupt the seedling roots and the first emerging leaves.

Manufacture

Copper sulfate is manufactured by treating copper metal with hot concentrated sulfuric acid. Copper oxides can be treated with a more dilute sulfuric acid to produce copper sulfate. Copper sulfate is also known as copper vitriol.

International Acceptance

While the majority of rice is grown in Asian countries, the top ten countries that contribute to global organic rice production include Italy and the USA, as shown in the table below.

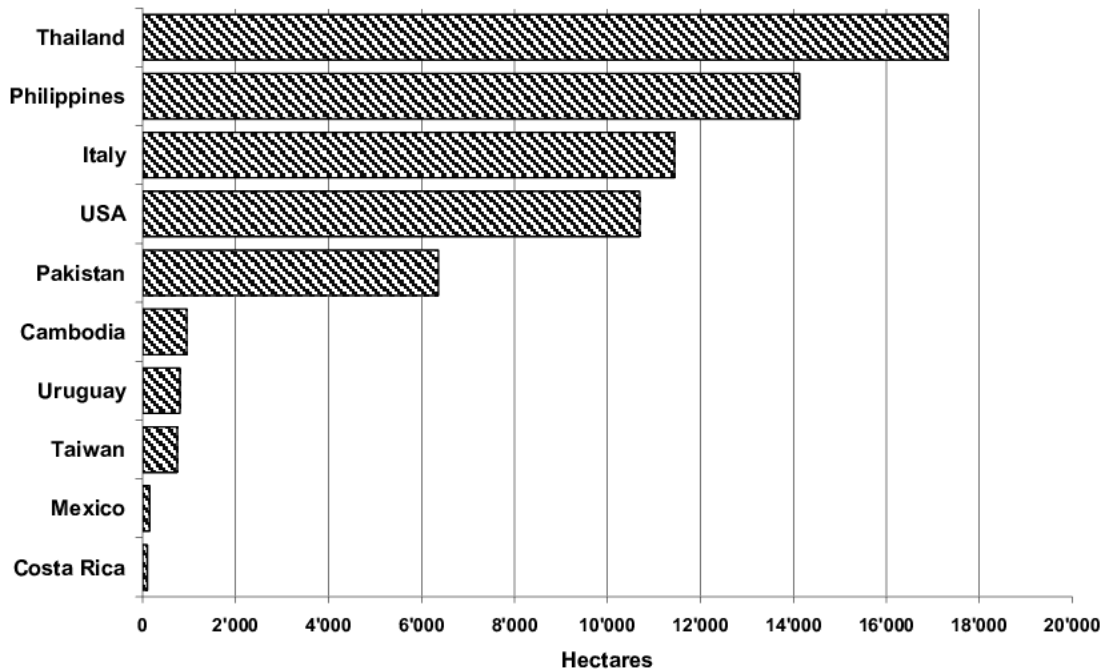


Figure 1. Top producers of organic rice globally (Willer and Yuseffi 2007).

Canadian General Standards Board Permitted Substances [List](#)

- Permitted for use as a wood preservative, fungicide on fruit and vegetables or for disease control.
- Shall be used with caution to prevent excessive copper accumulation in the soil. Copper buildup in soil may prohibit future use.
- Visible residue of copper products on harvested crops is prohibited.

There is very little rice grown in Canada, but the organic rice grown in Abbotsford is farmed without copper sulfate and using the seedling transplanting method that eliminates the need for copper sulfate.

European Economic Community (EEC) Council Regulation, EC No. [834/2007](#) and [889/2008](#). European Chemicals Agency (ECHA)

The EU does not permit copper sulfate for use in organic rice production.

ECHA states copper sulfate “is very toxic to aquatic life, is very toxic to aquatic life with long lasting effects, may cause cancer, may damage fertility or the unborn child, is harmful if swallowed, causes serious eye damage, may cause damage to organs through prolonged or repeated exposure, causes skin irritation and may cause an allergic skin reaction.”

Japan Agricultural Standard (JAS) for Organic [Production](#)

Copper sulfate is only [permitted in organic agriculture as a fungicidal spray](#), not for use in rice fields.

Environmental Issues

Copper is readily dissolved and suspended in the water and is lethal to fish and other aquatic organisms at fairly low concentrations. In amphibians, increasing concentrations of copper can alter behavior, reduce growth rates and final size, and at higher concentrations result in death. Copper also has algicidal effects and can disrupt the food chain in aquatic environments. For this reason, its direct introduction into flooded rice fields is contentious, particularly since rice fields serve as replacement wetlands for many flora and

fauna in agricultural areas like Northern California. Previous [comments to the NOSB](#) have highlighted specific concerns that the application rates in organic rice fields in California are several times higher than the amounts documented to kill the native amphibian species.

In the soil, it tends to concentrate heavily in the topsoil and leads to copper resistant fungal strains over time, as well as altering the soil microbiota and killing soil-dwelling animals such as earthworms. Copper toxicity in the soil can reduce the growth and nutrient value of crop plants, as well as damage the integrity of root systems (Van Assche and Clijsters, 1990). Because it accumulates in the soil over time and eventually results in poor plant outcomes, its use as a sustainable practice must be questioned.

Copper sulfate has been shown to be [toxic to bees](#), particularly in tropical environments. At sub-lethal levels, the heavy metal also changes behavior and movement ability (Rodrigues et al, 2016). Despite this, there are multiples statements on the National Pesticide Information Center ([NPIC](#)) and in US Environmental Protection Agency Office of Pesticide Programs documents stating that copper sulfate is virtually non-toxic to bees. This is an important point to clarify. The role that bees play in the pollination of commercial crops globally should make this a concern to farmers and the general public alike.

Copper sulfate has been classified as a human carcinogen by the European Chemicals Agency (ECHA), with specific concern for renal cancers (Buzio et al, 2002). Chronic exposure to fungicidal sprays elevated the risk of renal cancers by almost 3 times. While copper binds to soils readily, copper contamination of drinking water sources would also be a concern.

Discussion

Copper sulfate is a difficult substance to evaluate, as there appears to be broad consensus throughout the US, EU, and Canada that it is hazardous to both human health and the environment. Despite this, it has repeatedly had its use period extended in all three jurisdictions, as there isn't yet a viable organic alternative for copper in certain applications. The EU, Canada and Japan all exclude copper sulfate for organic rice production but allow it as a fungicidal spray in organic orchards and vineyards.

In terms of the copper sulfate use in rice paddies to control tadpole shrimp, it appears that there are ways to circumvent the need for chemical control. The tadpole shrimp emerge from eggs and most hatch within 1-3 days of flooding. Tadpole shrimp primarily cause injury to the rice through chewing young roots and shoots and disrupting the roots with burrowing activities (Tindall and Fothergill, 2012). The shrimp do not injure older seedlings once they have reached the water surface and roots are well established in the soil. In fact, at this later stage in seedling development, the tadpole shrimp can be beneficial to the crop by controlling algae and mosquitos.

Transplanting in older seedlings eliminates any threat from algal mats to the delicate young seedling stage, as do practices such as dry seeding the rice or ensuring that the rice is seeded directly at the time of flooding. Interestingly, transplanting seedlings has been the preferred method of rice production throughout most of human rice cultivation. In Asian rice cultivation, the tadpole shrimp are often deliberately introduced as a means of controlling algae and mosquitos. The current approach of flooding the fields and then direct wet-seeding didn't gain popularity until broad chemical use was implemented, and has been demonstrated to marginally reduce costs and increase yields.

In conclusion, it may be time to reconsider copper sulfate as an algicide and means of controlling tadpole shrimp. It appears there is sufficient evidence to conclude that:

- 1) use of copper sulfate in rice fields is environmentally detrimental,

- 2) alternative seeding practices could eliminate the need for the chemical as both algae and tadpole shrimp cease to be problematic once seedlings are established and
- 3) international standards do not allow for spraying of copper sulfate for organic rice production.

Questions to our Stakeholders

1. What are the roadblocks to transitioning to a dry-seeding or transplanting of rice seedlings in US rice production?
2. Are there viable practices that can be used to offset the toxic build-up of copper in the soil and water (i.e. crop rotation, phytoremediation with plants that draw copper from the soil)?

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Ozone gas

Reference: §205.601(a)(5) Ozone gas—for use as an irrigation system cleaner only.

Technical Report: [2002 TAP](#); [2021 TR Pending](#)

Petition(s): [2001](#)

Past NOSB Actions: [09/2002 meeting minutes and vote](#); [11/2007 recommendation](#); [12/2011 recommendation](#); [10/2016 sunset recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987](#)); Sunset renewal notice effective 11/03/2013 ([78 FR 61154](#)); Sunset renewal notice effective 5/29/2018 ([83 FR 14347](#))

Sunset Date: 5/29/2023

Subcommittee Review

Use

Ozone is a strong oxidant and works by oxidizing plant tissue and bacterial membranes. It is used as an antimicrobial agent to clean irrigation lines. It has been used in Europe for more than 100 years to treat

drinking water and it has been used in the United States to also disinfect water and to oxidize color and taste contaminants in water. It is found in nature at levels of 0.05 ppm but in levels of 0.5 ppm in cities with smog. Ozone is approved by the US Food and Drug Administration for use on food.

Manufacture

Ozone is usually formed by combining an oxygen molecule with an oxygen atom in an endothermic reaction. Because ozone is unstable it is generated at the point of use. It can be generated by irradiating oxygen-containing gas with UV light and other technologies, but the primary industrial method is by corona discharge. There are generally four system components to an ozone generating process: a power source or ozone generator; a gas source; an ozone delivery system; and an off-gas destruction system. The gas source may be air, high purity oxygen, or a combination of the two.

International acceptance

Canadian General Standards Board Permitted Substances [List](#)

The 2002 Technical Advisory Panel (TAP) review of ozone noted that ozone was not specifically listed.

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

The 2002 Technical Advisory Panel (TAP) review of ozone noted that ozone was not specifically listed.

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

The 2002 Technical Advisory Panel (TAP) review of ozone noted that ozone was not specifically listed.

International Federation of Organic Agriculture Movements (IFOAM) Norms

The 2002 Technical Advisory Panel (TAP) review of ozone noted that ozone was not specifically listed.

Japan Agricultural Standard (JAS) for Organic [Production](#)

The 2002 Technical Advisory Panel (TAP) review of ozone noted that ozone was not specifically listed.

Environmental Issues

When ozone is used for water treatment it oxidizes or disinfects many components that impact water quality. It will oxidize iron and manganese, which precipitate as ferric and manganese hydroxides. This could result in crop iron deficiencies. It partially oxidizes organic matter to forms that are more easily biodegradable. Ozone is also germicidal against many types of pathogenic organisms including viruses, bacteria, and protozoa. It is rated as a strong irritant via inhalation and to skin, eyes and mucous membranes. Ozone systems that inject directly into irrigation lines use relatively low concentrations of ozone and there is little potential for off-gassing. In water ozone decomposes rapidly and the only decomposition product is oxygen as opposed to chlorine which can generate trihalomethanes. Cleaning of irrigation lines should not lead to problems with soil structure because most of the ozone is contained in the irrigation tubing.

Discussion

Ozone is still in active use by the organic community. One certifier indicated they have ozone listed for use in 50 Organic system plans (OSPs). Users include wineries, mushroom operations, and grain handlers.

Questions to our Stakeholders

None.

Peracetic acid

Reference: §205.601(a)(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material. Also permitted in hydrogen peroxide formulations as allowed in §205.601(a) at concentration of no more than 6% as indicated on the pesticide product label; and, §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.

Technical Report: [2000 TAP](#), [2016 TR](#)

Petition(s): [2008](#)

Past NOSB Actions: [11/2007 recommendation](#); [11/2009 annotation change](#); [12/2011 sunset recommendation](#); [10/2016 sunset recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987](#)); Sunset Review 10/09/2008 ([73 FR 59479](#)) ; Annotation change 05/28/2013 ([78 FR 31815](#)); Sunset renewal notice effective 5/29/2018 ([83 FR 14347](#))

Sunset Date: 5/29/2023

Subcommittee Review

Use

In organic crop production, peracetic acid, or PAA, is used to disinfect equipment. It can also be used as a disinfectant to treat seeds or asexually propagated planting material. It can be used to disinfect pruning equipment to help prevent the spread of the fire blight bacterium and is also used in one of the hydrogen peroxide formulations for control on the tree canopy of this same disease. PAA is also used in formulations of hydrogen peroxide, allowed at a concentration of no more than 6%, for use in organic crop production. Peracetic acid was relisted during the 2016 sunset review for Handling and the 2017 sunset listing for Livestock.

Peracetic acid is an unstable oxidizing agent, which is what makes it such an effective sanitizer. According to the 2016 TR, solutions of peracetic acid, hydrogen peroxide, acetic acid and water are produced by reacting glacial acetic acid with hydrogen peroxide, frequently in the presence of a catalyst such as a mineral acid (e.g., sulfuric acid). Most commercially available PAA 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.

Manufacture

Peracetic acid appears to be a straightforward material in that it is made from, and decomposes back to, acetic acid, oxygen, and water. PAA is a very strong oxidizing agent and can be produced by the interaction between methyl (or acetaldehyde) and air, or by mixing acetic acid and hydrogen peroxide (methyl itself derives from plants, commonly coffee, bread grains, and ripe fruit). It can also be produced within laundry detergents and is considered a more effective bleach than hydrogen peroxide.

First industrially developed in 1950, it has historically been used to treat fruits and vegetables to reduce spoilage from bacteria and various fungi. It is used to treat bulbs, to disinfect potting soil, clean irrigation equipment, and in seed treatment to inactivate fungi or other plant diseases. Additionally, in organic crop production it is also used as a bactericide/fungicide in wash waters to help decrease *Escherichia coli* O157:H7 on some fruit and vegetable crops. With the removal of two antibiotics previously allowed for use in organic crop production to assist in fire blight reduction, use of this substance as part of a rotational

control and fire blight prevention program has increased in recent years, according to information provided by some organic stakeholders during public comment periods.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

Permits the use of peracetic (peroxyacetic) acid at paragraph 4.3 (Crop Production Aids and Materials) with the following annotation: “Permitted for: a) controlling fire blight bacteria; and b) disinfecting seed and asexually propagated planting material”. This allowance is consistent with NOP regulations.

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

Peracetic acid is not listed in Annex II – Pesticides – plant protection products. Nonetheless, as of June 1, 2012, the European Union and the United States have an equivalency agreement whereby organic products certified to the USDA or European Union (EU) organic standards may be sold and labeled as organic in both the U.S.A. and the EU.

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

Not listed.

International Federation of Organic Agriculture Movements (IFOAM) Norms

IFOAM norms permit the use of peracetic acid for cleaning equipment and/or disinfecting equipment with no final rinse (IFOAM Appendix 4, Table 2), for pest and disease control, and for disinfection of livestock housing and equipment (IFOAM Appendix 5).

Japan Agricultural Standard (JAS) for Organic [Production](#)

Not listed in the Japanese Agricultural Standard for Organic Production. However, the United States entered into an equivalency agreement with Japan, effective on January 1, 2104. The scope of the arrangement is limited to plants and plant-based products which undergo final processing, packaging, or labeling within the boundaries of those two countries.

Environmental Issues

If misused, peracetic acid can irritate eyes, skin, and breathing.

Discussion

Peracetic acid was registered by the EPA for indoor antimicrobial use in 1985. In the December 2, 2011, NOSB recommendation for the 2013 sunset review of peracetic acid for the two 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 with a slight change. The recommended 5% limit was 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. This point of concern was discussed at the

Spring NOSB meeting and it was decided that this slight increase in the percentages was necessary to adequately accommodate use rates.

While there do appear to be other materials that could be used as possible alternatives, peracetic acid is selected for use by many organic crop producers for many reasons: It is a strong oxidizing compound, works well in colder conditions, does not give off chlorine into the environment, used as part of a rotation process in fire blight disease control, and is the more benign of the sanitizers and disinfectants, since it reverts back to acetic acid, oxygen, and water in the environment. It has also been described as a no-rinse material. This is according to information provided during public comment, and also found in the 2016 TR.

Concerns were raised during public comment submitted for the Spring 2016 NOSB meeting regarding the various forms of peracetic acid mentioned in the TR. This was discussed during the meeting and the NOSB determined the majority of those other sources (that were raising a concern) would not be allowed for use in organic crop production or other currently allowed uses, as currently shown on the National List. Several commenters also mentioned that they felt that all sanitizers and disinfectants should be looked at for a determination of need and prioritization of allowed uses. It was determined that request was outside of the scope of this specific sunset review and would need to be addressed as a separate issue/topic.

Other public comment mentioned that the implementation of the Food Safety Modernization Act (FSMA), to oversee an enhanced approach to food safety both at the farm and at the handling levels, places an even higher degree of necessity in having this material and/or other sanitizers available for use in organic crop production.

There was overwhelming support for the continued (relisting) of peracetic acid for use in organic crop production. While a few commenters took a neutral position, there were no commenters, either during the written or oral public comment periods, that were specifically opposed to the relisting of peracetic acid. Based on the information provided (comments, new TR, etc.), discussion during public comment periods (in-person, webinar, and written), and Subcommittee review and Discussion it was determined this material satisfies the OFPA Evaluation criteria and the Crops Subcommittee supported the relisting of peracetic acid. Additionally, peracetic acid was relisted during the 2016 Sunset review for Handling and the 2017 Sunset listing for Livestock.

14 NOSB members (with one absent) voted for peracetic acid to remain on the National List for use at §205.601.

Questions to our Stakeholders

The NOSB, through its various Subcommittees is engaging in a critical assessment of how it reviews the full suite of sanitizers either available in organic or petitioned for use in organic. As part of that assessment, the following draft framework has been suggested as a means of polling stakeholders to determine the appropriateness of certain materials in organic production:

1. Base Process: How does the material fit into an adequate system of cleaning (contact time, scrubbing effort and force, water source, etc.), rinsing, and sometimes testing, as the essential first step in sanitation?
2. Use: Is it a direct food contact material or a surface contact material?
3. Need: Has the material met the need addressed by its original petition?
4. Efficacy: How well does the material work for the specific need identified?

5. Alternatives: Are existing alternatives adequate? Are there materials already on the list that can be employed in a new use, rather than adding or a new material or continuing to allow use of a less appropriate older material?
6. Rotation: How does this material fit into rotations and/or the need for back up materials?
7. Other Regulatory Reviews: How can we look to FDA and EPA to help us assess risk while, also evaluating against the OFPA criteria (particularly environmental fate and human contact impacts)?

EPA List 3 – Inerts of unknown toxicity

Reference: §205.601(m)(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.

Technical Report: N/A

Petition(s): N/A

Past NOSB Actions: [10/2002 meeting minutes and vote \(see pheromones\)](#); [11/2007 recommendation](#); [05/2012 recommendation](#); [08/2015 recommendation to change annotation at 7 CFR §205.601\(m\)](#); [10/2016 sunset recommendation](#); [NOSB resolution \(2020\)](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987](#)); Sunset Review 10/09/2008 ([73 FR 59479](#)) Sunset Review 10/03/13 ([78 FR 61154](#)); Sunset renewal notice effective 5/29/2018 ([83 FR 14347](#))

Sunset Date: 5/29/2023

Subcommittee Review

Use

The annotation for the List 3 Inerts limits their use in organic crop production to passive pheromone dispensers. The dispensers are normally manufactured as either tubes that contain pheromones or as an impregnated substance containing the pheromone. They may be used to trap and monitor insect populations or they may be used for control of a pest through pheromone mating disruption. For trapping, the pheromone-impregnated dispenser is placed in a trap and the insect catch is monitored to determine when an economic threshold is reached, and the particular insect needs to be controlled. For pheromone mating disruption, the dispensers are tied to branches of trees or placed in such a manner that they are distributed throughout an area being covered by the pheromones. Throughout the season the construction of the pheromone dispensers regulates the volatilization of pheromones into the air. Once in the air of the production area, the pheromones act to disrupt mating of the by interfering with the insect communication systems. A wide variety of insects, mostly Lepidoptera, can be managed with pheromones including codling moth, peach twig borer, peach crown borer, leafrollers, pink bollworm, boll weevil, gypsy moth, and others. When they are placed in the production area, the pheromone dispensers are not in contact with the organic product being grown but are instead suspended from the trees or plants. Since the pheromone dispensers do not contact the product grown, there is no movement of the pheromones into the product. Passive pheromone dispensers are different from other forms of dispensers such as microencapsulated products, which are sprayed throughout the production area and could be in direct contact with the fruit or other product being grown.

Manufacture

Manufacture varies based on which List 3 inert is being used, so will not be addressed. International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

Synthetic and non-synthetic pheromones and semiochemicals are permitted. For pest control. Use in pheromone traps or passive dispensers.

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

Pheromones, Attractant; sexual behaviour disrupter; only in traps and dispensers.

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

Pheromone preparations for traps.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Pheromones – in traps and dispensers only.

Japan Agricultural Standard (JAS) for Organic [Production](#)

Limited to the agent containing sex pheromone activity for pest as active ingredient.

Environmental Issues

Passive pheromone dispensers used for monitoring insects are crucial to integrated pest management programs in that they help to determine the size and impact of insect populations. The use of passive pheromone dispensers for mating disruption often precludes the need for other chemical controls. When used with adequate sanitation practices, monitoring, biocontrol methods, and environmental controls, pheromones can be effective in controlling certain Lepidoptera insects. Without pheromone use, and despite the other natural controls listed, other insecticides may be needed for control of the specific pest insect. These insecticides may be either natural or synthetic but would most often be applied directly to the product being grown and might require preharvest intervals. While pheromones are very specific to individual insect species, these other insecticides may be broader spectrum and affect more species than those requiring control and may have more detrimental environmental impacts.

Other potential environmental issues relate to the number of List 3 Inerts pheromone dispensers used per acre. Often maximum dispenser applications are in the range of 400 per acre. Information from the package of one manufacturer shows ingredients other than pheromones as 8% and that the total amount of pheromone applied per acres is 50 grams. Given the small amount of pheromone applied, there is a very small volume of List 3 Inerts applied to any given acre. This application rate might be compared to the amounts of allowed List 4 Inerts applied in spray materials or the amount of synthetics applied in allowed newspaper mulch. While any application of any material to organic acreage should be considered, it is also important to consider the scale of the application. In addition, the ingredients other than pheromones are heavier than the pheromone itself and remain inside the dispenser. Thus, the List 3 Inerts are not dispersed into the atmosphere and do not have direct fruit contact.

The manufacture of pheromones may have possible environmental impacts, but because these materials are grouped together as List 3 Inerts, these impacts cannot be independently categorized.

Discussion

For reference, the old EPA lists can be found at: <https://www.epa.gov/pesticide-registration/categorized-lists-inert-ingredients-old-lists>

As with the discussion of the listing for List 4 Inerts reviewed during 2020, this listing is outdated in that the EPA no longer maintains its listing of List 4 or List 3 inerts. Thus, the system to review materials for addition or removal is broken. The listing for List 3 Inerts is more specific than that for List 4 Inerts in that it is limited to only those materials needed for and used in passive pheromone dispensers. These dispensers do not come into direct contact with the agricultural product being produced, whether they be used for trapping or mating disruption.

During the previous review by the NOSB, the NOSB supported the recommendation that these inerts move into a separate listing that would cover all inert ingredients. The inert ingredients used in passive pheromone dispensers were to be a subheading of inerts. However, the process recommended by the NOSB in that review was not initiated and the review of these materials is similar to the previous review. As with List 4 Inerts, the NOSB strongly recommends and asks the National Organic Program to develop an alternative to these List 4/List 3 references that would allow for review (and addition or removal) of inerts and that would not rely on an antiquated list. Public comments from prior reviews supported moving quickly with an annotation change so that the List 3 Inerts could be systematically and thoroughly reviewed.

However, NOSB, in prior reviews, found that these materials are an essential component of passive dispensers and have a history of use in organic farming. They have reduced the use of many other pest control products. The specificity of the annotation leads to limited use in very controlled situations. There was no new information that caused the NOSB to question their safety to human health or the environment. In prior reviews, public commenters supported moving quickly with the annotation change so that the List 3 Inerts, as well as the other inerts, could be systematically and thoroughly reviewed. The continued need for the pheromones was a common theme in the public comments as well.

Questions to our Stakeholders

1. Are there any new health or environmental concerns with the use of the List 3 inerts in passive pheromone dispensers?
2. Are there any natural alternatives to the use of List 3 inerts in passive pheromone dispensers?
3. What percent of ingredients in passive pheromones do List 3 inerts represent?
4. Do the List 3 ingredients in the passive dispensers diffuse into the environment or do they remain in the dispensers?

Chlorine materials – Calcium hypochlorite

Reference: §205.601(a) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials -For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

(i) Calcium hypochlorite

Technical Report(s): [1995 TAP](#); [2006 TR](#); [2011 TR](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [04/2006 NOSB sunset recommendation](#); [04/2011 NOSB sunset recommendation](#); [10/2015 sunset recommendation](#); [11/2017 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice 3/21/2017 ([82 FR 14420](#)); Sunset renewal notice effective 10/30/2019 ([84 FR 53577](#))

Sunset Date: 10/30/2024

Subcommittee Review

Use

Calcium hypochlorite is an EPA-registered pesticide (OPP Nos. 014701). Calcium hypochlorite is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. Allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl₂).

Calcium hypochlorite is an "indirect" food additive approved by [FDA](#). Calcium hypochlorite may be used as a final sanitizing rinse on food processing equipment (21 CFR 178.1010). Hypochlorites also can be used in postharvest, seed, or soil treatment on various fruit and vegetable crops (EPA, 1991).

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration or the Environmental Protection Agency for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

In water, sodium and calcium hypochlorite separate into sodium, calcium, and hypochlorite ions, and hydrochlorous acid molecules. Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with the hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates triosephosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function.

Manufacture

Calcium hypochlorite is produced by passing chlorine gas over slaked lime. It is then separated from the coproduct, calcium chloride, and air dried or vacuumed.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

http://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-311-2020-eng.pdf

International Federation of Organic Agriculture Movements (IFOAM) Norms

Equipment cleaner/disinfectant: <https://www.ifoam.bio/our-work/how/standards-certification/organic-guarantee-system/ifoam-standard>. An intervening event or action must occur to eliminate risks of contamination

Environmental Issues

Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposures occur or from chronic lower-level exposures – especially in occupational environments when these materials are used on a daily basis. These compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) and can cause asthma, as classified by the Association of Occupational and Environmental Clinics (<http://www.aoecdata.org/ExpCodeLookup.aspx Code 332.10>). Given the similar chemistries and mechanisms of action, other chlorine-based oxidant sanitizers, already known to be respiratory irritants, also likely cause asthma. Chlorine compounds are toxic to fish and other aquatic organisms. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in a 2006 and 2011 Technical Reports (TR) (referenced above.).

Discussion

Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food-safety regulations under the Food Safety Modernization Act (FSMA). The Crops Subcommittee (CS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The CS supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.

Questions to our Stakeholders

The NOSB, through its various Subcommittees, is engaging in a critical assessment of how it reviews the full suite of sanitizers either available in organic or petitioned for use in organic. As part of that assessment, the following draft framework has been suggested as a means of polling stakeholders to determine the appropriateness of certain materials in organic production:

1. Base Process: How does the material fit into an adequate system of cleaning (contact time, scrubbing effort and force, water source, etc.), rinsing, and sometimes testing, as the essential first step in sanitation?
2. Use: Is it a direct food contact material or a surface contact material? *Do stakeholders see any distinction in the use of this material in this crop production context versus a food handling/processing context?*

3. Efficacy: How well does the material work for the specific need identified?
4. Alternatives: Are existing alternatives adequate? Are there materials already on the list that can be employed in a new use, rather than adding or a new material or continuing to allow use of a less appropriate older material?
5. Rotation: How does this material fit into rotations and/or the need for back up materials?
6. Other Regulatory Reviews: How can we look to FDA and EPA to help us assess risk while also evaluating against the OFPA criteria (particularly environmental fate and human contact impacts)?

Chlorine materials – Chlorine dioxide

Reference: §205.601(a) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials - For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

(ii) Chlorine dioxide

Technical Report(s): [1995 TAP](#); [2006 TR](#); [2011 TR](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [04/2006 NOSB sunset recommendation](#); [04/2011 NOSB sunset recommendation](#); [10/2015 sunset recommendation](#); [11/2017 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice 3/21/2017 ([82 FR 14420](#)); Sunset renewal notice effective 10/30/2019 ([84 FR 53577](#))

Sunset Date: 10/30/2024

Subcommittee Review

Use

Chlorine dioxide is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. It is allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl₂).

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration or the Environmental Protection Agency for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum

residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

Chlorine dioxide is a strong oxidant. It is likely a better bactericide than hypochlorous acid. In general, the disinfection efficiency of chlorine dioxide decreases as temperature decreases.

Manufacture

To form chlorine dioxide, sodium chlorate (NaClO₃) and sulfuric acid (H₂SO₄) are reacted with sulfur dioxide (SO₂), or chloric acid is reacted with methanol (CH₃OH) (HSDB, 2005). Alternatively, chlorine dioxide can be formed with chlorine (Cl₂) and sodium chlorite; sodium hypochlorite with hydrochloric acid; potassium chlorate with sulfuric acid; or by passing nitrogen dioxide through a column of sodium chlorate.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

http://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-311-2020-eng.pdf

International Federation of Organic Agriculture Movements (IFOAM) Norms

Equipment cleaner/disinfectant: <https://www.ifoam.bio/our-work/how/standards-certification/organic-guarantee-system/ifoam-standard>. An intervening event or action must occur to eliminate risks of contamination

Environmental Issues

Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposures occur or from chronic lower level exposures – especially in occupational environments when these materials are used on a daily basis. These compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) can cause asthma, as classified by the Association of Occupational and Environmental Clinics (<http://www.aocdata.org/ExpCodeLookup.aspx Code 332.10>). Given the similar chemistries and mechanisms of action, other chlorine-based oxidant sanitizers, already known to be respiratory irritants, also likely cause asthma. Chlorine compounds are toxic to fish and other aquatic organisms. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in 2006 and 2011 Technical Reports (TR) (referenced above).

Discussion

Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food-safety regulations under the Food Safety Modernization Act (FSMA). The Crops Subcommittee (CS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The CS supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.

Questions to our Stakeholders

The NOSB through its various Subcommittees is engaging in a critical assessment of how it reviews the full suite of sanitizers either available in organic or petitioned for use in organic. As part of that assessment, the following draft framework has been suggested as a means of polling stakeholders to determine the appropriateness of certain materials in organic production:

1. Base Process: How does the material fit into an adequate system of cleaning (contact time, scrubbing effort and force, water source, etc.), rinsing, and sometimes testing, as the essential first step in sanitation?
2. Use: Is it a direct food contact material or a surface contact material? *Do stakeholders see any distinction in the use of this material in this crop production context versus a food handling/processing context?*
3. Efficacy: How well does the material work for the specific need identified?
4. Alternatives: Are existing alternatives adequate? Are there materials already on the list that can be employed in a new use, rather than adding or a new material or continuing to allow use of a less appropriate older material?
5. Rotation: How does this material fit into rotations and/or the need for back up materials?
6. Other Regulatory Reviews: How can we look to FDA and EPA to help us assess risk while also evaluating against the OFPA criteria (particularly environmental fate and human contact impacts)?

Chlorine materials – Hypochlorous acid – generated from electrolyzed water

Reference: §205.601(a) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials -For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

(iii) Hypochlorous acid - generated from electrolyzed water.

Technical Report(s): [1995 TAP \(Chlorine materials\)](#); [2006 TR \(Chlorine materials\)](#); [2011 TR \(Chlorine materials\)](#); [2015 TR \(Hypochlorous acid\)](#)

Petition(s): [2015](#)

Past NOSB Actions: [04/2016 recommendation to add](#)

Recent Regulatory Background: Added to NL 12/27/2018 ([83 FR 66559](#))

Sunset Date: 1/28/2024

Subcommittee Review

Use

Hypochlorous acid is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. Allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl₂).

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration or the Environmental Protection

Agency for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates triosephosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function.

Manufacture

Electrolyzed water (EW) 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 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. (TR lines 48-68).

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

http://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-311-2020-eng.pdf

Japan Agricultural Standard (JAS) for Organic [Production](#)

https://www.maff.go.jp/e/policies/standard/jas/specific/attach/pdf/criteria_o-12.pdf

Environmental Issues

Hypochlorous acid, generated from electrolyzed water, is present in solutions of two chlorine sanitizers (sodium hypochlorite and calcium hypochlorite) currently allowed at §205.601(a)(2)(i, ii). Like other chlorine compounds, hypochlorous acid is also an oxidant and can pose risks to human health. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in 2006 and 2011 Technical Reports (TR) (referenced above).

As formulated via electrolyzed water, hypochlorous acid is effective as a sanitizer at a lower chlorine concentration and is likely safer for health and the environment than other currently listed chlorine sanitizers.

Discussion

Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food-safety regulations under the Food Safety Modernization Act (FSMA). The Crops Subcommittee (CS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The CS supports research priorities that investigate alternatives to

chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.

Questions to our Stakeholders

The NOSB through its various Subcommittees is engaging in a critical assessment of how it reviews the full suite of sanitizers either available in organic or petitioned for use in organic. As part of that assessment, the following draft framework has been suggested as a means of polling stakeholders to determine the appropriateness of certain materials in organic production:

1. Base Process: How does the material fit into an adequate system of cleaning (contact time, scrubbing effort and force, water source, etc.), rinsing, and sometimes testing, as the essential first step in sanitation?
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5. Rotation: How does this material fit into rotations and/or the need for back up materials?
6. Other Regulatory Reviews: How can we look to FDA and EPA to help us assess risk while also evaluating against the OFPA criteria (particularly environmental fate and human contact impacts)?

Chlorine materials – Sodium hypochlorite

Reference: §205.601(a) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials -For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

(iv) Sodium hypochlorite

Technical Report(s): [1995 TAP](#); [2006 TR](#); [2011 TR](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [04/2006 NOSB sunset recommendation](#); [04/2011 NOSB sunset recommendation](#); [10/2015 sunset recommendation](#); [11/2017 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice 3/21/2017 ([82 FR 14420](#)); Sunset renewal notice effective 10/30/2019 ([84 FR 53577](#))

Sunset Date: 10/30/2024

Subcommittee Review

Use

Sodium hypochlorite is an EPA-registered pesticide (OPP No 014703). Sodium hypochlorite is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses,

and fungi on inanimate objects and surfaces primarily in indoor environments. Allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl₂).

Sodium hypochlorite is an "indirect" food additive approved by [FDA](#). Sodium hypochlorite may be used as a final sanitizing rinse on food processing equipment (21 CFR 178.1010); sodium hypochlorite may be used in washing and lye peeling of fruits and vegetables (21 CFR 173.315). These hypochlorites also can be used in postharvest, seed, or soil treatment on various fruit and vegetable crops (EPA, 1991).

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration or the Environmental Protection Agency for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

In water and soil, sodium and calcium hypochlorite separate into sodium, calcium, and hypochlorite ions and hydrochlorous acid molecules. Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with the hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates triosephosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function.

Manufacture

Generally, sodium hypochlorite is produced by reacting chlorine with a solution of sodium hydroxide (NaOH, also called lye or caustic soda). This method is used for most commercial productions of sodium hypochlorite. A more active, but less stable formulation of sodium hypochlorite can be produced by chlorinating a solution of soda ash (Na₂CO₃).

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

http://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-311-2020-eng.pdf

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

<https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:250:0001:0084:EN:PDF>. Products for cleaning and disinfection referred to in Article 23 (4).

International Federation of Organic Agriculture Movements (IFOAM) Norms

Equipment cleaner/disinfectant: <https://www.ifoam.bio/our-work/how/standards-certification/organic-guarantee-system/ifoam-standard>. An intervening event or action must occur to eliminate risks of contamination.

Japan Agricultural Standard (JAS) for Organic [Production](#)

Environmental Issues

Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposure occurs or from chronic lower-level exposures – especially in occupational environments when these materials are used on a daily basis. These compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) can cause asthma, as classified by the [Association of Occupational and Environmental Clinics](#). Given the similar chemistries and mechanisms of action, other chlorine-based oxidant sanitizers, already known to be respiratory irritants, also likely cause asthma. Chlorine compounds are toxic to fish and other aquatic organisms. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in 2006 and 2011 Technical Reports (TR) (referenced above.).

Discussion

Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food-safety regulations under the Food Safety Modernization Act (FSMA). The Crops Subcommittee (CS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The CS supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.

Questions to our Stakeholders

The NOSB through its various Subcommittees is engaging in a critical assessment of how it reviews the full suite of sanitizers either available in organic or petitioned for use in organic. As part of that assessment, the following draft framework has been suggested as a means of polling stakeholders to determine the appropriateness of certain materials in organic production:

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5. Rotation: How does this material fit into rotations and/or the need for back up materials?
6. Other Regulatory Reviews: How can we look to FDA and EPA to help us assess risk while also evaluating against the OFPA criteria (particularly environmental fate and human contact impacts)?

Magnesium oxide

Reference: §205.601(j)(5) Magnesium oxide (CAS # 1309-48-4)—for use only to control the viscosity of a clay suspension agent for humates.

Technical Report(s): [2021 TR Pending](#)

Petition(s): [2013](#)

Past NOSB Actions: [5/2014 NOSB recommendation to add](#)

Recent Regulatory Background: Added to NL 12/27/2018 ([83 FR 66559](#))

Sunset Date: 1/28/2024

Subcommittee Review

Use

Magnesium oxide (MgO) is a synthetic substance approved for use in organic crop production to control the viscosity of a clay suspension agent for humates. MgO occurs as the mineral magnesia, and in its hydrated form – magnesium hydroxide - as the naturally occurring mineral periclase. Magnesium oxide appears to be a fairly benign compound that has a wide range of uses, including as an antacid and laxative (milk of magnesia), and in lots of industrial processes such as in producing cement, abrasive materials, and furnace linings.

MgO is neither a strong acid nor a strong base. Instead it acts as a buffering agent when in aqueous solution. Buffering agents are materials that create an effective resistance to change in pH of aqueous solution when a strong acid or base is added.

Manufacture

There are several manufacturing processes used to produce MgO. It is commonly made from sea water or salt brines but can also be made by heating magnesium carbonate (MgCO₃) limestone to drive off carbon dioxide (CO₂) and produce MgO. The production of MgO from sea water or salt brine uses the following procedure: The raw materials are lime and salt water -- either sea water or brine from salty wells. The lime is heated to produce calcium oxide. Fresh water is then added to the calcium oxide to produce calcium hydroxide. Sea water or salt brine from a well is treated with a small amount of sulfuric or hydrochloric acid which is then added to the calcium hydroxide, causing the magnesium chloride in the salt water to react with calcium hydroxide to produce magnesium hydroxide and calcium chloride. The magnesium hydroxide is then heated to produce magnesium oxide.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

There are no current references to synthetic magnesium oxide for use in crop production.

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

There are no current references to synthetic magnesium oxide for use in crop production.

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

There are no current references to synthetic magnesium oxide for use in crop production.

International Federation of Organic Agriculture Movements (IFOAM) Norms

There are no current references to synthetic magnesium oxide for use in crop production.

Japan Agricultural Standard (JAS) for Organic [Production](#)

There are no current references to synthetic magnesium oxide for use in crop production.

Environmental Issues

When magnesium oxide is produced using sea water or salt brine, a small amount of acid is used to lower the pH of the salt solution to prevent the formation of carbonates. When MgO is produced using magnesium carbonate limestone, carbon dioxide is released into the atmosphere. Additional carbon dioxide is produced through the burning of fossil fuels used to achieve the high heat required to decompose the limestone.

The code of federal regulations (CFR), title 21, Part 184-Direct food substances affirmed as generally recognized as safe lists magnesium oxide at § 184.1431 as an ingredient used in food with no limitation other than current good manufacturing practice and affirms the ingredient as generally recognized as safe (GRAS) as a direct human food ingredient.

The original petitioner noted that magnesium oxide is safely used in numerous applications in preference to other materials because it is considered to be nonhazardous, environmentally safe, and nontoxic. Some of the applications include:

- wastewater treatment
- toxic metal removal
- adsorption of dyes and excess phosphorus from industrial wastewater
- odor control
- treatment of acid mine drainage
- non-toxic flame retardant for clothing
- flue gas desulfurization
- hazardous spill clean up

Magnesium oxide and the hydrated form magnesium hydroxide have been used safely for over a century as a laxative and antacid (milk of magnesia).

Discussion

This is the first sunset review for magnesium oxide since it was added to the National List. There was a previous technical report which covered the uses of magnesium oxide in livestock production and the petitioner noted that aspects from that report were relevant to the listing for crops use. The NOSB has requested, but not yet received, a technical report specifically for the use of this material in crops. The technical report should be received in enough time to include the information in the review for the fall NOSB meeting.

According to the original petition, natural humic substances stimulate biological activity, foster cycling of resources by making fertilization more efficient, conserve water, promote ecological balance, conserve biodiversity, and improve soil and water quality. Non-synthetic humic substances are used in organic agriculture to improve soil structure and fertility, increase plant nutrient uptake, and improve root architecture.

The petitioner further stated that magnesium oxide is used to:

modify clays in such a manner to effectively suspend humic substances while simultaneously preventing recrystallization of any fertilizer or micronutrient salts that may be in solution. Reducing the growth of crystals is necessary to prevent the plugging of spray nozzles during spray applications. The use of the magnesium oxide-modified clay also increases the viscosity of aqueous

suspensions of humates, which in turn delays settling and keeps the solids from forming a hard cake when settling eventually occurs.

Alternatives to magnesium oxide include periclase and brucite, dolomitic limestone, phlogopite, wood ash, and pelletized non-synthetic humates. The petitioner states that these are either not commercially available or do not meet chemical or physical specifications for suspending humates in solution.

In the review to add magnesium oxide to the National List, the NOSB determined that magnesium oxide, as petitioned, satisfied all three evaluation criteria - minimal impact on humans and environment, essentiality for use in organic agriculture, no commercial availability of non-synthetic material, and compatibility & consistency with organic agriculture. They found that magnesium oxide appeared to be a fairly benign compound that has a wide range of uses. The petitioned use is for a very low level and specific use. The NOSB chose to add the restrictive annotation to clarify the language in the petition, which they felt was too broad.

Questions to our Stakeholders

1. Has magnesium oxide been used for the purposes of suspending humates in a clay solution as described in the original petition?
2. Are there any commercially available, non-synthetic alternatives that achieve the same purpose as magnesium oxide?
3. Is there still a need for liquid humates in organic agriculture?
4. Can non-synthetic acids be used in place of sulfuric acid in the manufacture of magnesium oxide?
5. Are there environmental or human health issues that should be noted in the decision to retain magnesium oxide on the National List?

Calcium chloride

Reference: §205.602(c) Calcium chloride, brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.

Technical Report: [2001 TAP](#); [2021 TR Pending](#)

Petition(s): [2005](#); [2015](#)

Past NOSB Actions: [09/1996 minutes and vote](#); [11/2006 annotation change \(failed\)](#); [11/2007 sunset recommendation](#); [12/2011 sunset recommendation](#); [10/2016 sunset recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#)); Sunset renewal notice effective 5/29/2018 ([83 FR 14347](#))

Sunset Date: 5/29/2023

Subcommittee Review

Use

Calcium chloride is used to manage almost three dozen physiological disorders on crops. These include a reduction of cork spot on pears, bitter pit in apples, fruit cracking on developing figs, rain cracking in cherries, blossom end rot on tomatoes, and tipburn on Chinese cabbage (TAP lines 156-175). "Application of foliar calcium sprays relieves calcium physiological disorders because these are local deficiencies due to

calcium transport problems. Local availability of calcium in new shoots and fruits can help solve the problem” (lines 197-98). Application of nonsynthetic calcium chloride in organic crop production is limited to foliar sprays to treat a physiological disorder associated with calcium uptake.

Manufacture

According to the 2007 TAP, “calcium chloride can be produced from a number of sources by various methods. Some of these are naturally occurring, some require extraction and beneficiation that is not considered by most reviewers to be a chemical reaction, and some are entirely synthetic. Those extracted from brine are generally considered nonsynthetic, although certain steps to purify the brine may be considered synthetic (lines 8-11).” The TAP goes on to explain that “calcium chloride can be obtained by extraction of nonsynthetic brines. When calcium chloride is extracted from a nonsynthetic source, its molecular structure is not changed during extraction and thus should be classified nonsynthetic. However, Dow (the major supplier) and other producers use synthetic chemicals during the purification of the brine (lines 62-4).” Industrial production of calcium chloride occurs mainly through 1) the hydrochloric acid method, 2) the Solvay process, and 3) the Dow process. “Productions by the Solvay process and by reaction of a calcium source with hydrochloric acid are both clearly synthetic” (lines 11-12). The 2001 TAP explains that:

Calcium chloride can be obtained by extraction of nonsynthetic brines. When calcium chloride is extracted from a nonsynthetic source, its molecular structure is not changed during extraction and thus should be classified nonsynthetic (lines 62-3).

Calcium chloride from naturally occurring brine is nonsynthetic as long as there are no manufacturing steps (see [NOP 5033 4.6 Extraction of Nonorganic Materials](#)) that change the classification to synthetic.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

States “non-synthetic calcium chloride may be used to address nutrient deficiencies and physiological disorders”.

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

Allows for calcium chloride as a “foliar treatment of apple trees, after identification of deficit of calcium” with the limitation that the need be “recognized by the inspection body or inspection authority”.

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

Lists calcium chloride for “leaf treatment in case of proven calcium deficiency”.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Permits calcium chloride under Appendix 2, Fertilizers and Soil Conditioners of mineral origin with no restrictions on use.

Japan Agricultural Standard (JAS) for Organic [Production](#)

Lists calcium chloride under Fertilizers and Soil Improvement Substances.

Environmental Issues

The 2007 TAP describes that, when used as a foliar spray, calcium chloride “probably has low potential for interaction or interference with other materials used in organic farming” (lines 295-96). It has a low toxicity to mammals, though it can be a skin, eye, and breathing irritant. When used in foliar applications, “it should not affect beneficial insects. It should not persist on foliage. Any not absorbed by the plant should

be washed off with rain. Calcium chloride is extremely soluble in water, and low concentrations from foliar use should not build up in soil, unless it is used in low rainfall areas with minimal irrigation. Any water-soluble calcium or chloride not absorbed by plant roots would drain into surface waters or be leached into groundwater (lines 304-08).” Additionally, during manufacture from brines, the liquid brines are pumped out from underground, and do not present the kind of problem usually seen with strip mining. The only toxic chemicals involved are chlorine and bromine, and they are handled so that environmental contamination is low. The chlorine is recycled, and bromine is isolated as bromide or bromine and is sold as a chemical product. Excess lime added in processing is isolated as part of the final calcium chloride. The magnesium hydroxide produced is used to prepare other magnesium salts and magnesium metal by electrolysis. It is not dumped into the environment. The sodium chloride isolated in the process is sold as table salt or for chemical production. Spent solutions are recycled and pumped back underground to isolate a new concentrated brine (lines 311-319). Finally, “calcium chloride obtained from natural salt brines has a significant amount of sodium chloride, usually about 3-4%. Sodium chloride has a high salt index and should not be applied to soil (Rader, et al., 1943)... Application to soil could lead to chloride phytotoxicity (Greenway and Munns, 1980) (TAP lines 355-58).

Discussion

This is a unique §205.602 material in that while not completely prohibited for use, the listing serves to annotate or the restrict use of this nonsynthetic. Since it is only allowed for a very specific use (foliar application to treat a calcium uptake disorder), Material Review Organizations list it with the restriction to reflect the very narrow permitted use. Certifiers are responsible for verifying that growers use it in a manner consistent with the restriction.

In 1996, the NOSB originally voted to allow calcium chloride for use to control bitter pit in apples and as an emergency defoliant for cotton; the material was categorized as nonsynthetic and was not included on sections 205.601 or 205.602. In 2003, calcium chloride was subsequently added to National List at § 205.602 as a non-synthetic substance prohibited for use in organic crop production with the current annotation. The annotation states: “brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.” In 2005, the NOSB rejected a petition to remove the prohibition for use as a soil-applied nonsynthetic substance due to high chloride and solubility concerns. The board received another petition in 2015 to remove the prohibition on direct soil applications but determined it to be ineligible as no new substantive information was presented to warrant reconsideration of the petition.

The NOSB has consistently concluded that brine process calcium chloride is a mined substance of high solubility, and as such, its use is subject to the conditions established on the National List of non-synthetic materials prohibited for crop production. The foundational principle for placing high solubility materials such as calcium chloride on the prohibited non-synthetic materials list is elaborated in §205.203(d) – 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...” The NOSB has established that the potential for overuse of this natural substance resulting in subsoil, surface water, and ground water contamination, warrant continued limitation through the annotation restrictions.

Questions to our Stakeholders

1. On which crops and for what physiological disorders associated with calcium uptake is calcium chloride used by producers?
2. The 2007 TAP states: “Since bitter pit of apples is a calcium deficit disorder, an alternate form of calcium, such as limestone, gypsum, or rock phosphate, could be used”. Please comment.

Rotenone

Reference: §205.602(f) Rotenone (CAS # 83-79-4).

Technical Report(s): N/A

Petition(s): N/A

Past NOSB Actions: [10/2012 NOSB recommendation to add](#)

Recent Regulatory Background: Added to NL 12/27/2018 ([83 FR 66559](#))

Sunset Date: 1/28/2024

Subcommittee Review

Use

Rotenone is a potent non-synthetic botanical pesticide that is also used as a piscicide. In the U.S. rotenone is registered only for piscidal (fish killing) purposes. Since it is no longer registered by the EPA as a pesticide, it is not available for purchase as an insecticide in the U.S. although it might be available for purchase in other countries. Rotenone was added to §205.602 in December 2018 as a non-synthetic substance that is prohibited for use in organic crop production.

Manufacture

Rotenone is commonly derived from the roots of various tropical plants native to Southeast Asia, South America, and East Africa. Historically farmers have used this extract as a foliar spray to control pests on vegetables, berries, tree fruit, nuts, and forage crops.

International Acceptance

The UK and European Economic Community (EEC) Council Regulation, EC No. [834/2007](#) and 889/2008
Rotenone is banned in the EU.

United Kingdom (UK)

The UK banned the sale of rotenone in 2009.

Environmental Issues

Adverse health effects from rotenone have been well documented since the NOSB reviewed botanicals in 1994. In 2004 the EPA required an inhalation neurotoxicity study to investigate the possibility of rotenone leading to Parkinson's Disease-like symptoms at high dose exposure in animals. Instead the companies distributing and selling rotenone products voluntarily cancelled all food use registration for it, except for piscicide uses.

Questions to our Stakeholders

None.

National Organic Standards Board
Crops Subcommittee Petitioned Material Discussion Document
Ammonia Extract
February 16, 2021

[Ammonia extract \(AE\) petition](#)

The petitioner seeks to prohibit non-synthetic ammonia extract for use in organic crop production. Specifically, the petition claims that both synthetic and naturally derived forms of ammonia can be synthesized or derived and applied to soils to meet the nitrogen demand of plants. Since non-synthetic sources of ammonia are not currently permitted by Certifiers or Material Review Organizations (but also not explicitly prohibited) in organic production and because such use of ammonia is claimed to be caustic, increases soil pH, is known to decrease soil biotic activity, and bypasses other soil based sources of nitrogen, the petitioner seeks to list ammonia extract at § 205.602 of the National List as a prohibited non-synthetic substance.

Public comments received for the Fall 2020 NOSB public meeting discussion document on the ammonia extract petition provided conflicting data as to whether the use of ammonia extracts promotes or degrades soil health. The question of the effects of ammonia extract on soil health directly relates to the OFPA criteria:

§ 205.203 Soil fertility and crop nutrient management practice standard.

- (a) The producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.
- (b) The producer must manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials.
- (c) The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances...

In general, comments in favor of prohibiting the use of natural ammonia extract indicated that these extracts would degrade soil health by reducing the biological condition of the soil. Ammonia fertilizer degrades the quality of organic soils by bypassing or reducing soil microbes which are imperative to the health of the soil and they would not be in line with improving soil organic matter content.

Comments opposed to the prohibition noted that the addition of ammonia extract does not degrade soil health and that they would not have a negative impact on biological activity and organic matter changes. In fact, they would increase the ability of soils to cycle nutrients and would lead to increased soil organic matter.

Soil Health:

Further details and quotes from the comments in favor of the prohibition include (some comments included references not included here):

Addition of organic fertilizers primarily feeds and activates the soil food web through the supply of abundant amounts of C[arbon] and engaging a large array of soil organisms involved in N[itrogen] mineralization. Expectedly, organic fertilization, as shown by numerous studies, enhances activity, diversity, and abundance of both microbial and non-microbial communities in soils. Improved soil biological status is one of the key advantages of organic crop production. In contrast, any N fertilization practice (i.e. ammonium extracts) that does not benefit or require soil organisms, although it may be technically “organic” or non-synthetic, compromises the “sustainability” benefits of organic farming. Ammonia is a chemical that when applied as a fertilizer, directly feeds the plant, bypassing the soil food web. The core issue at hand is the equivalency of nitrogen products independent of the pathway.

Whether synthetic or non-synthetic, ammonia extracts are incompatible with organic production because they cause harm to the soil and do not “foster soil fertility, primarily through the management of the organic content of the soil through proper tillage, crop rotation, and manuring...” as OFPA requires (7 USC § 6513).

Ammonia extract is chemically identical to the ammonia fertilizers commonly used in conventional growing systems: ammonia extract provides plant-available nitrogen directly to the crop without enhancing soil biology; ammonia extract creates detrimental chemical and biochemical effects on soil structure; and ammonia extract fosters nitrogen leaching.

The organic regulations limit substances of high solubility. In the preamble to the publication of the NOP Final Rule on December 21, 2000, NOP discusses how it decided to agree with the NOSB recommendation and to put specific regulation of substances of high solubility into the annotations for each of these materials where they appear on the National List of Allowed and Prohibited Substances. NOP goes on to say, "Based on the recommendation of the NOSB, the final rule would prohibit use of these materials [substances of high solubility], unless the NOSB developed recommendations on conditions for their use and the Secretary added them to the National List."

The Law of Return. In an organic system, residues are returned to the soil by tillage, composting, or mulching. While most organic growers depend on some off-site inputs, most of the fertility in a soil-based system comes from practices that recycle organic matter produced on-site. The cycling of organic matter and on-site production of nutrients—as from nitrogen-fixing bacteria and microorganisms that make nutrients in native mineral soil fractions available to plants—is essential to organic production. The Law of Return is not about feeding plants, but about conserving the biodiversity (including the microorganisms) of the soil-plant-animal ecological community... Feed the soil, not the plant. The dictum to “Feed the soil, not the plant” reminds us that the soil is a living superorganism that supports plant life as part of an ecological community. We do not feed soil organisms in isolation, to have them process nutrients for crop plants; we feed the soil to support a healthy soil ecology, which is the basis of terrestrial life. Biodiversity. Finally, biological diversity is important to the health of natural ecosystems and agroecosystems. Biodiversity promotes balance, which protects farms from outbreaks of damaging insects and disease. It supports the health of the soil through the progression of the seasons and stresses associated with weather and farming. It supports our health by offering a diversity of foods. Ultimately, holistically healthy, truly organic farms produce healthy plants that require far fewer applications of insecticides and fungicides (even if approved for organic

production). In the case of ammonia extracts, we are particularly interested in the principle of feeding the soil rather than the crop.

Further details and quotes from the comments against the prohibition include (some comments included references not included here):

Bio-based fertilizers have been shown to increase the characteristics related to soil health, e.g., organic matter, soil aggregates, enhanced biological activity, increased nutrient cycling because they stimulate biological activity through a balanced carbon - nitrogen (C:N) ratio. The ideal C:N ratio is 8:1 and ammonia-based extracts are in the range of 2:1 which would provide a balance for biological activity. Much has been written about soil biological fertility and is summarized in the book by Abbott and Murphy (2007). The aspect of soil-biological fertility is beginning to recognize that bio-based fertilizers that are organic concentrates high in ammonium have a large impact on the release of nutrients from organic materials in the soil and offer the potential to increase our ability to supply nutrient dense foods to feed the world. There is no evidence to suggest that adding organic concentrates high in ammonium from natural sources would have a negative impact on soil biological activity, organic matter changes, or soil health and would suggest that these additions would enhance the soil's ability to cycle nutrients and would lead to increases in organic matter contents and soil functionality.

Mineral nitrogen fertilizers, including ammonia-based fertilizer products, increase crop productivity and drive long-term increases in soil organic carbon, soil microbial biomass, and soil bacteria and fungi when compared to nonfertilized controls. Any potentially negative effects of ammoniacal fertilizers in soil (e.g., reduced fungal growth or stunted crop seedlings) are ephemeral and quickly subside after ammonium is either taken up by the plant or oxidized to nitrate. Moreover, ammonium is a product of mineralization of any organic nitrogen source (e.g., compost, animal manure, and green manure) and has the same temporary negative effects of ammonium toxicity that can be observed for at least three weeks after application as well. Compared to mineral nitrogen fertilizer alone, organic soil amendments usually lead to greater increases in soil health metrics. However, the research is clear that the same soil health benefits of organic soil amendments can be realized when used in combination with mineral nitrogen fertilizer – an approach called integrated nitrogen management. This is important because nonsynthetic ammonia-based fertilizer products cannot replace organic soil amendments as part of a USDA NOP Organic System Plan. Animal manure, compost, green manures, or other organic fertilizers will still be necessary for meeting other essential crop nutrient needs, including phosphorus. Phosphorus-rich organic soil amendments like manure also contain significant amounts of organic nitrogen and will continue to displace a portion of the crop demand for mineral forms of nitrogen. However, the reduced dependence on manure to meet the entirety of crop nitrogen demand (as has been historically practiced to the detriment of surface water quality) will allow growers to apply manure to meet crop phosphorus needs without over-applying phosphorous or other key nutrients, thus minimizing negative soil health and environmental impacts.

I foresee a grower using a product such as an ammonia extract as a supplement to their fertility program, possibly lowering the overall application of nitrogen on the front end of the crop, thus reducing the potential for residual nitrogen at the end of the crop where leaching and runoff of nitrate and phosphate could occur. For a grower to have access to a naturally derived available

nitrogen source that is low in phosphorus greatly increases the options available to myself and other organic growers to safely and effectively produce a high yielding crop.

The Petition wildly overstates and claims, without any basis in actual testing or ground truthing of the different materials, that all ammonium extracts will have a negative impact on soils, soil biology, and on organic farming systems. While some of the products included in the Petition may indeed cause similar damage as conventional ammonium fertilizers, our product does not share these same characteristics. Replicated research by third-party research firms and field trials by independent farmers involving our materials over the past two years have shown the materials to be stimulants to the biological systems the petition claims they should be damaging and repressing

The process by which [our] products are concentrated results in products which have a distinctive odor, color, C:N ratio, and isotopic ratio. This means that the products can easily be distinguished from synthetic ammonium fertilizers in the field and that this field assessment can be back checked with an in-lab isotope test.

Potential for Fraud:

In addition to soil health issues, the NOSB also received comments about the ability to distinguish between natural and synthetic ammonia extract in a product and the potential for fraud. Some commenters felt that a nitrogen mass balance approach from producers and formulators of products including ammonia extract would be adequate to prevent fraud. Others commented that a nitrogen isotopic assay would be needed to determine the source of the ammonia. Still others noted that the blending of synthetic and non-synthetic ammonias could be done in such a way that the resulting isotopic analyses would not be conclusive.

The proposed technology for ammonia extraction from natural sources is particularly suited for fraud by those in the organic fertilizer sector who are susceptible to the lures of making a lot of money quickly. If this technology is accepted for use in organic production, it would be a 'gift from heaven' to those who want to make easy money fast, and an absolute nightmare to those of us who compete honestly, and want to protect the "Certified Organic" seal and the integrity of the whole Certified Organic Food Movement and all its integral parts

A nitrogen mass balance approach could be used to routinely inspect, verify, and certify the manure-based origins of nonsynthetic ammonia-based fertilizer products. The mass balance approach to manure nitrogen management is already widely used among farmers and nutrient management regulators and could be easily deployed to ensure compliance with the NOP guidelines for allowable inputs. For the fertilizers in question, a portion of ammonia is removed from raw manure or anaerobic digestate during production. The relative amount of ammonia removed from manure or digestate – defined as the production efficiency – is specific to each production process and is routinely monitored through independent lab analyses. Production efficiency is calculated as the mass of ammonium-N in the fertilizer product divided by the mass of ammonia-N in the manure or digestate feedstock, and may be as high as 85% (the remaining 15% – ammonia-N not removed during production – is lost to the atmosphere or remains in the spent manure or digestate). If manufacturers document and disclose their production efficiencies (via third parties), the nonsynthetic origins of ammonia-based fertilizer products could be easily verified by comparing the mass of ammonium-N in the product to the mass of ammonia-N in the feedstock. If the mass of ammonium-N in the fertilizer product exceeded that

in the feedstock (or even if the production efficiency was significantly greater than expected), then there would be cause to suspect inclusion of synthetic ammonium in the product. Additional investigation or verification of the product could include isotopic analyses², but this would not be necessary for routine inspection or certification of the nonsynthetic origins of ammonia in a fertilizer product.

Practicality of use of these products is dependent on an isotope analysis to determine the source of nitrogen contained. These products, through testing by the manufacturer will have a specific profile of organic material, nutrient concentration, and other chemical and physical properties specific to these materials. Care must be taken to ensure no contamination takes place from source of manufacturing to end use

Though the ratio of N¹⁵ to N¹⁴ isotopes can provide some indication of the possibility of adulteration, OMRI considers it to be an unreliable indicator, particularly for fertilizer blends. The principle behind this testing protocol is to quantify nitrogen that has been derived from the air, as in the synthetic Haber-Bosch process used in ammonia production, and nitrogen derived from organic plant or animal materials. There are, however, some plant materials that can fix atmospheric nitrogen directly, such as some seaweeds and soy, so the isotope ratios may resemble those of synthetic nitrogen sources (Mukome et al., 2013). Further blending of fertilizer materials complicates the situation. At one point in its history, OMRI requested nitrogen isotope analyses for high nitrogen liquid fertilizer products but currently rarely uses the practice due to interpretation difficulties and unreliability. It can be assumed that other material review organizations would have equivalent difficulties in evaluating synthetic ammonia content using these laboratory methods, particularly for facilities that may produce conventional and organic lines of products. This situation may require testing of all fertilizer ingredients at a site for comparison rather than final product blends as a whole... While OMRI does not advocate for the allowance or prohibition of any specific material, it understands the risks of adulteration by synthetic substances to organic integrity. In the case of nonsynthetic ammonia sources, OMRI believes that the risk of adulteration by synthetic forms is significant due to the difficulties in identifying the sources of the material. The risk of adulteration is also higher for soluble nitrogen products given the potential economic gains from producing an input product with cheaper, synthetically derived nitrogen.

Given the range of public comments (not all are included in this document), the NOSB seeks additional input from stakeholders regarding this petition.

Questions/Information Requests:

1. Given the conflicting comments on the effects of ammonia on soil health, please provide further information that would help to resolve this conflict. Provide scientific citations so that the NOSB can have primary references as to the effect of ammonia extract on soil health.
2. Is there a range of concentrations in the soil solution in which ammonia is beneficial, while outside that range it is not?
3. Please provide additional information as to how the fraudulent use of synthetic ammonia could be prevented while at the same time allowing for the use of natural ammonia extract.
4. Should the use of natural ammonia extract be limited to a certain percent of nitrogen use in crops (similar to the Chilean nitrate restriction)?

5. If natural ammonia extract is limited to a certain percentage of nitrogen use, how can that amount be verified and separated from synthetic ammonia?
6. In mixed organic and conventional operations, how can the use of natural ammonia extract used in the organic crops be verified as opposed to synthetic ammonia used in the conventional crops?
7. Is there additional information about the effects of highly soluble organic fertilizers on soil health that the NOSB should be aware of?

Subcommittee vote

Motion to approve the discussion document on ammonia extract.

Motion by: Steve Ela

Seconded by: Rick Greenwood

Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 2

Approved by Rick Greenwood, Crop Subcommittee Chair, to transmit to NOP February 17, 2021.

National Organic Standards Board
Crops Subcommittee Petitioned Discussion Document
Kasugamycin
February 2, 2021

The NOSB received a [petition](#) for kasugamycin for use as an approved active ingredient in organic crop production at 7 CFR § 205.601. In support of its review, the Crops Subcommittee requested a technical report (TR), which was received January 21, 2021.

Summary and approved legal uses of the substance:

Kasugamycin is an antibiotic that inhibits bacterial protein synthesis and has been approved by the U.S. EPA for control of plant diseases, especially fire blight caused by *Erwinia amylovora* on apples and pears. The registered formulations are Kasumin 2L and Kasumin 4L containing the active ingredient kasugamycin hydrochloride hydrate. Kasugamycin is obtained by aerobic fermentation by the microorganism *Streptomyces kasugaensis*. The technical grade active ingredient, kasugamycin hydrochloride hydrate was registered with the EPA in 2014 and a formulation Kasumin 2L containing two percent kasugamycin was registered in 2018. In 2020 Kasumin 4L containing four percent kasugamycin was registered with the EPA. Kasumin 2L and 4L were registered with a number of restrictions including those that prohibit application where animals are grazing or in areas where crops have been fertilized with animal or human waste. Users are also required to follow a resistance management plan. Applications are limited to four per year with California limiting applications to two per year.

Composition:

Kasugamycin is an aminoglycoside antibiotic that is manufactured through fermentation and isolated as hydrochloride. Kasugamycin is a colorless solid at room temperature and is soluble in water. The hydrochloride has relatively low volatility and does not volatilize readily from soil into the air.

Assessing risks to human health and the environment:

Kasugamycin is characterized by the EPA as moderately persistent to persistent. A major source of degradation is aerobic microbial metabolism in soil with a half-life of 43-73 days. About 4% remains after a year. Hydrolysis in water is very slow and metabolites are also persistent (TR 278). Persistence on fruit is low and about half the amount applied to foliage ends up on the soil and non-target surface vegetation. Residues on fruit decrease 10-fold in 27-32 days.

Kasugamycin has low acute toxicity to mammals and is classified EPA Category IV (least toxic, no warning label) for all exposures other than dermal, for which it is classified EPA Category III (next least toxic, requires "Caution" warning on label). It also has low chronic toxicity from rat feeding studies and there was no evidence of carcinogenicity in mice or evidence of chromosome damage.

Normal labeled use of kasugamycin has led to field resistance in several pathogens. Kasugamycin was first used to control diseases of rice in Japan starting in 1965 with rice blast caused by *Magnaporthe grisea* and resistance was noticed in 1971. Field resistance to *Acidovorax* sp. occurred in 1990 and to *B. glumae* in 2001. In Florida, rapid field resistance to bacterial spot of tomato caused *Xanthomonas perforans* was also seen. In orchards that had been treated at least once with Kasugamycin studies found resistant bacteria in 401 field isolates from apple flowers, leaves and soil samples. Additionally, *Erwinia* resistance to kasugamycin has been generated in the laboratory. Kasugamycin has not been

evaluated to determine if its use for orchard sprays would lead to kasugamycin-resistant pathogens in animals grazing orchard grass, but spraying orchard grass with streptomycin at concentration levels used for fire blight leads to an increase in antibiotic-resistant human pathogens found in sheep grazing on sprayed grass. (TR 805).

It was reported in the TR (1152) that some level of resistance to kasugamycin with normal (labeled use) has occurred and therefore the Kasumin label requires a resistance management plan. The plan includes use of kasugamycin as part of an IPM program and less than four applications per year (2 in California).

The alternative to kasugamycin is an integrated organic program that attacks fire blight at every point in its life cycle. Cultural controls can be combined with application of fixed copper sprays in dormant and pre-bloom periods, application of lime sulfur for mildew control and thinning of apple blossoms, biological controls such as Blossom Protect during bloom time, and bio-control antagonists such as Serenade later in the blooming period. Other organic procedures are also available to control fire blight, but they are more effective on the West Coast.

Discussion:

Fire blight has grown resistant to every antibiotic used against it and there is good reason to believe it will become resistant to kasugamycin. The NOSB and NOP identified several reasons to stop the use of streptomycin in organic production: resistance is widespread and the USDA, in 2014, stated that the expectation is that antibiotics are not used in organic production. Other antibiotic petitions have been not been approved by the NOSB due to the potential for cross-resistance when used for human health.

Questions:

1. Is the use of kasugamycin necessary for the control of fire blight or are other integrated programs sufficient?
2. Would the use of kasugamycin decrease the need for other synthetic products used in organic agriculture such as coppers and lime sulfur?
3. Is the limitation to 4 applications (2 in California) sufficient to reduce or eliminate the chances for fire blight resistance?
4. If approved, should the use be annotated only for fire blight control in apples and pears?
5. Are there variable results of the efficacy of kasugamycin depending on region where it is used?

Subcommittee Vote:

Motion to accept the discussion document on kasugamycin

Motion by: Rick Greenwood

Seconded by: Steve Ela

Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Rick Greenwood, Crop Subcommittee Chair, to transmit to NOP February 19, 2021.

**National Organic Standards Board
Handling Subcommittee Proposal
Review of the Ion Exchange Filtration Process and Materials Used
February 17, 2021**

Background:

In an [August 27, 2019 memo](#), the National Organic Program (NOP) requested the NOSB provide a recommendation related to the process of ion exchange filtration in the handling of organic products. It has become clear that there is inconsistency between certifiers in how they approve or disapprove this type of process. Some certifiers require only the solutions used to recharge the ion exchange membranes be on the National List at § 205.605. Others require that all materials, including ion exchange membranes and resins be on the National List.

The National Organic Program provided clarification to certifying agents in an email sent on May 7, 2019, that nonagricultural substances used in the ion-exchange process must be present on the National List. This would include, but is not limited to, resins, membranes, and recharge materials. Originally, the NOP asked all operations to come into compliance with the statement above by May 1, 2020. However, in response to requests for clarification of NOP's rationale, as well as requests to extend the timeline for implementation, the NOP delayed the implementation date in order to gather more information and requested that NOSB review the issue.

The NOP has determined, and some Materials Review Organizations have agreed, that the ion exchange process is a chemical one and does affect the food in a way that chemically changes it. This process is different from physical filtration. In the ion exchange process, the liquid used in the process exchanges molecules with those being held on the surface of the resin. The FDA considers ion-exchange membranes and resins to be secondary direct food additives, since there is an effect on the liquid used in this process.

Manufacturers and certifiers who wish to continue allowance of the ion exchange process, disagree with some of the findings of the NOP on this complex issue. The different opinions about the need for resins, recharge materials, and membranes to be present on the National List, as well as how they interact with each other and the liquid run through the process, is complicated and the NOP therefore asked the NOSB to assess this issue.

A simplified summary of ion exchange, provided in the past from the Organic Materials Review Institute (OMRI), is as follows:

Ion exchange is based on the principle that a solid mass with immobilized charges can attract the mobile ions of the opposite charge in a fluid media. In practice, this involves a column that is like a large pipe packed with an exchanger, which may be in the form of beads, crystals, gels, or granules. The fluid can pass through, but the ions in solution will be pulled out and held to the exchanger. The process chemically changes the resulting fluid.

Techniques used to produce various sweeteners offer a good example of how the process works. Minerals, salts, proteins, and color bodies occur naturally in grape juice, cane juice, beet juice, and corn syrup. The refinement process seeks to remove these "impurities". They are also naturally present or—in the case of color bodies—are formed between naturally present

components during heating. These can be removed by a number of techniques. Some are physical, some are chemical, and some use both. However, the use of synthetic cross-linked polymeric resins—such as styrene-divinylbenzene (S-DVB)—to remove certain constituents of liquids based on their chemical properties is a chemical process. The liquified sweetener stream chemically reacts with the ions present on the ion exchange resin to purify and concentrate the desired sugar (Cantor and Spitz, 1956).

Other processing aids that are considered secondary food additives required petitions in order to be considered. In addition to the filtering / clarifying / fining agents mentioned above, these also included the boiler water additives, antifoaming agents, and certain enzymes. Other additives that are considered ‘de minimis’ in conventional processing—such as disinfectants and atmospheric gases—also required petitions, reviews, and recommendations to be added to the National List. Ion exchange resins are known to leak from columns and thus become incidental additives in the food.

Subcommittee Review:

The question before the Handling Subcommittee is whether only the recharge materials for the resins must be on the National List or whether both the resins and recharge materials must be reviewed and added to the List.

The 2020 technical review (TR) provides a thorough review of ion exchange filtration and should be referred to for details on this process. It is clear that there is widespread use of ion exchange filtration in organic processing, whether it be for removal of off-tastes, heavy metals, or clarification of the final product, among others. Alternatives to ion exchange filtration are not generally available.

As noted in the 2020 TR, ion exchange filtration differs from physical filtration processes in that there is an actual chemical change in the ensuing product – ions (either cations or anions depending on the resin and desired outcome) that were present on the resin have been substituted in the final product while ions that were initially found in the product are left attached to the resin. This is not just a physical removal of material or a reaction whereby another material is used to help process the initial substance and then removed after that process. The 2020 TR cites various research articles and states:

...ion exchange filtration requires the replacement of bound ions (ions initially present in the filtration material) by others with the same charge and requires electroneutrality...

...ion exchange filtration is based on the principle that if an ion is removed from the treated substance by the filtration material, it is replaced by an ion of the same charge that began in the filtration material (e.g., removal of positive ion from treated substance is replaced by a different positive ion from the filtration material). The ion exchange process is a result of electrostatic attractions between the ion of interest (ion to be removed from the treated substance) and the charged functional groups incorporated into the filtration material.

The final product, by passing through the ion exchange filter, does have a different ionic makeup than the initial product. In the case of removing “hardness” from water, the substitution of sodium for the original calcium in the water does not change that it is still water, per se, but it can change how that interacts with other materials. Thus, it seems difficult to argue that ion exchange filtration does not cause a chemical change in the final product, even though the chemical change may be beneficial. There is a different ionic makeup in the final product as compared to the initial product and the final product may behave slightly differently than the initial product.

Next, there is the question of whether the resins themselves contribute to a change in the final organic product or whether, as food contact substances, they are simply a structure that holds the ions to be exchanged. The 2020 TR states that there are studies that demonstrate that the resins do degrade over time, however that degradation is generally in terms of their loss of resin activity or efficiency or capacity. In other words, the resins are simply not as good at holding ions to be exchanged and thus need to be recharged sooner than they would when they were new. In some cases, this loss of efficacy may be because of a loss of functional groups that were originally present, however the citations referenced in the TR note that this loss seems to primarily occur during the recharge process. Thus, the loss of those functional groups would not be into an organic product, but rather into the recharge material. The 2020 TR further states that there were no published studies found on the human health effects of the degradation of the resins. Based on the findings of the TR and no public comments that provided scientific evidence that the resins degrade and cause changes in the final product it would seem that the resins act in the capacity of food contact substances and not primarily as direct food additives. However, these same resins can be included under secondary food additives.

There is a question of whether the ion exchange membranes and resins are secondary food additives or food contact substances. If they are food contact substances, then, based on past NOP guidance, they may be used unless explicitly prohibited. If they are secondary food additives, then they must appear on the National List. The NOSB received many public comments on both its Spring 2020 discussion document and Fall 2020 proposal with a number of viewpoints, however the comments from the Organic Trade Association provided the most details of FDA rule history on this topic:

In a policy statement issued on December 12, 2002, after consultation with FDA, NOP clarified which substances are subject to review and recommendation by NOSB for inclusion on the National List. According to the policy, substances that are listed in 21 CFR Part 173 as secondary direct food additives are subject to review, unless the substances are classified by the FDA as a food contact substance. In 2002, FDA clarified that ion exchange resins were food contact substances, therefore ion exchange resins under the 2002 policy were not subject to the National List process. The 2002 food contact substance policy was archived when the NOP Handbook was created; however, it has never been formally rescinded and remains in use by some certifiers.

FDA references are as follows:

- Ion exchange resins and membranes are listed in 21 CFR Part 173 as secondary direct food additives, which are substances that have a technical effect in food during processing but not in the finished food.
- According to FDA guidance, some secondary direct food additives also meet the definition of a food contact substance, which is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.
- Prior to 1997, FDA regulated ion exchange resins under 21 CFR 173.25. Once Congress established the term “food contact substance” in the Federal Food, Drug, and Cosmetic Act and initiated the Food Contact Notification Program (FCN) in 1999, all ion exchange petitions were converted to this approval method. There was no need to alter or change prior approvals under § 173.25, so they were left as is. Since that time, FDA has directed all new approvals of ion exchange resins through its FCN program. This clearly reflects FDA’s stance that they are food contact substances.

- FDA maintains a database of approved Food Contact Substances, which include ion exchange resins that have been classified and approved by FDA as food contact substances.

Additionally, Ingredion submitted comments that echoed the comments from the Organic Trade Association:

The regulatory classification for ion exchange resins is both a food contact substance AND a secondary direct food additive. <https://www.fda.gov/food/food-ingredients-packaging/food-ingredient-packaging-terms>:

- Food Contact Substance (FCS) - Section 409 of the FD&C Act defines an FCS as any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food.
- Secondary Direct Food Additive (SDFA) - This term is in the title of 21 CFR 173, which was created during recodification of the food additive regulations in 1977. A secondary direct food additive has a technical effect in food during processing but not in the finished food (e.g., processing aid). Some secondary direct food additives also meet the definition of a food contact substance.

The NOSB received no other comments that contradicted that materials could be listed as both a secondary direct food additive and food contact substance. It would seem that, even though a material might be listed both ways, the fact that they are listed by FDA as a food contact substance, exempts those materials from needing to be reviewed by the NOSB and placed on the National List. The argument can also be made that if a substance is listed as a secondary food additive, regardless of its listing as a food contact substance, that it is under the purview of OFPA and the resins would therefore need to appear on the National List. It is beyond the capacity of NOSB members to investigate the nuances of FDA rules and regulations and how they legally relate to OFPA. The legal ramifications of these decisions should be left to legal counsel for the National Organic Program.

Subcommittee Recommendation:

The inherent nature of ion exchange leads us to the conclusion that recharge materials used to recharge ion exchange resins must be on the National List if they are used in the processing of organic product. These recharge materials leave ions on the resins and those ions will ultimately end up in the final organic product. The public comments received at the Spring 2020 NOSB meeting support this recommendation.

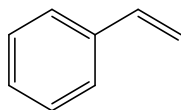
There is less consensus on the question of whether the resins themselves must be reviewed and included on the National List. From comments received, the resins appear to be classified as both secondary food additives and food contact substances, however there are countervailing arguments that should be noted. There are legal arguments and interpretations about how OFPA might apply to FDA regulations defining secondary food additives and food contact substances. A proposal advising the NOP that the resins should not have to appear on the National List was voted down by the full Board at the Fall 2020 NOSB meeting.

Further complicating this issue is that for a material to be classified by FDA as a food contact substance, the manufacturer need only submit an application to FDA requesting the classification. If FDA does not respond to the application (either denying it or asking for further clarification), the material is

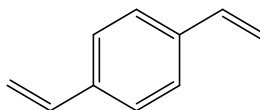
automatically added to the food contact substance list. There is no required review by FDA, no public comment and, with regard to organic classification, no review of how the material relates to OFPA. Once again, this process comes down to a legal opinion as to the interactions of OFPA and FDA regulations that is beyond the scope of the NOSB.

While there was no conclusive evidence in the 2020 TR or public comments that the resins degrade and alter the final organic product, this does not mean that there is no evidence. The quote from OMRI at the beginning of this document refers to ion exchange resins leaching from columns and thus becoming incidental additives. Further research into how and to what extent these resins degrade and whether the degradation occurs during the recharge process or during the food filtration process could help shed light as to whether these resins are strictly in contact with the organic product or are incidental food additives.

There is also the question of how these resins are manufactured. From the TR, the resins are polymeric materials that are synthetic. They are commonly produced as beads, resins, or membranes. Most are produced with the polymerization of styrene and divinyl benzene. While the evidence about the breakdown of the final resin is not conclusive, styrene itself is listed as a Proposition 65 carcinogen. The resins are very similar to plastics. Acidic or basic functional groups are incorporated into the polymeric backbone to make the ion exchange resin.



styrene



divinyl benzene

On a less technical level, there is a procedural context as well. Since some physical filtration materials are listed and resins are not, there are arguments that there is a disparity in the review of materials. There is also some disparity as to the level of scrutiny certifiers apply to reviews of food contact substances. Some certifiers require listing all the food contact substances and others may not. Regardless of the legal issues, these disparities should be noted and clarified.

There is also concern from some stakeholders that a de facto statement that resins do not need to be on the National List leaves a wide-open playing field for any resin to be used. While resins currently being used might be acceptable, the lack of a required review for resins could cause issues in the future with resins that would be less acceptable for use in organic production systems. Allowing resin use without review could provide an unintentional loophole to the requirements of OFPA.

An alternative to allowing all resins without review would be to create a section on the National List that includes all resins used in ion exchange filtration (similar to other broad categories on the List). Petitions to the NOSB could be used to annotate this broad listing to exclude problematic resins. This process, however, puts the onus on stakeholders to recognize which resins are being used and to act to exclude particular resins. A petition to remove a resin could take considerable time and forces the petitioner to provide documentation as to how the resin does not comply with OFPA. While this review was underway, the resin would continue to be used. This is opposite the normal procedures of the NOSB whereby the burden is put on the petitioner to document why something should be added to the

National List, and that substance is not allowed to be used until it is added. In the past, removal of substances already in use can be difficult due to economic impacts of that removal.

The final option is to require each resin to be added to the National List. This would require a petition for each specific resin, technical reports to be commissioned and reviewed, and for the Board to approve the addition of each resin. This would cause significant disruption to the processing industry since these ion exchange filtration practices are already in use and have been for some time. Without a long phase-in period, the requirement of listing currently used resins would cause significant economic harm. There could also be potential health consequences since some of these filtration processes remove heavy metals and other deleterious compounds from organic foods.

While the NOSB would like to give a clear sense of direction on this topic to the National Organic Program, the legal issues are beyond the capability of the Board. The allowance of the use of ion exchange filtration for many years, without requiring the listing of the resins used, also creates a difficult situation. Requiring the listing of these resins could cause significant economic impact and disruption of current organic supply chains; however, not requiring listing could leave an unintentional loophole that would subvert the requirements of OFPA. These technical and procedural issues are best left to legal interpretations and procedural interpretations that are beyond the capabilities of the NOSB.

Subcommittee vote:

Motion to accept the proposal on ion exchange materials

Motion by: Steve Ela

Seconded by: Jerry D'Amore

Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Approved by Jerry D'Amore, Handling Subcommittee Chair, to transmit to NOP February 17, 2021.

Sunset 2023
Meeting 1 - Request for Public Comment
Handling Substances § 205.605(a), § 205.605(b), § 205.606
April 2021

Introduction

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

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2021 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2021 public meeting. Comments should be provided via Regulations.gov at www.regulations.gov on or before April 5, 2021 as explained in the meeting notice published in the Federal Register.

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

Public comments should clearly indicate the commentor's position on the allowance or prohibition of substances on the National List and explain the reasons for the position. Public comments should focus on providing relevant new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance (e.g. scientific, environmental, manufacturing, industry impact information, etc.). Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

For Comments that Support the Continued Use of § 205.605(a), § 205.605(b), and/or § 205.606 Substances in Organic Production:

If you provide comments supporting the allowance of a substance at § 205.605(a), § 205.605(b), and/or § 205.606, you should provide information demonstrating that the substance is:

1. not harmful to human health or the environment;
2. necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
3. consistent with organic handling.

For Comments that Do Not Support the Continued Use of § 205.605(a), § 205.605(b), and/or § 205.606 Substances in Organic Production:

If you provide comments that do not support a substance on §205.605(a), §205.605(b), and/or §205.606, you should provide reasons why the use of the substance should no longer be allowed in organic production. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

1. harmful to human health or the environment;
2. unnecessary because of the availability of alternatives; and
3. inconsistent with organic handling.

For Comments Addressing the Availability of Alternatives:

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

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

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

For Comments on Nonorganic Agricultural Substances at Section § 205.606.

For nonorganic agricultural substances on section § 205.606, the NOSB Handling Subcommittee requests current industry information regarding availability of and history of unavailability of an organic form of the substance in the appropriate form, quality, or quantity of the substance. The NOSB Handling Subcommittee would like to know if there is a change in supply of organic forms of the substance or demand for the substance (i.e. is an allowance for the nonorganic form still needed), as well as any new information about alternative substances that the NOSB did not previously consider.

Written public comments will be accepted through April 5, 2021 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

§205.605(a) Sunsets: Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”:

- [Agar-agar](#)
- [Animal enzymes](#)
- [Calcium sulfate-mined](#)
- [Carrageenan](#)
- [Glucono delta-lactone](#)
- [Tartaric acid](#)

§205.605(b) Sunsets: Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”:

- [Cellulose](#)
- Chlorine materials
 - [\(i\) Calcium hypochlorite](#)
 - [\(ii\) Chlorine dioxide](#)
 - [\(iii\) Hypochlorous acid—generated from electrolyzed water](#)
 - [\(iv\) Sodium hypochlorite](#)
- [Potassium hydroxide](#)
- [Silicon dioxide](#)
- [Potassium lactate](#)
- [Sodium lactate](#)

Agar-agar

Reference: §205.605(a)

Technical Report: [1995 TAP](#); [2011 TR](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#); [11/2016 recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#)); Sunset renewal notice effective 5/29/2018 ([83 FR 14347](#))

Sunset Date: 5/29/2023

Subcommittee Review

Use

Agar-agar has been used as a food additive for over 350 years. Current uses in food include; stabilizer, thickener, gelling agent, texturizer, moisturizer, emulsifier, flavor enhancer, and absorbent. Agar-agar can be found in bakery products, confections, jellies and jams, dairy products, canned meat and fish products, and vegetarian meat substitutes. Useful characteristic of agar-agar includes the ability to withstand high temperatures. Since agar-agar is practically tasteless and does not require the addition of cations to form gels, it doesn't interfere with taste profiles. Agar-agar can be used in foods in combination with other thickening or gelling agents. Agar-agar is classified as Generally Recognized As Safe (GRAS) by the FDA.

Manufacture

Agar-agar is derived from red algae, the main species harvested being *Gelidium* and *Gracilaria*, the second of which can be cultivated. After harvesting, the algae is cleaned with water, dried in the sun, pressed into bales, and shipped to processors for agar-agar extraction. Prior to extraction the *Gracilaria* species are usually subjected to alkaline pretreatment (heated in a sodium hydroxide solution) followed by rinsing with water and sometimes a weak acid to neutralize the alkali. Alkaline pretreatment is used to bring about a chemical change in the polysaccharides. This chemical change produces agar-agar with increased gel strength. Without this pretreatment, the gels extracted from *Gracilaria* species would be too weak for most food applications (2011 Technical Report (TR), 165-176). After pretreatment, the algae is placed in tanks for extraction via hot water pressure, followed by filtration. The last step is to remove water from the gel either through a freeze-thaw process or by mechanical pressure. The gel is then dried with hot air resulting in a finished product of flakes, strips, or powder.

Based on this manufacturing information, the Handling Subcommittee acknowledges that a reclassification of agar-agar at § 205.605(b) Synthetics allowed, might be needed in the future once the NOP finalizes the Guidance for Material Classification.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

Agar-agar is permitted for use in organic production.

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

Agar-agar is permitted for use in organic production.

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

Agar-agar is permitted for use in organic production.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Agar-agar is permitted for use in organic production.

Japan Agricultural Standard (JAS) for Organic [Production](#)

Agar-agar is not permitted for use in organic production in Japan.

Environmental Issues

The current world demand for agar-agar is reportedly increasing, which has placed pressure on the overharvested natural sources. There were no studies found to indicate whether or not the harvesting of agarophytes, in particular, is harmful to the biodiversity on nearby beaches or in the algae beds. There are alkaline waste waters that result from the manufacture of agar-agar, but there were no documents found that show this to be a problem to the environment, at this time.

Discussion

Based on the different manufacturing processes, and the 2011 TR, there does appear to be a question as to whether two forms of agar-agar exist. While there are extraction processes that are natural (non-synthetic) and without chemical modifications, there are others that can be considered synthetic. An example of the synthetic method would be when the *Gracilari*a species of algae are subjected to an alkaline pretreatment (heated in sodium hydroxide solution) to modify the polysaccharides in the algae. This process brings about a chemical change in the polysaccharides (L-galactose-6-sulfate groups are converted to 3,6-anhydro-Lgalactose), increasing the gel strength of the agar-agar. Data indicates that without this treatment the gel extracted would be too weak for most food applications. While the 2011 TR lists several methods of extraction, it states that only 1 -2% of the agar-agar supply is from the natural form of extraction. Furthermore, the product from the natural extraction method does not appear to be readily available in the U.S. market.

Agar- agar is currently listed on the National List at §205.605(a) Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).” (a) Nonsynthetics allowed. During the 2018 sunset review it was suggested that based on the manufacturing process, agar-agar could also be listed at §205.605(b) Synthetics allowed.

Questions to our Stakeholders

1. Have there been any new developments with natural alternatives to agar-agar?
2. Are there sufficient quantities of agar-agar produced using non-synthetic extraction methods to exclude agar-agar produced using synthetic methods?

Animal enzymes

Reference: §205.605(a) Animal enzymes - (Rennet - animals derived; Catalase - bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin).

Technical Report: [2000 TAP](#); [2011 TR](#); [2015 Limited Scope TR \(ancillary substances in enzymes\)](#)

Petition(s): NA

Past NOSB Actions: [11/2000 meeting minutes and vote](#); [11/2007 recommendation](#); [12/2011 recommendation](#); [11/2016 recommendation](#)

Recent Regulatory Background: National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/2013 ([78 FR 61154](#)); Sunset renewal notice effective 5/29/2018 ([83 FR 14347](#))

Sunset Date: 5/29/2023

Subcommittee Review

Use

Enzymes are naturally occurring proteins that act as highly efficient catalysts in biochemical reactions. They are used to carry out naturally occurring biological processes that are useful in the processing of food products or ingredients (Enzyme Technical Association 2001) (2011 TR, lines 140- 142). Animal enzymes, such as rennet, are used as a coagulant to curdle milk, to be made into cheese or sour cream. Enzymes are used in very small amounts to achieve the desired effect. For example, the amount of animal-derived rennet used to clot milk is 0.036 percent (2011 TR , lines 727-728).

Manufacture

Traditionally, the fourth stomach or other organs of goat kids or calves are dried, cleaned, and then sliced into pieces, before being stored in either whey or saltwater. Vinegar or wine can be added to lower the pH. After allowing the solution to sit for a few days, it is filtered repeatedly. A small amount of boric acid is added to the filtrate. In industrial production, the stomach is minced and the pH adjusted by adding hydrochloric acid and sodium phosphate. (2011 TR, lines 444-458).

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

The use of enzymes is permitted in organic processing in Canada.

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

The use of enzymes is permitted in organic processing in the EU.

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

The use of enzymes is permitted in organic processing in CODEX.

International Federation of Organic Agriculture Movements (IFOAM) Norms

The use of enzymes is permitted in organic processing by IFOAM.

Japan Agricultural Standard (JAS) for Organic [Production](#)

The use of enzymes is permitted in organic processing in Japan.

Ancillary substances

Explained in the 2015 Limited Scope TR:

“Enzyme products used in food processing may be single ingredient, stand-alone preparations of the enzyme, or formulated with other ingredients (OMRI, 2015). In many cases the enzyme product which results from a fermentation process is not effective in food applications without further

formulation (Whitehurst & Van Oort, 2009). Enzyme preparations therefore commonly contain other substances, not only as incidental secondary metabolites and residual growth media from the enzyme production, but also intentionally added ingredients, which function as diluents, preservatives, stabilizers, antioxidants, etc. (FDA, 2010). These additives must be generally recognized as safe (GRAS), or be FDA approved food additives for this use (FDA, 2014).”

To prevent the loss of enzyme activity, ancillary substances, such as stabilizers, are added. This is especially true for liquid enzyme preparations due to the destabilizing effect of water. Stabilizers are also used to combat the degradation of enzyme structures due to autolysis or proteolysis. To control microbial contamination of enzyme preparations, preservatives are added. The development of alternatives to preservatives (plant extracts, peptides, compounds from herbs and spices) is increasing but there are microbial resistance challenges and the need for continued research. Currently it is unknown if natural preservatives are being used in any enzyme formulations.

Ancillary Substances by Food Additive Functional Class

Anti-caking & anti-stick agents	Magnesium stearate, calcium silicate, silicon dioxide, calcium stearate, magnesium silicate/talc, magnesium sulfate.
Carriers and fillers	Lactose, maltodextrins, sucrose, dextrose, potato starch, non-GMO soy oil, rice protein, grain (rice, wheat, corn, barley) flour, milk, autolyzed yeast, inulin, cornstarch, sucrose, glycerol, potassium chloride, ammonium sulfate, calcium phosphate, calcium acetate, calcium carbonate, calcium chloride, calcium sulfate, dextrin, dried glucose syrup, ethyl alcohol, glucose, glycol, lactic acid, maltose, mannitol, mineral oil, palm oil, purity gum (starch), saccharose, sorbitol, soy flour, sunflower oil, trehalose, vegetable oil, microcrystalline cellulose, propylene glycol, stearic acid, dicalcium phosphate.
Preservatives	Sodium benzoate, potassium sorbate, ascorbic acid, alpha (hops) extract, benzoic acids and their salts, calcium propionate, citric acid, potassium chloride, potassium phosphate, sodium acetate, sodium chloride, sodium propionate, sodium sulfate, sorbic acid and its salts, stearic acid, tannic acid, trisodium citrate, zinc sulfate.
Stabilizers	Maltodextrin, betaine (trimethylglycine), glucose, glycerol, sodium chloride, sodium phytate, sorbitol, sucrose.
pH control, buffers	Acetic acid, citric acid anhydrous, sodium citrate, sodium phosphate, trisodium citrate.

Environmental Issues

The manufacture or use of animal enzymes is not found to be harmful to the environment or biodiversity. Enzymes are used in small amounts, are biodegradable, and the release of enzymes into the environment is not an environmental concern.

Discussion

There are no true alternatives to animal enzymes. Enzymes can only be substituted with another enzyme with the same function. One alternative to animal derived rennet for the production of cheese is genetically engineered chymosin, which is incompatible with organic food handling due to the use of excluded methods to produce it. The 2000 TAP for animal derived enzymes indicated that animal derived enzymes could be produced from organic livestock.

Questions to our Stakeholders

1. Since the last review, have organic animal enzymes become commercially available?
 - a. If so, is there sufficient supply that meets the needs of the organic industry?
 - b. If not, what are the barriers?
2. Are there ancillary substances used in animal enzymes that are not found on the chart above, or are there ancillary substances on the chart that you think should not be allowed? Please submit public comment explaining which substance and why.

Calcium sulfate-mined

Reference: §205.605(a)

Technical Report: [1996 TAP](#), [2001 TAP](#)

Petition(s): [2000](#)

Past NOSB Actions: [09/1996 meeting minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#); [11/2016 recommendation](#)

Recent Regulatory Background: National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#)); Sunset renewal notice effective 5/29/2018 ([83 FR 14347](#))

Sunset Date: 5/29/2023

Subcommittee Review

Use

- Coagulate in tofu manufacturing. Calcium sulfate is essential to soft and silky tofu types.
- Yeast food and dough conditioner, water conditioner.
- Firming agent (in canned foods).
- Jelling ingredient.
- Baking powder.
- Dentistry (bone regeneration).

Manufacture

Calcium sulfate can be obtained from natural sources or synthetic sources. The listing restricts calcium sulfate to mined sources, and mined gypsum is the primary source. After crude gypsum is mined in open-cast quarrying or via deep mining, it is ground and separated. It is normally sold in pure form but may contain impurities of calcium carbonate and natural occurring silica. It can form as a by-product from many different kinds of processes, including from emissions from fossil fuel power stations. The material is Generally Recognized As Safe (GRAS) by the FDA.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

Restricted to “as a carrier for cakes and biscuits; for soybean products; and for bakers’ yeast” and source is restricted to “sulfates produced using sulfuric acid are prohibited.”

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

Restricted to use as a coagulation agent and carrier only but is not restricted to mined sources. Mexico – restricted to acidifiers, acidity, anti-caking agent, antifoam, filler and coagulant but not restricted to mined sources.

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

Restricted to “Cakes & biscuits/soybean products/baker’s yeast. Carrier” but not restricted to mined sources.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Restricted “For soybean products, confectionery and in bakers’ yeast” but not restricted to mined sources.

Japan Agricultural Standard (JAS) for Organic [Production](#)

Restricted to” Limited to be used as coagulating agent or used for confectionary, the processed beans products or bread yeast” but not restricted to mined sources.

Ancillary substances

None reported in the 2001 TAP.

Environmental Issues

Mining of calcium sulfate (as gypsum or alabaster) has exposed several public land areas, including Grand Staircase-Escalante National Monument in Utah, to extractive impacts. It is unclear the full extent of these activities to date, or landscape and critical area damage that could occur in the future. This question could potentially be addressed more fully in more current Technical Report (TR), as the most recent report on calcium sulfate is a 2001 Technical Advisory Panel (TAP), especially given that the sunset under consideration is the mined version.

Discussion

Several comments were received on this substance during the previous sunset review in 2016. Manufacturers and trade associations emphasized its use in tofu production. Several companies noted it was critical to production of tofu and soy cheese. One manufacturer noted they would like it retained but they currently use magnesium chloride instead. Another manufacturer noted magnesium chloride produced a softer tofu than calcium sulfate. It was also noted that calcium sulfate was used in the brewing industry to adjust the mineral content of water. One interest group asked that its use be limited to coagulation of bean curd noting evidence was not available for its use in other food applications. Another interest group raised concerns about the environmental and human health concerns of mining and noted a toxicological review completed by the National Toxicology Program in 2006. This review noted: “None of the long-term studies can be considered adequate tests of chronic toxicity or carcinogenicity by modern standards.” Furthermore, it focused more on exposure from the 2001 World Trade Center attacks, and the limited information from mine workers was from a 1976 study that was available during the original 1996 TAP. While the previous sunset review considered the renewal of calcium sulfate valid, a previous NOSB noted that future sunset reviews should consider if a new TR could help in a review of current data on alternative manufacturing methods, environmental or human health concerns, and/or whether an annotation should be recommended.

In 2016, the subcommittee agreed this material satisfies the OFPA evaluation criteria and the Handling Subcommittee supported the relisting of calcium sulfate, which subsequently was upheld by the full board.

Questions to our Stakeholders

1. Is there clear evidence of unacceptable environmental impacts from the mining of calcium sulfate?
2. Is there clear evidence of unacceptable human health impacts from calcium sulfate mining?

Carrageenan

Reference: §205.605(a)

Technical Report: [1995 TAP](#), [2011 TR](#); [2016 Limited Scope TR](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#); [11/2016 recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987 – misspelled as ‘carageenan’](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#)); Sunset renewal notice effective 5/29/2018 ([83 FR 14347](#))

Sunset Date: 5/29/2023

Subcommittee Review

Use

Carrageenan, also referred to as Irish moss, is a food additive used as an emulsifier, thickener, and gelling compound primarily in meat and dairy products. It is often used as a vegan alternative to animal sourced gelatin. It is listed as Generally Recognized as Safe (GRAS) on the FDA list of food additives.

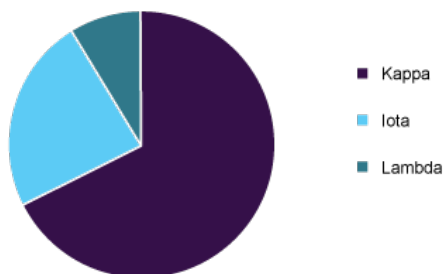
Manufacture

Carrageenan is made through a fairly simple process of heating edible red algae in a hot alkali solution, typically using potassium hydroxide. The cellulose from the plant is then removed through centrifuge and the remaining gel-like solution is the carrageenan, which can be evaporated and dried into a powder form for addition to foods.

There are three main kinds of carrageenan which are primarily extracted from different seaweed species (or different life stages) and are distinguished chemically by the number and position of ester sulphates on the carbohydrate units in the molecules. This information is relevant, as the different types have different properties and uses in the food industry.

- Kappa-carrageenan – forms strong gels in combination with potassium ions and is used primarily in dairy products
- Iota-carrageenan – forms soft gels in the presence of calcium ions
- Lambda-carrageenan – does not gel and is used to thicken dairy products

Global carrageenan market share, by product, 2019 (%)



Source: www.grandviewresearch.com

Figure 1. Most of the global production is of kappa-carrageenan (Source www.grandviewresearch.com).

Most of the seaweeds used in carrageenan production are sourced from the Philippines and China and are grown in seaweed farms.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

Canada allows carrageenan as a food additive under their organic standard with no limits on usage.

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

The EEC allows carrageenan as an additive to organic dairy foods. The joint FAO/WHO Expert Committee on Food Additives (JECFA) determined in 2015 that carrageenan is a safe additive for infant formula at doses up to 1000mg/L.

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

Carrageenan is listed as a food additive permitted for use in plant-based foods, dairy products, and dairy analogues (excluding fats, oils, and fat emulsions) within the guidelines for organically produced foods (Matthee, 2007).

International Federation of Organic Agriculture Movements (IFOAM) Norms

IFOAM allows carrageenan as a food additive with no annotations.

Japan Agricultural Standard (JAS) for Organic [Production](#)

JAS allows carrageenan as an additive to organic dairy products.

East African Organic Product Standard and the Pacific Organic Standard

Both list carrageenan as an additive allowed in organic food processing.

Environmental Issues

Farming of seaweed used to extract carrageenan raises several environmental issues. Seaweed farms can be a lucrative business for small scale aquaculture as the overhead is low (requiring at the most basic level nylon strings or netting in shallow coastal waters) and the turnover to harvest is quite short, at only 6 weeks. However, increased demand for seaweed has resulted in the establishment of some farms which involve first destroying important nearshore habitats like mangrove swamps or eelgrass beds to provide growing environments. Drifting mats from the established farms can also smother other nearby habitats, such as coral reefs. For example, when seaweed farming was introduced to India to promote aquaculture for carrageenan, the seaweed rapidly invaded and smothered coral reefs in a nearby marine reserve (Baglar, 2008).

Research into the ecological effects of seaweed farming indicates that the diversity of fish is reduced in and around the seaweed farms. Proximity to seaweed farming reduces the size and growth rates of sea grass beds. A proposed environmental mitigation strategy is to move seaweed farming to deeper, sandy-bottomed areas and ensure that the farms are a safe distance from vulnerable habitats like coral reefs (Kelly, Cannon and Smith, 2020).

The impacts of seaweed aquaculture are not all negative. It has been hypothesized that carefully placed seaweed aquaculture can help increase oxygenation in near-shore waters, removed impurities from the water, buffer against wave action, help stabilize marine pH and otherwise help mitigate against some of effects of climate change (Duarte, Wu, Xiao, Bruhn and Kraus-Jenson, 2017). In addition, it is a food source that requires no freshwater or chemical inputs, making it an attractive alternative to terrestrial-based crops. Lastly, seaweed farming can provide a viable alternative to fishing in areas where overfishing has depleted fish populations.

Discussion

Carrageenan has a long history of use as a food additive, used to make dairy-based puddings in Ireland for nearly 1500 years and found in soups in China since 600 BC. Also known as Irish moss, it did not become broadly used in industrial food preparation until the 1930s. It is currently a \$500 million dollar industry.

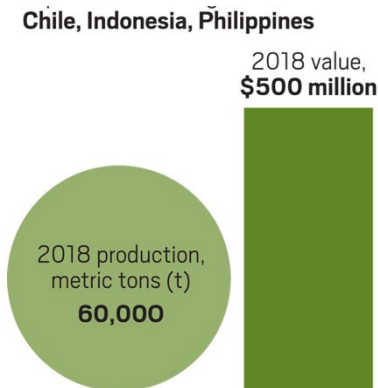


Figure 2. Carrageenan production in 2018 (Taylor, 2019).

Due primarily to their role as thickening and emulsifying agents, carrageenan and other algae-based foods represent one of the fastest growing segments of the food sector. Seaweed production is projected to grow an [additional 12.6% a year](#) over the 5 year period from 2020-2025 as the demand for processed foods continues to grow.

Despite this extensive history of human consumption, there have been concerns in the United States that carrageenan can cause a myriad of health problems as part of the human diet (Bixler, 2017). Most of this controversy stems from research led by Dr. Joanne Tobacman (Tobacman, Bhattachayya, Borthakur, and Dudeja, 2008). Her research has suggested that carrageenan promotes intestinal ulcers, contributes to Irritable Bowel Syndrome, and could be carcinogenic.

Critics of Dr. Tobacman and associates work believe that Tobacman has been conducting experiments using not carrageenan, but a degraded form of carrageenan, poligeenan, that is a known inflammatory agent and not considered safe for consumption. Poligeenan is only produced from carrageenan under high heat and extreme acid conditions and is therefore not created during the process of human digestion. Poligeenan “is distinct from food-grade carrageenan.” In fact, poligeenan is well-known for producing an inflammatory response and is used to provoke edema for study in rats when injected under the skin. The results from Tobacman’s studies have not been replicated when independently assessed.

Further muddying the waters, much of the early work on carrageenan and poligeenan do not distinguish between the intact and the degraded form, calling both carrageenan. Therefore, older scientific papers need careful reading to determine whether the researcher used poligeenan or carrageenan. Intact carrageenan, like cellulose and other fibre, is a large molecule that passes through the human digestive tract without being broken down or absorbed. Despite the lack of replication of this work, there are numerous anecdotal reports from people who find relief from digestive complaints when they remove carrageenan from their diet. Currently, changes in perceived health must therefore be considered correlative and not demonstrative of causation.

In 2007, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) considered it “inadvisable to use carrageenan or processed eucheuma seaweed in infant formulas,” but then partially reversed this position in 2014, concluding that “these new studies allay the earlier concerns that carrageenan, which is unlikely to be absorbed, may have a direct effect on the immature gut.” The Committee also took account of

the previous toxicological database on carrageenan, which “did not indicate other toxicological concerns” and “that the use of carrageenan in infant formula or formula for special medical purposes at concentrations up to 1000 mg/L is not of concern.” Infants are considered to be the most sensitive population to the potential effects of carrageenan. The 2011 Technical Report (TR) reports that “the group acceptable daily intake (ADI) for carrageenan and processed Eucheuma seaweed was categorized as “not specified” by JECFA, ... [which] means that the total dietary intake of the substance arising from its use at the levels necessary to achieve the desired effect in food and from its acceptable background levels in food does not... represent a hazard to health”.

As part of the 2016 NOSB sunset review, “an extensive list was prepared of all the food product categories in which carrageenan is used. In most of the product types there are versions that are currently being sold that do not contain carrageenan. These often contain other types of gums such as gellan, guar, or xanthan.” At that time, products for vegetarians and vegans where carrageenan is used in place of gelatine were singled out as difficult to produce without carrageenan.

Eliminating carrageenan may be achievable through the elimination of many processed foods where it is found essential by manufacturers. Most international organic standards permit use of carrageenan, including the EU, Canada, Japan, and IFOAM (see the International Acceptance section above). During the last sunset review, the NOSB recommended removal of carrageenan from the National List (Yes: 10 No: 3 Abstain: 1 Absent: 1 Recuse: 0). The basis of this decision largely reflected the intense consumer controversy associated with this substance, as well as concerns about its compatibility with a system of sustainable agriculture. Also invoked was the NOSB Guidance on Compatibility from the Appendix of the NOSB Policy and Procedures Manual that poses this question for consideration, “Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?” It is important to note that the NOP did not take the NOSB recommendation to remove carrageenan from the National List and carrageenan is currently allowed in organic production.

Questions to our Stakeholders

1. Should there be an effort to outline best management practices for seaweed farming and harvesting?
2. Do seaweed farming practices for carrageenan production conflict with the proposed Marine Materials guidelines passed by the NOSB last year?
3. Is carrageenan essential for production of organic products? Which products?
4. Are carrageenan alternatives available to replace all current uses?
5. Would lack of carrageenan availability limit opportunities to produce vegan products?
6. Is there new information on the safety of carrageenan?

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Glucono delta-lactone

Reference: §205.605(a) Glucono delta-lactone—production by the oxidation of D-glucose with bromine water is prohibited.

Technical Report: [2002 TAP](#); [2016 TR](#)

Petition(s): [2002](#)

Past NOSB Actions: [09/2002 meeting minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#); [11/2016 recommendation](#)

Recent Regulatory Background: National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/2013 ([78 FR 61154](#)); Sunset renewal notice effective 5/29/2018 ([83 FR 14347](#))

Sunset Date: 5/29/2023

Subcommittee Review

Use

Glucono delta-lactone (GDL) is primarily used in the production of tofu, particularly in the production of silken tofu, and is generally thought to be the only material that can produce the physical and sensory components favored in that product. In tofu production, GDL serves as a coagulant. GDL can also be used as a curing or pickling agent, leavening agent, pH control agent and sequestrant. It is also used in feta cheese in place of lactic acid bacteria to reduce pH. Less tangy than citric acid, GDL slowly undergoes hydrolysis in water and converts to gluconic acid to produce a tangy flavor in food applications. GDL is Generally Recognized As Safe (GRAS) by the FDA.

Manufacture

There are a variety of ways GDL can be produced. The most common method to produce gluconic acid is called the Blom process, where gluconic acid is produced by fermentation of glucose syrups by *Aspergillus niger*. Sodium hydroxide or calcium carbonate is added to the fermentation process to produce gluconate salt. The gluconate salt is then isolated via evaporation, crystallization and then conversion to acid via ion-exchange. This process produces GDL via acid base reactions and fermentation (2016 TR, pg. 10-11). Other processes to make GDL involve oxidation of D-glucose with bromine water (which is not allowed by the National List annotation) and purified enzymes (TR 281-282).

GDL is >99% pure and has no ancillary substances present. GDL is often sold in formulation with other additives specifically designed for the application. These substances should be reviewed separately as they are not ancillary substances.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

GDL is not listed on the permitted substances list of Canada.

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

GDL is not listed on the permitted substances list of the EU.

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

GDL is not listed on the permitted substances list of CODEX.

International Federation of Organic Agriculture Movements (IFOAM) Norms

GDL is not listed on the permitted substances list of IFOAM.

Japan Agricultural Standard (JAS) for Organic [Production](#)

GDL is not listed on the permitted substances list of Japan.

Environmental Issues

The Handling Subcommittee was unable to document any environmental or human health issues associated with the production or consumption of GDL. Some sources have indicated it may cause minor bladder discomfort and/or back pain.

The 2016 technical review examined human health and environmental impacts of GDL use and production but found low to no risk. The TR did raise the question of classification, given the substance is produced via fermentation and acid-base reactions similar to the production of citric acid (also listed at §205.605(a) nonsynthetic). The TR also raised concerns about the potential for GMO enzymes used in the production of GDL via the oxidation with enzymes production method (not the most common form of production).

Discussion

The original petition and primary use of GDL is for the coagulation of tofu. Other coagulants for tofu include magnesium chloride, calcium chloride, calcium sulfate, and magnesium sulfate. Acids such as citric or lactic acid can be used as well. Each of these substances produce a different type of tofu texture and flavor making distinctly different products. Calcium salts produce firmer tofu, sulfate salts produce soft tofu and GDL produces silken tofu. Citrus and lactic acids produce acidified tofu that is often undesirable. Precise control of temperature and processing environments may allow different coagulants to produce different types of tofu.

The Handling Subcommittee sought further information from the public, in particular, whether GDL is being used in applications other than tofu production for organic processed foods. One comment was received stating its use was necessary for a dairy product and another noted its use in a cosmetic product. Further, the Handling Subcommittee asked if alternative tofu coagulants such as calcium and sulfate salt would be sufficient to produce all forms of tofu if GDL were removed from the national list. In response, companies commented that alternatives on the list result in distinctly different and more firm tofu and that GDL is critical to silken, jelly-like tofu. Several tofu manufacturers commented in favor of retaining GDL.

Lastly, the Subcommittee asked stakeholders whether GDL produced from enzymes should be prohibited or further restricted due to concerns about GMOs, an issue that is referenced in the 2002 TAP and noted as an issue for ongoing monitoring. Interest groups expressed concern that enzymatic GDL could possibly be produced via GMO substrates or enzymes and recommended the listing be annotated if renewed at all. As annotation changes are not possible during sunset review, this would require separate action from the Board. Another commenter questioned the necessity of GDL stating it could be produced via alternative means, however, no information was presented on the commercial viability of this approach.

This material satisfies the OFPA evaluation criteria and the Handling Subcommittee supports the relisting of glucono delta-lactone.

Questions to our Stakeholders

1. How widespread is the use of GDL in organic applications?
2. Is there evidence that GDL being used in organic applications may derive from genetic modification of any kind?
3. Have alternatives to GDL emerged in recent years that deliver the same product quality and functionality?
4. Is the lack of International acceptance significant?
5. How is organic silken tofu produced in the EU, Japan, etc. without the use of GDL?

Tartaric acid

Reference: §205.605(a) Tartaric acid - made from grape wine.

Technical Report: [2011 TR](#)

Petition(s): [2011 Petition to remove from §205.605\(b\) - made from malic acid](#)

Past NOSB Actions: [NOSB meeting review 11/1995](#); [11/2005 recommendation](#); [12/2011 recommendation](#); [11/2016 recommendation](#)

Recent Regulatory Background: National List amended 10/31/2003 ([68 FR 61987](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#)); Sunset renewal notice effective 5/29/2018 ([83 FR 14347](#))

Sunset Date: 5/29/2023

Subcommittee Review

Use

According to the 2011 TR, tartaric acid naturally occurs in many plants, especially grapes, bananas, and tamarinds. Tartaric acid can be 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 of tartaric acid are associated with its salts.

The 2011 TR further notes that tartaric acid and its salts have a very wide variety of uses. These include use as an 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 confectionaries, 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.

Tartaric acid and its immediate byproducts are particularly useful in baking. Due to its acidic properties, tartaric acid is used in baking powder in combination with baking soda (sodium bicarbonate). When tartaric acid reacts with sodium bicarbonate, carbon dioxide gas is produced, causing various baking products to 'rise' without the use of active yeast cultures. This action alters the texture of many foods. Tartaric acid and its salts are used in pancake, cookie, and cake mixes because of these properties. Cream of tartar is used to make cake frosting and candies.

Although tartaric acid is isolated from wines, it may also be used in winemaking to alter acidity. For non-grape wines, it may be added to increase acidity or to help prevent degradation of the flavor from unwanted microorganisms (TR, 2011).

Tartaric acid and its salts (i.e. potassium acid tartrate, sodium potassium tartrate acid) are classified by FDA as Generally Recognized As Safe (GRAS).

Manufacture

The 2011 TR details the production of tartaric acid:

The nonsynthetic form of tartaric acid is isolated from the undesirable wastes created during the winemaking process. These unwanted materials include grape pomace, grape stalks, grape seeds, and vine, which naturally contain a significant amount of tartaric acid. An excess of tartaric acid is generally unwanted in winemaking because it creates a sour and undesirable taste. The available excess tartaric acid is precipitated using potassium hydroxide or calcium hydroxide in order to create a wine with the desired taste. Then the resulting waste mixture is evaporated. This process produces a powder containing calcium or potassium tartrate and additional substances including polyphenols and tannins. The powder is then sold to facilities that purify tartaric acid. The process for extracting tartaric acid from waste materials is similar to the processing of excess tartaric, in that potassium hydroxide is added to the waste mixture. Activated carbon is also added to remove unwanted pigmentation. The potassium tartrate is precipitated by adding saturated pure tartaric acid solution and then the precipitate is redissolved with acidic water at 70° C. Potassium and sulfate ions must be removed from the remaining solution so cation exchanges are performed followed by evaporation. The solution is then crystallized at 4° C.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

The use of tartaric acid (C₄H₆O₆; INS 334) is permitted for organic processing by the Canadian General Standards Board as a non-organic ingredient classified as a food additive in beverages. Use of the synthetic form is allowed only if the nonsynthetic form of tartaric acid is not commercially available. Tartaric acid derived from nonsynthetic sources is also permitted for use as a processing aid in beverages (the Canadian General Standards Board, 2020).

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

The European Economic Community (EEC) permits the use of tartaric acid as a food additive in organic food if derived from a plant source, which is presumably grapes (EEC 889/2008, 2008).

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

The CODEX Alimentarius Commission describe the functions of tartaric acid as an acidity regulator, adjuvant, anticaking agent, antioxidant, bulking agent, emulsifier, flour treatment agent, humectant, preservative, raising agent, sequestrant, and stabilizer. Tartaric acid from a plant source (i.e. nonsynthetic L (+) tartaric acid) is permitted for use as a food additive in organic food production (although exclusions of the GFSMA still apply). Tartaric acid is listed as an acceptable acidity regulator in the *Codex General Standard for Food Additives* (CODEX STAN 192-1995; CODEX Alimentarius Commission, 2011).

International Federation of Organic Agriculture Movements (IFOAM) Norms. Allows the use of tartaric acid only for wine.

Japan Agricultural Standard (JAS) for Organic [Production](#)

Limited to be used for processed foods of plant origin.

Environmental Issues

If appropriate use patterns and disposal recommendations are followed, it is unlikely that tartaric acid would cause harm to the environment. The biodegradability of tartaric acid is 95% after 3 days and the substance is considered readily biodegradable. No bioaccumulation is to be expected (TR 2011).

Discussion

Tartaric acid is a critical component in several areas of food handling. While baking powder can be replaced with baking soda, cream of tartar must be added to maintain the baking powder properties. While tartaric acid is made from grapes, it is also an important component in winemaking and there are no organic alternatives. Other natural components of grapes, such as malic acid, can be used to alter the acidity of wine and possess preservative characteristics, but they often contribute to the wines overall taste differently than tartaric acid (2011 TR)

For pH adjustment, citric acid and malic acid can be used, however, they impart certain flavors to the product. If a grape flavor is needed, tartaric acid would be the first choice.

Due to its low impacts on human health and the environment and the advantageous qualities that tartaric acid lends to baked goods, wines and other products, tartaric acid is a good candidate for relisting.

Questions to our Stakeholders

1. Is tartaric acid still an essential ingredient for organic processing?
2. Are there any organic/natural alternatives for wine making?
3. Is there a sufficient supply of organic grapes to make tartaric acid from organic grapes?
4. Are there any ancillary substances that are associated with tartaric acid?

Cellulose

Reference: §205.605(b) Cellulose (CAS #9004-34-6)—for use in regenerative casings, powdered cellulose as an anti-caking agent (non-chlorine bleached) and filtering aid. Microcrystalline cellulose is prohibited.

Technical Report: [2001 TAP](#); [2016 TR](#)

Petition(s): [2001](#)

Past NOSB Actions: [10/2001 meeting minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#); [11/2016 recommendation](#)

Recent Regulatory Background: National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#)); [Sunset renewal notice effective 5/29/2018 \(83 FR 14347\)](#); Annotation change effective 12/27/2019 ([83 FR 66559](#))

Sunset Date: 11/03/2023

Subcommittee Review

Use

Cellulose is used as a processing aid for filtration of juices; as an anti-caking agent ingredient for use in shredded cheese; and as a processing aid in the form of peelable/non-edible hot dog and sausage casings. Some of these uses in organic handling have been around since before the enactment of OFPA, with cellulose allowed by certifiers in organic cheeses since 1994 and for use in organic meat products since 1999.

Manufacture

Cellulose is available in several different forms, each with varying functional qualities used for multiple purposes in organic handling. There are two specific forms of cellulose currently permitted for use in organic processing and handling: amorphous powdered cellulose and inedible cellulose casing.

Cellulose in its natural form is the main structural component of higher plant cell walls and one of the most abundant organic substances on earth (EMBL, 2015)(TR 2-11-2016). Most commercially available cellulose (powdered) is produced from wood pulp or other plant sources, e.g. corn cobs, soybean hulls, oat hulls, rice hulls, sugar beet pulp, etc. The plant material goes through a delignification process that results in a chemically changed synthetic substance. The original process for making regenerated cellulose casing, the viscose method, dates to the 1890's and converts cellulose fibers into regenerated fibers and films. With some minor changes to the process, it is still in use today. Cellulose is considered GRAS under CFR 121.101 (LSRO 1973).

The 2016 TR and public comments submitted in previous sunset reviews of cellulose provided the following list of ancillary substances that are sometimes used in the production of cellulose. The TR was very clear that there are well defined sources of commercially available cellulose that do not include any ancillary substances, as well as those that might use ancillaries listed in the chart below. During the 2018 sunset review, public comment identified additional ancillary substances used in the production of cellulose. The review noted the Handling Subcommittee would develop a follow-up proposal to include these ancillaries, however it is not clear if this progressed.

Functional Class	Ancillary Substance Name
Carriers and fillers, agricultural or nonsynthetic	Potato starch, dextrose
Carriers and fillers, synthetic	Propylene glycol
Preservatives	Polysorbate 80, enzymes
Binder/Plasticizer	Lecithin, propylene glycol, mineral oil
Anti-caking & anti-stick agents	Mineral oil, animal oil, vegetable oil, resin
Releasing agents	Mineral oil

International Acceptance

The 2016 TR notes the following international allowances:

Canadian General Standards Board Permitted Substances [List](#)

Allowed as a filtering aid (non-chlorine bleached) and for use in inedible regenerative sausage casings (CAN/CGSB 2015).

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

Cellulose is authorized for use in the wine sector only for use as an inert filtering aid (EU Commission 2008).

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

No specific listing.

International Federation of Organic Agriculture Movements (IFOAM) Norms

In Appendix 4, Table 1 "List of approved additives and processing/post-harvest handling aids" as a processing and post-harvest handling aid with no annotation (IFOAM 2014).

Japan Agricultural Standard (JAS) for Organic [Production](#)

No specific listing.

Environmental Issues

During previous reviews, public comment, as well as the 2016 TR, raised concerns regarding the use of wood pulp as a source for cellulose and the environmental impact that logging of primary forests and replacement with monoculture plantations may have. Concerns were also raised about environmental problems caused by waste cellulose generated from food processing. The 2016 TR states that conversion of cellulosic food wastes, as well as cellulose waste from filtration aids and/or spent casings into useful products is the subject of research. The research is based more on seeking to add value, but is also driven by environmental concerns, rising disposal costs, and governmental regulations.

Discussion

Despite the concerns noted above, the Board noted that comments received during the 2018 Sunset review “helped to provide the full Board with a detailed rationale as to why this material is still essential to organic handlers, even though some have found alternative processes to work for their specific needs. There was no information presented that made this committee feel this material should not be re-listed.”

Questions to our Stakeholders

1. Is cellulose still essential to organic production?
2. Are there ancillary substances in use that are not identified in the table in this document?
3. Are there alternative sources of cellulose to those from virgin forests that might minimize concerns regarding impact on primary forests?
4. What percentage of cellulose in use is derived from grain and vegetable products vs. from wood/forestry?

Chlorine materials – Calcium hypochlorite

Reference: §205.605(b) Chlorine materials - disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.

(i) Calcium hypochlorite

Technical Report: [2006 TR \(Chlorine materials- Handling\)](#); [2011 TR - Crops](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [04/2006 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset review](#); [11/2017 sunset review](#)

Recent Regulatory Background: Amendment to annotation effective 1/28/2019 ([83 FR 66559](#)); Sunset renewal notice effective 10/30/2019 ([84 FR 53577](#))

Sunset Date: 1/28/2024

Subcommittee Review

Use

Calcium hypochlorite is an EPA-registered pesticide (OPP Nos. 014701). Calcium hypochlorite is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. Allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl₂).

Calcium hypochlorite is an "indirect" food additive approved by [FDA](#). Calcium hypochlorite may be used as a final sanitizing rinse on food processing equipment (21 CFR 178.1010). Hypochlorites also can be used in postharvest, seed, or soil treatment on various fruit and vegetable crops (EPA, 1991).

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration or the Environmental Protection Agency for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

In water, sodium and calcium hypochlorite separate into sodium, calcium, and hypochlorite ions and hypochlorous acid molecules. Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with the hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates triosephosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function.

Manufacture

Calcium hypochlorite is produced by passing chlorine gas over slaked lime. It is then separated from the coproduct, calcium chloride, and air dried or vacuumed.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

http://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-311-2020-eng.pdf

International Federation of Organic Agriculture Movements (IFOAM) Norms

Equipment cleaner/disinfectant: <https://www.ifoam.bio/our-work/how/standards-certification/organic-guarantee-system/ifoam-standard>. An intervening event or action must occur to eliminate risks of contamination.

Environmental Issues

Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposures occur or from chronic lower-level exposures – especially in

occupational environments when these materials are used on a daily basis. These compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) and can cause asthma, as classified by the Association of Occupational and Environmental Clinics (<http://www.aoecdata.org/ExpCodeLookup.aspx Code 332.10>). Given the similar chemistries and mechanisms of action, other chlorine-based oxidant sanitizers, already known to be respiratory irritants, also likely cause asthma. Chlorine compounds are toxic to fish and other aquatic organisms. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in a 2006 and 2011 Technical Reports (TR) (referenced above.).

Discussion

Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food-safety regulations under the Food Safety Modernization Act (FSMA). The Handling Subcommittee (HS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The HS supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.

Questions to our Stakeholders

The NOSB, through its various subcommittees, is engaging in a critical assessment of how it reviews sanitizers either approved for organic or petitioned for use in organic. As part of that assessment, the questions below have been suggested as a framework to evaluate the appropriateness of sanitizers and disinfectants used in in organic production and handling. We invite members of the organic community to address these questions in light of the current sunset review of calcium hypochlorite, sodium hypochlorite, chlorine dioxide, and hypochlorous acid.

1. Is calcium hypochlorite essential for organic food production and handling?
2. How well does calcium hypochlorite work for the specific need identified?
3. Since calcium hypochlorite was last reviewed, have additional commercially available alternatives emerged that would negate the need for this compound in organic handling?
4. How does calcium hypochlorite fit into an adequate system of cleaning (contact time, scrubbing effort and force, water source, etc.), rinsing, and sometimes testing, as the essential first step in sanitation?
5. Is calcium hypochlorite a direct food contact material or a surface contact material? If it is a food contact material, how is it used in food processing and handling?
6. How does calcium hypochlorite fit into rotations and/or the need for back up materials?
7. How can we look to FDA and EPA to help us assess the risks of chlorine sanitizers while also evaluating against the OFPA criteria (particularly environmental fate and human health impacts)?

Chlorine materials – Chlorine dioxide

Reference: §205.605(b) Chlorine materials - disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.

(ii) Chlorine dioxide

Technical Report: [2006 TR \(Chlorine materials\)](#); [2011 TR - Crops](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [04/2006 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset review](#); [11/2017 sunset review](#)

Recent Regulatory Background: Amendment to annotation effective 1/28/2019 ([83 FR 66559](#)); Sunset renewal notice effective 10/30/2019 ([84 FR 53577](#))

Sunset Date: 1/28/2024

Subcommittee Review

Use

Chlorine dioxide is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. It is allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl₂).

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration or the Environmental Protection Agency for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

Chlorine dioxide is a strong oxidant. It is likely a better bactericide than hypochlorous acid. In general, the disinfection efficiency of chlorine dioxide decreases as temperature decreases.

Manufacture

To form chlorine dioxide, sodium chlorate (NaClO₃) and sulfuric acid (H₂SO₄) are reacted with sulfur dioxide (SO₂), or chloric acid is reacted with methanol (CH₃OH) (HSDB, 2005). Alternatively, chlorine dioxide can be formed with chlorine (Cl₂) and sodium chlorite; sodium hypochlorite with hydrochloric acid; potassium chlorate with sulfuric acid; or by passing nitrogen dioxide through a column of sodium chlorate.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

http://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-311-2020-eng.pdf

International Federation of Organic Agriculture Movements (IFOAM) Norms

Equipment cleaner/disinfectant: <https://www.ifoam.bio/our-work/how/standards-certification/organic-guarantee-system/ifoam-standard>. An intervening event or action must occur to eliminate risks of contamination.

Environmental Issues

Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposures occur or from chronic lower level exposures – especially in occupational environments when these materials are used on a daily basis. These compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) can cause asthma, as classified by the Association of Occupational and Environmental Clinics (<http://www.aoecdata.org/ExpCodeLookup.aspx> Code 332.10). Given the similar chemistries and mechanisms of action, other chlorine-based oxidant sanitizers, already known to be respiratory irritants, also likely cause asthma. Chlorine compounds are toxic to fish and other aquatic organisms. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in 2006 and 2011 Technical Reports (TR) (referenced above).

Discussion

Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food-safety regulations under the Food Safety Modernization Act (FSMA). The Handling Subcommittee (HS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The HS supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.

Questions to our Stakeholders

The NOSB, through its various subcommittees, is engaging in a critical assessment of how it reviews sanitizers either approved for organic or petitioned for use in organic. As part of that assessment, the questions below have been suggested as a framework to evaluate the appropriateness of sanitizers and disinfectants used in in organic production and handling. We invite members of the organic community to address these questions in light of the current sunset review of calcium hypochlorite, sodium hypochlorite, chlorine dioxide, and hypochlorous acid.

1. Is chlorine dioxide essential for organic food production and handling?
2. How well does chlorine dioxide work for the specific need identified?
3. Since chlorine dioxide was last reviewed, have additional commercially available alternatives emerged that would negate the need for this compound in organic handling?
4. How does chlorine dioxide fit into an adequate system of cleaning (contact time, scrubbing effort and force, water source, etc.), rinsing, and sometimes testing, as the essential first step in sanitation?

5. Is chlorine dioxide a direct food contact material or a surface contact material? If it is a food contact material, how is it used in food processing and handling?
6. How does chlorine dioxide fit into rotations and/or the need for back up materials?
7. How can we look to FDA and EPA to help us assess the risks of chlorine sanitizers while also evaluating against the OFPA criteria (particularly environmental fate and human health impacts)?

Chlorine materials – Hypochlorous acid – generated from electrolyzed water

Reference: §205.605(b) Chlorine materials - disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.

(iii) Hypochlorous acid - generated from electrolyzed water.

Technical Report: [2006 TR \(Chlorine materials - Handling\)](#); [2011 TR - Crops](#); [2015 TR](#)

Petition(s): [2015](#)

Past NOSB Actions: [2016 NOSB Recommendation](#)

Recent Regulatory Background: Added to NL effective 1/28/2019 ([83 FR 66559](#))

Sunset Date: 1/28/2024

Subcommittee Review

Use

Hypochlorous acid is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. Allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl₂).

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration or the Environmental Protection Agency for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates triosephosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function.

Manufacture

Electrolyzed water (EW) 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 ions to pass through. In the process, hypochlorous acid, hypochlorite ion, and hypochlorite 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. (TR lines 48-68).

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

http://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-311-2020-eng.pdf

Japan Agricultural Standard (JAS) for Organic [Production](#)

https://www.maff.go.jp/e/policies/standard/jas/specific/attach/pdf/criteria_o-12.pdf

Environmental Issues

Hypochlorous acid, generated from electrolyzed water, is present in solutions of two chlorine sanitizers (sodium hypochlorite and calcium hypochlorite) currently allowed at §205.601(a)(2)(i, ii). Like other chlorine compounds, hypochlorous acid is also an oxidant and can pose risks to human health. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in 2006 and 2011 Technical Reports (TR) (referenced above.).

As formulated via electrolyzed water, hypochlorous acid is effective as a sanitizer at a lower chlorine concentration and is likely safer for health and the environment than other currently listed chlorine sanitizers.

Discussion

Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food-safety regulations under the Food Safety Modernization Act (FSMA). The Handling Subcommittee (HS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The HS supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.

Questions to our Stakeholders

The NOSB, through its various subcommittees, is engaging in a critical assessment of how it reviews sanitizers either approved for organic or petitioned for use in organic. As part of that assessment, the questions below have been suggested as a framework to evaluate the appropriateness of sanitizers and disinfectants used in in organic production and handling. We invite members of the organic community to

address these questions in light of the current sunset review of calcium hypochlorite, sodium hypochlorite, chlorine dioxide, and hypochlorous acid.

1. Is hypochlorous acid essential for organic food production and handling?
2. How well does hypochlorous acid work for the specific need identified?
3. Since hypochlorous acid was last reviewed, have additional commercially available alternatives emerged that would negate the need for this compound in organic handling?
4. How does hypochlorous acid fit into an adequate system of cleaning (contact time, scrubbing effort and force, water source, etc.), rinsing, and sometimes testing, as the essential first step in sanitation?
5. Is hypochlorous acid a direct food contact material or a surface contact material? If it is a food contact material, how is it used in food processing and handling?
6. How does hypochlorous acid fit into rotations and/or the need for back up materials?
7. How can we look to FDA and EPA to help us assess the risks of chlorine sanitizers while also evaluating against the OFPA criteria (particularly environmental fate and human health impacts)?

Chlorine materials – Sodium hypochlorite

Reference: §205.605(b) Chlorine materials - disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.

(iv) Sodium hypochlorite

Technical Report: [2006 TR \(Chlorine materials\)](#); [2011 TR - Crops](#);

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [04/2006 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset review](#); [11/2017 sunset review](#)

Recent Regulatory Background: Amendment to annotation effective 1/28/2019 ([83 FR 66559](#)); Sunset renewal notice effective 10/30/2019 ([84 FR 53577](#))

Sunset Date: 1/28/2024

Subcommittee Review

Use

Sodium hypochlorite is an EPA-registered pesticide (OPP No 014703). Sodium hypochlorite is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. Allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl₂).

Sodium hypochlorite is an "indirect" food additive approved by FDA (<http://www.cfsan.fda.gov/~dms/opa-indt.html>). Sodium hypochlorite may be used as a final sanitizing rinse on food processing equipment (21 CFR 178.1010); sodium hypochlorite may be used in washing and lye peeling of fruits and vegetables (21 CFR 173.315). These hypochlorites also can be used in postharvest, seed, or soil treatment on various fruit and vegetable crops (EPA, 1991).

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration or the Environmental Protection Agency for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

In water and soil, sodium and calcium hypochlorite separate into sodium, calcium, and hypochlorite ions and hydrochlorous acid molecules. Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with the hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates triosephosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function.

Manufacture

Generally, sodium hypochlorite is produced by reacting chlorine with a solution of sodium hydroxide (NaOH, also called lye or caustic soda). This method is used for most commercial productions of sodium hypochlorite. A more active, but less stable formulation of sodium hypochlorite can be produced by chlorinating a solution of soda ash (Na₂CO₃).

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

http://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-311-2020-eng.pdf

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

<https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:250:0001:0084:EN:PDF>

Products for cleaning and disinfection referred to in Article 23 (4).

International Federation of Organic Agriculture Movements (IFOAM) Norms

Equipment cleaner/disinfectant: <https://www.ifoam.bio/our-work/how/standards-certification/organic-guarantee-system/ifoam-standard>. An intervening event or action must occur to eliminate risks of contamination.

Japan Agricultural Standard (JAS) for Organic Production

https://www.maff.go.jp/e/policies/standard/jas/specific/attach/pdf/criteria_o-12.pdf

Environmental Issues

Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposure occurs or from chronic lower-level exposures – especially in occupational environments when these materials are used on a daily basis. These compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) can cause asthma, as classified by the Association of Occupational and Environmental Clinics (<http://www.aocedata.org/ExpCodeLookup.aspx Code 332.10>). Given the similar chemistries and mechanisms of action, other chlorine-based oxidant sanitizers, already known to be respiratory irritants, also likely cause asthma. Chlorine compounds are toxic to fish and other aquatic organisms. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in 2006 and 2011 Technical Reports (TR) (referenced above.).

Discussion

Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food-safety regulations under the Food Safety Modernization Act (FSMA). The Handling Subcommittee (HS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The HS supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.

Questions to our Stakeholders

The NOSB, through its various subcommittees, is engaging in a critical assessment of how it reviews sanitizers either approved for organic or petitioned for use in organic. As part of that assessment, the questions below have been suggested as a framework to evaluate the appropriateness of sanitizers and disinfectants used in in organic production and handling. We invite members of the organic community to address these questions in light of the current sunset review of calcium hypochlorite, sodium hypochlorite, chlorine dioxide, and hypochlorous acid.

1. Is sodium hypochlorite essential for organic food production and handling?
2. How well does sodium hypochlorite work for the specific need identified?
3. Since sodium hypochlorite was last reviewed, have additional commercially available alternatives emerged that would negate the need for this compound in organic handling?
4. How does sodium hypochlorite fit into an adequate system of cleaning (contact time, scrubbing effort and force, water source, etc.), rinsing, and sometimes testing, as the essential first step in sanitation?
5. Is sodium hypochlorite a direct food contact material or a surface contact material? If it is a food contact material, how is it used in food processing and handling?
6. How does sodium hypochlorite fit into rotations and/or the need for back up materials?

How can we look to FDA and EPA to help us assess the risks of chlorine sanitizers while also evaluating against the OFPA criteria (particularly environmental fate and human health impacts)?

Potassium hydroxide

Reference: §205.605(b) Potassium hydroxide - prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.

Technical Report: [2001 TAP](#); [2016 TR](#)

Petition(s): [2001 petition](#), [2011 petition to amend annotation](#)

Past NOSB Actions: [10/1995 meeting minutes and vote](#); [11/2005 recommendation](#); [12/2011 recommendation](#); [11/2016 recommendation](#)

Recent Regulatory Background: Added to the National list 12/21/2000 ([65 FR 80548](#)); National List amended 11/03/2003 ([68 FR 62215](#)); National List amended 05/28/2013 ([78 FR 31815](#)); Sunset renewal notice effective 5/29/2018 ([83 FR 14347](#))

Sunset Date: 5/29/2023

Subcommittee Review

Use

Potassium hydroxide is a synthetic, inorganic compound produced by the electrolysis of potassium chloride. Also known as potash, it is a strong base, and alkaline in solution. Much of its utility in food processing is based on its function as a caustic strong base. Potassium hydroxide is widely used in food processing as a pH adjuster, cleaning agent, stabilizer, thickener, and poultry scald agent (2016 TR).

Potassium hydroxide in poultry chill water increases the shelf life of broilers and other meat birds by killing various spoilage organisms, particularly when used in combination with lauric acid. To a limited extent, potassium hydroxide will also act as a preservative in the curing of certain foods, such as olives.

The 2016 TR notes that potassium hydroxide is also used in the lye peeling of fruits and vegetables. The FDA lists potassium hydroxide as Generally Recognized As Safe (GRAS) for humans (21 CFR 184.1631), which is allowed under 21CFR 173.315(a)(1) - Chemicals used in washing or to assist in the peeling of fruits and vegetables. According to the TR, peaches peeled for canning or pickling use a 1.5% solution of lye at a temperature slightly below 145°F (<62°C) for about 60 seconds, followed by a wash and dip into a solution of 0.5 - 3.0% citric acid. Because hot water cannot be used for freezing peaches, they require a higher solution - about 10% - and a treatment time of about 4 minutes to be peeled. Lye is removed by thorough washing, and again citric acid is used to neutralize the pH of the fruit.

For certain grains and legumes potassium hydroxide is used to remove tannins that interfere with nutrient uptake. For example, it increases solubility of protein in soybeans. It can be also be used as a solvent to determine protein quality and total soluble protein in assays. Potassium hydroxide can be used as a substitute for the traditional calcium hydroxide (lime water) used to remove the pericarp of corn, a process known as 'nixtamalization' - part of the process to make masa from corn. Furthermore, the removal of the pericarp or bran from corn, sorghum, and other grains increases the nutritional quality and digestibility of those grains (2016 TR).

Manufacture

The 2016 TR notes that the FDA specifies that food grade potassium hydroxide is made by the electrolysis of potassium chloride (KCl) and water in the presence of a porous diaphragm [21 CFR 184.1631(a)]. Potassium chloride, also known as muriate of potash, is a naturally occurring mineral, with the main global source being Canada. Most U.S. production occurs in New Mexico and Utah. Potassium chloride is put into aqueous solution and is electrolyzed by various processes. Diaphragm cells will produce a liquor that contains 10 - 15% by weight of KOH and about 10% KCl. Most of the KCl crystallizes by evaporation and subsequent cooling during concentration. The concentrated KOH is about a 50% solution with about 0.6%

KCl. Potassium hydroxide is regarded by the chemical industry as a by-product of the process for producing hydrochloric acid.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

Allowed for pH adjustment only. Prohibited for use in lye peeling of fruits and vegetables (C CAN-CGSB-32.311-2015E).

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

Caustic potash is on Annex VII, “Products for cleaning and disinfection” (EU Commission 2008). However, it does not appear in Annex VIII, “Certain products and substances for use in production of processed organic food, yeast and yeast products.”

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

Permitted for use in cereals and cereal products, derived from cereal grains, from roots and tubers, pulses and legumes, excluding bakery wares of food category 07.007.1.1.1 yeast-leavened.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Not found.

Japan Agricultural Standard (JAS) for Organic [Production](#)

“Limited to be used for processing sugar as pH adjustment agent” (Japan MAFF 2000).

Environmental Issues

The amount of fresh water used in the lye peeling process and the release of effluent that increases biological oxygen demand are two key environmental concerns about the lye peeling process. The release of potassium hydroxide in untreated or improperly treated wastewater will raise the pH and potassium levels of the body of water receiving it. Soap manufacturing can also threaten environmental health in the immediate vicinity of the soap manufacturing facility nutrient loading of potassium may result in algal blooms and eutrophication (2016 TR).

Human health toxicity mainly involves the risk of ingestion of concentrated potassium hydroxide. Ingestion of lye inevitably leads to esophagus damage, with over 90% of the cases also involving stomach damage.

Discussion

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 used for peeling peaches during the Individually Quick Frozen (IQF) production process. The 2001 TAP review for that expansion noted that —The 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 that 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 for the peeling of fresh peaches to be canned. 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 Subcommittee supported the expansion of this annotation to allow potassium hydroxide to be used in the peeling of both IQF and canned peaches. Accordingly, since canning and freezing are the primary commercially processing methods 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.

During previous reviews a number of stakeholders commented about the use of potassium hydroxide as a cleaning and sanitizing agent. As such, it provides a different mode of action as compared to chlorine materials.

Alternatives to potassium hydroxide include naturally occurring alkali substances such as sodium carbonate and sodium bicarbonate. The drawbacks of these natural materials are that they are less soluble than potassium hydroxide and they may not be effective in raising the pH. For fruit peeling, mechanical, steam, or hand peeling is an alternative. As noted above, while potassium hydroxide was not initially allowed for peeling in organic processing, subsequent petitions and NOSB decisions allowed for its limited use for the peeling peaches.

Questions to our Stakeholders

1. Is potassium hydroxide still critical for the lye peeling of peaches?
2. Are there alternatives to potassium hydroxide for cleaning/sanitizing?
3. For what other purposes is potassium hydroxide currently being used in organic processing?
4. Are there any ancillary substances that are used with potassium hydroxide?

Potassium lactate

Reference: §205.605(b) Potassium lactate - for use as an antimicrobial agent and pH regulator only.

Technical Report: [2015 TR](#)

Petition(s): [2004](#); 2014 [NOP memo to NOSB](#)

Past NOSB Actions: [4/2016 recommendation](#)

Recent Regulatory Background: Added to NL effective 1/28/2019 ([83 FR 66559](#))

Sunset Date: 1/28/2024

Subcommittee Review

Use

Potassium lactate comes as a liquid and may be added to meat as an antimicrobial ingredient. It is affirmed as Generally Recognized As Safe (GRAS) at 21 CFR 184.1639. The FDA does not authorize its use in infant foods and formulas.

Manufacture

Potassium lactate is generally produced from natural (fermented) lactic acid, which is then reacted with potassium hydroxide. Lactic acid is produced from the fermentation of natural food sources such as dextrose (from corn) and sucrose (from sugar cane or sugar beets) or starch.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

Sodium lactate and potassium lactate are not listed for use in processing. Lactic acid is allowed.

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

Potassium lactate is not permitted for use in organic food processing in the European Union. Lactic acid, the precursor substance, is allowed.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Sodium and potassium lactates are not specifically listed on any of the appendices in the IFOAM, but the precursor, lactic acid, is allowed.

Japan Agricultural Standard (JAS) for Organic [Production](#)

Sodium lactate and potassium lactate are not listed in the JAS standard and therefore are not permitted. The [JAS standard](#) specifically states, "The use of any materials except for those described as below is prohibited."

Environmental Issues

There does not appear to be any human health concerns associated with potassium lactate as provided by the 2015 TR. There was an environmental issue raised about the amount of gypsum created in the manufacturing of lactic acid, the necessary precursor of potassium lactate. However, according to a report published by the EPA, lactic acid and its salts are readily biodegradable and have low potential to persist in the environment (Environmental Protection Agency 2008).

Discussion

Many stakeholders view this listing as "enormously complicated" saying that it is the procedural history that is complicated and not the material itself. Potassium lactate has been allowed for use in organic handling since its approval in January of 2004. The decision to not require a petition for this material for inclusion to the NL was based on the fact that both of the materials used to produce potassium lactate (lactic acid and potassium hydroxide) were already approved on the NL. It was later determined that this decision was not consistent with previous NOSB recommendations on classification of materials and that the material needed to go through the petition process leading to it being added to the NL effective 1/28/2019. The Handling Subcommittee finds significant merit to keep potassium lactate on the NL under section 205.605 (b) with the annotation: for use as an antimicrobial agent and pH regulator only.

While sodium lactate and potassium lactate appear to be used nearly interchangeably, there are certain uses, such as "low sodium" meat alternatives that require potassium lactate specifically. This is relevant, as the US has an equivalency agreement with the EU for organic standards and the EU does not permit the use of potassium lactate as a food additive. A better understanding of the EU rationale for excluding potassium lactate but allowing sodium lactate could be helpful.

Questions for our Stakeholders

1. What distinguishes potassium lactate from sodium lactate in terms of functionality? Is that difference important?

Silicon dioxide

Reference: §205.605(b) Silicon dioxide - Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.

Technical Report: [1996 TAP](#), [2010 TR](#)

Petition(s): [2010 petition to remove](#)

Past NOSB Actions: [09/1996 minutes and vote](#); [11/2005 recommendation](#); [12/2011 recommendation](#); [11/2016 recommendation](#)

Recent Regulatory Background: Added to NL 12/21/2000 ([65 FR 80548](#)); National list amended 05/28/2013 (effective 11/03/2013) ([78 FR 31815](#)); Sunset renewal notice effective 5/29/2018 ([83 FR 14347](#))

Sunset Date: 5/29/2023

Subcommittee Review

Use

Synthetic amorphous silicon dioxide is used as a food additive for various functions including as:

- An anticaking agent in foods
- A stabilizer in beer production, and filtrated out of the beer prior to final processing
- An adsorbent in tableted foods
- A carrier
- A defoaming agent

Manufacture

Synthetic amorphous silicon dioxide can be manufactured by three methods: a vapor-phase hydrolysis process, a wet process, or a surface-modified treatment. According to FDA regulations, silicon dioxide (as a food additive) is manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect. Silicon dioxide can be produced as a nanomaterial, but for use in organic production such a material would have to be petitioned and placed on the National List. As stated in NOP Policy Memorandum from March 2015:

As with other substances, no engineered nanomaterial will be allowed for use in organic production and handling unless the substance has been

- 1) petitioned for use;
- 2) reviewed and recommended by the NOSB; and
- 3) added to the National List through notice and comment rulemaking.

Currently there is no silicon dioxide produced with nanotechnology on the National List.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

Silicon dioxide is listed in Table 6.3 Ingredients Classified as Food Additives, and Table 6.5 Processing Aids.

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

Silicon dioxide is listed in Annex VIII of the Commission Regulation, Section A Food Additives, Including Carriers for use in preparation of foodstuffs of plant origin as an anticaking agent for herbs and spices. Also listed as a gel or colloidal solution in Section B Processing Aids and Other Products, Which May Be Used for Processing of Ingredients of Agricultural Origin from Organic Production.

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

Silicon dioxide (Amorphous) is listed in Annex 2 Permitted Substances for the Production of Organic Foods, Table 3 Ingredients of Non-Agricultural Origin as an additive in foods of plant origin permitted for use in herbs, spices, seasonings, and condiments (e.g. seasonings for instant noodles). Also allowed as a processing aid in gel or colloidal solution.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Silicon dioxide (amorphous) is listed in Appendix 4, Table 1 List of Approved Additives and Processing/Post-Harvest Handling Aids.

Japan Agricultural Standard (JAS) for Organic [Production](#)

Silicon dioxide listed in Attached Table 1 Food Additives, limited to be used for processed foods of plant origin as gel or colloidal solution.

Ancillary Substances

None reported in the 2010 TR and none noted in public comment during the 2016 sunset review.

Environmental Issues

The 2010 TR stated silica dust is produced during its manufacture and use, however at the time of writing there was no data on ambient air concentrations of amorphous silica and ambient levels are not well quantified for crystalline silica. Exposure levels are considered the highest in occupations involved with packing, weighing, reprocessing, and cleaning. While the Subcommittee recognizes the risk of exposure to crystalline silica dust during the mining, manufacture and processing of silica, there does not appear to be a great deal of study on the effects of amorphous silica as is used in the manufacture of silicon dioxide. Studies that have explored exposure to amorphous silica dust suggest such exposure may not lead to silicosis or fibrosis as can result from crystalline silica exposure. These existing studies point to the need for further work in this area. ([Merget R, Bauer T, Küpper HU, Philippou S, Bauer HD, Breitstadt R, Bruening T. Health hazards due to the inhalation of amorphous silica. Arch Toxicol. 2002 Jan;75\(11-12\):625-34. doi: 10.1007/s002040100266. PMID: 11876495](#); [McLaughlin JK, Chow WH, Levy LS. Amorphous silica: a review of health effects from inhalation exposure with particular reference to cancer. J Toxicol Environ Health. 1997 Apr 25;50\(6\):553-66. doi: 10.1080/15287399709532054. PMID: 15279029.](#))

The 2010 TR noted the EPA concluded that silicon dioxide and silica gel do not pose unreasonable risks to the environment, including non-target organisms, when used at their registered levels. This conclusion is based on the belief that silicon dioxide and silica gel are chemically unreactive in the environment, occur naturally in various forms, and are practically non-toxic to non-target organisms.

Discussion

A 2010 petition to remove silicon dioxide was put forward by RIBUS, the manufacturer of a commercially produced rice-based certified organic alternative to silicon dioxide. In 2011, the NOSB did not move the petition to remove forward and silicon dioxide remained on the list. Data was presented in the petition claiming that a reformulation of the rice-based alternative could be substituted for silicon dioxide at nearly 1:1 ratio. However, the Handling Subcommittee felt the data was limited, not published from a third-party source and did not conclusively demonstrate its applicability in all products and processes.

The Subcommittee did however wish to acknowledge the availability of a natural alternative. Even though the Subcommittee did not vote to remove silicon dioxide, it passed a recommendation in 2011 to amend the annotation of silicon dioxide, resulting in its current listing which requires the use of organic rice hulls when commercially available. In its recommendation, the Subcommittee noted that additional information and clarification of processors' needs regarding silicon dioxide is needed for future deliberations by the NOSB.

In its last sunset review in 2016, public comment indicated that organic rice hulls are *not* a viable alternative for all current uses:

- As an anticaking agent in organic powders, including organic cheese powders
- In organic dry flavors in which rice hulls have not adequately or evenly dispersed flavor actives and have taken up moisture
- As an anticaking agent at a recommended 2% application rate, when instead the rice hull rate has been 15-50%
- As a flow agent for rice syrup solids
- As a clarifier in the production of beer

Questions to our Stakeholders

1. Are there organic alternatives to silicon dioxide that are more suitable to the uses described above, in which rice hulls are not viable?
2. Is there reliable, consistent commercial availability of rice hulls for the applications in which it performs well?
3. How prevalent is the use of silicon dioxide as a defoamer?
4. How prevalent is the use of silicon dioxide for other allowed purposes, e.g. anticaking agent, flow agent, flavor disbursement?

Sodium lactate

Reference: §205.605(b) Sodium lactate - for use as an antimicrobial agent and pH regulator only.

Technical Report: [2015](#)

Petition(s): [2004](#); [2014 NOP memo to NOSB](#)

Past NOSB Actions: [4/2016 recommendation](#)

Recent Regulatory Background: Added to NL effective 1/28/2019 ([83 FR 66559](#))

Sunset Date: 1/28/2024

Subcommittee Review

Use

Sodium lactate comes as a liquid and may be added to meat as an antimicrobial ingredient. It is affirmed as Generally Recognized as Safe (GRAS) at 21 CFR 184.1639. The FDA does not authorize its use in infant foods and formulas.

Manufacture

Sodium lactate is generally produced from natural (fermented) lactic acid which is then reacted with sodium hydroxide. Lactic acid is produced from the fermentation of natural food sources such as dextrose (from corn) and sucrose (from sugar cane or sugar beets) or starch.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

Sodium lactate and potassium lactate are not listed for use in processing.

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

The European Chemicals Agency (ECHA) primarily evaluates sodium lactate by its precursor, lactic acid, and [concluded](#) “Lactic acid does not have to be labeled for environmental effects, and no short or long-term effects are expected for any exposure levels that do not lower the pH to unacceptable levels. As such no relevant hazards are foreseen.”

Sodium lactate is allowed for use in processing foodstuffs of animal origin only and is listed for use in: “Milk-based and meat products.”.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Sodium and potassium lactates are not specifically listed in any of the appendices in the IFOAM, but the precursor, lactic acid, is allowed.

Japan Agricultural Standard (JAS) for Organic [Production](#)

Sodium lactate and potassium lactate are not listed in the JAS standard and therefore are not permitted. The [JAS standard](#) specifically states, “The use of any materials except for those described as below is prohibited.”

Environmental Issues

There does not appear to be any human health concerns associated with sodium lactate as provided by the 2015 TR. There was an environmental issue raised about the amount of gypsum created in the manufacturing of lactic acid, however, according to a report published by the EPA, lactic acid and its salts are readily biodegradable and have low potential to persist in the environment (Environmental Protection Agency 2008).

Discussion

Many stakeholders view this listing as “enormously complicated” saying that it is the procedural history that is complicated and not the material itself. Sodium lactate has been allowed for use in organic handling since its approval in January of 2004. The decision to not require a petition for this material for inclusion to the NL was based on the fact that both of the materials used to produce sodium lactate (lactic acid and sodium hydroxide) were already approved on the NL. It was later determined that this decision was not consistent with previous NOSB recommendations on classification of materials and that the material needed to go through the petition process leading to it being added to the NL effective 1/28/2019. The Handling Subcommittee finds significant merit to keep sodium lactate on the NL at § 205.605 (b) with the annotation: for use as an antimicrobial agent and pH regulator only.

Questions to our Stakeholders

1. Why do JAS, IFOAM, and the Canadian standard prohibit the use of sodium lactate?

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Discussion Document
Zein
February 16, 2021**

SUMMARY

This document includes a brief review of the petitioned use of zein, or corn protein, as a “Nonorganic agricultural substance[s] allowed in or on processed products labelled as organic,” as well as the recently submitted technical review.

INTRODUCTION

The NOSB was petitioned in February of 2020 to consider zein, otherwise known as “maize protein”, “protein coating” or “confectioner’s glaze”, for addition to the National List. The full petition may be found [here](#). The petitioner, Flo Chemical Corporation, asked for inclusion of zein under “Nonorganic agricultural substance[s] allowed in or on processed products labeled as “organic” (§ 205.606).” The NOSB asked for a [technical report](#) which was produced in January 2021 and deemed sufficient in February 2021.

Zein is the protein component of corn, which has the useful quality of being hydrophobic, but easily dissolved in an alcohol solution. This allows zein to be dissolved into the solution and then sprayed or otherwise applied on the food item. The alcohol then evaporates off and leaves behind a thin layer of zein that acts as a protective coating. This zein layer serves as a moisture barrier and effectively extends the shelf life of dried nuts and fruits, candies, and fresh fruits and vegetables much in the same way plastic wrap would. In contrast to plastic sheeting, the zein layer is fully edible and adds nothing but a small amount of protein of poor nutritional quality to the consumed product.

BACKGROUND

This is the first time that zein has been petitioned for inclusion on the National List. It was first designated as GRAS (generally recognized as safe) by the FDA in 1984. The petitioner states that there is currently only one North American manufacturer of zein, the petitioner - Flo Corporation. Their stated manufacturing process is:

“Zein is derived from dent corn gluten meal. All of our zein production for the food industry comes from USA sourced, non-GMO corn. In addition, all of our production is certified OU Kosher.

Manufacturing: Flo Chemical Corporation manufactures (isolates) zein utilizing a proprietary process (Freeman Process), which was developed in 1976 by the company’s founders. Process starts with the following raw materials: non-GMO CGM, water and ethanol.”

While it would be possible to manufacture organic zein with organic starting products, the manufacturer states that sourcing certified organic corn gluten meal for the production of organic zein is not currently possible. In addition, organic ethanol is reported by the petitioner to be prohibitively expensive.

RELEVANT AREAS OF THE RULE, NOP GUIDANCE, NOP POLICY MEMO, and OMRI

The TR states, “*Zein is a food substance Generally Recognized as Safe (GRAS) by FDA [21 CFR 184.1984] as a direct human food ingredient, for use as a surface-finishing agent, and for technical effects (i.e., as*

an anticaking agent or free-flow agent, a drying agent, and a humectant). Zein also is allowed as an indirect food additive used as a component of adhesives [21 CFR 175.105]. A major use of zein is for coating foods and pharmaceutical products. The most common production process for zein uses corn gluten, also known as corn gluten meal, as the starting material. Corn gluten itself is a GRAS food ingredient [21 CFR 184.1321].”

Zein has not been previously considered for addition to the National List. There are no current NOP policy memos that relate to zein or its category of proposed use. Despite this, the rulings that have been made on corn steep liquor (CSL) are directly relevant to any review of zein as they are different products created during the same wet-milling process. The bulk of the corn gluten meal is produced via wet-milling with sulfur dioxide as the alternative wet milling strategies are not cost-competitive and dry-milling produces very little of the desired zein protein in the end-product.

In determining whether or not to allow corn steep liquor as a non-synthetic agricultural product, The Organic Materials Review Institute (OMRI) reported the following decision-making process:

“For technical questions such as these, OMRI relies on our Advisory Council, an independent body made up of experts in their fields, to determine the status of a substance. The Advisory Council was provided with peer-reviewed literature, patents, manufacturing processes and a copy of the 2006 NOSB synthetic/nonsynthetic decision tree catered to CSL to help inform their votes. In May 2009, the Advisory Council voted 8-2 that corn steep liquor is synthetic.

Later, OMRI received additional information that lent to the argument that it was not synthetic; mainly that lactic acid is the driving force for the chemical change rather than sulfurous acid. Lactic acid is produced naturally in the steeping process through the conversion of dissolved sugars. The Advisory Council was asked to vote again, taking into account the new information. Again, the council voted that CSL was synthetic, 7-3. This comment from an Advisory Council member summarizes the prevailing argument: “As long as any of the active species [Sulfurous acid] is present, it can react with the proteins. Breaking of disulfide bonds is an irreversible reaction that goes to completion. Once the sulfite ion reacts, more of it is produced by the ionization process to maintain equilibrium conditions. The suboptimal pH of the industrial process does not stop breaking of disulfide bonds by sulfite ion. It only slows it down. In the industrial process some of the bonds are probably broken by lactic acid, but it is unreasonable to assume that the entire degradation process is due to unilateral action of lactic acid produced in the fermentation reaction.”

In a memo on November 12, 2009, the NOP asked the organic industry to consider CSL nonsynthetic and allowed for use in organic agriculture until the NOSB can discuss it at the Spring 2010 meeting. Although the OMRI Advisory Council voted twice that CSL is synthetic, OMRI has followed the NOP directive and currently lists products with CSL.”

In 2011, the NOSB reviewed corn steep liquor and through a similar rationale, came to the same conclusion.

“Recommendation: *The Crops Committee recommends that Corn Steep Liquor produced via the traditional countercurrent corn wet milling process be considered as non-synthetic and allowed for use in organic crop production.*

Committee Vote Motion: Consider CSL to be non-synthetic when produced via the traditional countercurrent corn wet milling process only.

Motion: Jeff Moyer Second: Tina Ellor Yes: 4 No: 3 Abstain: 0 Absent: 0”

PREVIOUS PUBLIC COMMENT AND TECHNICAL REPORT SUMMARY OF REVIEW

As this is the first time zein has been considered, there are no previous public comments or reviews to draw upon. For questions of whether or not the product should be allowed and/or how to classify it, referencing the relevant discussions surrounding corn steep liquor is useful. The NOSB determination on how to categorize corn steep liquor can be found [here](#).

DISCUSSION

The potentially contentious areas for understanding zein’s suitability for inclusion on the National List fall under three main categories: a) the environmental impacts of the corn wet-milling process used to create the corn gluten meal, b) whether the zein product can be considered non-synthetic and c) whether zein fills a unique functionality not already filled by currently allowed substances.

Corn wet-milling

There are legitimate concerns regarding the environmental impacts of the corn wet-milling process. Corn wet-milling is the primary means used to create the corn gluten meal that is the starting product for zein. As evidence that it is a concern to the regulatory agencies, from 1999-2004 the Agricultural Research Service Southern Regional Research Center received a grant from the USDA titled, “Development of environmentally acceptable technologies for processing corn.” A specific aim of the research was to reduce the use of sulfur dioxide in wet-milling of corn as it was determined to be environmentally detrimental. (Full text of the grant report can be found [here](#).) If and when sulfur dioxide is released into the air through the drying process, it reacts with air and water to form sulfuric acid and becomes one of the major contributors to acid rain. While there are steps that can be taken to remove the sulfur dioxide before exhaust is released into the environment, the potential for negative environmental effects exists.

The previous decision-making on that point is outlined above. Having summarized that, it is important to note that there does seem to be an effective pathway to avoiding the wet-milling process entirely in the production of zein. Researchers from the University of Illinois have developed another zein product that is created directly from whole corn. They plan to market this product under the name Amazein and point to the fact that direct production from corn bypasses need for sulfur dioxide or the other caustic chemicals that are used during the wet milling process that creates much of the corn gluten meal on the market. This method of direct extraction from whole organic corn may also allow for the creation of a truly organic zein product as organic ethanol is available in the US, though perhaps prohibitively expensive (see questions regarding expense of organic ethanol.)

Classification as a non-synthetic

There has been ongoing debate about whether the end products of the corn wet-milling process can be considered non-synthetic. Wet-milling steeps the corn for 24-48 hours in a hot water solution that is 0.1% - 0.2% sulfur dioxide, allowing the sulfur dioxide to break protein bonds and add itself to the resulting molecule. This means that a chemical reaction has occurred, raising debate as to whether the zein should be considered an agricultural product or a synthetic. As the NOSB has evaluated this question previously for corn steep liquor, the precedent has been established to consider these end products as non-synthetics.

Alternatives

There are products currently on the National List that can serve a similar role to zein in forming a protective coating around foodstuffs. Examples of this include beeswax, shellac, vegetable proteins and carnauba wax. Zein's functionality is unique because it offers a vegan/vegetarian option to replace shellac and beeswax as coatings. As opposed to other vegetable proteins (such as wheat), zein is not a major food allergen. The final other option, carnauba wax, can be sourced and grown only in Brazil.

Questions for Stakeholders

1. If zein is made from cornmeal that is wet-milled, how much (if any) sulfur residue is left in the final product?
2. What are the hurdles to achieving organic zein?
3. What sectors of the organic food market would benefit the most significantly from the addition of zein to the National List and how much will shelf-life be improved?
4. Do we need to revisit the classification as a non-synthetic, or is the established precedence sufficient rationale?

Subcommittee vote:

Motion to accept the petition discussion document on zein

Motion by: Jerry D'Amore

Seconded by: Steve Ela

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Jerry D'Amore, Handling Subcommittee Chair, to transmit to NOP February 17, 2021.

**National Organic Standards Board
Handling Subcommittee Discussion Document
Fish Oil Annotation
February 18, 2021**

Re-Issue of Discussion Document

The Handling Subcommittee (HS) has decided to re-issue the fish oil annotation discussion document with new information requesting additional stakeholder input on possible options.

Summary Work Agenda

In May 2019, the National Organic Standards Board (NOSB) requested to work on an annotation for fish oil to address environmental concerns. Specifically, the NOSB request stated:

During the sunset review of fish oil at the Spring 2019 NOSB meeting, the NOSB asked for comment on how to address environmental and conservation concerns raised about the manufacturing of fish oil. Public comment was received validating these concerns as well as suggesting annotative language to address this area of concern. These annotations were proposed by industry and trade associations as well as interest groups. The Handling Subcommittee would like to request a work agenda item to propose an annotation to fish oil to address environmental concerns.

In August 2019, the National Organic Program (NOP) agreed to add this item to the NOSB work agenda. Specifically, the NOP stated:

You have requested to review the current listing of fish oil and develop recommendations to address the environmental impact of harvesting of fish directly for their oil. Please limit your work to this topic; this work agenda item does not include the organic certification of fish (i.e. aquaculture or wild seafood standards). In your review, please consider how your recommendations would align with other Federal regulations addressing fish harvesting.

Citations

OFPA § 6517. National List

(c) Guidelines for prohibitions or exemptions

(1) Exemption for prohibited substances in organic production and handling operations
The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this chapter only if—

(A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that the use of such substances—

(i) would not be harmful to human health or the environment;

OFPA § 6518. National Organic Standards Board

(l) Requirements

In establishing the proposed National List or proposed amendments to the National List, the Board shall—

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

OFPA § 6518. National Organic Standards Board

(m) Evaluation

In evaluating substances considered for inclusion in the proposed National List or proposed amendment to the National List, the Board shall consider—

...

(6) the alternatives to using the substance in terms of practices or other available materials; and

(7) its compatibility with a system of sustainable agriculture.

7 CFR § 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as “organic,” only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.

...

(e) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8)—stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606.

Summary of Review

Fish oil was added to the National List in 2007, based on a petition from a manufacturer. At that time the NOSB did not request a Technical Report (TR) or Technical Advisory Panel Report (TAP). The 2007 NOSB recommendation indicated that the Organic Foods Production Act (OFPA) criteria were met in all categories but provided no scientific rationale or citations to support such findings. However, the NOSB final recommendation from May 9, 2007, stated ...”pursuant to the judgment in *Harvey v. Johanns*, the NOSB was instructed to develop criteria for determining commercial availability, an essential tool in evaluating whether or not petitioned materials could be listed at § 205.606.” These criteria were finalized in the NOSB “Recommendation for the Establishment of Commercial Availability Criteria National List § 205.606” of October 19, 2006. “That recommendation allows for pro-active listing on § 205.606 of materials that may currently be available in an organic form, but the supply of which has a history of fragility due to factors such as limited growing regions, weather, or trade-related issues. “.... After discussion, the Board decided to add an annotation to the recommendation to list fish oil to the National List. The annotation is “stabilized using only allowed ingredients on the National List.” The Board felt that this annotation was not overly prescriptive since a nonorganic material that falls within the annotation exists on the market.” The NOSB (2007) further noted that “There were no public comments specifically opposing the listing of fish oil on §205.606....”.

While the NOSB has submitted several recommendations on organic aquaculture standards, the NOP has not proceeded with rulemaking on these recommendations. At this time organic fish and therefore, organic fish oil, cannot be produced under the USDA organic regulations. If fish oil is to be used by organic food manufacturers it must remain on the National List.

In subsequent sunset reviews in 2015 and 2019, public comment indicated that the listing as is left room for concern based on how the fish for the fish oil were harvested. Sustainability of fishing is a key environmental concern and the U.S. has been a leader in managing sustainable fishing. The management of U.S. Fisheries is primarily governed by the Magnuson-Stevens Fishery Conservation and Management Act of 1976. This act recognized the need to manage fisheries to ensure fish stocks would be able to continually produce without depletion. Specifically, it sought to prevent overfishing, rebuild overfished stocks, increase long-term economic and social benefits, and ensure a safe and sustainable supply of seafood. National Oceanic and Atmospheric Administration (NOAA) fisheries manage this program for federal waters (extending 200 miles offshore but excluding state managed water within 3

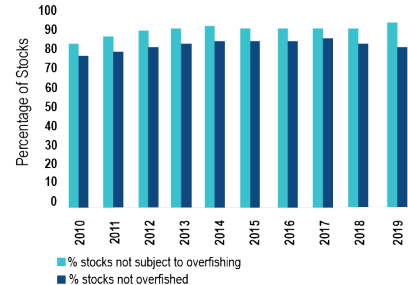
miles of the shoreline) and states “U.S. fisheries are scientifically monitored, regionally managed, and legally enforced under 10 national standards of sustainability. Managing sustainable fisheries is a dynamic process that requires constant and routine attention to new scientific information that can guide management actions. According to the World Wildlife Fund, “seven of the world’s top ten fisheries (by volume) target forage—also known as low trophic level—fish, 90 percent of which are processed into fishmeal and fish oil”. Fish and shellfish are renewable resources—they can reproduce and replenish their populations naturally. Because of this, we can sustainably harvest fish within certain limits without depleting the resource. Fishery management is the process of using science to determine these limits—some fish are caught while some are left to reproduce and replace the fish that are caught.” As part of its regulatory duties, NOAA maintains a Fish Stock Sustainability Index. In this index fish stocks by region are described as:

- **Maximum sustainable yield (MSY):** The largest long-term average catch that can be taken from a stock under prevailing environmental and fishery conditions.
- **Overfishing:** A stock having a harvest rate higher than the rate that produces its MSY.
- **Overfished:** A stock having a population size that is too low and that jeopardizes the stock’s ability to produce its MSY.
- **Rebuilt:** A stock that was previously overfished and that has increased in abundance to the target population size that supports its MSY.

In the U.S., NOAA data shows a slightly decreasing trend in the number of fish stocks that are not overfished or subject to overfishing.

The United Nations Food and Agricultural Organization (FAO) similarly recognizes concerns about over-exploitation of fish. In its 2016 report, FAO recognized that worldwide overfished stocks had increased from 10% of total stocks in 1974 to 33.1% in 2015. The FAO classifies fish stock fisheries around the world in terms of population stability. The FAO categories include:

1. Over-exploited
2. Fully exploited.
3. Non-fully exploited.



Proposed Annotation Discussion

Significant U.S. regulation and international regulation exists to address the environmental concerns of overfishing. In addition, there are numerous private standards established to monitor fishing, including, but not limited to, voluntary third-party organizations that certify fishery practices to sustainability standards such as the Marine Stewardship Council (MSC), Friend of the Sea, Global Standard for Responsible Supply (IFFO RS), and Sustainable Fisheries Partnership. In contrast to third-party certifiers, there are groups like Seafood Watch (<https://www.seafoodwatch.org/>) that grade fish products by environmental criteria (i.e., red, yellow, green) but do not certify products on a fee basis. Thus, fish producers have no choice as to whether their products are assessed against environmental criteria by Seafood Watch.

Previously, the HS presented a [discussion document](#) at the April 2020 NOSB meeting that argued that

while private third-party standards may be sufficient to address potential environmental concerns related to fishing, the use of sufficient and recognized U.S. government National and United Nations International standards may be preferred because legal definitions have been defined and are potentially more enforceable compared with third-party private entities.

Public Comment Summary

Several comments raised objections to the listing of fish oil on the National List. Those comments, however, are relevant to the sunset reviews and are not relevant to this proposed annotation.

Several dairy and other producers reported using fish oil in milk and other products and projected lost sales if fish oil was not allowed as part of the non-organic 5% of USDA organic labeled products.

As described in the April 2020 discussion document, the HS originally suggested adding three elements to the current fish oil annotation. This first element would state that fish oil should be sourced from fishing industry by-product only. This annotation would restrict the use of fish caught directly for the sole use of its oil to that of by-products only. Note, it is possible that profit from oil extraction from fish by-products may tip the balance in favor of additional stock exploitation and population declines. Not addressed was the possibility that krill may also be harvested to extract fish-oil for human consumption. However, krill are not recognized as fish. Because the National List specifically identifies “fish oil”, oils derived from krill are not allowed in organic products and not the subject of this annotation.

In public comment in 2019 and 2020, it was noted by industry and trade associations that fish oil is always a byproduct due to economics, but environmental groups remain concerned that fisheries may be exploited exclusively for fish oil production. Overall, public comment supported restricting fish oil production only as a byproduct.

The 2020 HS discussion document also proposed annotating fish oil production from fisheries that were harvested such that *“Where within NOAA’s jurisdiction, only from fish species and regions not listed on NOAA’s current “Overfishing” or “Overfished” list. Where outside NOAA’s jurisdiction, only from fish species and regions not listed on FAO’s “Overexploited,” “Depleted,” or “Recovering.”*

This annotation received substantial public comment and reflected concerns by some certifiers and fish-oil industry representatives. Certifiers were concerned about their lack of expertise to ensure compliance with either NOAA or FAO standards, and recommended a simple affidavit by processors verifying compliance. Other were concerned that while NOAA and FOA standards were similar in objectives, they were not directly comparable because they used different timeframes and population assessment methods, including different data sources and mathematical modeling techniques. Thus, application of standards based on NOAA and FOA classifications would likely not be uniform across producers or verifiable by organic certifiers, would introduce regulatory inconsistency, and therefore are not a practical bar to set fishery sustainability standards. Other limitations to these governmental standards include:

- There are state managed marine fisheries where NOAA doesn’t have jurisdiction and thus doesn’t assess the populations. In these cases, there may be specific populations that are overfished while the species as a whole may not be;
- Many fisheries in foreign waters are not necessarily tracked by FAO but may, in fact, meet sustainability standards, or be over-exploited;
- Many fisheries in international waters are not tracked by governmental or international agencies but may, in fact, meet sustainability standards, or be over-exploited;

- For some species, some populations may be at risk of over-exploitation, whereas other local populations may be sustainable, without clear market demarcation of fish origin.

In response to these concerns, the HS reached out to scientists at NOAA, Seafood Watch, and MSC. These individuals and groups recommended annotation language consistent with public comments suggesting certification of environmental sustainability “by a third-party certifier” as more likely to achieve OFPA goals (although concerns were raised that “byproduct” is not formally defined).

This suggested reliance on third part certification for National List annotation raises several concerns, including:

1. Organic environmental sustainability standards would be sourced outside USDA and other U.S. government agencies;
2. There is potential for “greenwashing” if an unscrupulous third-party certifier did not meet environmental sustainability standards;
3. Requiring third - party certification could exclude smaller-scale producers that cannot afford third party certification even though their fishery meets sustainability standards.

According to MSC and other scientists consulted, “certification schemes are complex and, within seafood, cover varying issues related to environmental sustainability and social responsibility. As GOED mentioned [in public comments], the question on which certifications meet the requirements laid out by the NOSB for fish oil will undoubtedly come up. It would be a challenge for the NOSB to create and maintain a list of acceptable certification schemes for fish oil in organic products and would require constant vetting of the changes of each certification... Therefore, we would like to bring to your attention two organizations that determine which certification schemes meet global best practice: International Social and Environmental Accreditation and Labeling (ISEAL) and Global Seafood Sustainability Initiative (GSSI). ISEAL is a global membership organization for ambitious collaborative, and transparent sustainability systems. One of their core work streams is defining credible practice of programs based on emerging global consensus. GSSI created and operates a Global Benchmark Tool for seafood and seafood-derived products. This tool assesses seafood certification schemes...against the FAO Code of Conduct for Responsible Fisheries, the FAO Guidelines for Ecolabelling of Fish and Fishery Products from Marine/Inland Capture Fisheries and the FAO Technical Guidelines on Aquaculture Certification.”

In response to public comments and further discussions with scientists and groups involved in marine fishery ecology and policy, the HS developed three possible fish oil annotations and requests input from organic stakeholders on the merits and feasibility of each approach. For reference, we include the original annotation proposal from the April 2020 meeting.

Original April 2020 Discussion Document Proposal:

205.606 (e) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8) - stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606. *Sourced from fishing industry by-product only. Where within NOAA’s jurisdiction, only from fish species and regions not listed on NOAA’s current “Overfishing” or “Overfished” list. Where outside NOAA’s jurisdiction, only from fish species and regions not listed on FAO’s “Overexploited,” “Depleted,” or “Recovering”.*

Note, given that the FAO fish stock categories have been consolidated to three categories (noted above), the April 2020 annotation proposal should be corrected to read “*not listed on FAO’s ‘Overexploited’.*”

Option 1 Current Proposal – Please comment:

205.606 (e) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8) - stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606. **Sourced from fishing industry by-product only and certified as sustainable by a third-party certifier.**

Option 2 Current Proposal – Please comment:

205.606 (e) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8) - stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606. **Sourced from fishing industry by-product only and certified as sustainable against a third-party certification that is International Social and Environmental Accreditation and Labeling (ISEAL) Code Compliant or Global Seafood Sustainability Initiative (GSSI) recognized with full utilization of said scheme.**

Option 3 Current Proposal – Please comment:

205.606 (e) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8) - stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606. **Sourced from fishing industry by-product only and has either a green or yellow Seafood Watch rating or is eco-certified to a standard recommended by Seafood Watch (<https://www.seafoodwatch.org/>).**

Questions

1. Which is the best option to mitigate environmental concerns about the over-exploitation of fisheries used to produce fish oil sourced for organic products?
2. Are these requirements clear and enforceable?
3. What impacts would these requirements have on the availability of fish oil for organic products?

Citations

<https://www.worldwildlife.org/industries/fishmeal-and-fish-oil>
2019 Fall Sunset Review – Fish Oil, NOSB Public Comments Fall 2019 NOSB meeting
<https://www.fishwatch.gov/sustainable-seafood/managing-us-fisheries>
<https://www.fisheries.noaa.gov/national/2018-report-congress-status-us-fisheries>
<https://www.fisheries.noaa.gov/national/population-assessments/status-us-fisheries>
<https://www.fisheries.noaa.gov/national/sustainable-fisheries/status-stocks-2019>
<http://www.fao.org/3/I9540EN/i9540en.pdf>
<http://www.fao.org/newsroom/common/ecg/1000505/en/stocks.pdf>
<https://www.msc.org/>
<https://friendofthesea.org/>
<https://www.iffors.com/>
<https://ivopure.org/>
<https://www.sustainablefish.org>

Subcommittee Vote

Motion to accept the discussion document on fish oil.

Motion by: Asa Bradman

Seconded by: Jerry D'Amore

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Jerry D'Amore, Handling Subcommittee Chair, to transmit to NOP February 18, 2021.

Sunset 2023
Meeting 1 - Request for Public Comment
Livestock Substances § 205.603 & § 205.604
April 2021

Introduction

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

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2021 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2021 public meeting. Comments should be provided via Regulations.gov at www.regulations.gov on or before April 5, 2021, as explained in the meeting notice published in the Federal Register.

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

Public comments should clearly indicate the commentor's position on the allowance or prohibition of substances on the National List and explain the reasons for the position. Public comments should focus on providing relevant new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance (e.g. scientific, environmental, manufacturing, industry impact information, etc.). Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

For Comments that Support the Continued Use of §205.603 Substances in Organic Production:

If you provide comments supporting the allowance of a substance at §205.603, you should provide information demonstrating that the substance is:

1. not harmful to human health or the environment;
2. necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
3. consistent with organic livestock production.

For Comments that Do Not Support the Continued Use of §205.603 Substances in Organic Production:

If you provide comments that do not support a substance at §205.603, you should provide reasons why the use of the substance should no longer be allowed in organic production. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

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

For Comments that Support the Continued Prohibition of §205.604 Substances in Organic Production:

If you provide comments supporting the prohibition of a substance on the §205.604 section of the National List, you should provide information demonstrating that the substance is:

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

For Comments that Do Not Support the Continued Prohibition of §205.604 Substances in Organic Production:

If you provide comments that do not support the prohibition of a substance at §205.604, you should provide reasons why the use of the substance should no longer be prohibited in organic production. Specifically, comments that support the removal of a substance from the §205.604 section of the National List should provide new information since its last NOSB review to demonstrate that the substance is:

1. not harmful to human health or the environment; and/or
2. consistent with organic livestock production.

For Comments Addressing the Availability of Alternatives:

Comments may include information about the viability of alternatives for a substance under sunset review.

Viable alternatives include, but are not limited to:

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

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

Written public comments will be accepted through April 5, 2021, via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

§205.603 Sunsets: Synthetic substances allowed for use in organic livestock production:

- [Activated charcoal](#)
- [Calcium borogluconate](#)
- [Calcium propionate](#)
- Chlorine materials
 - [\(i\) Calcium hypochlorite](#)
 - [\(ii\) Chlorine dioxide](#)
 - [\(iii\) Hypochlorous acid—generated from electrolyzed water](#)
 - [\(iv\) Sodium hypochlorite](#)
- [Kaolin pectin](#)
- [Mineral oil](#)
- [Nutritive supplements \(Injectable trace minerals, vitamins, and electrolytes\)](#)
- [Propylene glycol](#)
- [Sodium chlorite, acidified §205.603\(a\)\(28\); and Sodium chlorite, acidified §205.603\(b\)\(9\)](#)
- [Zinc sulfate](#)

§205.604 Sunsets: Nonsynthetic substances prohibited for use in organic livestock production:

- None

Activated charcoal

Reference: §205.603 (a)(6) Activated charcoal (CAS # 7440-44-0) - must be from vegetative sources.

Technical Report: [2002](#); [2021 TR Pending](#)

Petition(s): [2002](#)

Past NOSB Actions: [2002 recommendation/vote](#)

Recent Regulatory Background: Added to NL effective 1/28/2019 ([83 FR 66559](#))

Sunset Date: 1/28/2024

Subcommittee Review

Use

The principal veterinary use for activated charcoal is as an antidote to toxic substances—and analogous medical applications include use as a detoxifier. According to the 2002 TAP Review, it is regarded as the poison antidote of choice and the universal antidote to toxic substances. There is no reported overdose or acute toxicity. Activated charcoal is highly effective against both natural and synthetic toxins. Studies show activated carbon to be effective in removing various mycotoxins, such as aflatoxin, fumonisins, ochratoxin A, trichothenes, and zearalenone. Natural toxins from plants are also removed or attenuated by activated charcoal treatment or supplementation.

Activated carbon can also be used to remove synthetic pesticides from animals that might contaminate milk or meat. Treatment with activated carbon when using certain parasiticides can help reduce the residual levels in flesh and fatty tissue. However, it should be noted that use of such substances and withdrawal from milk or meat production is subject to the applicable USDA organic regulations.

Activated charcoal is used to treat animals for drug overdoses, with efficacy established on pigs, dogs, and rabbits.

Manufacture

Activated charcoal of vegetative origin can be made from a large variety of sources such as hardwoods, grain hulls, corn cobs, and nut shells. The material undergoes pyrolysis at a very high heat. These agricultural byproducts may be chemically activated using a variety of acids and bases. Acids may be acetic acid, and potassium hydroxide and sodium hydroxide are possible bases. The charcoal may also be activated through exposure to oxygenated gas or steam.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

Table 5.3 of the Permitted Substances List includes activated charcoal, stating “shall be of plant origin.”

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

While there is no specific listing for activated charcoal, Article 14 notes that “suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.” The regulation further notes “disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined.”

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods ([GL 32-1999](#), Part B, Section 22)

While there is no specific listing for activated charcoal (carbon), the Guidelines state the following:

The use of veterinary medicinal products in organic farming shall comply with the following principles:

- a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted;
- b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended;
- c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours;
- d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited.

International Federation of Organic Agriculture Movements (IFOAM) Norms

While activated charcoal is not specifically listed, the general principles state management practices should be directed to the well-being of animals, achieving maximum resistance against disease, and preventing infections. Sick and injured animals must be given prompt and adequate treatment. Further, the standards note the well-being of the animals is the primary consideration in the choice of illness treatment. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available. Withdrawal periods shall not be less than double of that required by legislation.

Japan Agricultural Standard (JAS) for Organic [Production](#)

While activated charcoal is not specifically listed, the standard states that when veterinary drugs are used, the withholding period shall be twice the period of conventional standards.

Environmental Issues

Activated charcoal has minimal impact on human health and the environment. It may cause respiratory problems for those who handle it, especially as the particle size decreases. Its use in processing doesn't generally have an effect or chemical interaction in the agroecosystem. The greatest impact of activated charcoal from vegetative sources is the removal of organic matter from the system.

Because of concern regarding the use of certain acids in manufacture, during the 2021 sunset review for activated charcoal listed at §205.605(b), some stakeholders commented that they would like to see use limited to sources derived solely from steam activation.

Discussion

This substance was among 35 NOSB recommendations on amendments to the National List, made from November 2000 to November 2016, that were acted upon in a final rule published in December 2018. Because of this recent addition, this is the first sunset review of activated charcoal at this listing.

Questions to our Stakeholders

1. Is activated charcoal essential to organic livestock health care and production?

Calcium borogluconate

Reference: §205.603 (a)(7) Calcium borogluconate (CAS # 5743-34-0) - for treatment of milk fever only.

Technical Report: [2000 TAP](#)

Petition(s): N/A

Past NOSB Actions: [2000 recommendation/vote](#)

Recent Regulatory Background: Added to NL effective 1/28/2019 ([83 FR 66559](#))

Sunset Date: 1/28/2024

Subcommittee Review

Use

Calcium borogluconate is used for treatment of hypocalcemia (also called parturient paresis and commonly called milk fever) in cattle, sheep, and goats. Milk fever is the result of metabolic stress occurring only at or near parturition (giving birth). The mother mobilizes large amounts of calcium to produce milk to feed its newborn, and blood calcium levels can drop below the point necessary for impulse transmission along the nerve tracts. There are three discernable stages of milk fever for cows: in stage one, cows are able to stand but show signs of hypersensitivity and excitability. In stage two, cows are unable to stand. In stage three, cows lose consciousness progressively to the point of coma.

Manufacture

Calcium borogluconate is prepared by the reaction of five parts calcium gluconate to one-part boric acid in an aqueous solution. Boric acid esterifies the alcohol groups on the gluconate. Excess boric acid is removed by distillation with ethanol.

Calcium gluconate is prepared by several methods, including the reaction of gluconic acid with calcium hydroxide. Calcium hydroxide was also reviewed by the NOSB for processing and was classified as synthetic and allowed. Gluconic acid is most commonly produced in the U.S. by fermentation.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

Table 5.3 of the Permitted Substances List includes calcium borogluconate “[f]or milk fever. No withdrawal period required.”

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

While there is no specific listing for Calcium borogluconate, Article 14 notes that “suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.” The regulation further notes “disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular, restrictions with respect to courses of treatment and withdrawal periods shall be defined.”

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods ([GL 32-1999](#), Part B, Section 22)

While there is no specific listing for calcium borogluconate, the Guidelines state the following:

The use of veterinary medicinal products in organic farming shall comply with the following principles:

- a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted;

- b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended;
- c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours;
- d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited.

International Federation of Organic Agriculture Movements (IFOAM) Norms

While calcium borogluconate is not specifically listed, the general principles state management practices should be directed to the well-being of animals, achieving maximum resistance against disease, and preventing infections. Sick and injured animals must be given prompt and adequate treatment. Further, the standards note the well-being of the animals is the primary consideration in the choice of illness treatment. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available. Withdrawal periods shall not be less than double of that required by legislation.

Japan Agricultural Standard (JAS) for Organic [Production](#)

Calcium borogluconate is not specifically listed.

Environmental Issues

The TAP review did not discuss environmental issues related to the manufacture of calcium borogluconate. The review noted, “[t]he material is metabolized by the animal, with the calcium entering the blood stream and some being expressed as milk. The animal’s urine and feces may contain higher levels of boron as a result, but none of the literature reviewed partitioned the fate. Some claim that introduction of boron and sugar is either unnecessary or causes complications, but these are not specified.”

Discussion

This substance was among 35 NOSB recommendations on amendments to the National List, made between November 2000 and November 2016, that were acted upon in a final rule published in December 2018. This is the first sunset review of calcium borogluconate at this listing.

Calcium borogluconate is also classified on the National List under electrolytes which are currently listed at §205.603 as synthetic substances allowed for organic livestock production when they do not contain antibiotics. According to the TR, electrolytes are needed in organic livestock production to restore ionic balance, thus treating metabolic conditions such as hypocalcemia, scours, dehydration, milk fever, erratic heartbeat, loss of muscle control, mastitis, ketosis, alkalosis, acidosis, difficulty in labor and prostration.

Questions to our Stakeholders

1. The National List references multiple substances for the treatment of ketosis and milk fever, including propylene glycol, calcium propionate, calcium borogluconate and electrolytes. Are they equally necessary and effective? Do organic producers have the correct tools for treatment of all stages of the development of these related conditions?
2. Calcium borogluconate also appears on the National List under allowed electrolytes. Please describe the history and the importance of calcium borogluconate’s consideration by organic systems as a stand-alone substance.

Calcium propionate

Reference: §205.603 (a)(8) Calcium propionate (CAS # 4075-81-4) - for treatment of milk fever only.

Technical Report: [2002 TAP](#); [2015 TR \(Electrolytes\)](#)

Petition(s): [2002](#)

Past NOSB Actions: [2002 recommendation/vote](#); [2002 position paper](#)

Recent Regulatory Background: Added to NL effective 1/28/2019 ([83 FR 66559](#))

Sunset Date: 1/28/2024

Subcommittee Review

Use

Calcium propionate is used for treatment of hypocalcemia (also called parturient paresis and commonly called milk fever). Milk fever is the result of metabolic stress occurring only at or near parturition (giving birth). The mother mobilizes large amounts of calcium to produce milk to feed its newborn, and blood calcium levels can drop below the point necessary for impulse transmission along the nerve tracts. There are three discernable stages of milk fever for cows: in stage one, cows are able to stand but show signs of hypersensitivity and excitability. In stage two, cows are unable to stand. In stage three, cows lose consciousness progressively to the point of coma.

Calcium propionate was originally petitioned as both a mold inhibitor and as a treatment for livestock for milk fever but was approved with an annotation limiting the use as a treatment for milk fever.

Calcium propionate is an electrolyte that is needed in organic livestock to restore ionic balance, thus treating metabolic conditions such as milk fever (hypocalcemia), scours, dehydration, erratic heartbeat, loss of muscle control, mastitis, ketosis, alkalosis, acidosis, difficulty in labor and prostration. Lack of treatment can often result in death. The FDA considers electrolyte formulations to be animal drugs, but many of the formulations have not been formally approved by the FDA. Often this is because they are non-proprietary, general use materials, and no company has applied for a New Animal Drug Approval (NADA) (OMRI 2013; USDA 2005b)

Propionate is used by the liver to make glucose, which is used by the cow to make lactose, the sugar in milk. Milk production is very closely related to the total glucose supply at the udder. Propionate's second function involves the cow's fat metabolism. When the cow's energy demands for milk production exceed the amount of energy she is eating, she begins to break down some of her body fat stores. Fats are first broken down into smaller pieces, called non-esterified fatty acids (NEFA's), and carried to the liver. At the liver, they are broken down to form acetate to generate energy. Acetate is broken down to carbon dioxide and water to yield more energy; however, this process requires Propionate. If there is not enough propionate available (which is often the case when cows are making a lot of milk sugar), the excess acetate builds up in the liver, then acetate molecules combine to make acetone, acetoacetate, and beta-hydroxybutyrate. These products are released from the liver into the cow's bloodstream, causing the ketosis symptoms.

When lactation starts, milk fever can be treated by intravenous administration of electrolytes containing calcium to the animal. Calcium can be added by oral boluses, pastes, or drenching if the animal is still standing, but when the animal is down, intravenous injection is needed. Oral doses of calcium chloride can be effective, but it is caustic, causing ulcerations. It can also lead to acidosis. Calcium propionate is less caustic, does not cause acidosis, and the propionate fatty acid is glucogenic. One dose is given at calving, and another 24 hours later.

Manufacture

Electrolytes are mostly synthetic materials produced by chemical processes. Since many are salts, they are often produced by acid-base reactions. Calcium propionate is produced by reacting propionic acid with an aqueous solution of calcium hydroxide. It is also produced by reacting calcium hydroxide with propionitrile.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

In Canada, the Permitted Substances List for Organic Animal Production allows electrolytes as part of Table 5.3 'Health Care Products and Production Aids.' Electrolytes without antibiotics are permitted, and electrolyte solutions 'with no added active ingredients' are permitted (Canadian Standards 2011). No withdrawal period required.

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

Electrolytes are not mentioned specifically in 834/2007. However, Annex V, Feed Materials of Mineral Origin (EU EEC 2008, Article 14 Section 1 (e) (ii) states "chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions" (EU EEC 2007). In 889/2008 many of the electrolyte salts are permitted as feed additives.

While there is no specific listing for calcium propionate, Article 14 notes that "suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter." The regulation further notes "disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods ([GL 32-1999](#), Part B, Section 22)

Electrolytes are not specifically mentioned. However, under Health Care, Section 22 "where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted."

International Federation of Organic Agriculture Movements (IFOAM) Norms

In the IFOAM NORMS for organic production and processing version 2012, electrolytes are not specifically mentioned for organic animal production. In Section III (5) on Animal Husbandry, only natural sources are permitted for vitamins, trace elements, and supplements. Use of synthetic allopathic veterinary drugs or antibiotics will cause the animal to lose its organic status (IFOAM 2012). But many of the electrolyte substances are mentioned in Appendix 4 as additives and processing aids (IFOAM 2012).

While Calcium Propionate is not specifically listed, the general principles state management practices should be directed to the well-being of animals, achieving maximum resistance against disease, and preventing infections. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available. Withdrawal periods shall not be less than double of that required by legislation.

Japan Agricultural Standard (JAS) for Organic [Production](#)

The Japanese Agricultural Standard (JAS) for Organic Production originally considered only crops and processing (JAS 2005). Later revisions included livestock. A summary in 2007 mentions that organic livestock must be fed organic feed, have exercise and access to pasture, and must not be fed antibiotics or GMOs. Electrolytes for organic animal production were not mentioned; therefore, it is unknown whether they are specifically allowed or prohibited (JAS 2007).

Soil Association Standards, United Kingdom

The Soil Association Standards at Section 10.10.22 specifically allow calcium borogluconate, magnesium and phosphorus salts for milk fever. Section 10.10.34 specifically allows glucose/electrolytes as oral rehydration therapy for scours. Antibiotics and other non-allowed substances cannot be used (Soil Association 2005).

Environmental Issues

Electrolytes are used in animal production situations. Since electrolytes are usually added to correct deficiencies, concentrations in the environment due to excretion would be no more than a normal untreated animal with normal electrolyte balances. Most of these materials are produced by acid-base reactions. Environmental contamination from production of calcium propionate is unlikely for the salts, as reactions are simple neutralizations, producing the needed salt and water. Any problems would come from excess stocking rates. Excess stocking rates could lead to an excess of metabolic by-products in the immediate environment, plus adds extra stress to the animals.

Discussion

The 2015 TR on electrolytes, including calcium propionate, discussed whether there were alternative non-synthetic materials or alternative practices that would make the use of calcium propionate unnecessary. The TR concluded that the electrolytes are on the list of allowed synthetics, and non-synthetic sources of electrolyte formulations are typically not commercially available.

Alternative practices that would make the use of calcium propionate less necessary for the prevention and treatment of milk fever (hypocalcemia) are low calcium prepartum diets, Dietary Cation Anion Difference (DCAD) diets (prior to parturition), and administration of oral electrolytes. Sometimes combinations of these treatments are used. DCAD diets involve adding electrolytes to food to provide an excess of strong anions or choosing food that will have this effect. Body condition should be managed in late lactation to prevent cows from becoming too fat, which adds to the risk of milk fever. Modifying diets of late lactation cows to increase the energy supply from digestible fiber and reduce the energy supply from starch may aid in partitioning dietary energy toward milk and away from body fattening.

Questions to our Stakeholders

1. Are there any new practices or non-synthetic materials that would make the use of calcium propionate unnecessary?
2. Do our livestock stakeholders think the listing for calcium propionate is necessary at §205.603(a)(8) since electrolytes are listed as a group at §205.603(a)(11) *Electrolytes—without antibiotics*?

Chlorine materials

Reference: §205.603 (a)(10) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

- (i) Calcium hypochlorite
- (ii) Chlorine dioxide
- (iv) Sodium hypochlorite

Technical Report: [2006 TR](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [05/2006 NOSB sunset recommendation](#); [10/2010 NOSB recommendation](#); [10/2015 sunset recommendation](#); [11/2017 Recommendation to add hypochlorous acid](#); [11/2017 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice 3/15/2017 ([82 FR 14420](#)); Sunset renewal notice effective 10/30/2019 ([84 FR 53577](#))

Sunset Date: 10/30/2024

Subcommittee Review

Use

Sodium and calcium hypochlorite are chlorinated inorganic disinfectants used to control bacteria, fungi, and slime-forming algae that can cause diseases in people and animals (EPA, 1991, 1992). These disinfectants also are used in cleaning irrigation, drinking water, and other water and wastewater systems. Chlorine dioxide is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. It is also used in cleaning water systems and disinfecting public drinking water supplies (Agency for Toxic Substances and Disease Registry (ATSDR), CDC, 2004a). It also is used as a bleaching agent in paper and textile manufacturing, as a food disinfectant (e.g., for fruit, vegetables, meat, and poultry), for disinfecting food processing equipment, and treating medical wastes, among other uses (EPA, 2003a). Chlorine materials are currently used for disinfection of livestock facilities (NOP Guidance [5026](#)).

Manufacture

Calcium hypochlorite, sodium hypochlorite, and chlorine dioxide are all synthetic materials that are manufactured by chemical processes. Calcium hypochlorite is produced by passing chlorine gas over slaked lime. It is then separated from the coproduct, calcium chloride, and air dried or vacuumed. Generally, sodium hypochlorite is produced by reacting chlorine with a solution of sodium hydroxide (NaOH, also called lye or caustic soda). This method is used for most commercial productions of sodium hypochlorite. A more active, but less stable formulation of sodium hypochlorite can be produced by chlorinating a solution of soda ash (Na₂CO₃). Chlorine dioxide is formed by reacting sodium chlorate (NaClO₃) and sulfuric acid (H₂SO₄) with sulfur dioxide (SO₂), or chloric acid is reacted with methanol (CH₃OH) (HSDB, 2005). Alternatively, chlorine dioxide can be formed with chlorine (Cl₂) and sodium chlorite; sodium hypochlorite with hydrochloric acid; potassium chlorate with sulfuric acid; or by passing nitrogen dioxide through a column of sodium chlorate.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

Bleach (not exceeding drinking water standards) is permitted in packaging and sanitation.

European Economic Community (EEC) Council Regulation, EC No. [834/2007](#) and [889/2008](#)
Sodium hypochlorite (e.g., as liquid bleach) is authorized for the clearing and disinfecting of livestock buildings and installations.

Environmental Issues

Information available from EPA and FDA on chlorine dioxide, sodium, and calcium hypochlorite, and hypochlorous acid indicates that there is no environmental contamination resulting from proper manufacture, use, or disposal.

Discussion

Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food-safety regulations. The Livestock Subcommittee (LS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for livestock handling and processing. The LS supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards. However, at this point in time, chlorine materials are an essential part for maintaining hygiene in livestock facilities.

Questions to our Stakeholders

1. Are there alternatives to chlorine materials that are less toxic sanitizer options in livestock operations?
2. Should we be considering chlorine materials through a more holistic point of view and, as per the sanitizer panel during the Fall 2020 NOSB meeting, are there practices we should look to prior to using chlorine materials in livestock operations?
3. Are there practices we should look to prior to using chlorine materials in livestock operations?
4. Are there any new recommendations for how to rotate sanitizers to maintain maximum efficacy?

Chlorine materials – Hypochlorous acid – generated from electrolyzed water

Reference: §205.603 (a)(10) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(iii) Hypochlorous acid - generated from electrolyzed water

Technical Report: [2006 TR \(Chlorine materials\)](#); [2017 Limited Scope TR \(Hypochlorous Acid\)](#)

Petition(s): [2016 \(Hypochlorous Acid\)](#)

Past NOSB Actions: [11/2017 Recommendation to add hypochlorous acid](#);

Recent Regulatory Background: Hypochlorous acid added to NL effective 1/28/2019 ([83 FR 66559](#));

Sunset Date: 1/28/2024

Subcommittee Review

Use

hypochlorous acid, as formulated via electrolyzed water, is effective as a sanitizer at a much lower chlorine

concentration and is safer for health and the environment than the currently listed chlorine sanitizers. Chlorine materials are currently used for disinfection of livestock facilities (NOP Guidance [5026](#)).

Manufacture

Electrolyzed water (EW) 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 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. (TR lines 48-68).

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

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Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food-safety regulations. The Livestock Subcommittee (LS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for livestock handling and processing. The LS supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards. However, at this point in time, chlorine materials are an essential part for maintaining hygiene in livestock facilities.

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1. Are there alternatives to chlorine materials that are less toxic sanitizer options in livestock operations?
2. Should we be considering chlorine materials through a more holistic point of view and, as per the sanitizer panel during the Fall 2020 NOSB meeting, are there practices we should look to prior to using chlorine materials in livestock operations?
3. Are there practices we should look to prior to using chlorine materials in livestock operations?
4. Are there any new recommendations for how to rotate sanitizers to maintain maximum efficacy?

Kaolin pectin

Reference: §205.603 (a)(17) Kaolin pectin - for use as an adsorbent, antidiarrheal, and gut protectant.

Technical Report: [2002 TAP](#); [2021 TR Pending](#)

Petition(s): [2002](#)

Past NOSB Actions: [2002 recommendation/vote](#); [2002 Position Paper](#)

Recent Regulatory Background: Added to NL effective 1/28/2019 ([83 FR 66559](#))

Sunset Date: 1/28/2024

Subcommittee Review

Use

Kaolin pectin is used in livestock for the same reasons that it is administered to humans: as an adsorbent, anti-diarrheal, and gut protectant. It may also be combined with vitamin A to treat bacterial diarrhea in calves.

Status

According to the 2002 TAP, the FDA has declared kaolin to be GRAS as an indirect food additive, and pectin to be GRAS as a direct food additive, both with the limitation that the levels in food are consistent with good manufacturing practices.

In addition to kaolin pectin having been placed on the National List as an allowed synthetic substance, kaolin and pectin are also separately allowed for use in organic systems.

In the 2002 TAP, there was some disagreement about whether kaolin pectin should be categorized as a synthetic or non-synthetic substance.

Manufacture

Both kaolin and pectin are formed naturally. Kaolin is a mineral dust formed by weathering of aluminum silicates. Pectin may be obtained for use by extraction into an aqueous medium from appropriate edible plant material, usually citrus fruits or apples. No organic precipitants are used other than methanol, ethanol, and isopropanol. In some types a portion of the methyl esters may have been converted to primary amides by treatment with ammonia under alkaline conditions. The commercial product is normally standardized with sugars and may be buffered with suitable food grade salts.

International Acceptance:

Canadian General Standards Board Permitted Substances [List](#)

Kaolin pectin not listed.

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

Kaolin pectin not listed.

Note that while there is no specific listing for kaolin pectin, the use of this substance is consistent with Article 14, which states that “suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.” The regulation further notes “disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined.”

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

Kaolin pectin not listed.

Note that while there is no specific listing for kaolin pectin, the use of this substance is consistent with the Guidelines, which state the following:

The use of veterinary medicinal products in organic farming shall comply with the following principles:

- a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted;
- b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended;
- c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours;
- d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Kaolin pectin not listed.

Note that while there is no specific listing for kaolin pectin, the use of this substance is consistent with IFOAM's general principles that state that "management practices should be directed to the well-being of animals, achieving maximum resistance against disease and preventing infections. Sick and injured animals must be given prompt and adequate treatment. Further, the standards note the well-being of the animals is the primary consideration in the choice of illness treatment. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available. Withdrawal periods shall not be less than double of that required by legislation."

Japan Agricultural Standard (JAS) for Organic [Production](#)

Kaolin pectin in not listed.

Environmental Issues

According to the 2002 TAP:

- There is no evidence that kaolin and pectin will contaminate environment.
- In the manner in which kaolin is to be used, in kaolin pectin, there is unlikely chance of environmental contamination. However, if workers are to be exposed to kaolin dust during manufacture, they must take appropriate precautions.

Discussion

Under §6509 of OFPA ("Animal production practices and materials"), Section (d) ("Health care") states:

(1) Prohibited practices

For a farm to be certified under this chapter as an organic farm with respect to the livestock produced by such farm, producers on such farm shall not—

- (A) use subtherapeutic doses of antibiotics;
- (B) use synthetic internal parasiticides on a routine basis; or
- (C) administer medication, other than vaccinations, in the absence of illness.**

To the degree to which kaolin pectin is used to address actual livestock illnesses in the context of organic livestock production, its allowance is consistent with OFPA Section 6509.

Given that the TAP on kaolin pectin is from 2002 and a TR on kaolin pectin requested in 2020 is pending, the subcommittee should conduct another review of kaolin pectin once the TR becomes available, especially if it raises any significant concerns about the continued use of the substance in organic production.

Questions to our Stakeholders:

1. How widely used is kaolin pectin in organic livestock production?
2. Are there any equally effective non-synthetic/natural substances available that serve the same functions as kaolin pectin?
3. What problems/issues, if any, are there associated with the use of kaolin pectin in organic livestock production?
4. Is there any concern that organic livestock producers may be using kaolin pectin on a routine, prophylactic basis, rather than solely to address livestock illness?

Mineral oil

Reference: §205.603 (a)(20) Mineral oil—for treatment of intestinal compaction, prohibited for use as a dust suppressant.

Technical Report: [2002 TAP](#); [2015 TR](#); [2021 Limited Scope TR Pending](#)

Petition(s): [2002 Petition](#)

Past NOSB Actions: [11/1995 NOSB minutes and vote](#); [2002 recommendation/vote](#); [5/2003 recommendation](#)

Recent Regulatory Background: Added to NL effective 1/28/2019 ([83 FR 66559](#))

Sunset Date: 1/28/2024

Subcommittee Review

Use

The National Organic Program regulations currently permit the use of mineral oil in organic livestock production for treatment of intestinal compaction, prohibited for use as a dust suppressant in 7 CFR 205.603(a)(20). Mineral oil is also approved as a topical application and as a lubricant under 7 CFR 205.603(b)(7), but this sunset review is limited to 205.603(a)(20).

In the case of “omasal impaction”, the ruminant’s third stomach (omasum) becomes tightly bound and compacted, resulting in severe pain for the affected animal. Omasal impaction is related to type II vagal indigestion (failure of omasal transport), which develops from any condition that prevents ingested material from passing through the omasal canal into the abomasum, the fourth and final stomach

compartment in cattle. In organic livestock production, operators orally administer mineral oil to lubricate the intestinal tract and dislodge intestinal obstructions in cattle and other ruminants.

In general, impactions in various segments of the gastrointestinal tract may develop in pregnant beef cows during cold winter months when cattle consume less water and are fed lower-quality roughage. Mineral oil may be applied as an oral drench at a rate of one to two gallons every 12 hours until the viscous mineral oil treatment lubricates the impaction. Abomasal impaction is treated using four liters (approximately one gallon) of mineral oil per day for three days. In the 2015 TR review it was noted that some livestock producers indicated that failure to regularly treat for omasal impaction often results in the need for surgery. In a related ailment known as “retained meconium” the baby calf’s first manure is blocked, thus rendering the animal unable to excrete normally. Mineral oil serves as an internal lubricant in conjunction with the administration of an enema to unblock the digestive obstruction.

In conventional cattle production, mineral oil is also commonly used to control bloat. Bloat generally occurs in animals after grazing young, lush pasture, particularly if the pasture contains significant amounts of legume species (clover, medics or lucerne). As a preventative measure in conventional systems, veterinary specialists suggest that cattle producers drench each animal twice daily with an anti-bloat preparation or oil when the pasture is conditions may be likely to cause bloat (i.e. young, lush pasture, and/or presence of significant amounts of legume species). However, this medical practice is not approved in organic production.

Manufacture

Crude petroleum oil is the predominant source of mineral oil used in organic and conventional agriculture, as well as food for human consumption, cosmetic products, and drugs. Refined mineral oil is obtained through physical separation, such as distillation and solvent extraction, and chemical conversion processes, including cracking, hydrogenation, alkylation, isomerization and/or other chemical transformations. The composition of mineral oil is dependent upon the crude oil source (e.g., location of procurement) and the processing that occurs in the refinery, such as physical separations and chemical conversions. Because of the complexity of the mineral oil mixtures, refined mineral oil is identified using several CAS numbers depending on the treatment processes utilized and the intended use pattern of the mineral oil product. The mineral oil used in organic livestock production is hydrocarbon molecules containing 34 carbon atoms. These untreated mineral oil products may also contain small amounts of nitrogen- and sulfur containing compounds.

According to USDA organic regulations, the NOP defines synthetic as “a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources” (7 CFR 205.2). The industrial production of highly refined, food-grade mineral oil involves chemical processing and refinement using various chemical reagents and/or catalysts. Crude oil is desalted, distilled, and subjected to solvent extraction, de-aromatization with fuming sulfuric acid or sulfur trioxide, and/or catalytic hydrocracking treatments to reduce the concentration of polar constituents containing heteroatoms (nitrogen, oxygen and sulfur atoms) as well as polynuclear aromatic hydrocarbons (PAHs) and other aromatic compounds. Crude oil, itself, is considered an economically significant natural resource throughout the world, and would likely be classified as a naturally derived, non-synthetic substance according to NOP definitions. However, the production of mineral oil requires the alteration of crude oil through physical separation (distillation) followed by reactions/combination with synthetic substances and reagents (aromatic solvents, strong acids and/or catalysts). As such, the mineral oil is classified as a synthetic material on the National List.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

Canadian regulations permit numerous uses for mineral oil of varying purity. Mineral oil is allowed for external application only under Section 5.3 (health care products and production aids) of the permitted substances list for livestock production (CAN, 2011).

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

According to Annex II of the European Organic Regulation (EC) No 889/2008, mineral oil may be used as an insecticide and/or fungicide only in fruit trees, vines, olive trees and tropical crops (e.g., bananas). Mineral oil is not mentioned specifically in 834/2007 for the use in livestock. However, Annex V, Feed Materials of Mineral Origin (EU EEC 2008, Article 14 Section 1 (e) (ii) states “chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions” (EU EEC 2007). While there is no specific listing for mineral oil in livestock, Article 14 notes that “suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.” The regulation further notes “disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phyto-therapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined.”

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods ([GL 32-1999](#); Part B, Section 22)

The Codex Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (CAC/GL 32-1999) indicate that mineral oil is only permitted for use in traps for organic crop production. Mineral oil is not specifically mentioned for livestock applications. However, under Health Care, Section 22 “where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted.”

International Federation of Organic Agriculture Movements (IFOAM) Norms

The IFOAM Norms permit the use of “light mineral oil (paraffin)” under Appendix 3 (crop protectants and growth regulators). There are no approved uses for mineral oil or related substances in organic livestock production under the IFOAM Norms (IFOAM, 2014).

Japan Agricultural Standard (JAS) for Organic [Production](#)

The Japanese Agricultural Standard (JAS) for Organic Production originally considered only crops and processing (JAS 2005) with later revisions including livestock. Japanese regulations for the organic production of livestock only mentions the use of “petroleum oil aerosol” and “petroleum oil emulsion” for plant pest and disease control (Table 2). Otherwise, it does not appear that Japanese organic regulations permit the use of mineral oil or related products in organic livestock production (JMAFF, 2012).

However, on July 16, 2020 USDA and Japan signed an Organic Livestock Equivalency. Livestock products include beef, eggs, etc., and processed products of animal origin include ham, cheese, chocolate milk, etc. The arrangement is limited to domestic animals (cattle, horses, sheep, goats, and pigs) or domestic poultry (chickens, quails, ostriches, ducks, and wild ducks. Due to this equivalency agreement, livestock treated with mineral oil would be allowed for export to Japan.

Environmental Issues

In the 2007 risk assessment for mineral oil, the EPA indicated that most manufacturers are currently using modified refining and cleanup processes to remove the more toxic components and generate refined minerals largely devoid of PAHs as well as nitrogen and sulfur compounds. Because of their complexity, it is not possible to resolve mineral oil mixtures into individual components for quantification. Indeed, 46 classes of chemicals contained in crude and refined mineral oil mixtures have a wide variety of forms (isomers, carbon chain lengths, etc.) (EFSA, 2012).

Mineral oil may be classified as highly refined or mildly treated/untreated. The white mineral oil that is likely to be used to treat intestinal compaction in organic livestock production are highly refined oils that contain negligible quantities of toxic contaminants compared to untreated and mildly treated oils. Testing in laboratory animals has demonstrated that mineral oil is slightly to practically non-toxic to mammals on an acute exposure basis. Mineral oil is a mild irritant, classified as Toxicity Category IV (lowest toxicity) for skin irritation and Category III for eye irritation. Highly refined “white” mineral oil produced no sensitization reactions in guinea pigs repeatedly exposed to the substance.

The carcinogenicity and genotoxicity potential for mineral oil is generally dependent upon the degree of refinement and presence of PAHs in the mixture. White mineral oil—which has undergone the most severe acid, solvent, or hydrocracking treatment—showed no activity in a series of skin-tumor bioassays. Much like the mammalian studies, the results of avian and honeybee studies suggest that refined mineral oil is practically non-toxic to birds and honeybees via acute oral and contact exposure, respectively. Refined mineral oil is generally characterized as minimally toxic to aquatic organisms on an acute exposure basis.

Discussion

Mineral oil was petitioned in 2002 to be used for treatment of intestinal compaction and topical application, and as a dust suppressant in organic livestock feedstuffs. After reviewing the 2003 TAP review, the Board recommended adding mineral oil for treatment of intestinal compaction. They did not recommend adding mineral oil as a dust suppressant additive in feedstuffs since they determined there were sufficient alternative supplies of other natural materials for that use that are not prone to rancidity. Some alternative products to mineral oil as a dust suppression include grapeseed, citrus, and certain other vegetable oils.

Following the NOSB recommendation of inclusion of mineral oil for use as a veterinary treatment for omasal impaction in organic livestock production other issues came to light. Based on consultations with the US Food and Drug Administration (FDA), the NOP was informed that mineral oil has not received approval through the FDA drug approval process to be authorized as a medical treatment in cattle, and the substance would not qualify for extra-label use by a licensed veterinarian. Animal drugs containing mineral oils—such as AgriLabs Mineral Oil Light and UNAVET Mineral Oil Light NF—are currently marketed for relief of obstruction or impaction of the intestinal tract in cattle, sheep, goats, swine, and horses. Because these animal drugs are not FDA approved, the labels carry the disclaimer: “this drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA.” FDA has yet to take regulatory action against these mineral oil products or require safety and efficacy testing for animal drugs containing mineral oil. The US Environmental Protection Agency (US EPA) deferred to FDA as the appropriate regulatory body for use of the substances.

Best management practices may prevent the development of omasal impaction in cattle, sheep, and other livestock under certain conditions. There are cultural practices that may decrease the incidence of intestinal compaction requiring treatment using natural and/or synthetic substances in organic livestock production. Omasal impaction generally occurs when the feed provided to cattle is tough and fibrous, particularly alfalfa stalks and cuttings from fodder trees, or under drought feeding conditions in sheep that are fed on the ground. The latter form of impaction in sheep is typically due to the accumulation of soil in the omasum.

In healthy animal stock, providing the necessary nutritional requirement for wintering pregnant beef cattle can prevent abomasal impaction. Producers using low-quality roughage should augment the ration with grain to meet energy and protein requirements, especially if laboratory analyses indicate these key nutrient parameters are low in the roughage alone. Adequate drinking water should be supplied continually for animal welfare, and to encourage proper digestion of feed and pasture materials. Omasal impaction may

be prevented through provision of rations containing 10–15% cut or chopped roughage mixed into the complete feed to ease the digestion of fibrous materials. The roughage should be a cereal, grain straw, grass hay, or equivalent, and grains should be rolled or cracked as opposed to finely ground.

Questions to our Stakeholders

1. Are there new studies that indicate that the use of mineral oil as a treatment of intestinal compaction is no longer necessary?
2. Are there differences in interpretations by certifiers for allowed use of mineral oil as a treatment of intestinal compaction in livestock (7 CFR 205.603(a)(20))?
3. If there are differences in interpretations amongst certifiers for the use of mineral oil as a treatment of intestinal compaction in livestock, what clarification or guidance could be provided that would eliminate the differences in interpretation?

Nutritive supplements – injectable trace minerals, vitamins, and electrolytes

Reference: §205.603 (a)(21) Nutritive supplements - injectable supplements of trace minerals per paragraph (d)(2) of this section, vitamins per paragraph (d)(3), and electrolytes per paragraph (a)(11), with excipients per paragraph (f), in accordance with FDA and restricted to use by or on the order of a licensed veterinarian.

Technical Report: [1995 TAP \(\(a\)\(11\) electrolytes\)](#); [2015 TR \(\(d\)\(3\) vitamins\)](#); [2015 TR \(\(a\)\(11\) electrolytes\)](#); [2019 TR \(\(d\)\(2\) trace minerals\)](#);

Petition(s): [2009](#)

Past NOSB Actions: [05/2009 recommendation to add to NL](#)

Recent Regulatory Background: Added to NL effective 1/28/2019 ([83 FR 66559](#))

Sunset Date: 1/28/2024

Subcommittee Review

Use

Nutritive supplements (Injectable trace minerals, vitamins, and electrolytes) are allowed to treat livestock ailments when administered or ordered by a licensed veterinarian.

Manufacture

Trace minerals used as feed additives are produced by chemical reactions resulting in inorganic forms of the mineral. Organic compounds are used for some of the trace minerals.

Vitamins can be extracted from foods or synthesized by chemical or biofermentation processes. Regarding the former, certain vitamins can be obtained from natural dietary sources in varying quantities. For example, Vitamin C (ascorbic acid) is a major nutritional component of citrus fruits and Vitamin D is a natural constituent nutrient of cold-water fish.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

From the Permitted Substances List (CAN/CGSB-32.311- 459 2006), vitamins may be used for enrichment or fortification of livestock feed, and synthetic vitamins may be used if non-synthetic sources are not

commercially available (CAN, 2011b). Under no circumstances should vitamins be used to stimulate growth or production (CAN, 2011b).

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

EC No. 834/2007 and 889/2008, state that “feed of mineral origin, trace elements, vitamins or provitamins shall be of natural origin. In case these substances are unavailable, chemically well-defined analogic substances may be authorized for use in organic production.” Specifically, vitamins are allowed nutritional additives for use in animal production under the following conditions: (1) Vitamins derived from raw materials occurring naturally in feedstuffs; (2) Synthetic vitamins identical to natural vitamins for monogastric animals and aquatic animals; (3) Synthetic vitamins A, D, and E identical to natural vitamins for ruminants with prior authorization of the Member States based on the assessment of the possibility for organic ruminants to obtain the necessary quantities of the said vitamins through their feed rations.

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

The Codex Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced 466 Foods (CAC GL 32-1999) provides criteria for feedstuffs and nutritional elements. Specifically, section 467 of these guidelines pertaining to livestock production states that “feedstuffs of mineral origin, trace minerals, vitamins, or provitamins can only be used if they are of natural origin. In case of shortage of these substances, or in exceptional circumstances, chemically well-defined analogic substances may be used” (Codex, 2013).

United Kingdom Soil Association

Nature identical synthetic vitamins may be used in the production of non-herbivores without permission, while producers of herbivores must seek approval to use nature identical synthetic vitamins A, D and E. Regarding the latter group, the operator must demonstrate nutritional deficiency of the animals’ feed. Soil Association standards do not permit the use of concentrated vitamins and minerals to encourage early maturity or high levels of production (Soil Association, 2014).

Japan Ministry of Agriculture, Forestry, and Fisheries.

The Japan Ministry of Agriculture, Forestry, and Fisheries Standard for Organic Feed does not specify the allowed or prohibited status of vitamins in organic livestock feed materials. However, the standard permits 493 natural feed additives: Feed additives (except for those produced by using antibiotic and recombinant DNA technology), which are natural substances or those derived from natural substances without being chemically treated. In case of a difficulty to obtain feed additives listed in 8, the use of similar agents to the described food additives are permitted only for supplementing nutrition and effective components in feeds. This statement suggests that synthetic vitamins may be allowed if naturally derived substitutes are not available (JMAFF, 2012).

Environmental Issues

The potential exists for environmental contamination resulting from the industrial production of several vitamin compounds. In particular, materials safety data sheets (MSDS) for several feedstock chemicals and other chemical reagents used in the synthesis of calcium pantothenate (vitamin B5) and biotin (vitamin B7) indicate the potential for ecological damage if accidentally released into the environment. Isobutyraldehyde and cyanide salts used in the synthesis of calcium pantothenate as well as ethylene oxide used for choline chloride generation have shown toxicity toward fish and aquatic invertebrates. Further, hydrogen sulfide, which is used in the synthesis of biotin, is toxic to fish at low doses, and is therefore listed as very toxic to aquatic life. Strong acids (e.g., nitric acid, hydrochloric acid) used in the syntheses of numerous vitamins may alter the pH of aquatic systems if accidentally released to the environment. Strong acids and bases are also utilized in the extraction of tocopherols from vegetable oils and may lead to environmental impairment if accidentally released or improperly handled. Many of the vitamins

synthesized for supplements and feed fortification are derived from petroleum products or genetically modified crop materials.

Discussion

There can be times of stress when certain individual animals need high amounts of vitamins and minerals delivered to target tissues in a rapid manner. If for whatever reason animals are not eating, then they are not taking in the oral forms of vitamins and minerals. They may need nutritive supplementation best delivered by injection. Additionally, with the prohibition of the use of antibiotics in certified organic livestock, farmers and veterinarians need as many of the remaining tools as possible to prioritize animal health. Injectable forms of vitamins and minerals, allowed strictly on an as need basis, provide valuable support to an animal's immune system and is a method that works to assist livestock health, well-being and promotes animal welfare.

Questions to our Stakeholders

1. Do advances in organic ration formulations change the need for injectable nutritive supplements?

Propylene glycol

Reference: §205.603 (a)(27) Propylene glycol (CAS #57-55-6) - only for treatment of ketosis in ruminants.

Technical Report: [2007 TAP](#); [2021 TR Pending](#)

Petition(s): [2002](#)

Past NOSB Actions: [2002 Position Paper](#); [9/2002 recommendation to add to NL](#)

Recent Regulatory Background: Added to NL effective 1/28/2019 ([83 FR 66559](#))

Sunset Date: 1/28/2024

Subcommittee Review

Use

Propylene glycol is used as a drench for the treatment of ketosis in ruminants, and is considered GRAS, except when used in or on cat food. According to the TR, propylene glycol is used as an anticaking agent, emulsifier, flavor agent, formulation aid, humectant, processing aid, solvent and vehicle, stabilizer and thickener, surface-active agent, and as a texturizer.

Manufacture

Propylene glycol is manufactured by treating propylene with chlorinated water to form chlorohydrin, which is then converted to glycol by treatment with sodium carbonate solution. Propylene glycol is also prepared by heating glycerol with sodium hydroxide and distilling the mixture.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

Propylene glycol listed in Table 5.3 as a permitted health care product/production aide for livestock, specifically limited to use as an ingredient in foot baths.

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

While there is no specific listing for propylene glycol, Article 14 notes that “suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.” The regulation further notes “disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict

conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular, restrictions with respect to courses of treatment and withdrawal periods shall be defined.”

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

While there is no specific listing for propylene glycol, the Guidelines state the following:

The use of veterinary medicinal products in organic farming shall comply with the following principles:

- a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted;
- b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended;
- c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours;
- d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited.

International Federation of Organic Agriculture Movements (IFOAM) Norms

While propylene glycol is not specifically listed, the general principles state management practices should be directed to the well-being of animals, achieving maximum resistance against disease, and preventing infections. Sick and injured animals must be given prompt and adequate treatment. Further, the standards note the well-being of the animals is the primary consideration in the choice of illness treatment. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available. Withdrawal periods shall not be less than double of that required by legislation.

Japan Agricultural Standard (JAS) for Organic [Production](#)

While propylene glycol is not specifically listed, the standard states that when veterinary drugs are used, the withholding period shall be twice the period of conventional standards.

Environmental Issues

The 2007 TAP review states; the intended use of propylene glycol as a drench treatment would not result in direct interaction with other materials used in organic farming systems. There is no indication of detrimental interactions from this application. Additionally, when released into the soil, this material is expected to readily biodegrade and leach into groundwater. When released into water, this material is expected to readily biodegrade. When released into the air, this material is expected to be readily degraded by reaction with photochemically produced hydroxyl radicals.

According to the TAP Review on propylene, also known as propene, is an unsaturated hydrocarbon. It is an important petrochemical feedstock. It is obtained as a by-product of gasoline manufacture by the fluid cracking of gas oils, or from ethylene in the steam cracking of hydrocarbons, in which a mixture of steam and hydrocarbon is passed through a tube heated to 600- 900°C (1110-1650°F). About 10% of the propylene that is manufactured is converted into propylene oxide, C₃H₆O, either by a reaction with hypochlorous acid, HOCl, followed by calcium hydroxide, or in a one-step reaction with hydroperoxide,

ROOH, in the presence of a molybdenum or vanadium catalyst. Propylene oxide is then hydrolyzed to propylene glycol or polymerized to polypropylene glycol, or used in the preparation of polyurethanes, detergents, hydraulic fluids, etc.

Discussion

This substance was among 35 NOSB recommendations on amendments to the National List, made from November 2000 to November 2016, that were acted upon in a final rule published in December 2018. Because of this recent addition, this is the first sunset review of propylene glycol at this listing.

A TR is pending for propylene glycol. In the original TAP review, all three TAP reviewers found propylene glycol to be a synthetic material. Two reviewers supported allowance of the substance in livestock with restrictions, while the other supported allowance for all petitioned purposes and without restriction. Concerns included the consistency of the method of manufacturing of propylene glycol with organic practices, and the availability of other methods of treatment and prevention of ketosis.

Questions to our Stakeholders

1. When preventative measures do not work, are there natural/non-synthetic alternative treatments for ketosis in ruminants since approval of the petition? Are there any alternative synthetic treatments on the NL that make this listing redundant?
2. Are there developments in manufacturing of propylene glycol that would require new evaluation of source materials?

Sodium chlorite, acidified

Reference: §205.603 (a)(28) Sodium chlorite, acidified - allowed for use on organic livestock as a teat dip treatment only; and

§205.603 (b)(9) Sodium chlorite, acidified - allowed for use on organic livestock as a teat dip treatment only.

Technical Report: [2013 TR](#)

Petition(s): [2012](#); [2014 Addendum #1](#); [2014 Addendum #2](#)

Past NOSB Actions: [4/2015 recommendation](#)

Recent Regulatory Background: Added to NL effective 1/28/2019 ([83 FR 66559](#))

Sunset Date: 1/28/2024

Subcommittee Review

Use

Acidified sodium chlorite is used as a disinfecting teat dip for organic livestock producers. Acidified sodium chlorite breaks down in the environment to water and salt and is more benign than other teat dip materials currently listed on the National List.

Manufacture

Acidified sodium chlorite solutions are made by mixing an aqueous solution of sodium chlorite with a food-grade acid, such as citric acid. Several industrial synthetic procedures are utilized in the production of sodium chlorite. As examples, the treatment of chlorine dioxide, sodium hydroxide, and a reducing agent (e.g., sodium sulfite) or reaction of chlorine dioxide with sodium peroxide (i.e., Na₂O₂ or an alkaline solution of hydrogen peroxide, H₂O₂) are commercially utilized methods for the synthesis of sodium chlorite.

Generally Recognized as Safe (GRAS) acids, such as citric and lactic acids, are typically produced through fermentative means; however, these naturally occurring compounds may also be extracted from plant-based sources or generated using chemical synthetic methods.

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

Acidified sodium chlorite is not specifically listed.

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

While there is no specific listing for acidified sodium chlorite, Article 14 notes that “suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.” The regulation further notes “disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined.”

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods ([GL 32-1999](#), Part B, Section 22)

While there is no specific listing for acidified sodium chlorite, the Guidelines state the following:

The use of veterinary medicinal products in organic farming shall comply with the following principles:

- a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted;
- b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended;
- c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours;
- d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited.

International Federation of Organic Agriculture Movements (IFOAM) Norms

While acidified sodium chlorite is not specifically listed, the general principles state management practices should be directed to the well-being of animals, achieving maximum resistance against disease, and preventing infections. Sick and injured animals must be given prompt and adequate treatment. Further, the standards note the well-being of the animals is the primary consideration in the choice of illness treatment. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available. Withdrawal periods shall not be less than double of that required by legislation.

Japan Agricultural Standard (JAS) for Organic [Production](#)

Acidified sodium chlorite is not specifically listed.

Environmental Issues

While the manufacture and use of acidified sodium chlorite solutions have resulted in releases to the environment, the risk of environmental contamination from released acidified sodium chlorite is minimal. Certain manufacturing facilities have reported releases of chlorine dioxide, a portion of which was generated through reaction of chlorite with a strong acid, to air, water, and soil (ATSDR, 2004). Strong acids (e.g., hydrochloric acid) and bases (sodium hydroxide) are used in the commercial production of sodium chlorite, and their release due to improper handling/disposal could lead to serious environmental impairments. Likewise, the release of strong oxidizing agents in large quantities may lead to ecotoxicity in both terrestrial and aquatic environments. This is true of both the chemical feedstocks (e.g., hydrogen peroxide) used in the manufacture of acidified sodium chlorite precursors and the chemicals in acidified sodium chlorite solutions (i.e., chlorous acid, chlorine dioxide, chlorite). Regarding the former, several lower reactivity sulfur-containing and carbonaceous substances have been evaluated for the conversion of chlorine dioxide to sodium chlorite.

Discussion

Acidified sodium chlorite was among 35 NOSB recommendations on amendments to the National List, made between November 2000 and November 2016, that were acted upon in a final rule published in December 2018. Because of this recent addition, this is the first sunset review of acidified sodium chlorite at this listing.

Preventive health care is an essential part of organic farming, and mastitis prevention through clean milking parlors and clean animals is always of paramount importance on a dairy farm. Organic farmers cannot use antibiotics and thus the use of pre milking and post milking teat dips is a normal practice and may be the most critical factor in preventing mastitis. Acidified sodium chlorite satisfies the criteria related to impact on humans and the environment and is compatible with organic agriculture. Iodine is widely used in teat dips. The technical report (TR) on iodine, received on January 7, 2015, provides recent research information and comparative data on iodine-based teat dips and on teat dips whose primary ingredient is acidified sodium chlorite. The following is excerpted from the iodine TR in its discussion of alternatives to iodine in teat dips: "Information regarding the availability of natural, non-synthetic agricultural commodities or products that could substitute for iodine and iodophor disinfectants is limited." Acidified sodium chlorite thus appears to be a potentially important ingredient in teat dips.

Questions to our Stakeholders

1. Are there preferred alternatives to acidified sodium chlorite for preventative care in dairy cows?
2. Have there been changes in the availability of iodine that would reduce the need for acidified sodium chlorite?

Zinc sulfate

Reference: §205.603 (b)(11) Zinc sulfate - for use in hoof and foot treatments only.

Technical Report: [2015 TR](#)

Petition(s): [2014](#)

Past NOSB Actions: [4/2015 recommendation](#)

Recent Regulatory Background: Added to NL effective 1/28/2019 ([83 FR 66559](#))

Sunset Date: 1/28/2024

Subcommittee Review

Use

Zinc sulfate is allowed for use in organic livestock as a footbath for control of foot rot in livestock-- primarily dairy cattle, sheep, and goats.

Manufacture

Zinc sulfate is produced synthetically by combining zinc ash with aqueous sulfuric acid (TR line 53). Commercially, zinc sulfate is manufactured from zinc ore mined from underground or open pit mines (TR line 60).

International Acceptance

Canadian General Standards Board Permitted Substances [List](#)

Operators of organic livestock production facilities must establish a provision for prompt treatment for animals with detectable disease, lesions, lameness, injury, and other physical ailments. Where preventive practices and vaccines are inadequate to prevent sickness or injury and where disease and health problems require treatment, the use of biological, cultural, and physical treatments and practices is permitted, in accordance with CAN/CGSB-32.311, Organic Production Systems — Permitted Substances Lists, but maybe relaxed under veterinary supervision if listed substances fail to work. Products from sick animals or those undergoing treatment with restricted substances shall not be organic or fed to organic livestock (CGSB, 2011a). Sulfates of zinc may be used only to correct for deficiencies determined by soil or plant tissue testing. Sulfates produced using sulfuric acid are prohibited. Zinc sulfate may be used to correct a documented zinc deficiency (CGSB, 2011b). TR lines 216 – 225.

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

Disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. Restrictions with respect to courses of treatment and withdrawal periods are defined (EU, 2007); Animal health is based on prevention of disease, but treated livestock may not be sold as organic products if treatment involves an unapproved medication. Treated livestock must be submitted to the defined conversion periods. Zinc sulfate may be used as a trace element in the production of organic livestock. The maximum concentration for zinc in composted or fermented household waste to be used as fertilizer or soil conditioner is 200 milligrams per kilogram (EU, 240 2008). TR lines 231-240.

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

Where specific disease occurs, and no management practice exists, therapeutic use of veterinary drugs is permitted; Zinc can be used as a trace element supplement when the need is recognized by the certification body or authority. The use of zinc sulfate for control of foot rot in cattle sheep and goats has not been specifically addressed (Codex, 2007). TR lines 226-230

International Federation of Organic Agriculture Movements (IFOAM) Norms

Organic animal management systems follow the principle of positive health, which consist of a graduated approach of prevention (including vaccinations and anti-parasite treatments only when essential), then natural medicines and treatment, and finally if unavoidable, treatment with allopathic chemical drugs. Organic animal management never withholds medical treatment considered necessary for the welfare of an animal to maintain the organic status of the animal (IFOAM, 2014). TR lines 245-250

Japan Agricultural Standard (JAS) for Organic [Production](#)

Veterinary Drugs specified by Article 1. 1 of the Ministerial Ordinance for Handling by the Ministry of Health, Labor and Welfare (No.4 of 1961) are permitted. Zinc sulfate use is limited to the case where livestock is unable to grow normally because of its shortage as a trace element (MAFF, 2012). TR lines 241-244

Environmental Issues

Excess applications of zinc sulfate could disrupt essential nutrient balances in soils and in extremes could become toxic to plants or animals. Zinc sulfate is toxic to fish and aquatic invertebrates. Direct application to water where these exist should be avoided. It should also be noted that the use of zinc sulfate should decrease the use of copper sulfate in treating foot diseases. The buildup of persistent copper in agricultural soils is a serious issue. While zinc sulfate can also accumulate in soils, its persistence is less certain due to the mode of attachment to soils. Zinc sulfate is therefore considered a more benign material compared to copper sulfate.

Discussion

Copper sulfate and zinc sulfate are two of the most accepted treatments and are comparable in efficacy. Zinc sulfate has proven particularly effective at controlling the bacteria associated with foot rot, and is sometimes used in combination with other materials, including copper sulfate. The combination of zinc sulfate with sodium lauryl sulfate (as an excipient) has proven to be more effective than zinc sulfate with copper sulfate.

The Livestock Subcommittee will again seek public comments regarding the effectiveness of alternative methods for controlling foot rot, including management practices, and the use of hydrogen peroxide, peracetic acid or other materials. Further, the subcommittee will seek feedback on whether the availability of zinc sulfate for use in organic livestock production would likely reduce the use of copper sulfate for treatment of foot rot.

Questions to our Stakeholders

1. Has the use of zinc sulfate reduced the use of copper sulfate in treating foot disease in livestock?

USDA National Organic Standards Board
Research Priorities Discussion Document
Spring 2021
Executive Summary

Overall: The National Organic Standards Board (NOSB) presents an annual list of research priorities for organic food and agriculture. The NOSB requests that integrated research be undertaken with consideration of the whole farm system, recognizing the interplay of agroecology, the surrounding environment, and both native and farmed species of plants and animals.

Livestock

1. Determine the efficiency of natural parasiticides and methodologies, including but not limited to, nutritional programs, use of herbs, essential oils, homeopathic remedies, Diatomaceous Earth, and the genetic pool of laying hens in controlling *A. galli* and *H. gallinarum* in laying and replacement chickens intended to become hens.
2. Evaluate natural alternatives to DL-Methionine in a system approach for organic poultry feed program.
3. Evaluate ways to prevent and manage parasites in livestock, examining breeds, geographical differences, alternative treatments, and pasture species.
4. Research and develop livestock breeding programs resulting in livestock that are adapted to outdoor life and living vegetation.

Crops

1. Examination of decomposition rates, the effects of residues on soil biology, and the factors that affect the breakdown of biodegradable bio-based mulch film.
2. Conduct whole farm ecosystem service assessments to determine the economic, social, and environmental impact of farming systems choices.
3. Organic no-till practices for diverse climates, crops, and soil types.
4. Develop cover cropping practices that come closer to meeting the annual fertility demands of commonly grown organic crops.
5. Development of systems-based plant disease management strategies are needed to address existing and emerging plant disease threats.
6. The demand for organic nursery stock far exceeds the supply. Research is needed to identify the barriers to expanding this market, then develop and assess organic methods for meeting the growing demand for organically grown nursery stock.
7. Strategies for the prevention, management, and control of invasive insects and weeds.
8. Factors impacting organic crop nutrition, and organic/conventional nutrition comparisons.

9. Side-by-side trials of organic synthetic materials, natural materials, and cultural methods, with a request for collaboration with the IR4 project.
10. Impartial evaluation of microbial inoculants, soil conditioners, and other amendments is needed as there is little objective evidence upon which to assess their contribution to soil health.
11. More research, extension, and education are needed to fully understand the relationship between on-farm biodiversity and pathogen presence and abundance.
12. Elucidate practices that reduce greenhouse gas emissions and that contribute to farming systems resilience in the face of climate change.

Food Handling and Processing

1. Evaluation of alternatives to chlorine materials in processing: impact mitigation, best management practices, and potential for chlorine absorption by produce.
2. Suitable alternatives to BPA (Bisphenol-A) for linings of cans used for various products.
3. Chlorine sanitizers pose potential occupational health risks in food handling and processing environments. Given anecdotal reports of health problems associated with exposure to chlorine sanitizers by food workers, the Handling Subcommittee recommends additional research, including monitoring for chlorine breakdown products, chlorine gas, and chloroform in organically certified food handling and processing facilities to quantify worker exposures and health risks.

Coexistence with GE and Organic Crops

1. Outcome of genetically engineered (GMO/GE) material in organic compost.
2. Evaluation of public germplasm collections of at-risk crops for the presence of GE traits, and ways to mitigate small amounts of unwanted genetic material in breeding lines.
3. Develop, then implement, methods of assessing the genetic integrity of crops at risk to quantify the current state of the organic and conventionally produced non-GMO seed.
4. Techniques for preventing adventitious presence of GE material in organic crops, and evaluation of the effectiveness of current prevention strategies.
5. Testing for fraud by developing and implementing new technologies and practices.

General

1. Examination of the factors influencing access to organically produced foods.
2. Production and yield barriers to transitioning to organic production to help growers successfully complete the transition.

**National Organic Standards Board
Materials Subcommittee Discussion Document
2021 Research Priorities
Spring 2021**

INTRODUCTION

The National Organic Standards Board (NOSB) presents an annual list of research priorities for organic food and agriculture. The NOSB's Livestock, Crops, Handling, and Materials/GMO Subcommittees proposed an updated set of priorities at the Fall 2020 board meeting. That substantially updated list arose from public comments received by the NOSB and by concerns raised during the course of the Board's work in the preceding year. The Board requests input from stakeholders on the 2021 research priorities and will review those comments for the Fall 2021 proposal.

BACKGROUND

The list of priorities is revisited each year by the NOSB. The list is made meaningful by input through the written and oral public comments shared with the Board, through the expertise of the Board itself and through interactions throughout the year with those engaged in some dimension of the organic farm to fork continuum. When the NOSB has determined that a priority area has been sufficiently addressed, it is removed from the list of priorities. Priorities are also edited each year to reflect the existing need more accurately for new knowledge.

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

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

Livestock

1. Efficiency of Natural Parasiticides and Methodologies – Nutritional programs, use of herbs, essential oils, homeopathic remedies, Diatomaceous Earth, and the genetic pool of laying hens in controlling *A. galli* and *H. gallinarum* in laying and replacement chickens intended to become hens – among other interventions – may be helpful in ensuring flock health. Ongoing research into the usefulness and viability of such innovations is consistent with NOSB action.

2. Evaluation of Methionine in the Context of a System Approach in Organic Poultry Production - Methionine is an essential amino acid for poultry. Prior to the 1950's, poultry and pigs were fed a plant and meat-based diet without synthetic amino acids such as methionine. One former NOSB member stated, in §205.237(5) (b), "We have seemingly made vegetarians out of poultry and pigs". As the organic community moves toward reducing, removing, or providing additional annotations to synthetic methionine in the diets of poultry, a heightened need exists for the organic community to rally around omnivore producers to assist in marshaling our collective efforts in finding viable alternatives to synthetic methionine and to help find approaches for making them more commercially available.

Continued research on the use of synthetic methionine in the context of a systems approach (nutrition, genetic selection, management practices, etc.) is consistent with the NOSB unanimous resolution passed at the La Jolla, California, Spring 2015 board meeting. A systems approach that includes industry and independent research by USDA/ARS, on farms, and by agricultural land grant universities is needed for (1) evaluation of the merits of natural alternative sources of methionine such as herbal methionine, high

methionine corn, and corn gluten meal in organic poultry production systems; (2) evaluation of poultry breeds selection that could be adaptive to existing organic production systems – inclusive of breeds being able to adequately perform on less methionine; (3) assessment of management practices for improving existing organic poultry welfare under different conditions; and (4) and with the European Union as a case study, assess how it is that EU farmers manage the methionine needs of their flocks in the absence of synthetic methionine use. Research findings and collaborations under various climates, housing types, geographical regions, and countries should be noted and researched, where applicable. Certainly, the fruition of these types of research topics could take years to achieve the expressed NOSB resolution; however, an aggressive and/or heightened research focus could lead to findings that can positively impact the organic poultry industry and the organic brand. The continued focus on methionine with a systems approach is imperative and necessary. The key research areas should include the efficacy and viability of alternatives such as: herbal methionine, corn gluten meal, potato meal, fishmeal, animal by-products, and other non-plant materials. Additional research on the more promising alternatives to bring them into commercial production is also encouraged. Additionally, management practices impacting the flock's demand for methionine should be included, such as flock management practices, access to pasture, and pasture management.

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

The research question on prevention and management of parasites must be systems based. What farm systems, bird and animal breeds, herd or flock management systems have shown the best results with parasite control over the last twenty years? What regional differences are there in the US in parasite prevention? Are there specific herbal, biodynamic, diatomaceous earth, or other treatments that have been proven to work overtime? What are the parasite-resistant breeds? Are there plant species in pastures, hayfields, and scrublands that could be incorporated into the annual grazing system to reduce the spread of parasites or to provide prevention through the flora, fauna, and minerals ingested? Which pasture management systems appear to be best for parasite prevention in various parts of the country? Are pasture mixes being developed that include plants known to prevent parasites in various breeds?

4. Organic Livestock Breeding - Organic rules require livestock products originate from animals that are not confined and are adapted to outdoor living as well as obtaining feed from living vegetation. A current FAO report states that globally one third of pigs, half of all egg layers, two thirds of milk animals, and three quarters of meat chickens are produced with breeds more suited to confinement or "industrial" production systems than a typical organic farm or ranch. Similar to plant breeding, the organic community sees a great need for regionally adapted and publicly available livestock breeds that can thrive in organic systems. Heritage, native regional breeds, and breeds used in the EU and other areas of the world that are typically more adapted to organic systems are still present but in small numbers. Increased research on the breeding, production needs, and improvement of these breeds is needed. Traits for good conversion rates from grazing and foraging to eggs, milk or meat, meeting consumer expectations for quality, as well as having the constitution and temperament to thrive outdoors would increase both the profitability and resiliency of organic livestock operations. Animal breeds that may have immunity to a variety of diseases and parasites would be useful traits to research and incorporate in a breeding program.

Crops

1. Biodegradable Bio-based Mulch Film - Biodegradable mulch was recently approved by the NOSB but did not specify a required percentage of biologically derived (i.e., bio-based) content. In 2015, NOP issued a Policy Memo that states that certifiers and material organizations should review biodegradable mulch film products to verify that all (100%) of the polymer feedstocks are bio-based. This requirement makes bio-based mulches unavailable to organic producers because petroleum-based polymers are present in these mulch films. In order to provide a recommendation to the NOP addressing the presence of petroleum-based polymers in these mulches, the answers to the following questions are important to develop more clarity on mulch films and possibly develop an additional annotation to address producer needs for biodegradable mulch films even if petroleum-based polymers are used:

- How rapidly do these mulches fully decompose, to what extent does cropping system, soil type, and climate mediate decomposition rates, and does the percentage of the polymers in the mulch film affect the decomposition rate?
- Are there metabolites or breakdown products of these mulches that do not fully decompose? Do any of these mulches fully decompose?
- Do breakdown byproducts influence the community ecology and ecosystem function of soils, plants, and the livestock that graze on crops grown in these soils?
- As fragments degrade, do they pose a problem to terrestrial and aquatic wildlife? What are the environmental fates of micro- and nano-plastic fragments resulting from biodegradable mulch film degradation, and what hazards do they present to organisms that they interact with on the way to that fate?
- Do the residues of these films accumulate after repeated use?
- Are the testing protocols in place to insure decomposition standards?

2. Ecosystem service provisioning and biodiversity of organic systems - How do organic systems impact ecosystem service provisioning, both on-farm and off-farm through the materials and inputs sourced and used for production? For example, life-cycle analysis of environmental costs and benefits of inputs used for organic production, such as manure, seaweed, and fish-based soil amendments, would be beneficial. Additionally, what is the impact of diversified and agroecologically designed organic farming systems on biodiversity and ecosystem services within the farm and in its surroundings? Can farm-mapping be performed to quantify the impact of the location of a farm (in a broader landscape) and the arrangement of fields and non-crop habitat to enhance biodiversity and ecosystem service provisioning?

3. Organic No-Till and Minimum Tillage - Organic no-till can increase soil health and provide for increased biodiversity. Organic no-till preserves and builds soil organic matter, conserves soil moisture, reduces soil erosion, and requires less fuel and labor than standard organic row crop farming.

Farmers are employing several different approaches to organic no-till. Some are using a roller-crimper to terminate cover crops for in-place mulching. They then transplant or seed directly into the cover crop mulch. Others are utilizing polyethylene sheets (silage tarps) to prepare land for no-till planting. This approach often involves termination of a cover crop, as with the roller-crimper systems, but seemingly as often, or more frequently, is utilized to prepare fallow ground (for stale seed bedding, termination of crop residue and subsequent incorporation via soil fauna), or in conjunction with large applications of compost or other sources of organic matter.

Increased research is needed to develop organic no-till systems that function for a wide variety of crops in diverse climates and soil types. Annual crops such as commodity row crops and specialty crops, as

well as perennial crops such as tree fruits, berries, and grapes would all benefit from these organic no-till practices. Research areas that could be covered include:

- Development of plant varieties that have specific characteristics, such as early ripening, to aid in the effectiveness and practicality of organic no-till.
- What combination of mulch crops and cultural systems sustain crop yields, provide soil health benefits, and suppress weeds?
- How does organic no-till influence pest, weed, and disease management?
- What potential pest problems can be caused or exacerbated by cover crops used as mulches, and how can those problems best be managed?
- In perennial cropping systems, such as fruits, what are the benefits or drawbacks of using this mulching system on weed, pest, and disease management, as well as soil fertility?
- What are the biodiversity benefits to living and/or killed mulches, and how does this contribute to pest, weed, and disease management?
- Do these systems affect the nutrient balance of the soil and subsequent fertilization practices, including use of outside inputs?
- Based on the improved soil health, when there is less soil disturbance and more plant decomposition resulting in higher organic matter, how does this system affect soil microbial life and nutrient availability, and does this then result in crops that are less susceptible to disease and pests?
- Research is needed on seeds, specifically for good cold germination, rapid emergence and establishment, seedling vigor, nutrient uptake efficiency, and overall weed competitiveness to crop cultivar development goals for organic conservation tillage systems.
- How can reduced tillage weed management be improved, including development of new tools and techniques that provide greater weed control for less soil disturbance?

Finally, organic farmers use whole-farm planning when deciding what will be done in each of their fields. Research that assesses the ecosystem benefits of reducing tillage in patches (field-level) across a farm is also needed. For example, the relative benefits of reducing tillage are greater in areas prone to surface water runoff. Research is needed to “inform” where reduced tillage practices are likely to have their greatest impact.

4. Managing Cover Crops for On-Farm Fertility - Growing cover crops and green manures is a foundational practice on many organic farms. In addition to conserving soil, increasing water holding capacity, and providing weed suppression, cover crops supply important plant nutrients and increase soil organic matter. As farmers seek to grow their own fertility, more research is needed on the efficacy of relying primarily on cover crops to meet production needs, particularly for horticultural crops. At present, there is inadequate data on the nutrient benefits of different cover crop mixes and how those benefits vary according to species mix, mowing practices, tillage regimes, subsequent planting time of the cash crops, and importantly the preceding practices that define the legacy of individual fields.

5. Disease Management - Disease management in organic fruit and vegetable production relies on a systems approach to succeed, but even with current systems plans in place, growers frequently struggle to manage commonly occurring blights and citrus greening. The NOSB underscores the need for systems research that addresses solutions to these and related diseases that are workable for farmers, that reduces adverse health effects on farmers and fieldworkers, and that also limits adverse effects on the soil and water in which the crops grow. To this end, we call for systems research that identifies disease resistant material while at the same time identifying biological controls that limit the use of copper-based compounds where possible.

Specifically, targeted research is needed to identify management practices and less toxic alternative materials for a wide range of crops. More research is needed on many of the crop/disease combinations, including:

- Comprehensive, systems-based approaches for managing individual crops in a way that decreases the need for copper-based materials, including researching crop rotations, sanitation practices, plant spacing, and other factors that influence disease.
- Breeding plants that are resistant to the diseases that copper controls.
- Developing alternative formulations of materials containing copper so that the amount of elemental copper is reduced.
- Developing biological agents that work on the same diseases that copper is now used on.
- Evaluating plant nutritional strategies to mitigate the impacts of plant diseases.
- Research on scum and algae control in rice and whether sodium carbonate peroxyhydrate or other materials are suitable alternatives in an aquatic environment.
- Soil management and crop cultivar development for enhanced beneficial crop-root microbe partnerships that protect organic crops from soil borne and foliar pathogens.
- Alternatives to antibiotics (tetracycline and streptomycin) for fire blight control, particularly in pears and apples.

6. Identify Barriers and Develop Protocols for Organic Nursery Stock Production

The demand for organic nursery stock far exceeds the supply. Research is needed to identify the barriers to expanding this market, then develop and assess organic methods for meeting the growing demand for organically grown nursery stock. That work could include but is not limited to assessing phytosanitary rules for shipping plants and quantifying the production and demand for organic rootstock. Research has shown that application of the correct ectomycorrhizal inoculants to roots can substantially (50% or more) enhance establishment and early growth of woody perennial horticultural crops. How can fine tuning the use of mycorrhizal inoculants to make organic nursery stock production easier and more profitable, thereby helping to close the demand/supply gap? Research centered on development of practical organic methods for the nursery industry to implement is needed, including:

- Disease and insect control materials that are allowed under organic standards and may be accepted under specific phytosanitary regulatory requirements.
- New materials for controlling pests addressed by phytosanitary rules that show promise of compatibility with National List review criteria.
- Alternative protocols for phytosanitary certification of nursery stock that are based on outcomes (such as testing or inspection) rather than requirements for use of synthetic materials during production.

7. Management and Control of Invasive Insects and Weeds - There is a large pool of research on the control of insects and diseases using organic methods. Many controls use a systems approach and are quite effective. The introduction of new invasive species into cropping systems threatens these systems approaches, and in several cases the organic control options are very limited or nonexistent. For example, spotted wing drosophila is a relatively recent invasive insect that infests soft fruits, such as berries, and many other fruits as well. Infestation renders fruit unusable since insect larvae feed inside the fruit and may reach critical levels before fruit is harvested. This insect is particularly problematic in that it has the ability to oviposit in green fruit, and it has multiple generations throughout the summer, creating an extensive control period. There is only one control material available, and it is in danger of overuse. The control period may also extend so long that maximum label rates are used before the season ends. A second invasive insect is brown marmorated stinkbug, and currently there are no organic control measures beyond attempts at mass trapping. Research into organic control options for both these invasive pests, and others, is critical so that organic growers can integrate controls into their

organic systems. Prevention is critical. Because invasive insect species lack native predators, the organic community needs more information on their biology in order to implement prevention strategies before they become established and are more difficult to control.

Weeds pose one of the greatest barriers to successful organic crop production. Invasive weeds include exotic species that aggressively displace both crops and native plant species, as well as creeping perennial species (exotic or native) that are difficult to control without repeated, intensive tillage. The NOP standards require certified organic producers to use tillage and cultivation practices that maintain or improve soil conditions. Development of integrated, organic management strategies that effectively control invasive weeds without excessive tillage continues to emerge as a top research priority for organic producers.

8. Nutritional Value of Organic Crops - How do organic soil health and fertility practices—crop rotations, cover crops, compost and other organic or natural mineral amendments, etc. — affect the nutritional value or “nutrient density” of organically produced crops? How do organic production and shipping methods (including methods of production, handling, and time in transport) influence the nutritional quality, taste, palatability, and ultimately preference for organic vegetables and fruits? There is a lack of sound, rigorously conducted studies of this kind. How can growers and handlers retain nutrition through post-harvest handling and transportation? Additionally, can providing organic producers information on soil biology and soil nutrient composition help improve nutrition? Finally, more studies are needed examining how organic crops compare to conventional crops with regards to nutritional value.

9. Side-by-Side Efficacy Comparisons Between National List Allowed and Petitioned Synthetic Inputs Versus Non-synthetic Alternative Inputs or Practices - During its five-year review of sunset materials on the National List and in the evaluation of newly petitioned materials, the NOSB often lacks sufficient information of the effectiveness of these materials as compared with other synthetics on the National List, natural materials, and cultural methods. Side-by-side trials with approved organic inputs, both synthetic and natural, and cultural methods to evaluate efficacy would strengthen the review process and provide growers with valuable information in pest and disease management decisions. The NOSB specifically requests collaboration with the Minor Crop Pest Management Program Interregional Research Project #4 (IR4) to include materials on the National List in their product trials. Such studies would help inform the NOSB review process of sunset materials and to determine if materials are sufficiently effective for their intended purpose, particularly when weighed against the natural and cultural alternatives. It should be noted that growers commonly rely on a mix of cultural practices and both non-synthetic materials and materials from the National List to produce crops of marketable quality and sufficient yield for profitability; it is understood that such studies would serve as a starting point and would form part of the comprehensive material review process.

10. Evaluation of Microbial Inoculants, Soil Conditioners, and Other Amendments – Vendors of organic amendments now offer a large and growing array of microbial inoculants, organic soil conditioners, and other materials claimed to improve soil health, crop vigor and quality, and combat weeds, pests and diseases. There is an urgent need for impartial evaluation of these materials to help producers decide which products to use and to avoid unnecessary expenditures on products that are unlikely to yield benefits.

11. Pathogen Prevention - Third-party food safety auditors believe that some biodiversity-maintenance strategies employed by organic farmers may increase the risk for introduction of human pathogens on the field. While some research has been conducted disproving this hypothesis, more research,

extension, and education are needed to fully understand the relationship between on-farm biodiversity and food safety – and this research must be communicated to third-party food safety auditors and incorporated into their audits.

12. Climate Change (Reducing Greenhouse Emissions and Sequestering Carbon) - A growing body of research demonstrates that organic farming can help prevent anthropomorphic climate change, and some strategies employed by organic farming can also help with resilience to current climate challenges such as drought and flooding. Although a number of researchers are examining this issue, additional work is needed to pinpoint specific strategies that organic farmers can take to reduce greenhouse gas emissions and respond to current climate challenges threatening the future of our food security.

Handling

1. Chlorine Materials and Alternatives - Chlorine materials currently allowed for use in organic agriculture are widely used in farming and handling to clean and disinfect equipment, surfaces, and produce. There have been some concerns raised about these materials and their impact on the environment and human health when/or if they form trihalomethanes and other toxic compounds. Chlorine materials are also acutely toxic to workers. New sanitizers and disinfectants are regularly petitioned to the NOSB for addition to the National List. FDA regulations on food safety (Food Safety Modernization Act) and best management practices for cleaning in handling operations both require a suitable level of cleanliness and disinfection to prevent pathogens from entering the food supply.

Producers and handlers are looking for alternatives to chlorine while continuing to provide a safe end-product to their customers and the consumer. Addressing food safety while adhering to the fundamental organic principles involving human health and environmental impact is a concern.

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

Points of consideration for future research activities:

- Comparison of alternatives to chlorine such as: citric acid, hydrogen peroxide, ethanol, isopropanol, peracetic acid, and ozone. How would each compare to the different chlorine materials for specific uses? The strengths and weaknesses would need to be considered.
- Potential human health and environmental impacts of each chlorine material versus the possible alternative materials listed above. Are there ways that these impacts can be mitigated and still allow the material to work as needed?
- Determination of which of the above-mentioned alternatives would NOT be a suitable substitute for chlorine. What specific uses and/or conditions would this apply to?
- Identification of practices that could be used to help reduce the formation of trihalomethanes in those specific situations where chlorine is the best material to use.
- Could the rotation of materials for cleaning and disinfecting help lower the risks from chlorine materials and still be effective in providing the desired control of pathogens?
- Research on the absorption of chlorine by produce from its use in wash tanks, including information about the amount of time of exposure, would help inform understanding of human exposure to chlorine and health risks. Are residues from produce washing a persistent residual effect or temporary (if temporary – how long is it a viable residue), and would it be harmful if consumed at these levels?

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

3. Occupational Health Risks of Chlorine Sanitizers - Chlorine sanitizers pose potential occupational health risks in food handling and processing environments. Given anecdotal reports of health problems associated with exposure to chlorine sanitizers by food workers, the Handling Subcommittee recommends additional research, including monitoring for chlorine breakdown products, chlorine gas, and chloroform in organically certified food handling and processing facilities to quantify worker exposures and health risks.

Materials/GMO

In previous years, the Materials Subcommittee has prioritized the Reduction of Genetically Modified Content of Breeding Lines (2013) and Seed Purity from GMOs (2014), issues which are currently being addressed through a comprehensive stream of work on Excluded Methods. The following research priorities are among the areas that the Excluded Methods work continues to elevate:

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

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

3. Assess the Genetic Integrity of Organic Crops At Risk - Develop then implement methods of assessing the genetic integrity of crops at risk to quantify the current state of the organic and conventionally produced non-GMO seed. Such assessments are needed on the front (seed purchased by farmers) and back end (seed harvested from a farmer's field) of the production chain as well as on points of contamination in the production chain.

4. Prevention of GMO Crop Contamination: Evaluation of effectiveness - How well are some of the prevention strategies proposed by the NOSB working to keep GMOs out of organic crops? For instance, how many rows of buffer are needed for corn? How fast does contamination percentage go up or down if there are more or fewer buffer rows? Other examples could be whether cleanout of combines and hauling vehicles reduces contamination using typical protocols for organic cleaning, whether situating at-risk crop fields upwind from GMO crops can reduce contamination, and what the role may be of pollinators in spreading GMO pollen. Lastly, research is needed on a mechanism to provide conventional growers incentives to take their own prevention measures to prevent pollen drift and its impact on

organic and identity-preserved crops. This is policy research rather than field research but is equally as important.

5. Testing for Fraud: Developing and implementing new technologies and practices New technologies, tests, and methodologies are needed to differentiate organic crop production from conventional production to detect and deter fraud. Testing to differentiate conventional and organic livestock products, for example omega 3 or other indicators, is also needed. Additional tools to identify fraudulent processed and raw organic crops require research to combat this problem. Current methodologies include pesticide residue testing, in field soil chemical analysis, and GMO testing. Areas in need of further testing methodology include phostoxin residues, fumigant residues, carbon isotope rations for traceability, validating nitrogen sources using nitrogen isotope rations, or other experimental testing instruments that can be utilized to distinguish organic raw and/or processed crops from conventional items. Additionally, there is a need to develop rapid detection technologies for adaptation to field-testing capacities.

General

1. Increasing Access to Organic Foods - What factors influence access to organically produced foods? Individual-based studies are needed to assess the constraints to accessing to organic food. Research should be funded that builds on an understanding of constraints by asking what community, market, and policy-based incentives would enhance access to organic foods.

2. Barriers to Transitioning to Organic Production - What are the specific production barriers and/or yield barriers that farmers face during the three-year transition period to organic? Statistical analysis of what to expect economically during the transition is needed to help transitioning growers prepare and successfully complete the transition process.

Questions to Our Stakeholders

During the Fall 2020 comment period, stakeholders identified several additional items for consideration as research priorities, on which, the Materials Subcommittee is seeking further input from the community.

Should the following items be considered by the NOSB for inclusion in its proposal on 2021 research priorities?

- Research into the economics of organic livestock more broadly as producers continue to face difficult economic circumstances, including challenges with access to meat processing, varying price premiums, and high cost of feed
- Research into the effects of organic crop production on water
- Research into novel ammonia inputs, their field-level impact in organic systems, and their traceability and vulnerability to fraud
- Benefits and risks of livestock integration into crop rotations
- Nutritional value of organic animal products (such as dairy, meat, and eggs)
- Comparisons of pesticide, antibiotic, and synthetic growth hormone residues in organic and conventional products

Subcommittee Vote:

Motion to accept the discussion document on the 2021 NOSB Research Priorities

Motion by: Wood Turner

Seconded by: Steve Ela

Yes: 6 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Wood Turner, Materials Subcommittee Chair, to transmit to NOSB, February 12, 2021

National Organic Standards Board
Materials/GMO Subcommittee Discussion Document
Excluded Methods Determinations Spring 2021
February 12, 2021

Introduction and background

Organic originators, stakeholders, producers, consumers, and many iterations of the NOSB have operated under the consensus that, at its foundation, the USDA's National Organic Program (NOP) requires food labeled as organic to be produced without the use of genetic manipulation. Developments in biotechnology continue to spread across the food system, touching all points of the supply chain. To address these changes, the NOSB is working to examine, track, and define excluded methods as part of the effort to maintain the mandates of the USDA's organic regulations.

Until the US Food and Drug Administration (FDA) & the US Department of Agriculture (USDA) provide transparency in the effort to track and inform the public on the presence of genetic engineering in the food system, the NOSB will engage expertise from the community at large, to maintain a foundational principle of organic: that GMOs are a transgression on the integrity of the entire organic supply chain from cell to table. As stakeholders in the democracy of food and agriculture, this discussion document seeks to articulate current understanding, while expanding the communities' tools for protecting the integrity of the organic label from excluded methods.

Goals of this document

This discussion document continues the work of identifying emerging technologies in the food sector and determining whether they will be considered excluded methods in the organic system. At the same time, this document seeks to re-establish the community's understanding of the rapidly expanding presence of biotechnology directly in the food system and transiently as technology is being applied farther and farther up the supply chain.

The Materials Subcommittee recognizes the topic of genetic engineering and evaluation of excluded methods will remain on our work agenda. It is recognized that additional criteria may become necessary as the field of genetic manipulation expands. As a process based regulatory framework, organic does not rely only on testing to determine the presence of prohibited materials. The community consensus recognizes that awareness of emerging technologies along with a well-educated community of producers, inspectors, NOSB members, and regulators, is currently, the most efficient and reliable path to protecting organic as a food sector that prohibits the breaching of the integrity of the genome.

Definitions and Criteria

Under the NOP organic regulations, methods that employ genetic engineering techniques are excluded from use in organic production. The current regulation defines an excluded method at §205.2 Terms defined:

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.

Below are the criteria listed in the 2016 (Appendix A), 2017, 2018 and 2019 NOSB recommendations to determine if methods should be excluded.

1. The genome is respected as an indivisible entity, and technical/physical insertion, deletions, or rearrangements in the genome is refrained from (e.g. through transmission of isolated DNA, RNA, or proteins). In vitro nucleic acid techniques are considered to be an invasion into the plant genome.
2. The ability of a variety to reproduce in a species-specific manner has to be maintained, and genetic use restriction technologies are refrained from (e.g. Terminator technology).
3. Novel proteins and other molecules produced from modern biotechnology must be prevented from being introduced into the agro-ecosystem and into the organic food supply.
4. The exchange of genetic resources is encouraged. In order to ensure farmers have a legal avenue to save seed and plant breeders have access to germplasm for research and developing new varieties, the application of restrictive intellectual property protection (e.g., utility patents and licensing agreements that restrict such uses to living organisms, their metabolites, gene sequences, or breeding processes) are refrained from.

The NOSB has voted on the following and determined them to be excluded methods:

Method and synonyms	Types	Excluded Methods	Criteria Applied	Notes
Targeted genetic modification (TagMo) syn. Synthetic gene technologies syn. Genome engineering syn. Gene editing syn. Gene targeting	Sequence-specific nucleases (SSNs) Meganucleases Zinc finger nuclease (ZFN) Mutagenesis via Oligonucleotides CRISPR-Cas system (Clustered regularly interspaced short palindromic repeats) and associated protein genes TALENs (Transcription activator-like effector nucleases) Oligonucleotide directed mutagenesis (ODM) Rapid Trait Development System	YES	1, 3, 4	Most of these new techniques are not regulated by USDA and are currently difficult to determine through testing.

Method and synonyms	Types	Excluded Methods	Criteria Applied	Notes
Gene Silencing	RNA-dependent DNA methylation (RdDM) Silencing via RNAi pathway RNAi pesticides	YES	1, 2, 4	
Accelerated plant breeding techniques	Reverse Breeding Genome Elimination FasTrack Fast flowering	YES	1, 2, 4	These may pose an enforcement problem for organics because they are not detectable in tests.
Synthetic Biology	Creating new DNA sequences Synthetic chromosomes Engineered biological functions and systems	YES	1, 3, 4	
Cloned animals and offspring	Somatic nuclear transfer	YES	1, 3	
Plastid transformation		YES	1, 3, 4	
Cisgenesis	The gene modification of a recipient plant with a natural gene from a crossable-sexually compatible-plant. The introduced gene includes its introns and is flanked by its native promoter and terminator in the normal-sense orientation.	YES	1, 3, 4	Even though the genetic manipulation may be within the same species; this method of gene insertion can create characteristics that are not possible within that individual with natural processes and can have unintended consequences.
Intragenesis	The full or partial coding of DNA sequences of genes originating from the sexually compatible gene pool of the recipient plant and arranged in sense or antisense orientation. In addition, the promoter, spacer, and terminator may originate from a sexually compatible gene pool of the recipient plant.	YES	1, 3, 4	Even though the genetic manipulation may be within the same species, this method of gene rearrangement can create characteristics that are not possible within that individual with natural processes and can have unintended consequences.

Method and synonyms	Types	Excluded Methods	Criteria Applied	Notes
Agro-infiltration		YES	1, 3, 4	<i>In vitro</i> nucleic acids are introduced to plant leaves to be infiltrated into them. The resulting plants could not have been achieved through natural processes and are a manipulation of the genetic code within the nucleus of the organism.
Transposons- Developed via use of in vitro nucleic acid techniques		YES	1,3,4	Does not include transposons developed through environmental stress such as heat, drought or cold.
Induced Mutagenesis		YES	1	Developed through in vitro nucleic acid techniques does not include mutagenesis developed through exposure to UV light, chemicals, irradiation, or other stress-causing activities.

The following genetic engineering methods were found by the NOSB NOT to be excluded methods:

Method and synonyms	Types	Excluded Methods	Criteria Applied	Notes
Marker Assisted Selection		NO		
Transduction		NO		
Embryo rescue in plants		NO		IFOAM's 2018 position paper on Techniques in Organic Systems considers this technique compatible with organic systems.
Embryo transfer, or embryo rescue, in animals		NO		*use of hormones not allowed in recipient animals.
Transposons		NO		Developed through environmental stress, such as heat, drought, or cold.

The following TBD methods will continue to be researched in future NOSB proposals:

Terminology				
Method and synonyms	Types	Excluded Methods	Criteria Used	Notes
Protoplast Fusion		<i>TBD</i>		There are many ways to achieve protoplast fusion, and until the criteria about cell wall integrity are discussed and developed, these technologies cannot yet be evaluated.
Cell Fusion within Plant Family		<i>TBD</i>		Subject of an NOP memo in 2013. The Crops Subcommittee will continue to explore the issue.
TILLING	Eco-TILLING	<i>TBD</i>		Stands for “Targeted Induced Local Lesions In Genomes.” It is a type of mutagenesis.
Doubled Haploid Technology (DHT)		<i>TBD</i>		There are several ways to make double haploids, and some do not involve genetic engineering while some do. It is difficult or impossible to detect DHT with tests.
Induced Mutagenesis		<i>TBD</i>		Induced mutagenesis developed through exposure to UV light, chemicals, irradiation or other stress.
Transposons		<i>TBD</i>		Produced from chemicals, ultraviolet radiation, or other synthetic activities.

Discussion

The NOSB is seeking answers to the following questions to aid in creating guidance and/or regulation on excluded methods.

Questions

1. What new emerging methods in biotech should be added to the TBD list? Please also describe the primary purpose and how far from commercialization for use in food processing and/or agriculture the method is in its development.
2. Please prioritize the remaining TBD list methods according to the definitions, principles and criteria established in the 2016 Proposal (see Appendix A)
 - a. Would methods newly determined to be excluded by the NOSB/NOP be retroactive for commercial varieties already in the marketplace?
 - b. Should the NOSB grandfather in methods that have long been used in organic plant breeding (e.g., double haploids) and focus its energy entirely on new and emerging technologies?
 - c. How do we regulate technologies used to develop new seed varieties that companies are otherwise under no obligation to disclose?
3. Are unintentional excluded methods hiding in organic systems when the actual material produced and used has no trace of excluded method in the final organic product? Do we have the inspection, testing, and enforcement tools to keep prohibited methods out of the organic marketplace?
4. Given the lack of transparency around emerging technology entering food and agricultural systems, how can Organic producers, handlers, certifiers, and this Board, etc. stay educated on emerging methods and the potential for contamination?

Subcommittee Vote:

Motion to accept the discussion document on Excluded Methods

Motion by: Mindee Jeffery

Seconded by: Brian Caldwell

Yes: 6 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Wood Turner, Materials Subcommittee Chair, to transmit to NOSB, February 12, 2021

Appendix A

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

Date: November 18, 2016

Subject: Excluded Methods Terminology Recommendation

NOSB Chair: Tracy Favre

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement: X

Other:

Statement of the Recommendation:

The NOSB Materials/GMO subcommittee approves the three sections of this proposal:

1. Approve the definitions of Genetic Engineering (GE), Genetically Modified Organism (GMO), Modern Biotechnology, Synthetic Biology, Non-GMO, and Classical/Traditional Plant Breeding as written above.
2. Approve the Principles and Criteria above that will be used in the evaluation of new technologies and terminologies.
3. Adopt the Terminology chart proposed above and the listings in it as presented, with the removal of the Dupont Seed Production Technology term, recognizing that this will be added to as further deliberations occur in the future.

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

Excluded Methods are prohibited in the USDA organic regulations, but the definition in the regulation that was adopted in 1995 needs updating in light of new technologies and processes. The NOSB recommends that this set of supplemental definitions, criteria for review of new technologies, and terms that are included in the definition of excluded methods, be addressed in guidance on interpreting the excluded methods provision in the regulations.

NOSB Vote:

Motion by: Zea Sonnabend

Seconded by: Emily Oakley |

Yes: 14 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Motion Passed

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

Introduction and Background

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

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

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

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

The first NOSB Discussion Document on excluded methods in 2013,¹ discussed each of the terms in the above definition, defined and discussed other terms involved in traditional breeding, such as

mutagenesis and conjugation, and brought up new terms that may be considered to be genetic engineering. No conclusions were suggested except that there is a need to do more work on the subject. The discussion questions posed asked commenters to suggest principles on which to base GE distinctions, to offer opinions on what terms were and were not excluded methods, and to bring forward new terms that may need consideration.

The second NOSB discussion document posted in September 2014 and in April 2015² analyzed the comments received and proposed several options for an updated definition, and principles and criteria to use when evaluating the various genetic modification issues. Additional terms were collected and the beginnings of some definitions were started. A structure was proposed similar to the one in use by the Research Institute of Organic Agriculture (FiBL) in Europe that involves an itemized chart with a yes/no column where the specific techniques could be itemized and evaluated. The Subcommittee made an informal recommendation, which was not voted upon, that these revisions to the definition and structure for evaluating techniques be regulated through NOP guidance rather than additional rulemaking. Lastly it was acknowledged that there will be some unresolved issues that will need continued public discussion because they pose enforcement challenges, are totally hidden from view, or not enough is known about them yet.

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

Goals of This Proposal/Document

The need for forward motion on this subject is more pressing every month. The fact that over 1000 pages of scientific references were submitted in public comment, with most of it consisting of research published since the NOSB GMO ad hoc Subcommittee was formed in 2012, indicates that the biotech community is rapidly outpacing any regulatory structure. The U.S. Department of Agriculture (USDA) has already ruled that certain plants produced with novel approaches to genetic manipulation will not be regulated in the United States³ as genetically modified organisms. It is more imperative than ever that the organic community be very clear about where the line is drawn regarding genetic engineering.

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

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

A separate discussion document contains the technologies, terms, and issues that the NOSB has not been able to agree on or on which it does not yet have enough information, or that pose challenges that have not yet been addressed. These items are put forth for discussion to collect further public

comment and will be reviewed at future NOSB meetings.

Definitions

In the previous discussion document, the NOSB suggested a couple of possible definitions that would update the text in the rule to be more comprehensive and be flexible enough to accommodate future technologies and terms. The Board favors the definitions in use by Codex Alimentarius that were also in the Cartagena Protocol.

During the course of public comment and subsequent discussion, it has become clear that more than one definition is important to the organic community, but that all the terms the NOSB suggests defining here would fall under the Excluded Methods definition in the rule and would not change, but would strengthen that definition. These definitions are to be used in guidance to supplement and update the definition in the regulations, while leaving the rule itself intact. It is important to adopt some definitions that are widely accepted internationally and thus provide common ground with other countries who are concerned about GMOs in organics.

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

In October 2015 the International Federation of Organic Agriculture Movements (IFOAM) published a Discussion Paper on a proposed revision to their Position on Genetic Engineering.⁴⁵ Since other countries do not use the concept of "Excluded Methods", IFOAM proposed new definitions for three terms: Genetic Engineering (GE), Genetically Modified Organism (GMO), and Synthetic Biology. After examining their definitions, the Materials/GMO Subcommittee (MS) agrees that these three terms are important to define in the guidance it are proposing. However, we do not wish to use the old approach (that IFOAM is still using) of trying to capture all the methods and terms into one definition, in because it will be out of date as soon as the next round of new technologies arrives.

Instead we are proposing that the following definitions of terms and acronyms, with sources, be adopted by the NOSB as Excluded Methods¹:

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

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

Modern Biotechnology – (i) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family, that overcomes natural, physiological reproductive or recombination barriers, and that are not techniques used in traditional breeding and selection. (From Codex Alimentarius⁶)

Synthetic Biology⁷ – A further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems. (Operational Definition developed by the Ad Hoc Technical Expert Group on Synthetic Biology of the UN Convention on Biological Diversity⁸)

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

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

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

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

Principles and Criteria

The NOSB has its own set of Principles of Organic Production and Handling in its Policy and Procedures Manual⁹. The principles start with:

- 1.1 Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that

regional conditions require locally adapted systems. These goals are met, where possible, through the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system.

Regarding Genetic Engineering:

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

The following principals of Organic Agriculture are used by IFOAM¹⁰ and summarize well the guidance for developing a position on GMO technology.

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

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

1. The genome is respected as an indivisible entity and technical/physical insertion, deletions, or rearrangements in the genome is refrained from (e.g. through transmission of isolated DNA, RNA, or proteins). *In vitro* nucleic acid techniques are considered to be invasion into the plant genome.
2. The ability of a variety to reproduce in species-specific manner has to be maintained and genetic use restriction technologies are refrained from (e.g. Terminator technology).¹¹
3. Novel proteins and other molecules produced from modern biotechnology must be prevented from being introduced into the agro-ecosystem and into the organic food supply.
4. The exchange of genetic resources is encouraged. In order to ensure farmers have a legal avenue to save seed and plant breeders have access to germplasm for research and developing new varieties, the application of restrictive intellectual property protection (e.g., utility patents and licensing agreements that restrict such uses to living organisms, their metabolites, gene sequences or breeding processes are refrained from.¹²

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

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

Process and Product

Since the whole underpinning of the U.S. organic regulations is a process-based system, it makes sense that this concept carry over to defining excluded methods. This is indeed the basis of the current definition. However, this is not currently how U.S. government agencies regulate GMOs¹⁴, or handle other issues such as pesticide residues or water quality standards.

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

Forward Movement towards Structure

FiBL Research Institute for Organic Agriculture from Switzerland submitted a comment in 2013 that included a chart that describes methods with a yes/no column for compatibility with organic standards for both plants and animals¹⁶. The NOSB posed adopting such a chart on the methods that receive consensus and can be incorporated into guidance. It is important to identify all these terms so that it is clear that they fall under the definition of excluded methods, but these terms do not need to be added to the definition itself.

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

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

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

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

Terminology Chart				
Method and synonyms	Types	Excluded Methods	Criteria Applied	Notes
Plastid Transformation		YES	1, 3, 4	
Marker Assisted Selection		NO		
Transduction		NO		

* CRISPR-Cas = Clustered regularly interspaced short palindromic repeats and associated protein genes.

** TALENs = Transcription activator-like effector nucleases.

Proposal

This proposal has three sections, to be used in NOP guidance on excluded methods:

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

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

Appendix A –

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

Only terms that are marked YES or NO as Excluded Methods are defined here. All those marked TBD are still being worked on in discussion. Those marked "syn." are defined in cited reference from Center for Food Safety Public Comment in April 2015¹⁸. Some other definitions are from the NOSB previous discussion document¹⁹ and from the FiBL 2015 plant breeding dossier.²⁰

Targeted genetic modification (TaqMo) (Kuzma and Kokotovich 2011, Kokotovich and Kuzma 2014) - a collective term for the zinc finger nuclease techniques that create DNA double-stranded breaks at specific genomic locations that can then be used to alter the target gene. The genetic

modification would not necessarily involve transfer of nucleic acids from another species, nor would it be easy to detect in a final product.

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

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

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

Accelerated Plant Breeding Techniques

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

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

Synthetic Biology (see definition in main document)

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

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

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

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

¹ NOSB 2013. Excluded Methods Terminology Discussion Document. April 2013.

<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5102656>

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

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

⁴ IFOAM – Organics International, 2015, 2015 Discussion Paper on a Proposed Revision to Position on Genetic Engineering and Genetically Modified Organisms in Organic Agriculture.
https://gallery.mailchimp.com/75bdff144a46c1e451eecd10/files/Discussion_paper_on_GMO_position_2015.pdf ⁵ IFOAM – Organics International, 2002, Position on Genetic Engineering and Genetically Modified Organisms, P01,

https://gallery.mailchimp.com/75bdff144a46c1e451eecd10/files/IFOAM_GMO_Position_Paper.pdf

⁶ Codex Alimentarius Commission (2003). "Principles for the Risk Analysis of Foods Derived from Modern Biotechnology," *CAC/GL 44>2003*. Amended 2008, 2011, *available at*:

http://www.fao.org/faoDwhoDcodexalimentarius/shDproxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCAC%2BGL%2B44D2003%252FCXG_044e.pdf.

⁷ Two other definitions were looked at when this one was chosen: **Synthetic Biology** – Designing and constructing biological devices, biological systems, biological machines and biological organisms using a range of methods derived from molecular biology and biotechnology, including in virtually all cases

the techniques of genetic engineering or genetic modification. (From IFOAM Position cited above).

Synthetic biology is a maturing scientific discipline that combines science and engineering in order to design and build novel biological functions and systems. This includes the design and construction of new biological parts, devices, and systems...as well as the re-design of existing, natural biological systems for useful purposes.” (from SynBerc, the University of California/Department of Energy synthetic biology research consortium)

⁸ Link to the European Commission's draft definition with discussion:

http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihr_consultation_21_en.htm

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

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

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

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

¹³ IFOAM – Organics International, 2015, 2015 Discussion Paper on a Proposed Revision to Position on Genetic Engineering and Genetically Modified Organisms in Organic Agriculture.

https://gallery.mailchimp.com/75bdf144a46c1e451eecd10/files/Discussion_paper_on_GMO_position_2015.pdf ¹⁴ Kuzma J, Kokotovich A (2011) Renegotiating GM crop regulation. *EMBO reports* 12: 883–888.

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

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

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

¹⁸ CFS Comments to the NOSB, 2015. Reference List.

<http://www.regulations.gov/#!documentDetail;D=AMS-NOP-15-0002-0875>

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

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