National Organic Standards Board Meeting
October 13 & 14 (Comment webinars), and October 19 - 21, 2021 (NOSB meeting)

PLEASE NOTE:
Discussion documents, proposals, reports and/or other documents prepared by the National Organic Standards Board, including its subcommittees and task forces, represent the views of the National Organic Standards Board and do not necessarily represent the views and policies of the Department of Agriculture. Please see the NOP website for official NOP policy, regulations, guidance and instructions.

National Organic Standards Board
Compliance, Accreditation, and Certification Subcommittee (CACS)
Proposal - Letter to Secretary Vilsack regarding USDA Climate Change Initiatives
August 10, 2021

Secretary of Agriculture
US Department of Agriculture
Washington, DC 20250

Subject: USDA Climate Change Initiatives

Dear Secretary Vilsack,

The climate focus of USDA is an encouraging step forward for the U.S., as scientific research provides evidence for the ability of agriculture to help mitigate climate change. As members of the National Organic Standards Board, the federal advisory committee to the National Organic Program, and our stakeholders who commented on this document during the October 2021 public meeting, we want you to know that we are wholly supportive of USDA engaging agriculture as a tool for mitigating climate change.

Organic farming systems have significant potential to contribute to climate change solutions through both avenues, by emitting fewer GHGs and carbon sequestration by healthy soils under organic management. The 90 Day Progress report, dated May 2021, fails to mention the potential contributions to climate change mitigation that certified organic production systems may offer. We believe this is a grave omission that USDA needs to rectify as concrete plans for the department's climate change strategies are developed. Furthermore, the National Organic Program is already well established at USDA. Rather than reinventing the wheel, we urge USDA to leverage organic agriculture as the department moves forward to incorporate climate smart strategies into U.S. agriculture.

The extant body of research provides strong support that organic farming systems emit lower levels of GHG. Organic agriculture does not rely on synthetic inputs,[1] and when paired with good organic farming practices, an organic farm emits fewer GHGs. Concerns have been raised that, since organic field crop yields are below those of conventional crop yields, the net GHG 'footprint' per unit production may not be lower than that of conventional farming (Lee et al., 2015; McGee, 2015). That said, some of the farmers on the NOSB report achieving yields equivalent to those realized on conventional farms, indicating that yield differentials are crop and location specific. Research supports the experience of the NOSB farmers, and finds that an overall reduction in GHG emissions, due to the widespread adoption of organic farming systems, is possible (Muller et al., 2017; Skinner et al., 2019; Squalli and Adamkiewicz, 2018).

While soils under organic management have more soil organic matter, there are numerous problems that make it difficult to definitively tie the higher soil organic matter to increased carbon sequestration. These challenges are related to measurement, testing, and understanding which types of soil organic

[1] Synthetic inputs are disallowed unless included on the National List; environmental impact is one factor considered prior to the inclusion of a synthetic input. Note that the majority of inputs used on a certified organic farm are non-synthetic.

carbon are best able to sequester carbon (OFRF, 2018). Other obstacles identified include the lengthy time period required to build soil organic carbon, the reduced yields of some organic systems,[2] and lack of technical assistance for organic farming systems in many areas of the country. We encourage additional research on this important topic.

Nevertheless, research finding that organic farms produce fewer GHG emissions, coupled with the research showing that regenerative organic practices build soil carbon, should lead USDA to emphasize organic as a climate mitigation centerpiece as research continues. Organic farms start from the vantage of having higher soil organic carbon, as research has consistently shown, suggesting that there is potential for these farms to contribute to climate change mitigation. We believe that USDA should support research and other efforts to improve our understanding of the potential contribution of organic farming systems to climate change mitigation.

Furthermore, the higher levels of soil organic matter allow farmers to better cope with the extreme weather associated with climate change (Bellprat *et al.* 2019). Soil under organic management offers benefits such as higher water holding capacity, more filtration, and less erosion, which helps ensures a food supply amongst increasingly irregular drought and flooding conditions. Recent research is helping to narrow down which organic practices are better at promoting soil health (Tully and McAskill 2019).

We have direct responses to several points made in the 90 Day Progress Report:

- *Support new and better markets* (page 9): The organic market is already thriving, with organic food retail sales exceeding $56 billion in 2020 as reported by OTA. Prioritizing transition-to-organic market development is strongly encouraged to continue to remove barriers for producers choosing to convert to organic production. Overall, a greater reliance on certified organic products in the climate smart strategy would solve the 'finding a market' for environmentally friendly food and agricultural products, and investing federal funds into further developing the domestic organic market is likely to have a sizeable impact.
- *Education and technical assistance* (page 8): There is just one extension agent in the US who works exclusively with organic producers. Increasing the number of trained organic extension agents, housed at land grant universities, would provide producers with important technical assistance and education. Better technical assistance would help organic producers manage their risk and help farmers identify best organic farming practices.
- *Leverage existing USDA programs to support CSAF strategies* (page 6): Prioritize updating Risk Management Agency (RMA) programs, including adjusting actuarial data for transition and organic t-yields. Additionally, adjust RMA programs by allowing innovative production practices to be eligible for risk management insurance for those in transition, certified organic, and other climate-smart producers. All organic farmers, including those newly certified, *need equal access to federally subsidized crop insurance and other incentives*, on the same scale and scope as those available to non-organic farmers.
- *Strengthen the role of USDA climate hubs* (page 8): Each USDA climate hub should have at least one researcher with organic production as a key part of their research portfolio.
- *Increased research Comment 1* (page 13): More research is needed to understand the organic-conventional yield gap, by crop and by location. For some crops in some locations, the gap is nonexistent or minimal, and for others it is larger. This key area has not been adequately examined. Additional investment in the NASS/ERS data collection of the Agricultural Resource

[2] Depending on crop, yields may be lower on organic farms, whereas for other crops, yields are equivalent to those obtained via conventional production.

Management Survey for more complete coverage of organic crops is a great way to leverage and enhance existing USDA resources.

- *Increased research Comment 2* (page 13): Closing any existing organic-conventional yield gap is an important component of reducing GHG emissions of organic systems, particularly when measured in terms of pound or kilo of product grown. Historically, the US lacks a sufficient investment in organic agricultural research and into crop cultivars well-adapted to climate-friendly organic production systems (Hultengren et al., 2016; Ponisio et al, 2014). Thus, we suggest developing specific seed varieties for organic crops, improving organic farm weed mitigation through technology, no-till/ minimum till practices, cover cropping and other innovations specifically targeting organic systems can close the organic-conventional yield gap and reduce input dependency, leaving organic systems as better climate mitigators. This work should be done by ARS scientists and university researchers (through NIFA funding).
- *Supporting research and data collection* (page 4): We encourage USDA to invest in data collection on soil organic matter and its ability to sequester carbon. The data collection needs to take place over long time periods, to see how carbon sequestration changes as soil health improves. Additionally, research identifying 'early indicators' of soil health would allow organic farmers to understand whether their soil is on an optimal trajectory for building soil health. Sites for this type of research are the existing long term cropping system trials and working organic farms. At least some of the data collected should be from farms at the beginning of the transition period.
- *Integrate climate smart strategies into existing conservation program*s (page 9): expanding access of organic farmers (an existing USDA program) for conservation programs would better support the economic health of organic farms.
- *Transition payments*, which would provide support to farmers during the critical transition period when risks are high, yields and revenues typically decline, would help farmers adopt organic farming systems. However, these payments should go to farmers who are transitioning into sectors that are able to support a greater number of operations, as economic viability is a critical aspect to a healthy organic farming sector. Any federal support via a transition payment should be attached to a requirement that the newly transitioned farms obtain organic certification.
- At the same time, as mentioned on page (6), early adopters of organic systems need to be recognized. Allow eligibility for early adopters to have access to current offerings such as RCCP, EQIP, and other programs that are available to encourage continued deployment of these practices on organic farms.

The Organic Foods Production Act (OFPA), 7 U.S.C. §§ 6501-6522, requires that organic farmers *select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.* Furthermore, OFPA requires that organic farmers *Maintain or improve soil organic matter content.* In other words, OFPA codifies regenerative agriculture through the requirements it places on organic farmers to build and maintain soil health.

OFPA further requires investment in soil health on organic farms, which supports climate change mitigation: *An organic plan shall contain provisions designed to foster soil fertility, primarily through the management of the organic content of the soil through proper tillage, crop rotation, and manuring.* (OFPA §6513(b)(1)).

In closing, we stress the importance of explicitly including organic production systems in the climate-smart strategy of the department. We urge you to portray organic farmers and ranchers as models for

climate responsible producers. Then, as the rest of the US agricultural sector moves towards adopting climate-mitigation practices, they can rely on the example of the organic agriculture sector, which is both economically viable and climate friendly in its farming practices.
We would be happy to talk with you or any of your representatives about this important issue.

Best regards,

National Organic Standards Board

Steve Ela, Chair
Sue Baird
Asa Bradman
Jerry D'Amore
Rick Greenwood
Amy Bruch
Brian Caldwell
Kim Huseman
Mindee Jeffery
Nate Powell-Palm
Wood Turner
Kyla Smith
Carolyn Dimitri
Logan Petrey

References

Bellprat, O., Guemas, V., Doblas-Reyes, F. and Donat, M.G., 2019. Towards reliable extreme weather and climate event attribution. *Nature communications*, *10*(1), pp.1-7.

Di Sacco, A., Hardwick, K.A., Blakesley, D., Brancalion, P.H., Breman, E., Cecilio Rebola, L., Chomba, S., Dixon, K., Elliott, S., Ruyonga, G. and Shaw, K., 2021. Ten golden rules for reforestation to optimize carbon sequestration, biodiversity recovery and livelihood benefits. *Global Change Biology*, *27*(7), pp.1328-1348.

Hayek, M.N., Harwatt, H., Ripple, W.J. and Mueller, N.D., 2021. The carbon opportunity cost of animal-sourced food production on land. *Nature Sustainability*, *4*(1), pp.21-24.
IPCC, 2014: *Climate Change 2014: Synthesis Report. Contribution of Working Groups I, II and III to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change* [Core Writing Team, R.K. Pachauri and L.A. Meyer (eds.)]. IPCC, Geneva, Switzerland, 151 pp.

Lee, K.S., Y. C. Choe, and S. H. Park. 2015. *Measuring the environmental effects of organic farming: a meta-analysis of structural variables in empirical research*. J. Environ. Manag. 162, 263–274.

McGee, J.A., 2015. *Does certified organic farming reduce greenhouse gas emissions from agricultural production?* Agric. Hum. Values 32, 255–263.

Muller, A., Schader, C., Scialabba, N.E.H., Brüggemann, J., Isensee, A., Erb, K.H., Smith, P., Klocke, P., Leiber, F., Stolze, M. and Niggli, U., 2017. Strategies for feeding the world more sustainably with organic agriculture. *Nature communications*, *8*(1), pp.1-13.

Organic Farming Research Foundation. 2018. Organic Practices for Climate Mitigation, Adaptation, and Carbon Sequestration. Santa Cruz, CA.

Skinner, C., Gattinger, A., Krauss, M., Krause, H.M., Mayer, J., Van Der Heijden, M.G. and Mäder, P., 2019. The impact of long-term organic farming on soil-derived greenhouse gas emissions. *Scientific reports*, *9*(1), pp.1-10.

Squalli, J. and Adamkiewicz, G., 2018. Organic farming and greenhouse gas emissions: A longitudinal US state-level study. *Journal of Cleaner Production*, *192*, pp.30-42.
Yang, Y., Tilman, D., Furey, G. and Lehman, C., 2019. Soil carbon sequestration accelerated by restoration of grassland biodiversity. *Nature communications*, *10*(1), pp.1-7.

Tully, K.L. and McAskill, C., 2020. Promoting soil health in organically managed systems: a review. *Organic Agriculture*, *10*(3), pp.339-358.

Motion to accept the proposal on the letter to the Secretary re: climate change initiatives
Motion by: Nate Powell-Palm
Seconded by: Kyla Smith
Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Nate Powell-Palm, CAC Subcommittee Chair, to transmit to NOP August 10, 2021.

National Organic Standards Board
Compliance, Accreditation & Certification Subcommittee (CACS)
Oversight Improvements to Deter Fraud:
Modernization of Organic Supply Chain Traceability Discussion Document
August 13, 2021

Background:
This discussion document aims to build on two related topics: Strengthening Organic Enforcement (SOE) (proposed rule) and Human Capital, by seeking input from the organic community on modernizing supply chain traceability to best match the size and scale of today's industry and future needs. While the pending SOE rule pulls the industry forward in many ways, the Compliance, Accreditation & Certification Subcommittee (CACS) is suggesting additional tools such as an electronic organic link system (OLS), which could capture business-to-business sales providing continuity across the supply chain.

The Organic program is a fully traceable food system. When operating at its full potential, products are traceable through the supply chain back to the fields in which the ingredients were grown. It's commendable that stakeholders from across organic sectors were able to collaborate to develop such a robust system. The CACS is seeking stakeholder input as it considers the next steps in modernizing the system.

In 2021, the organic industry exceeded **$60 billion** in sales. While technology has drastically improved since the implementation of OFPA the organic community must acknowledge that the original infrastructure used to track fraud and provide transparency needs to be updated based on today's standards and available technology.

Human Capital and Data Management in Organics:
Inspectors and certifiers do an incredible job maintaining a system using the tools they have. Organic operations undergo annual inspections, and at every annual inspection, organic inspectors test the integrity and traceability of an operation's record-keeping system by conducting a trace-back and mass balance audit. This process ultimately tests record-keeping to see if all products are fully traceable and to confirm there's no evidence of product substitution (conventional for organic). However, this traceability system and the tools inspectors and producers use to verify records and test integrity can be significantly improved with current technological systems.

The decentralized, opt-in system that has sustained the inspection process so far and offered exceptional (for the food industry) transparency is impaired by its decentralization and lack of industry-wide consistency. How one operation proves its system integrity versus another makes the inspection process inconsistent and reliant on the inspector's information on the day of inspection.

Currently, there is not a centralized database to track business-to-business sales and purchases. Also, lack of mandatory reporting to a central database, i.e., the Organic Integrity Database, restricts the ability to glean large, supply chain-wide insights into potential fraud in the organic system. If each business-to-business purchase of ingredients or sales of organic products were recorded and reported to a central database, instances of fraud could be easily identified and addressed. Inspectors would have a way to cross check and reconcile data on both sides of a transaction. In other words, inspectors don't have a tool to check that information reported to them by one operation reconciles with that operation's customers or suppliers.

To address this, the CACS would like to explore the "organic link" concept, a data point, which would show the date, NOP number, lot number, growing year, and quantity of organic goods processed through business-to-business sales.

SOE Defines Four Integral Concepts Providing Guidance for Improvements:

1. *Organic integrity:* The unique attributes that make a product organic and define its status as organic. A product that fully complies with the USDA organic regulations has integrity, and its organic qualities have not been compromised.

2. *Organic fraud:* Intentional deception for illicit economic gain, where non-organic products are labeled, sold, or represented as organic. This may include substitutions or deliberate mislabeling, falsified records, and/or false statements in applications or organic system plans or during inspections, investigations, and audits. (Proposed added term 205.2)

3. *Audit trail:* Documentation that is sufficient to determine the source, transfer of ownership, and transportation of any agricultural product labeled as "100 percent organic," the organic ingredients of any agricultural product labeled as "organic" or "made with organic (specified ingredients)" or the organic ingredients of any agricultural product containing less than 70 percent organic ingredients identified as organic in an ingredients statement (7 CFR 205.2).

4. *Supply chain traceability:* The ability to identify and track a product (including its location, history, and organic nature) along its entire supply chain, from source to consumption and/or "backward" from consumption to the source. A supply chain audit assesses supply chain traceability for specific products, verifying whether records show all movement, transactions, custody, and activities involving the products.

The Strengthening Organic Enforcement proposed rule presents a significant step forward for the industry. By requiring brokers and previously exempt handlers to seek certification, SOE closes significant loopholes for fraud while improving overall system integrity. However, with considerable progress comes the need for comparably powerful tools. The CACS is exploring resiliency of the tools at hand.

Continuous Improvement Exists for Supply Chain Traceability:
The proposed SOE guidelines for improvements are helpful. However, the standard tools that certifiers, inspectors, and the organic community need to improve supply chain traceability are undefined. The SOE proposed rule challenges the organic community to answer the call for continuous improvement post-rule implementation.

Increased inspections and certifications for brokers and previously exempt handlers within the organic supply chain will undoubtedly enhance the system's integrity. Still, suppose these inspections, and all inspections, continue to occur in isolation. In that case, the increased surveillance is left impeded by the inability to glean deeper insights forwards and backwards throughout the supply chain.

Many technologies exist to assist in the process. Electronic systems, digital ledger technology (DLT), blockchain, etc., are being tested or leveraged commercially in the food and agriculture industry. The current form of the proposed SOE rule points to technology as playing an essential role in entire supply chain traceability, fully verifiable organic products, and near-instantaneous tracking at the item level in complex supply chains. Technology will ultimately enhance and support the enforcement of OFPA requirements.

Organic Link System (OLS):
To further build upon the SOE proposed rule, and import certificates, which are a requirement of the SOE proposed rule, the CACS is exploring ways to address the need for additional granularity to verify all sales at a field level and throughout the supply chain. -There can be many landing spots for shelf-stable products like grain, including warehouses, ports, handlers, etc., leading to higher risks of co-mingling or contamination that require additional verification. Therefore, the CACS is suggesting an organic link system (OLS), which could provide an extra level of granularity.

OLS is best defined as an electronic tool that captures registered business-to-business transactions, providing continuity in verification and traceability across the supply chain. OLS could provide a bi-directional look back by certifiers and inspectors involved across the different product exchanges and could prevent sales duplication of a specific parcel or co-mingling organic and non-organic products.

OLS Implementation and SOE Compatibility:
OLS implementation requires that business-to-business transactions be electronically recorded into a centralized database. Specific data to be captured would include the date, NOP certificate number (found on the SOE standardized certificate), year product was grown, the quantity of organic goods exchanged, etc. This critical data would be recorded by businesses (handlers, brokers, importers, etc.) involved in the transactions within the organic supply chain. The information would be accessible to certifiers and inspectors through a variety of different permission levels.

An organic link system allows certifiers and inspectors to conduct bi-directional traceability along the supply chain (source to consumer) more effectively and efficiently. As quoted in the current SOE proposed rule, “We (AMS) anticipate that electronic tracking technologies will allow AMS to achieve its goal of complete supply chain traceability and foresee incorporation of electronic tracking systems into future enforcement strategies.”

Through leveraging the OLS, the amendment put forth in the SOE stating, “Certifying agents must share information with other certifying agents to verify supply chains and conduct investigations (§ 205.501 and § 205.504)” can more easily be accomplished.

Without an OLS, it will be challenging to execute SOE’s requirement for “certifying agents to create fraud prevention procedures to identify high-risk operations, conduct risk-based unannounced inspections, supply chain trace-back and mass-balance audits, and share information with other certifying agents to verify supply chains and conduct investigations.”

Barriers and Solutions for OLS Integration:
In looking at an electronic organic link system (OLS), the organic stakeholder community must identify and help solve barriers that exist or could exist for future technology integration. Three known barriers are as follows:

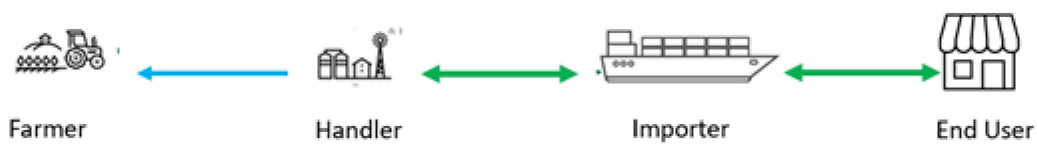
1. **Inadequate access to technology and connectivity:**

Solutions to consider: Accessibility to technology and connectivity doesn't have to become a limiting factor. Specifically, the NOSB recognizes the need to not burden organic farmers, certifiers, or inspectors with additional paperwork. Therefore, the first documented exchange occurs at the point-of-sale from a farmer to their buyer and then each step following. Handlers, brokers, importers, and others involved in business-to-business exchanges will bear the recording responsibilities. Re-positioning the initial point of data capture to the first transaction will provide valuable information for a two-sided look back through the various business-to-business transactions in a complex supply chain.

Since an organic link system is a business-to-business look-back system, producers who sell directly to consumers (i.e., CSA's, direct meat sales, and farmer/processors packaging their goods for sale to customers) would be exempt from this system.

Organic Link System Illustration Example:

1) Handler to Farmer   **2)** Handler to Importer   **3)** Importer to Handler
4) Importer to End User   **5)** End User to Importer



Despite the potential of having various certifiers and inspectors for each of the entities listed below, an organic link system can provide comprehensive verification.

2. **The expense of implementing an electronic system:**

Solutions to consider: The USDA's Organic Integrity database (INTEGRITY) was designed with expansion in mind and will become an even more critical clearinghouse of industry-wide data with the future implementation of the SOE proposed rule. As stated in the SOE, "certifying agents to issue standardized certificates of organic operation generated from INTEGRITY and to keep accurate and current certified operation data in INTEGRITY. This would require an initial upload of mandatory data for each operation and maintenance, at lease annually, to ensure that data in INTEGRITY are current and accurate."

Therefore, standard operating procedures are being implemented and point to further use of technology. Adding additional reporting capabilities to capture transactional level exchanges is the next phase.

3. Human Capital:

Solutions to consider: Public comments at the Spring 2021 NOSB meeting highlighted concerns that certifiers believe organic systems are continuously becoming more complex. In addition to increased numbers of certifications and inspections across the supply chain, the SOE proposed rule states "to facilitate trace-back audits, investigations, and verification, AMS proposes amending the organic regulations to clarify that certifying agents must share information with one another for the purposes of certification and enforcement."

Further developing electronic tools and centralized electronic reporting will aid in enforcement and oversight through more efficiency, not less. The SOE proposed rule captures this sentiment stating, "Standardization will simplify the verification of valid organic certificates and import certificates. It will also reduce reporting, by eliminating the need to provide notices of approval or denial of certification and annual lists of certified operations to USDA."

Without an organic link system or a similar system, a one-way look back is achievable, however, complete supply chain traceability is extremely difficult. With an OLS, dual-process verification of complex supply chains involving multiple certifiers and inspectors can be a reality through leveraging universally recognized certified NOP numbers and other vital data. This data would be available for inspectors to use as an audit framework when conducting inspections on site.

Summary:
Technology integration to further modernize the organic verification and traceability system is fundamental. Creating a system to report transactional data to a centralized database would provide the most significant insights for preventing fraud. The industry can then operate in a pre-competitive space to create a uniform system under which all operations, foreign and domestic, will perform. Therefore, transitioning our current system from process-driven certification to data-driven certification with electronic verification is imperative. Integrating technology to identify fraud in the supply chain quickly is essential, ultimately ensuring a level playing field between all producers, foreign and domestic.

Formalizing technology integration for complete supply chain traceability within the organic system could be incorporated into the 2023 Farm Bill. Technologically driven organic supply chain traceability insures an even playing field. It supports organic growers who are investing in climate-smart farming practices and supports developing rural America.

As discussed in this document, it is imperative to continuously improve and modernize transparency in a post-SOE implementation world. Barriers always exist for continuous improvement, but with the collective participation of the stakeholder community, we can ensure integrity by modernizing organic supply chain traceability through technology integration.

The NOSB calls on the organic community to share best practices and ideas regarding the most appropriate and innovative technologies that can be leveraged to execute the aims of an organic link system.

Questions for Stakeholders:

1. How can technology efficiently and effectively be deployed to enhance supply chain traceability?

2. What form does an organic link system (OLS) must take to be non-burdensome for organic stakeholders, including certifiers, inspectors, handlers, operations, importers, etc.?

3. What challenges exist with the implementation of an organic link system (OLS)?

4. Is there value in AMS, certifiers, and inspectors getting more granular with transaction-level detail to gain transparency throughout the complex supply chain?

5. What other methods exist for enhancing transparency?

6. Are there additional areas that need to be considered for improvement to prevent fraud or react to fraud?

7. Should the industry require the registration of land 36 months before certification?

Note: The USDA Risk Management Agency (RMA) currently tracks the organic status of the land when transitional land is insured. RMA also requires a registered plan on transitional acres. Domestic and International operations reporting the last restricted use pesticide data for land could stabilize markets and allow for enhanced risk assessments simply by knowing what is coming down the pipeline.

Vote in Subcommittee
Motion to accept the discussion document on oversight improvements to deter fraud: Modernization of Organic Supply Chain Traceability
Motion By: Amy Bruch
Seconded By: Nate Powell-Palm
Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Nate Powell-Palm, Subcommittee Chair, to transmit to NOSB, August 13, 2021.

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Chitosan for Plant Disease Control
June 1, 2021

Summary of Petition:

Chitosan has been petitioned for use in organic crop production for addition to the National List at §205.601(j)(4) for plant disease control. The NOSB requested a technical review (TR) of chitosan since the last one was from 2004 when there was a petition for its use as an adhesive adjuvant. Much of the material in the current analysis comes from the TR received by the NOP in July 2020. Chitosan is a copolymer composed of two different chemical subunits that repeat in particular order: glucoseamine and N-acetyleglucosamine. It is derived from chitin which is structurally similar to cellulose. The petitioner stated that chitosan is an alternative to sulfur-based pesticides, which can be phytotoxic to plants. The petitioner bases the request on chitosan's antimicrobial properties as well as its role in plant defense signaling pathways.

Most commercial chitin, from which chitosan is derived, is produced from shrimp, prawn, and crab waste. Chitin forms structures that strengthen cell walls, insect skeletons, crustacean shells, and internal mollusk body parts. The manufacture of chitosan uses relatively large amounts of corrosive chemicals, notably sodium hydroxide and hydrochloric acid. That said, relatively little chitosan is produced. Only 2000 metric tons of chitosan are produced each year while 70 million tons of sodium hydroxide are produced for use in all types of industrial processes. In contrast to the chemicals used to isolate and synthesize the material, chitosan is produced from chitin, a food related marine biowaste and is thus, part of a recycling process. However, as part of an industry that requires the use of sodium hydroxide and hydrochloric acid, considerable energy is consumed producing these products with concomitant production of chlorine gas, carbon dioxide, carbon monoxide, freon and mercury.

Chitosan has a variety of potential uses. It is a registered pesticide (OPP No. 128930) that is used in crop production as a plant growth enhancer and plant defense booster (EPA 2003). Chitosan is applied to treat field crops, ornamentals, turf, home gardens, and nurseries. It is also listed as an animal feed component in the Official Publication of the Association of Animal Feed Control Officials. The State of Oregon has approved the use of chitosan in unrestricted amounts as a soil amendment (fertilizer). Chitosan was recommended to be added to the National List in 2005 as an adjuvant although it was already present on EPA List 4, and therefore would have been redundant. Chitosan also has a variety of other uses that include as a flocculant allowed for precipitating proteins during animal food production, a plant growth regulator in or on wheat, and as a seed treatment for specific crops. The FDA also allows chitosan produced from the fungus *Aspergillus niger* as a secondary direct food ingredient in alcoholic beverages.

Chitosan is not toxic as demonstrated in acute toxicity studies in mice, rats and rabbits and is naturally occurring in the environment in large concentrations. EPA exempted chitosan from the requirement for a tolerance limit due to its low toxicity and abundance in the environment. As mentioned in the summary above, EPA states that chitosan is not expected to harm people, pets, wildlife, or the environment when used according to label direction.

Summary of Review:
A survey of regulations for organic production from a number of countries and international organizations indicates that chitosan is not included within the Canadian Organic standards as an allowed material. CODEX Alimentarius does not include chitosan within the Codes guidelines. European Economic Community (EEC) Council Regulation shows that chitosan hydrochloride is allowed for pest and disease management under European Union organic regulations but may not be used as an herbicide.

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.

   The petition describes the process of producing chitosan from chitin as proprietary so the exact process they use is unknown. Generally, however, chitosan is produced from chitin by using dilute sodium hydroxide to separate and extract chitin from shells or acids for demineralization, but a more concentrated solution is required to effectively deacetylate chitin to form chitosan at a range of 40 to 60% concentration. Chitin can also be converted into chitosan using a high-heat process or a lower temperature process using enzymatic conversion

2. Reference to appropriate OFPA category:

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

   The petitioner is requesting that chitosan be added to 7 CFR 205.601(j)(4) as a synthetic substance allowed for use in organic crop production as a plant disease control.

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)]

   Based on information in the 2020 Technical Report, the application of chitosan as an active ingredient in pesticidal products is unlikely to be harmful to the environment. It occurs naturally in quantities exceeding what would be used in organic crop production and it degrades into substances that are non-toxic and readily used as nutrients.

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)]

Due to the variety of results found in different studies it is likely that chitosan has multiple antibacterial modes of action. One hypothesis is that positively charged chitosan binds to negatively charged cell surface molecules. Another hypothesis is that smaller chitosan molecules move through cell walls and inhibit gene transcription. There is also another thought that chitosan chelates essential nutrients making them unavailable to bacteria. Chitosan can also initiate systemic resistance in plants and may act directly between host and pathogen to block the growth of the pathogen itself. Since chitosan is used at low levels and is degraded by soil microorganisms the is expected to be no increase in the environment.

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

   Because of the low toxicity of chitosan, the misuse of the product or its disposal are expected to have minimal effects on the environment. Both chlorine and sodium hydroxide are used in production of chitosan, and are toxic in the environment if not contained in transport.

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

   According to numerous sources as reported in the Technical Report chitosan is nearly non-toxic to humans and most other animals and its degradation products do not cause side effects in the body (US EPA).

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)]

   Pesticide studies about the use of chitosan as an active ingredient have shown that there might be temporary changes to soil microbial communities. Being a large polymer with numerous reactive sites, it is difficult to characterize all possible chemical interactions involving chitosan. the Technical Report found studies that chitosan can limit the ability of some microorganisms to absorb nutrients, but it can also act as a chelator. It has been suggested because of this, it might be used as a material to improve the anionic exchange capacity of soils to limit the leaching of anionic nutrients and improve nutrient delivery to plants

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

   At the rates this substance is applied, no adverse impacts on biodiversity are expected.

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)]

   As the Technical Report emphasizes, good farming practices, including suppressive soils, creating unfavorable conditions for pathogens, managing disease vectors such as aphids, sterilizing soils with heat and planting resistant cultivars reduce the need to use disease control substances. Also, there are more than 200 products listed by OMRI for use as plant disease control. Some do contain synthetic active ingredients, but many contain nonsynthetic active ingredients such as bacteria, microorganism extracts, botanical substances, oils, and natural acids.

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

   Chitosan is a relatively benign product and also has the advantage of taking a waste stream of seafood shells and converting them to a useful recycled product. Both chlorine and sodium hydroxide are energy-intensive, toxic chemicals used in the production of chitosan, and must be considered. Additionally, chitosan is classified as synthetic, and the Subcommittee questions whether there is a need for an additional synthetic plant disease control product on the National List. The Crops Subcommittee is divided on whether chitosan should be added to the National List.

Classification Motion:

Motion to classify chitosan as synthetic
Motion by: Rick Greenwood
Seconded by: Brian Caldwell
Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National List Motion:

Motion to add chitosan to the National List at 205.601(j)(4) for plant disease control
Motion by: Rick Greenwood
Seconded by: Steve Ela
Yes: 4 No: 4 Abstain: 0 Absent: 0 Recuse: 0

Approved by Rick Greenwood, Crop Subcommittee Chair, to transmit to NOP June 1, 2021.

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Cow Manure Derived Biochar (CMDB)
August 3, 2021

Summary of Petition [link]:
A petitioner has requested an annotation to the listing at § 205.602(a) "Ash from manure burning" that would indicate that ash from manure burning does not include biochar derived from pyrolysis of cow manure. The petitioner contends that cow manure derived biochar, or CMDB, not only provides a solution to nutrient leaching and other adverse impacts to raw manure handling in large scale dairy operations but also has other benefits for organic crops that may exceed those of plant-based biochar.

The organic use of the petitioned material falls under the OFPA category for Crop and Livestock Materials and is characterized as a fertilizer and carbon storage soil amendment/soil conditioner to aid in organic crop production. In addition to CMDB, it can also commonly be referred to as cow manure biochar, dairy biochar, dairy manure biochar, dairy manure sourced biochar, manure derived char, or dairy manure char.

Biochar is defined in NOP guidance document 5034 "Materials for Organic Crop Production" as: "[…] biomass that has been carbonized or charred. Sources must be untreated plant or animal material. Pyrolysis process must not use prohibited additives."

The following annotation (in bold) at § 205.602(a) has been requested relevant to CMDB:

§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.

The following nonsynthetic substances may not be used in organic crop production:

> (a) Ash from manure burning **– unless derived as part of the production of biochar from pyrolysis of cow manure.**
>
> *****
> [68 FR 61992, Oct. 31, 2003, as amended at 83 FR 66572, Dec. 27, 2018]

Subcommittee Review:
"Ash from manure burning" has been prohibited explicitly under OFPA since 1995 and reiterated every five years since then through 2015. In 2016, the NOSB unanimously denied a 2014 petition to annotate the prohibited use of ash from manure burning at §205.602(a) "[…] where the combustion reaction does not involve the use of synthetic additives and is controlled to separate and preserve nutrients" or the basis of the fact that it reduces the carbon and nitrogen present in the feedstock and thus does not contribute to soil-building processes. Around the same timeframe (fall 2015 NOSB meeting), the Board reiterated this position during the review of substances due to sunset in 2017 (in keeping with the position of the NOP), stating, "ash from manure burning was placed at §205.602 based on its incompatibility with organic production; burning these materials is not an appropriate method to recycle organic wastes."

In response to the current petition in early 2020, the Crops Subcommittee requested a Technical Report (TR) of the petitioned substance, both to understand the implications of the process of pyrolysis in the context of the prohibited “ash from manure burning” (in other words, is pyrolyzed manure the same thing as ash?) and to understand more fully the potential carbon storage benefits of crop systems that utilize biochar, and more specifically CMDB, given member interest in more fully evaluating the potential to improve the contributions of organic agriculture to climate stability.

The Crops Subcommittee received a draft TR and requested additional information in an updated draft including the following questions. That draft was received in March 2021 and deemed sufficient in April 2021.

The substance does not appear – at least by the name referenced here – on Canadian, EU, IFOAM, Codex, or Japanese lists of accepted materials, although biochar is referenced indirectly on Canadian, CODEX and Japanese lists.

Category 1: Classification

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

   CMDB derives from the manure of dairy cows and the combustion in the absence of oxygen (i.e., pyrolysis) of that manure. It does not undergo a chemical transformation. NOP has previously categorized biochar as non-synthetic and classifies transformations of “heating or burning of biological matter (e.g., plant or animal material)” as “a natural process that does not result in the classification of ash as synthetic.”

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

   CMDB does not contain any active synthetic ingredients. The only related question that has been raised about the substance is whether there are residues from dairy cow husbandry that persist in manure and further into CMDB. As reported in the TR, the presence of any such residues has not been documented.

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)]

   It does not appear that detrimental chemical interactions can occur from the use of CMDB in organic farming. However, agronomically, some crops are appropriate for applications of biochar and CMDB and others may not be.

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)]

   It appears that CMDB does not meet any relevant criteria for toxic persistence in the environment and may even contribute to the reduction of other toxics in the soil and the environment. Additionally, the expectation of biochar applications is that they can remain stable in the environment for hundreds or thousands of years, hence their potential value as a means of sequestering permanent carbon.

   That said, biochar can harbor toxics such as polycyclic aromatic hydrocarbons (PAH), which are typically formed using high-temperature production methods and heavy metals that are typically carried over from the feedstock, as noted in the TR, and can vary depending on the temperature at which the biochar was produced. According to the TR, "there have been reports of bio-accumulated PAH in food crops that were grown in biochar-amended soils," as well as localized accumulation of pollutants in biochar contexts over time.

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

   Documented evidence appears to suggest that the production of biochar and CMDB results in net negative carbon emissions due to slower decomposition than raw biomass sources. The larger question about manufacturing impacts relates to the kind of scaled dairy operation from which the manure derives. This raises questions about the fundamental climate/water, environmental, and animal welfare impacts of those operations as well as whether or not organic agriculture should have a role in reducing or neutralizing negative aspects of those operations.

   While the TR clearly asserts that carbon is sequestered through the use of biochar, it does not cite data on the net carbon emitted or sequestered through the use of whatever energy feedstock is required to achieve optimal heat for carbonization.

   The TR also points out the net positive benefits of recycling "waste" material that would otherwise need to be disposed of were it not being pyrolyzed into CMDB. Recycling of manure-based feedstocks, as such, could attribute to reduced impacts typically associated with the disposal of such waste.

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

   There do not appear to be any documented human health impacts from the petitioned substance.

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

The TR suggests that biochar and CMDB can lead to a less dense soil structure that can promote root growth and that it can have mixed results related to water retention in the soil (wood-based biochar is more porous than manure and thus can support more water retention). The TR also suggests that biochar and CMDB can improve the Cation Exchange Capacity (CEC) of soil which effectively improves the retention of nutrients in the soil. Nutrient bioavailability can vary in biochar-amended soil, depending on the feedstock, with CMDB being more nutrient-rich than other forms of biochar. CEC benefits can also lead to the sequestration of heavy metals, effectively immobilizing or neutralizing them.

The TR also indicates that most biochar has base pH which can be beneficial in acidic soils, with CMDB having a higher pH than other biochar. It can also increase the solubility of nutrients and other substances, for example aluminum which the TR notes is toxic to plants.

Sources cited in the TR indicate the biochar can have a wide range of positive and negative impacts on soil microbial communities but is most generally thought to improve microbial growth: "Grass and manure feedstocks and biochar with low production temperatures (<500 ˚C) typically result in positive priming due to their relatively high nutrient content and bioavailability (Verheijen et al. 2010, Zimmerman et al. 2011, Tenic et al. 2020)." (Priming is increased or decreased microbial activity resulting from changes to physical and chemical properties of the soil, "specifically the availability of nutrients.") TR sources suggest this combination of attributes of biochar and CMDB are what help with its contribution to crop resilience.

The TR also points out that biochar can sequester "pesticides, herbicides, antibiotics, and pharmaceutical compounds" and that there is inconsistency as to whether biochar can neutralize and/or degrade those substances. It reduces nutrient cycling soil and retains nitrogen in soils as ammonia and ammonium. This can reduce soil acidification and climate-polluting N_2O emissions.

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

   The substance does not appear to have any biodiversity impacts, other than the soil microbe considerations noted above.

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)]

   In appropriate crop applications, wood-derived biochar can be an alternative to CMDB. CMDB and biochar in general are petitioned as soil amendment for their potential crop benefits as a soil amendment and for the unique role they can play in sequestering carbon and climate-polluting substances. It is unclear from the petition or the TR that biochar or CMDB are more effective at soil building than other common practices, such as cover cropping, manure and compost applications, and reduced tillage.

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

This is perhaps a more complicated petition than the history of NOSB decisions on this substance would indicate. The TR is quite comprehensive about the potential for all forms of biochar to play significant roles in storage soil-based carbon and neutralizing pollutants that could otherwise adversely affect the environment. At the same time, it appears the viability of this petitioned material at scale is contingent upon access to manure deriving from a wide range of dairy operations, including but not limited to conventional operations and CAFOs.

The argument as to whether pyrolyzed manure is the same as ash produced from burning manure is complex. However, the presumed production of ash appears to be the primary issue for previous board actions on related topics. The issue with biochar is that what could be considered "ash" is actually part of the substance and is contained by the substance and is not a byproduct of the substance. So, by tightly restricting use of ash from manure burning, organic agriculture may be losing a useful soil amendment and may be limiting its ability to serve as a climate solution. Following that argument, the use of biochar – for its recycling benefit, for its soil building benefit, and for its stable carbon sequestration – could be considered to be not only compatible with sustainable agriculture but promoting it.

Most consulted sources suggest biochar and CMDB can be produced in a net negative carbon emissions content, presumably relying on the source material itself to be the primary fuel. However, sources are clear about this, and as the TR suggests, highest heat produced biochar (>500°C) – coming from vegetative sources – offers many of the key soil nutrient retention benefits. Manure-sourced biochar typically is produced at lower temperatures. It may be important for the subcommittee and the Board to understand more about necessary fuel sources – if any – required to produce CMDB. It has been difficult to document pyrolysis fuel sources clearly, but the assumption is that fossil sources would be necessary to achieve the heat required to produce an optimal biochar/CMDB product.

Precedent would follow that this petition should be denied, but a careful review and discussion is merited. The NOP has as recently as 2016, articulated a position that pyrolysis is not its own unique mode of processing but in fact should be viewed as analogous to burning or combustion, and thus a source of ash.

Classification Motion:
Motion to classify cow manure derived biochar (CMDB) as nonsynthetic
Motion by: Wood Turner
Seconded by: Rick Greenwood
Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National List Motion:
Motion to annotate the listing of ash from manure burning at § 205.602(a) to read "Ash from manure burning **– unless derived as part of the production of biochar from pyrolysis of cow manure."**
Motion by: Wood Turner
Seconded by: Steve Ela
Yes: 5 No: 3 Abstain: 0 Absent: 0 Recuse: 0

Approved by Rick Greenwood, Crop Subcommittee Chair, to transmit to NOP August 3, 2021.

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Ammonia Extracts

August 3, 2021

Summary of Petition:

Note: Throughout this document references are made to the 2020 technical report (TR). It is intended that the citation of the TR inherently includes the citations of the references contained within the TR. When the TR is quoted the citations noted in the text of the TR have been removed for clarity – for a full list of references, please refer to the TR.

References to ammonia or ammonium are specifically intended to include both unless specifically stated otherwise.

Use

Ammonium extracts are used as a source of nitrogen (N) for the production of a wide range of annual and perennial crops. In the past, ammonia products have been produced via synthetic processes and have not been allowed for use in organic production. The synthetic production methods primarily use the Haber-Bosch process, and that process has allowed for widespread commercial use of nitrogen for conventional farms. From this process, urea accounts for about 50% of nitrogen fertilizers. Other common forms include aqueous ammonia, ammonium nitrate, ammonium sulfate, ammonium phosphates and other ammonium salts. Ammonia compounds can be used as bioavailable fertilizer sources and can be rapidly taken up by plants (2020 TR).

More recently, non-synthetic processes for the production of ammonium fertilizers have been developed. These processes produce high ammonia/ammonium products that can potentially be used in organic agriculture since they meet the criteria for use as non-synthetic fertilizer compounds. Before development of these non-synthetic processes for ammonia production, other N containing fertilizers have been allowed for organic use. These include, but are not limited to, soy protein hydrolysate, liquid fish products, and sodium nitrate.

Nitrogen is often a major limitation to crop yields and is biologically important as a macronutrient. It contributes to plant growth through the formation of amino acids and as the building blocks for proteins and can improve photosynthetic efficiency (2020 TR).

It should be noted that there is a wide range of ammonia/ammonium products that are approved for use in food processing and manufacturing. These include ammonium carbonate and bicarbonate which appear on the National List. Several products are approved for agricultural use, such as ammonium carbonates and ammonium soaps, but are limited by annotation to uses that do not directly contact crops.

Manufacture

While the Haber-Bosch process is the primary method for making nitrogen fertilizers, it is not relevant to organic processing and use. More recently, several methods have been developed to produce ammonia products non-synthetically. As noted in the 2020 technical report and through public comment on the two NOSB discussion papers (Fall 2020 and Spring 2021) regarding ammonium extracts, the two methods are defined as ammonia stripping and ammonia concentration:

> Ammonia stripping – ammonium compounds occur in a number of agricultural, biological, and other sewage wastes. Ammonium is commonly produced through the metabolism, hydrolysis, or anaerobic digestion of these feedstocks. Once the ammonium ions are converted to ammonia by adjusting the pH to alkaline, the ammonia is extracted from the feedstock as a gas by the use of a combination of pressurized air and/or heating. After further processing, the ammonia is reacted with an acid to re-form ammonium. This stabilizes the nitrogen at which point the ammonium can be isolated as an aqueous solution or slurry or isolated as a solid by precipitation. The direct output of the "ammonia stripping" process is a pure ammonia gas (or when cooled and distilled, a pure aqueous ammonia condensate) isolated from the original agricultural feedstock. Products produced by this method are considered novel; new products are only recently being approved and/or are still in development and not yet fully commercialized.
>
> Ammonia concentration – rather than isolating only the ammonia ions, ammonia concentration uses a physical process to remove solids from the nitrogen containing liquid waste mixture. The remaining filtrate includes only water-soluble components. These include ammonia and ammonium, as well as phosphate, potash, secondary and micronutrients, and other organic compounds. This liquid is subjected to pressured air and/or heat to remove water by evaporation. This concentrates the remaining ammonium/ammonia compounds while also retaining the other nutrients and organic compounds from the original feedstock. Products produced by this method have been Organic Materials Review Institute (OMRI) listed.

The output of the stripping method produces a near pure ammonia that would be similar to that produced by the Haber-Bosch process whereas the product of ammonia concentration retains more of the original compounds of the feedstock. The specific quantities and types of nutrients in the remaining concentration vary depending on the original feedstock.

The other aspect of these concentrated and stripped ammonia products is that the nitrogen isotope ratio is different than ammonia from synthetic sources. Testing for isotope ratios of nitrogen is common. The nitrogen isotope ratio (δ15N) of natural materials also rarely falls below five and they are typically greater. Any products that go beyond this threshold (i.e., show higher δ15N values) are almost certainly not adulterated (California Department of Agriculture, public comment, Spring 2020).

International

As discussed in the 2020 TR:

Canadian General Standards Board Permitted Substances List (CAN/CGSB-32.311-2015), Organic Production Systems Permitted Substances List - Ammonia extract is not listed in the Canadian Standards Board Permitted Substances List (CAN/CGSB- 2.311-2015); however, it does include a variety of ammonium compounds. Copper ammonia base, copper ammonium carbonate, ammonium forms of micronutrients, potassium sulfate made with ammonia reactants, and ammonium stillage are prohibited for "soil amendments and crop nutrition" uses. Ammonium carbonate is allowed "as an attractant in insect traps." Ammonium soaps are allowed "as a large animal repellent," with the stipulation that "direct contact with soil or edible portion of crop is prohibited." Ammonium lignosulphate is prohibited for "crop production aids and materials." Ammonium bicarbonate and ammonium carbonate are allowed "as leavening agent[s]." Dibasic ammonium phosphate (diammonium phosphate, DAP) is allowed as a "yeast food for use in alcoholic beverages," with the limitation that concentrations are "restricted to 0.3 g/L (0.04 oz./gal.) for cider, mead and wine."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999) Ammonia extract is not listed in the CODEX; however, ammonium carbonates are listed in the CODEX as a "food additive."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 Ammonia extract is not listed in the EEC Council Regulation EC No. 834/2007 and 889/2008. However, several ammonium compounds are listed in EC No. 889/2008. Ammonium stillage is prohibited for use as a "fertilizer and soil conditioner." Diammonium phosphate is allowed as an "attractant" for traps in "pesticides and plant protection products." Ammonium molybdate is allowed as a nutritional "trace element" in animal feeds. Ammonium carbonates are allowed for the "preparation of foodstuffs of plant origin." Ammonium hydroxide is allowed for the "preparation of foodstuffs of animal origin" in gelatine production.

Japan Agricultural Standard (JAS) for Organic Production Ammonia extract is not listed in the JAS for Organic Production. However, ammonium bicarbonate and ammonium carbonate are listed in Notification No. 1606 and allowed for use as "food additives, limited to use for processed foods of plant origin."

International Federation of Organic Agriculture Movements (IFOAM) Ammonia extract is not listed in the IFOAM; however, it does list several ammonium compounds. Ammonium phosphate is allowed as an "additive," with the stipulation that concentrations are "restricted to 0.3gm/l in wine." Ammonium sulfate is allowed as an "additive," with the stipulation that it is only allowed for wine and is "restricted to 0.3 mg/l." Ammonium carbonates are allowed as "additives," with uses limited to "cereal products, confectionary, cakes and biscuits."

While not addressed specifically, sodium nitrate is not allowed in Canadian production and crops grown with sodium nitrate may not be exported to Canada. While it is unknown, comments received at the Spring 2021 NOSB meeting included concerns that the use of ammonia extracts in the United States might result in the rejection of exported products by other countries.

Summary of Review
The review of this petition has resulted in a wide variety of public comments and perspectives. These perspectives range from issues with soil health and environmental concerns, the use of multiple sources of highly soluble nitrogen fertilizers, and the potential for fraud. Commenters argued both pro and con on each of these issues.

In general, the comments from long-time organic organizations and growers tend to be in favor of the petition to prohibit ammonia extracts based on the organic principles of enhancing soil biological processes rather than applying a nutrient that is immediately available to the plant. They also noted the low carbon to nitrogen ratio, the high solubility of these extracts in terms of environmental issues, and the potential for these materials to increase the chances for fraud.

Opponents of the petition cite the need for immediately available nitrogen sources to act as a short-term nitrogen bridge. This would be needed when unusual events cause nitrogen deficits to crops and soil processes have not had a chance to recharge the available nitrogen. They also note that some use of these materials can help prevent nitrogen loss since they could allow better targeting of nitrogen applications to specific crop needs. In terms of fraud, they note that many organic nitrogen fertilizers could also be subject to fraud. Rigorous inspections, unannounced site visits, nitrogen isotope testing, and mass balance reviews make fraud very unlikely.

As noted previously, there are several materials already in the organic marketplace. These materials have been approved by OMRI and other material review organizations, although, with the caveat that nonsynthetic, liquid fertilizers that have a nitrogen analysis greater than 3 percent must comply with additional recordkeeping and inspection requirements in accordance with NOP Guidance on the Approval of Liquid Fertilizers for Used in Organic Production (NOP 5012). Non-synthetic fertilizers that test above 3 percent ammoniacal nitrogen are considered at higher risk for violating the soil fertility and crop nutrient management practice standards at §205.203. OMRI attaches a note that "this product contains highly soluble nitrogen and must be applied in a manner that does not contribute to the contamination of crops, soil or water. Its use must be part of an organic system plan that maintains or improves the natural resources of the operation, including soil and water quality, and comply with crop nutrient and soil fertility requirements."

Soil Health

The USDA organic regulations at § 205.203(a) requires that a producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of the soil and minimize soil erosion. At §205.203(c) and (d) the organic regulations state that the producer must manage plant and animal materials or crop nutrients and soil fertility to maintain or improve soil organic matter content.

Many commenters noted that the use of ammonia extracts runs counter to this principal by directly applying plant nutrients rather than applying nutrients that improve the biological condition of the soil. Inherently, the annotation added to high N, ammonia/ammonium containing products notes that "this product contains highly soluble nitrogen and must be applied in a manner that does not contribute to the contamination of crops, soil, or water. Its use must be part of an organic system plan that maintains or improves the natural resources of the operation, including soil and water quality, and comply with crop nutrient and soil fertility requirements." This annotation would not be added unless there was a risk that the materials do not contribute to the stated OFPA criteria. Indeed, a number of oral commenters testifying at the Spring 2020 NOSB meeting in favor of the use of ammonia extracts reinforced this by stating that ammonia extracts should not be used alone, but must be used with other soil building practices to comply with OFPA.

An example of a comment that refers to basic tenets of organic agriculture and prior OFPA and NOSB actions was submitted at the Spring 2020 meeting:

> In contrast to the reductionism of "conventional" chemical-intensive agriculture, the origins of organic agriculture are in holistic and ecological thinking. Historically, perhaps the most important principle of organic production is the "Law of Return," which, together with the foundational philosophy "Feed the soil, not the plant" and the promotion of biodiversity, provide the ecological basis for organic production. Together these three principles describe a production system that mimics natural systems. 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 of the soil-plant-animal ecological community. The Law of Return says that we must return to the soil what we take from the soil. Non-crop organic matter is returned directly or through composting plant materials or manures. To the extent that the cash crop removes nutrients, they must be replaced by cover crops, crop rotation, animal manures, or additions of off-site materials, when necessary. 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. OFPA §6513(b) requires that organic operations establish a plan designed to "foster soil fertility, primarily through the management of the organic content of the soil through proper tillage, crop rotation, and manuring." **Substances of high solubility, i.e., those materials that provide nutrients directly to the plant because they are quickly taken up into the plant from the soil solution, are counter to foundational organic principles, so they have always been restricted.** Such materials are listed in §205.602—Nonsynthetic substances prohibited for use in Organic Crop Production or the "prohibited naturals" section of the National List:

1) Calcium chloride is limited to treating a physiological disorder;
2) Potassium chloride must be used in a manner that minimizes chloride accumulation in the soil and;
3) Sodium nitrate is restricted to no more than 20% of the crop's total nitrogen requirement.

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." At the time, the discussion was about mined substances of high solubility because there were no concentrated, highly soluble plant nutrient materials other than mined sources available at that time. New materials of high solubility should be prohibited or restricted.

These concerns were echoed by another commenter that stated that there are significant concerns with the compatibility of purified natural ammonia with organic principles: their mimicry of conventional synthetic fertilizers and their use requires the removal of carbon value from organic waste.

There are studies that show the addition of nitrogen to nitrogen-limited fields can increase plant production. Addition of N increased production yields, biomass and thus, additional carbon resources that can be returned to the soil. Some of these studies show that the addition of nitrogen, no matter what the source, can improve soil health indices (Miner, Delgado, et al., 2020). Fertilizing nutrient-deficient soils usually results in greater crop yields. Higher yields achieve greater amounts of crop residue—roots, stems, and leaves—resulting from larger and healthier plants (Magdoff and Van Es, 2021). A caveat is that a number of these studies are conducted on conventionally treated soils and focus on nitrogen deficient systems where the addition of any nitrogen enhances plant production. If nitrogen were not deficient and additional nitrogen did not result in greater plant growth, then it is unlikely that any nitrogen addition would improve soil health indices.

Other studies show that long-term organic fertilizer inputs enrich carbon related soil functions. Manure additions can strongly influence the formation, storage and cycling of soil organic carbon and nitrogen and soil microecology (Sharaf, Thompson, et al., 2021; Ozlu, Sandhu, et al., 2019). The total amount (weights) of living organisms varies in different cropping systems. In general, soil organisms are more abundant and diverse in systems with complex rotations that return more diverse crop residues and use other organic materials such as cover crops, animal manures, and composts. When crops are rotated regularly, fewer parasite, disease, weed, and insect problems occur than when the same crop is grown year after year (Magdoff and Van Es, 2021). These biotic links can also have a positive influence on the ability of plants to resist insect pests. Plants grown in a balanced nutrient system are less likely to be attacked by pests as compared to plants that have readily available nitrogen added (Phelan, Mason, et al., 1995).

There were several public comments noting that the use of ammonia extracts could increase the rate of mineralization in soils and thus be beneficial. In a short timeframe this could be true, but this accelerated rate of mineralization could come at the cost of long-term soil carbon resources. Wang, Juliang, et al., 2018, found that long-term application of N-fertilizers causes an abundance of bacterial groups responsible for the denitrification process, which causes the turnover of nitrogen to increase and results in greater nitrogen loss over time. Essentially, adding more nitrogen fertilizer results in a long-term loss of nitrogen while altering other soil components, like decreasing soil pH and C:N ratio. When soil carbon and nitrogen are reduced in response to the application of chemical fertilizers, beneficial enzymatic activity of the soil also decreases (Ozlu, Sandhu, et al., 2019). Another study concluded:

> Annual nitrate leaching was 4.4–5.6 times higher in conventional plots than in organic plots, with the integrated plots in between. This study demonstrates that organic and integrated fertilization practices support more active and efficient denitrifier communities, shift the balance of N2 emissions and nitrate losses, and reduce environmentally damaging nitrate losses. Although this study specifically examines a perennial orchard system, the ecological and biogeochemical processes we evaluated are present in all agroecosystems, and the reductions in nitrate loss in this study could also be achievable in other cropping systems (Kramer, Reganold, et al., 2006).

Of interest is that nearly all the public comments stating that ammonia extracts help prevent environmental damage from excess application of manures and composts neglected to mention that an organic systems approach uses multiple sources of crop fertility. Comparing the use of ammonia extracts to a system that only uses manures focuses on only one part of an organic system. An organic system includes cover cropping, interplanting, and varied crops, in addition to manures and composts. This mix of fertility sources is used to mitigate issues of nutrient excesses.

> The **incorporation of crop residues and compost** [emphasis added] provides a potential long-term alternative to ammonia extract and other nitrogen fertilizers. Nitrogen content in compost is slowly released through mineralization processes in the soil, primarily facilitated by its metabolism by microorganisms in the soil. Unlike ammonia extract, the use of compost also contributes to soil organic matter, and available carbon, phosphorous, and micronutrients, as well as soil microorganism populations and activities. The incorporation of compost into the agro-ecosystem has been reported to improve soil characteristics, specifically water holding capacity and cation exchange capacity (CEC). Increased soil CEC allows it to retain cations more effectively, including ammonium ions and metal cations required as micronutrients (e.g., iron [Fe], copper [Cu], zinc [Zn]) (2020 TR)

Public comments and scientific research publications demonstrate that much more research regarding the use of these materials and of the soil health, plant health, and biological interactions is needed. There is conflicting information from studies on conventional soils and very little research conducted on organic soils. For example, a study on tomatoes in California, (Bowles, Hollander, et al., 2015) found that the complex plant and microbial processes that affect nitrogen cycling are affected by the ecology of each farm as well as between fields within a farm. Most research oriented toward nitrogen cycling takes place at research stations with fixed factors and limited soil variation. There has been little research about how nitrogen cycling occurs on working organic farms. The study detailed how organic tomato farms can achieve high yields even though tests showed relatively low nitrogen availability. They attributed this to the possibility that the nitrogen cycling was tightly coupled with tomato plant needs. While tests showed low nitrogen with respect to conventional standards, the sustained release curve of the nitrogen in those plots met plant needs. They concluded that new indicators of N availability are needed that consider active C and N processes in organic systems. This is another indicator of our lack of understanding of nutrient processes and needs in organic systems. This lack of understanding results in conclusions about the need for fast acting nitrogen applications and is problematic.

In the absence of consistent research showing overwhelming benefits from the applications of ammonia extracts, and with the requirement to fulfill OFPA criteria, use of ammonia compounds raises questions regarding soil health and the maintenance or improvement of soil organic matter. There are effective organic systems that pay close attention to nitrogen needs through the use of multiple approaches to fertility that include the basics of crop rotations and applications of manure and composts. By paying attention, these systems do not result in large buildups of phosphorous or in excessive loss of nitrogen to the environment. While there is a segment of organic stakeholders that express an interest in using these extracts, there is a larger segment that believes ecosystem management to maintain or increase soil organic matter does not include reliance on a highly soluble fertilizer.

Total Use of High N Fertilizers:

While USDA organic regulations criteria require an organic soil fertility plan to maintain or improve soil organic matter (§205.203), the interpretation of this requirement can be very difficult for certifiers to enforce. Does growing the same crop for several years, followed by a different crop, and then back to the first crop conform to this requirement? What level of highly soluble, low carbon-to-nitrogen ratio materials can be used before they are too much and do not comply with OFPA. Given the wide range of organic soil fertility options available, it can be very difficult for certifiers to enforce a notice of non-compliance.

The restriction on the use of sodium nitrate to 20% of crop needs limits the potential for overuse of that form of highly soluble nitrogen fertilizers. In fact, the prior vote of the NOSB to completely prohibit this form of nitrogen illustrates the concern the organic community has for the use of these high nitrogen fertilizers. One comment received at the Spring 2020, meeting demonstrates the slippery slope of using these types of fertilizers, including ammonia extracts:

> Fertilizing through drip irrigation systems allows for precise placement and timing of the fertilizer for optimum crop production. Drip irrigation has become a major method of irrigating crops, especially in California. The growth in drip irrigation is driven by drought, over-draft of aquifers, and the need for more precise fertilization… The type of crops irrigated with drip irrigation include all types of vegetables, tree fruit, strawberries, cane berries, and tomatoes. Many of these crops, such as tree fruit and berries, are only irrigated using drip irrigation systems. These crops often have very long cropping cycles making it impossible to apply nutrients by a method other than through the drip irrigation system. Any fertilizing material added to drip irrigation water **must have little to no solids with most of the nutrients in a soluble form** [emphasis added]. Two of the major liquid nitrogen products are made with liquid fish (fish solubles, fish protein, fish emulsion, hydrolyzed fish) and or corn steep liquor. These ingredients contain high levels of insoluble material which cause costly plugging of drip irrigation lines.

This illustrates a system that utilizes a large amount of highly soluble fertilizer for the fertility program with little or no attention to other organic fertilizer inputs. At what point would ammonia extracts become the main source of nitrogen while other organic soil building practices become a minority?

Sodium nitrate, another highly soluble, immediately available nitrogen source is approved for organic use with a limitation to 20% of crop nitrogen needs. Like ammonia extracts, sodium nitrate is a non-synthetic alternative of bioavailable nitrogen for plants. Unlike other naturally derived substances that must undergo mineralization to be plant available, ammonia extracts and sodium nitrate act more like conventional fertilizers. The 2020 TR cites a number of sources that demonstrate the benefits of materials that need to undergo mineralization as opposed to those that are immediately available and states:

> Many substances derive from natural products that are allowed as organic fertilizers, including fish meal, liquid fish residues, feather meal, bird or bat guano, alfalfa meal, soybean meal, bone meal, kelp, seaweed, blood meal, and meat meal. Like crop residues and compost, organic fertilizers require additional mineralization processes and provide a slow release of nitrogen, which is primarily present in complex molecules. Like crop residues and compost, organic fertilizers also contribute to increased soil organic matter, CEC capacity, and other nutrients and micronutrients. Unlike nitrogen fertilizers used in conventional agriculture, organic fertilizers have been reported to have minimal negative to long-term positive effects.

There is the potential to use multiple sources of low C:N ratio, high bioavailability fertilizers to replace basic soil fertility methods such as crop rotation, intercropping, and appropriate manure and compost use. Traditional organic materials, with the exceptions of sodium nitrate and guano, have a C:N ratio above 3:1 :

Material	C:N ratio range
Sodium nitrate	0.02: 1
Sea bird guano	1.2 - 3.3: 1
Blood meal	3.1 - 3.8: 1
Fish powder	3.4 - 4.0: 1
Feather meal	3.5 - 3.8:1
Bone meal	3.6: 1
Liquid food-based fertilizer	4.6-5.2: 1
Liquid fish emulsion	5.2: 1
Cotton seed	5.5: 1
Poultry litters	8-12: 1
Composts	10.7 - 99.3:1
Soil	10-12
Clover and alfalfa (early)	13
Alfalfa meal	15.9: 1
Dairy manure (low bedding)	17
Alfalfa hay	20
Green rye	36
Corn stover	60
Wheat, oat, or rye straw	80
Oak leaves	90
Fresh sawdust	400
Newspaper	600

Sources: Cassity-Duffey, Cabrera, et al., 2020; Hartz and Johnstone, 2006; Lazicki, Geisseler, et al., 2020; Magdoff and Van Es, 2021.

Ammonia extracts have C:N ratios below 3:1 as compared to other liquid products:

Type of product	Ammonia-N (%)	Total N (%)	Ammonia-N/Total N (%)	C:N
manure tea	0.003 - 0.42	0.09 - 0.71	3.3 - 59.2	17:1
restricted ammonia product	4.2 – 7.47	5.78 – 8.23	51.0 – 99.6	2:1
liquid fish fertilizer	0.4 - 0.95	3.96 – 5.25	7.6 – 20.7	3.35
anaerobic digestate	0.048 - 0.68	0.28 – 2.21	2.2 – 43.2	1.25 - 5.48

Source: OMRI

Any amendment that is over 40:1 can cause temporary plant nitrogen deficits since nitrogen must be taken from surrounding soil to enable breakdown of these materials. Conversely, amendments with lower C:N ratios can contribute available nitrogen to the system (Magdoff and Van Es, 2021).

As written by one public commenter (Spring 2021):

> The prohibition of synthetic nitrogen fertilizers manufactured through the Haber-Bosch process is a longstanding and fundamental prohibition in organic agriculture. The proliferation of these fossil-fuel based synthetic fertilizers in conventional agriculture was a primary motivator of the modern organic agricultural movement. The principles of organic (as described in the 2001 NOSB Recommendation) seek to achieve agricultural and environmental goals through the "use of cultural,

biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system." Therefore, substances that mimic the chemistry and functionality of synthetic nitrogen fertilizers can understandably be considered as equally incompatible with traditional organic principles. Purified natural ammonia and ammonium compounds mimic conventional synthetic nitrogen

Another commenter stated:

> Highly soluble sources of nitrogen cannot be addressed in a vacuum, and we cannot look at one material at a time. We must take a broader approach to limiting highly soluble sources of nitrogen as a whole. To evaluate and list each individually, even with a restriction, is a slippery slope and raises the concern of "stacking." [Question #4 of the Spring 2020 Discussion document] asks: "Should the use of natural ammonia extract be limited to a certain percent of nitrogen use in crops (similar to the Chilean nitrate restriction)?" With this approach, producers could potentially "stack" highly soluble sources of nitrogen, using 20% of the crop's needs from Chilean nitrate, 20% of the crop's needs from another source, and 20% of the crop's needs from yet another source.

Products that are immediately plant bioavailable mimic conventional nitrogen sources. Products that require additional mineralization, such as protein sources, require soil biotic transformation to be bioavailable to plants. While not perfect, organic products with greater than a 3:1 C:N ratio fit into the category of materials that require soil biotic transformation. Non-synthetic products that are below a 3:1 ratio tend to be those that are immediately plant available.

Fraud potential

While the potential for fraud is not specifically referenced in OFPA, it does affect the ability of certifiers and the NOP to evaluate whether organic standards are being followed by crop producers. Given additional emphasis on organic enforcement and that both the petitioner and public commenters are concerned with the potential for fraud with these ammonia extracts, it seems prudent to note the issues. However, commenters have noted that the potential for fraud exists with many fertilizers.

OMRI stated in public comments that it conducts audits and inspections of high nitrogen liquid fertilizer (HNLF) facilities twice a year. NOP guidance states that "the material evaluation program must…Conduct a balance-in/balance-out analysis of all ingredients and finished products including, when appropriate, by nitrogen content." A mass balance exercise should expose fraudulent uses of synthetic nitrogen. If concentrated ammonia products of concern are those liquid fertilizers with above 3% ammoniacal nitrogen, they are considered HNLF and subject to regular mass balance audits. Formulations that may contain less than 3% ammoniacal nitrogen would not be subject to the same requirements, so the risk of adulteration remains. However, that risk already exists for all liquid fertilizer products that are not subject to inspection. OMRI's inspectors certainly encounter challenges in completing mass balance calculations for complex formulations, particularly those derived from waste stream materials. OMRI therefore is not suggesting that the mass balance calculation is an absolute fail-safe measure against fraud, but rather a risk mitigation measure.

In terms of N15 to N14 isotope ratio testing, OMRI expressed its concerns in public comments at the Fall 2020 NOSB meeting. OMRI no longer requests isotope ratio testing due to the unreliability of test results for complex blended formulations.

A public commenter, citing a study from the University of California presented a different perspective. The University determined that there is a very marked difference in N15 isotope concentration between natural and synthetic ammonia, and the test for determining nitrogen isotopes in products is common.

The nitrogen isotope ratio (δ15N) of natural materials also rarely falls below a certain threshold, with a few exceptions. Fish tissue and guano, for example, do not have ratios less than 5, and they are typically greater. Any products that go beyond this threshold (i.e., show higher δ15N values) are almost certainly not adulterated. It is important to note, however, that plants that rely on symbiotic nitrogen uptake can have δ15N values as depleted, or close to atmospheric values, as nonorganic nitrogen sources. So, in fertilizers where biomass from nitrogen-fixing plants (e.g., legumes) has been added, it may be difficult to distinguish them from nonorganic sources. (http://californiaagriculture.ucanr.edu • OCTOBER–DECEMBER 2013)

The California Department of Agriculture submitted public comments that state they can use isotope ratios and inspections to prevent fraud:

> Concerns about fraud, i.e., fraudulent use of synthetic materials to produce organic input materials, have prompted calls to employ stable isotope techniques to help detect adulteration of organic liquid ammonia products with synthetic ammonium. Therefore, the potential usefulness and limitations of stable isotope testing will be discussed below. Nitrogen-containing materials have unique isotope ratios, or “isotopic signatures.” In a solution, N isotope ratios [15N/(14N+15N)] are uniform and stable, and measurements by isotope mass spectrometers are repeatable with great precision.
>
> Therefore, adulteration of an organic liquid ammonia product can be detected if the isotopic signature of a product is different from that obtained of the same product analyzed earlier, for example right after its manufacture. Comparing N isotope ratios of finished product batches with those of products offered in the marketplace can bring adulteration to light. CDFA-OIM measures the isotopic signature of finished liquid ammonia product batches at the manufacturing sites. The N isotopic signatures of products in the channels of trade must match the ones in the records.
>
> While changes of the isotopic signature of a given product can reliably be detected, using stable isotopes to distinguish between organic and synthetic sources of N is more problematic. The differences in N isotope ratios, or isotopic signatures, occur due to discrimination against the heavier (15N) isotope during biochemical and physical processes, such as soil-to-atmosphere fluxes of N gases. The N isotopic signature of the atmosphere, the source of synthetic N, is generally lower than that of organic materials. Thus, the N isotopic signatures of ammonium from organic sources are slightly, but consistently, higher than those of ammoniacal-N in synthetic fertilizer…
>
> It is not possible to use the isotopic signature alone to verify the integrity of the OIM liquid ammonia manufacturing processes due to the fact that there is a wide range of N isotope ratios among organic sources of N that in some cases overlap those of synthetic fertilizer. Thus, isotopic signatures are useful for discovering fraud committed in the channels of trade, but not as a tool to determine whether a product has been made solely from non-synthetic source materials. CDFA-OIM relies on thorough inspections of manufacturing plants, including N mass balance audits at announced and non-announced visits to deter fraud by manufacturers of organic liquid ammonia products.

Other comments received at the Fall 2020, and Spring 2020, noted that the overlap in isotopic ratios between synthetic and natural ratios makes using isotope ratios alone difficult. Without extensive sampling of the exact ratios of lots at manufacture and at use, the chance for comixing or ammonia products exists. Other commenters noted that, while California is deliberate about testing, their purview does not extend nationally or internationally. Likewise, adulterations at the farm scale are possible and farm inspections are often performed after nitrogen has been applied to crops.

A public comment from the Spring 2020 meeting notes:

> Certifiers already face an uphill battle with those clients who treat soil as merely something to hold plants up and do all feeding through liquid injection rather than soil building. Adding more successful liquid to the system is just not in keeping with the intent or spirit of organic farming. How to stop people from cheating is also a major hurdle. Cheating has historically been an issue in making similar products by spiking them with synthetic nitrogen, and it is also an issue in users becoming too dependent on these products at the expense of cover crops, compost, and other fundamental organic practices.

Finally, several commenters stated that the potential for fraud is increased when there is a significant cost difference between the biological ammonia fertilizers and the synthetic materials. The cost differences create an economic incentive for comingling products and presenting them as products approved for organic use. While legal penalties deter fraudulent activity, NOP enforcement activities have demonstrated that economic gains continue to motivate fraudulent activities.

Category 1: Classification

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

   The processing of ammonia extracts does not change the form of the ammonia/ammonium product. Naturally occurring biological processes, such as anaerobic digestion and fermentation, can be used to produce ammonia and ammonium compounds. While the production of ammonia and ammonium compounds (ammonia extract) occurs through natural, biological processes, isolation via ammonia stripping generally utilizes acid and base reactions. The classification of ammonia extract as synthetic or nonsynthetic is dependent on the identity of the acids and bases used in the production of ammonia extract. According to NOP decision trees, the use of synthetic substances for pH adjustment or other processing would result in the classification of the ammonia extract as synthetic, while the use of natural acids and bases would result in the classification of ammonia extract as nonsynthetic (2020 TR).

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

   Ammonium extracts do not include an active synthetic ingredient.

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)]

   To the extent that the application of ammonia/ammonium extracts can affect soil pH and other microbial processes, other nutrients may or may not be released based on the soil pH effects.

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)]

   Ammonia, ammonium, and their byproducts have short lifetimes in the environment, typically ranging from hours to days based on environmental conditions. The short environmental lifetimes of ammonia, ammonium, and their by-products are due to the bioavailability of nitrogen in these compounds, which are readily incorporated into amino acids and other biologically important molecules. The exception in the byproducts of ammonia and ammonium ions is the oxidation product nitrous oxide (dinitrogen oxide [N_2O]), which can persist for approximately 120 years in the atmosphere. When excess ammonia is present in the environment, it is likely to volatize and move into the atmosphere as a gas (2020 TR).

   Furthermore, the TR states that the high-water solubility of ammonia, ammonium and nitrate ions makes them conducive to leaching into water ecosystems. While these compounds can be metabolized by aquatic microorganisms, if they are overabundant eutrophication can occur and ammonia and ammonium can be toxic to aquatic life. Algal blooms can be caused by the influx of high concentrations of nitrogen nutrients. Algal blooms can reduce oxygen concentrations and result in hypoxic and anoxic environments.

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

   The production of ammonia extracts can result in the release of ammonia to the environment. This is expected due to the inability of ammonia isolation processes to capture 100% of the ammonia content of feedstocks. The efficiency of capture depends on the feedstock and isolation conditions, but is reported to be in the range of 17-95% of total ammonia content with a 90% recovery considered acceptable. The remaining ammonia is lost to the environment either as a gas or as residual amounts that remain in the feedstock effluent (2020 TR).

   Other issues of environmental contamination are true of all ammonia compounds and are not specific to non-synthetic ammonias. The release of these compounds to the atmosphere can contribute to degradation of air quality and visibility due to the formation of ammonium aerosols. Additionally, the primary issue of environmental contamination is the over application of nitrogen products and their subsequent leaching into non-agricultural environments. Dramatic losses of 20-80% have been noted. (2020 TR).

   Finally, the disposal/use of the feedstock material that remains after filtration and/or ammonia isolation has not been mentioned in the TR or from public comments. Depending on the use of that feedstock there are potential environmental issues with that remaining material. Comments have focused on issues with phosphorous increases and issues when using manures/composts. This same problem could be an issue when a feed stock is disposed of after ammonia has been removed.

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

   FDA allows the use of a number of ammonium substances or lists them as Generally Recognized as safe. However, these substances differ from those used in agriculture.

   The 2020 TR refers to several human health effects. Ammonium is a positive ion and its effect on human health are dependent on the remaining negative portions of the ionic compound Ammonium ions play a critical role in the Krebs cycle.

   Ammonia is classified as a respiratory irritant – long term exposure to gaseous ammonia can result in bronchial or pulmonary inflammation. Repeated exposure can lead to pulmonary fibrosis. Direct inhalation or ingestion can cause esophageal burns.
5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

   The 2020 TR states:
   Ammonia and ammonium compounds can readily migrate from the applied soil system into the atmosphere and marine environments. When ammonia and ammonium compounds remain in their applied soils, they also induce changes to the local environment. The acidity of ammonium ions is recognized as a cause of soil acidification, reducing the soil pH. These pH changes result in changes to the solubility and bioavailability of other nutrients, affecting both crops and soil organisms. Changes to soil pH may also have negative impacts on the viability of soil organisms, including earthworms and various microbial populations. High soil concentrations of ammonia and ammonium have been shown to retard the natural nitrogen fixation processes of plants. This shift in natural ammonia production reduces the natural efficiency of the soil, making it more reliant on continued nitrogen inputs. The release of ammonia to the atmosphere directly contributes to ozone depletion and global warming (ammonia is a greenhouse gas). Ammonia and ammonium compounds contribute to the degradation of air quality and visibility due to the formation of ammonium aerosols. The production of nitric oxide and nitrous oxide contribute to ozone depletion.

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

   The use of high nitrogen available fertilizers can alter the uptake rates of nitrogen and alter plant nutrient production. Studies by Phelan, Mason, et al., 1995, demonstrate that these altered plant nutrient production cycles can lead to increased susceptibility to pests.

   Other studies show that long-term organic fertilizer inputs enrich carbon related soil functions. Manure additions can strongly influence the formation, storage and cycling of soil organic carbon and nitrogen and soil microecology (Sharaf, Thompson, et al, 2021; Ozlu, Sandhu, et al., 2019). The total amounts (weights) of living organisms vary in different cropping systems. In general, soil organisms are more abundant and diverse in systems with complex rotations that return more diverse crop residues and that use other organic materials such as cover crops, animal manures and composts. When crops are rotated regularly, fewer parasite, disease, weed, and insect problems occur than when the same crop is grown year after year (Magdoff and Van Es, 2021)

There were several public comments noting that the use of ammonia extracts could increase the rate of mineralization in soils and thus be beneficial. In a short timeframe this could be true, but this accelerated rate of mineralization could come at the cost of long-term soil carbon resources. Wang, Juliang, et al., 2018, found that long-term application of N-fertilizers causes an abundance of bacterial groups responsible for the denitrification process, which causes the turnover of nitrogen to increase and results in greater nitrogen loss over time. Essentially, adding more nitrogen fertilizer results in a long-term loss of nitrogen while altering other soil components, like decreasing soil pH and C:N ratio. When soil carbon and nitrogen are reduced in response to the application of chemical fertilizers, beneficial enzymatic activity of the soil also decreases (Ozlu, Sandhu, et al., 2019). Another study concluded:

> Annual nitrate leaching was 4.4–5.6 times higher in conventional plots than in organic plots, with the integrated plots in between. This study demonstrates that organic and integrated fertilization practices support more active and efficient denitrifier communities, shift the balance of N2 emissions and nitrate losses, and reduce environmentally damaging nitrate losses. Although this study specifically examines a perennial orchard system, the ecological and biogeochemical processes we evaluated are present in all agroecosystems, and the reductions in nitrate loss in this study could also be achievable in other cropping systems (Kramer, Reganold, et al., 2006).

The TR states that the incorporation of crop residues and compost provides a potential long-term alternative to ammonia extract and other nitrogen fertilizers. Nitrogen content in compost is slowly released through mineralization processes in the soil, primarily facilitated by its metabolism by microorganisms in the soil. Unlike ammonia extract, the use of compost also contributes to soil organic matter, and available carbon, phosphorous, and micronutrients, as well as soil microorganism populations and activities.

Category 3: Alternatives/Compatibility

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

   The following statements are taken from the 2020 TR.

   There are many natural soil amendments that can be used to deliver nitrogen for crops. Manure is a source of nitrogen compounds, including ammonia, ammonium ions, and urea, which are biological waste compounds. However, manure has a relatively low level of biologically available nitrogen compared to ammonia extract. The biologically available forms of nitrogen in manures may also lead to similar issues with nutrient leaching as ammonia extract, potentially polluting surrounding water systems and leading to atmospheric ammonia emissions. Manure from both organic and conventional livestock is permitted for use in the production of organic crops. However, the availability of manure may be limited regionally due to the continued segregation of crop and animal agricultural production.

In addition to manure, crop residues and compost may be added as a source of bioavailable nitrogen. This includes the direct integration and composting of both manure and other organic agricultural wastes. The high protein and amino acid content of these feedstocks allows for their conversion to ammonia and ammonium compounds through anaerobic digestion and metabolism by soil microorganisms. When composts do not include manures, they are generally low in nitrogen containing compounds (2020 TR).

The incorporation of crop residues and compost provides a potential long-term alternative to ammonia extract and other nitrogen fertilizers. Nitrogen content in compost is slowly released through mineralization processes in the soil, primarily facilitated by its metabolism by microorganisms in the soil. Unlike ammonia extract, the use of compost also contributes to soil organic matter, and available carbon, phosphorous, and micronutrients, as well as soil microorganism populations and activities. The incorporation of compost into the agroecosystem has been reported to improve soil characteristics, specifically water holding capacity and cation exchange capacity (CEC). Increased soil CEC allows it to retain cations more effectively, including ammonium ions and metal cations required as micronutrients (e.g., iron [Fe], copper [Cu], zinc [Zn]) (2020 TR).

Chilean nitrate (mined sodium nitrate) is a natural source of bioavailable nitrate ions. Sodium nitrate offers a natural alternative to ammonia extract as a nitrogen fertilizer, and is the historical source of nitrogen fertilizer prevalent before the advent of the Haber-Bosch process. Nitrate has been shown to be less toxic to terrestrial and aquatic organisms than ammonium ions, although it is toxic to some species at high concentrations. However, nitrate is more likely to contribute to environmental contamination than ammonium, and is the primary nitrogen compound associated with leaching into aquatic systems. Sodium nitrate is highly water soluble and may leach into aquatic systems as run-off. Nitrate also contributes to atmospheric contamination in the form of various nitrogen oxide compounds that are formed through denitrification reactions (2020 TR).

Many other substances derived from natural products are allowed as organic fertilizers. These include fish meal, liquid fish residues, feather meal, bird or bat guano, alfalfa meal, bone meal, kelp, seaweed, and meat meal. These materials may be more readily available to crops due to their low C:N ratio, but all require mineralization to be plant bioavailable. The mineralization is required due to the nitrogen available in these materials being present as more complex molecules and proteins. These materials provide a slower N release than ammonia extracts. They also contribute to increased soil organic matter, CEC capacity and other nutrients and micronutrients. Unlike conventional fertilizers, organic fertilizers have been reported to have minimal negative to long-term positive effects on soil health (2020 TR).

Crop rotation and intercropping are traditional methods to ensure soil health. They can be especially effective if legumes are included in the rotations. Legumes have the ability to fix nitrogen from the atmosphere by converting atmospheric dinitrogen into bioavailable nitrogen. Legumes and other nitrogen-fixing plants produce higher quantities of bioavailable nitrogen when there are low soil concentrations of ammonia and ammonium. Intercropping offers the potential of direct input of bioavailable nitrogen from legumes to other crops by growing them alongside each other. Intercropping has been shown to increase crop yields and these yields have been shown to be less dependent on nutrient inputs compared to monocropping systems. Cover cropping also promotes increased organic matter, increases CEC properties, and prevents soil erosion. Cover crops use can be limited by regional climates and require adequate soil temperatures to grow between agricultural seasons (2020 TR).

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

   To further evaluate compatibility, the Subcommittee review includes answers to the following 12 questions as noted in the NOSB Policy and Procedures Manual

- **Does the substance promote plant and animal health by enhancing the soil's physical chemical, or biological properties**?

  A number of public commenters from the Spring, 2021, NOSB meeting indicated that ammonia extracts must be used with other soil building practices in order to comply with OFPA criteria. These comments would indicate that the use of ammonium extracts alone do not enhance the soil's biological properties. For example:

  > The Petition ignores that the use of any fertilizer, including presently approved ammonia extracts, can only be applied under a holistic certified organic system plan

  This is a complex issue and commenters also provided a range of responses that either indicated that these extracts would harm soil biological properties or that they would enhance these properties. However, it seems contradictory that proponents of ammonia extracts state that they must be used with other organic soil building materials to comply with OFPA. They then turn around and argue that these extracts promote soil biological properties and soil health.

  Of particular note, the comments supporting the use of ammonia extracts were often referring to extracts produced using the concentration method. This method simply concentrates the ammonia containing materials by the removal of water. The carbon and other nutrients are not removed and thus these materials are not the nearly pure ammonia product that is derived from the stripping method. Thus, from comments received it may be important to distinguish these two types of ammonia materials since they cause different soil effects:

  > For instance, "ammonia concentration" can result in innumerable combinations and concentrations of ammonia salts, minerals, and organic matter depending on the starting feedstock used for the digestate as well as the concentration method (e.g., filtration versus evaporation, etc.), resulting in different types and concentrations of biofertilizers (e.g., liquid versus granular). Therefore, the interactions with plants, soil, and microbial communities will differ depending on the resulting end-use formula of the concentrate. In contrast, "ammonia stripping" results in specific ammonia compounds: some variation of ammonium salt depending on the acid used to trap (stabilize) ammonia gas at the end of the stripping process. Ammonia stripping from anaerobic digestion of animal manure, simply put, converts ammonium from organic matter (NH4) to ammonia (NH3) gas, which is then typically absorbed in an acid solution to create ammonium sulfate or ammonium nitrate

  Additionally, commenters often compared the use of all types of ammonia extracts in relation to the use of manures and composts. These references noted the use of manures and composts can create potential for increased phosphorous levels in the soil, nitrogen leaching in seasons where crops are not present and other environmental issues:

> Concerns about damage to the health of the soil system are not unjustified when applying ammonium fertilizers. However, these problems are not any more pronounced with ammonium fertilizers than they are with fertilizers in general. In fact, the targeted use of liquid fertilizers can be less damaging to the soil ecosystem and surrounding water systems than the application of large amounts of manure or even compost, which are both commonly used in organic systems to supply nitrogen

However, other commenters (see comments submitted by Hatfield) noted that a good organic soil program does not rely solely on manures and composts, but also incorporates crop rotations, cover crops and interplanting. In order to avoid phosphorus or calcium build up in the soils after manure or compost application, a complete wholistic approach is necessary for the organic farming system as OFPA states. Crop rotations that cycle between high and low consumption or nitrogen in addition to cover crops in the off-season or intercropping with cover crops during the season help reduce the dependency of consecutive topical applications of manures or compost that can leave phosphorus deposits over time. If phosphorus deposits over time occur, then switching to forage grasses such as alfalfa or other forms of hay can assist in "growing out" the soil problems over time, but the soil will need to be remediated if excesses exist and not ignored for long term soil health and viability. The use of these methods can limit the potential for environmental issues that could result from manure use alone. And, in fact these diverse soil fertility practices can increase soil biological activity:

> The impact of soil carbon on soil biological response was more closely related to the inputs of carbon due to crop rotations than fertilizer practice (Geisseler, 2014). These complexities have been explored by Hijbeeks et al. (2017) when they compared soil and crop responses to organic and inorganic fertilizers on a range of crop from long-term experiments across Europe. Their results showed no significant effect of the organic inputs on crop yield with the effects from organic additions dependent upon the clay content, climate, and the soil organic matter at the beginning of the experiment as shown from their results (Fig. 4). These findings are consistent with those from Lori et al. (2017) in their meta-analysis of 56 experiments across the world. They found organic systems exhibited 32-84% greater microbial biomass carbon, microbial biomass nitrogen, total phospholipid fatty acids, and dehydrogenase, urease, and protease activities than conventional systems. When they used subgroup analyses, they found that crop rotation, inclusion of legumes in the rotation, along with the organic inputs were all significant factors affecting the soil microbial size and activity.

There were few comments comparing the environmental effects of any type of ammonia extract to a complete organic system using manures, composts, crop rotations, cover crops and interplanting. Several commenters wrote that this is an area where research is limited, and effects may largely be unknown.

Given that the comments and citations supporting the use of ammonia extracts generally compare these extracts to the use of manures and composts rather than whole soil systems, that these materials can only be used in conjunction with other carbon contributing soil practices, and that some research indicates their negative effects on soil biology, a conservative approach to this answer is that the use of these extracts does not positively contribute to plant health over the long term.

- **Does use of the substance encourage and enhance preventative techniques including cultural and biological methods for management of crop**, livestock, and/or handling operations?

  As noted by commenters, the use of ammonia extracts must include the uses of other cultural and biological processes to meet the OFPA criteria for maintaining or increasing soil organic matter. The ammonia extracts themselves do not encourage or enhance preventative techniques for crop management.

  Commenters have argued that the limited use of these materials, in situations where nitrogen might be limited due to unusual weather events or cold soils, could "prime" the soil system to increase biological activity or to bridge short term nitrogen deficits. But these situations do not meet the criteria of the wording "encourage and enhance preventative techniques" since they would be a response in an unusual situation when other techniques have failed. Others have noted that if soils are wet or cold during planting time, this points to inefficiency of the mycorrhizal fungi or the root system itself. Nitrogen is not generally needed in large amounts early on, and it is actually phosphorus that is needed. If mycorrhizal fungi are not active due to weather, they cannot process the needed phosphorus to assist with early plant germination. Even in excess phosphorus soils, there can be a phosphorus deficit in the plants when cold / wet soils occur. With the viewpoint of conventional farmers, a true starter fertilizer is actually 10-34-0, indicating more phosphorus is needed early on to charge the soil for the plant "pop-up" than nitrogen itself. This same issue goes for an organic soil.

  Additionally, the purified ammonia compounds require the removal of the carbon value of organic waste, either through filtration or by stripping. In the past, the NOSB has prohibited materials sourced from agricultural waste when the carbon value of the original source material was not retained in the final product. The prohibition of ash from manure burning is an example where the carbon from the manures is removed by burning and the value of the materials for restoring soil organic matter is destroyed.

- **Is the substance made from renewable resources? If the source of the product is non-renewable, are the materials used to produce the substance recyclable? Is the substance produced from recycled materials? Does use of the substance increase the efficiency of resources used by organic farms, complement the use of natural biological controls, or reduce the total amount of materials released into the environment?**

  The substance is made from renewable materials in the form of animal manures and crop wastes. They can increase the efficiency of use since large volumes of manure and compost do not have to be hauled from their source to farms. Ammonia extracts are concentrated and thus much easier to haul and handle.

  Ammonia extracts can be applied when needed and only in the amounts needed at that point in time by the crop. Arguments are made both ways as to whether the applications of these materials and their ready availability to plants reduces their leaching potential (since only the amounts needed can be applied) or whether they bypass soil systems that tie up and release soil nitrogen dynamically (those systems only have a small proportion of nitrogen available to leach). The timing of nitrogen application can be controlled with ammonia extracts and they can be applied in quantities that the crop needs at that point. This could lead to a better match of nitrogen added to nitrogen needed by the crop. However, there is also evidence that dynamic soil systems that release and then reabsorb nitrogen can supply crop needs while minimizing free nitrogen (Bowles, Hollander, 2015). The free nitrogen would be limited and thus leaching potential reduced.

One researcher (Phelan, Mason, et al., 1995) has conducted studies showing that plants are more resistant to insect damage when organic fertilizers are used, as opposed to readily available mineral materials. Thus, the use of ammonia extracts (or sodium nitrate for that matter), since they are readily available, can disrupt biological controls.

- **Does use of the substance have a positive influence on the health, natural behavior, and welfare of livestock?**

  N/A

- **Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?**

  While the answer to this question is not referenced in the TR or other research reports, one public commenter noted that:

  > Objections to the compatibility of these substances with organic principles are serious enough to potentially lead to fragmentation of the organic market. Some companies have indicated they may be prepared to establish private standards that exclude products produced with this input from their supply chain. This is an indication that the substance could fail to align with the 2004 NOSB Recommendation which asks NOSB to consider whether the substance would "satisfy expectations of organic consumers regarding the authenticity and integrity of organic products."

- **Does the substance allow for an increase in the long-term viability of organic farm operations?**

  This is a complex question. Some commenters argue that the potential for yield increases, precision application of nitrogen, and reduction of environmental contamination from excess nitrogen or phosphorous from composts and manures will increase long-term viability of organic farms.

  Others argue that the use of ammonia extracts will degrade soil biological systems and interfere with biological processes that are important to plant and soil health. The use of these extracts may give short term yield increases but are not promoting long term carbon building of the soil. Thus, long-term resiliency and viability may be hurt by the use of these materials.

  Using OFPA and deploying a total systems approach is necessary. Precision technology is independent of ammonia extract and should be adopted by organic farmers that are interested in increasing their yields and applying the right nutrients in the right places. Excess nitrogen or phosphorus applications need to be currently regulated through soil samples, removal rates, etc., and should not be an issue if the total systems approach is applied. Also, if there are nutrient management problems on a particular soil, avoiding solving them and bypassing them with a material that mimics conventional materials should not be permitted in an organic system. At a minimum, ammonia extracts should be listed as a restriction on the OMRI certificate that they cannot be applied if work has not been done to remediate excess phosphorus or calcium build up in soils due to over applications in prior years.

- **Is there evidence that the substance is mined, manufactured, or produced through reliance on child labor or violations of applicable national labor regulations?**

  There is no evidence that these materials violate labor regulations.

- **If the substance is already on the National List, is the proposed use of the substance consistent with other listed uses of the substance?**

  N/A

- **Is the use of the substance consistent with other substances historically allowed or disallowed in organic production and handling?**

  This is a petition to prohibit a natural material. There are other materials currently used in organic production (liquid fish, soy protein hydrolysate, sodium nitrate) that are similar in use. Of these, only sodium nitrate has significant nitrogen in an immediately plant usable form. Sodium nitrate is annotated on the National List to a limit of not more than 20% of crop needs. It is an allowed alternative to ammonia extracts. It should be noted, however, that a previous NOSB voted to prohibit use of sodium nitrate due to concerns of salt buildup and similar concerns regarding soil biology effects.

  In general, natural substances allowed in organic production are made up of complex chemical structures including lignins, proteins, carbon, nitrogen and other minerals and materials. Ammonia extracts produced through the concentration method may be similar to these historically allowed substances except that the ammonia content is concentrated and substantially higher than these naturally occurring substances. That concentration may cause these ammonia extracts to behave differently these other traditional natural materials. As noted above, that different behavior in the soil may be beneficial or detrimental. These differences may be exhibited by the differing C:N ration between ammonia extracts and other organic inputs. With the exception of sodium nitrate, most other traditional non-synthetic organic fertilizers have ratios of at least 3:1 and often greater. The low C:N ratio of ammonia extracts would be expected to cause different soil effects than those materials with higher carbon amounts.

  Proponents for the use of ammonia extracts argue that they are similar to other substances allowed and that they are only more immediately available. When used in moderate quantities they enhance soil biology and can cause soil and plant ecosystems to be more productive.

  Opponents argue that ammonia extracts bypass and short circuit soil biological processes and do not enhance long term carbon build up in the soil. Their low C:N ration is contrary to the original intent of the organic regulations in that soil fertility methods should promote long term soil health and ecosystem stability.

- **Would approval of the substance be consistent with international organic regulations and guidelines, including Codex?**

As noted in the TR, there are a number of ammonia materials listed for use in handling, but there are no listings regarding the use of ammonia extracts for crop production. The use of sodium nitrate for products exported to Canada is limited. Since ammonia extracts and sodium nitrate are similar in plant availability and solubility, it is possible that the use of ammonia extracts in products destined for Canada could also be restricted, but this is unknown at this point. Furthermore, Europe and Canada have systems of closed positive lists, meaning a material cannot be used unless it is on the allowed list. This contrasts with the United States where a non-synthetic material can automatically be used unless it is prohibited or annotated. If ammonia extracts do not appear on the Canadian or European lists, then growers in those countries are unable to use them.

Inconsistencies between international certifiers reduces export market potential and creates additional confusion with countries that have substantially different standards that the United States receives imports from.

- **Is there adequate information about the substance to make a reasonable determination on the substance's compliance with each of the other applicable criteria? If adequate information has not been provided, does an abundance of caution warrant rejection of the substance?**

Given the conflicting information regarding ammonia extracts, it seems prudent to prohibit the use of extracts. These materials have only been developed in the last ten years and there is not adequate research that would demonstrate that these high nitrogen, carbon limited materials comply with OFPA criteria for the maintenance and increase of soil organic matter. As noted above, arguments can be made that these materials have a positive effect or a negative effect. Given that there is no clear answer and that negative effects on soil health have been documented, an abundance of caution warrants a prohibition of these extracts. If future research conclusively demonstrates that these materials comply with the OFPA criteria to maintain and build soil organic matter, a petition could be submitted to remove the prohibition. Additionally, the prohibition could be allowed to expire during future sunset reviews.

Furthermore, an abundance of caution warrants a close look at the use of low (below 3:1) C:N ratio materials, such as ammonia extracts, for organic fertility. The NOSB has set precedents to the limitation of these types of materials. Sodium nitrate is limited to 20% of crop needs. Other highly soluble, non-nitrogen materials are also limited by annotation. It was noted in public comments that:

> 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." At the time, the discussion was about mined substances of high solubility because there were no concentrated, highly soluble plant nutrient materials other than mined sources available at that time.

Another commenter in favor of the use of ammonia extracts stated:

> I also believe that there should be a limit on the amount or percent of AE Nitrogen applied to the crop where no more than 20 – 30% of a crops total N comes from an AE or any high Nitrogen product that contains less than a C:N ratio of 2.

This long-time concern for the use of highly soluble plant nutrients and the criteria of "an abundance of caution" is an important aspect of this petition. With respect to this petition, several options are open to the NOSB. The first is to prohibit ammonia extracts that meet the proposed definition. The second is to reject the petition altogether and allow any use of non-synthetic ammonia extracts. The third would be to annotate the use of these extracts to some maximum percent of crop needs, similar to sodium nitrate.

If an annotation to limit the use of ammonia extracts were to be put in place, the potential exists for sodium nitrate and ammonia extracts to both be used up to each of their maximum allowed rates. This stacked rate would allow for the use of higher applications than either alone. The combined use would put the burden on certifiers to identify whether the total use of these highly soluble products violated the OFPA criteria to maintain or build soil organic matter. It is likely that different certifiers would have different interpretations and that notices of non-compliance would be difficult to enforce.

Additionally, the effectiveness of a prohibition or limitation is dependent on an exact definition of ammonia extracts. If new products are developed that fall outside the definition, a future petition would have to be submitted to determine if they should or should not be allowed. This could create additional work loads and a perpetual cycle of review for each new product produced. It would seem prudent to set an additional limitation for these extracts that might fall outside the current definition, as well as for other highly soluble nitrogen materials. A limitation that would restrict the total use of highly soluble nitrogen fertilizers would prevent the "stacking" of multiple highly soluble fertilizer types. The NOSB should not have to be continually concerned about the introduction of different novel ammonia extracts or other novel non-synthetic nitrogen materials before a petition is submitted to restrict them.

Sodium nitrate was prohibited in part for this same rationale. As stated by NOSB in a past review to justify its recommendation to prohibit, the "use and dependence on sodium nitrate also can tend for producers to put off the need for strong soil-building practices, consistent with §205.203, since it behaves similarly to conventional synthetic nitrogen fertilizers." This is evidence that the substance could fail to align with the 2004 NOSB Recommendation which asks NOSB to consider whether "use of the substance is consistent with other substances historically allowed or disallowed in organic production and handling." Highly soluble sources of nitrogen cannot be addressed in a vacuum, and we cannot look at one material at a time. We must take a broader approach to limiting highly soluble sources of nitrogen as a whole. To evaluate and list each individually, even with a restriction, is a slippery slope and raises the concern of "stacking".

- **Does use of the substance have a positive impact on biodiversity**?

Some commenters argue that ammonia extracts enhance soil biological processes, many others argue that these materials either do not impact or decrease biodiversity. A proponent of the use of ammonia extracts cited Jerry Hatfield in that:

> Bio-based fertilizers 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

Contrarily, the 2020 TR states:

> While bioavailable nitrogen is also important for the function of microorganisms, high concentrations of ammonia and ammonium compounds result in changes to the native soil communities. These changes vary based on the initial soil communities and may result in either an increase or decrease in total population. However, while there are cases of population growth in some communities, the application of nitrogen fertilizers is associated with decreases to the diversity of these microbial communities

Given the conflicting information regarding biodiversity impacts, it would be very difficult to state unequivocally that the use of ammonia extracts has a positive impact on biodiversity. While there is a chance that these extracts do increase diversity, there is a very likely chance that they decrease biodiversity.

References

Bowles, T.M., Hollander, A. D., Steenwerth, K. L., Jackson, L. E.; 2015; Tightly-coupled plant-soil nitrogen cycling: Comparison of organic farms across an agricultural landscape. *PLoS ONE* 10(6): e0131888.

Cassity-Duffey, K., Cabrera, M., et al.; 2020; Nitrogen mineralization from organic materials and fertilizers: Predicting N release; Soil Science Society of America Journal, March/April, 84:2, p. 522-533.

Geisseler, D. A; 2014; Long-term effects of mineral fertilizers on soil microorganisms: A Review; Soil Biology & Biochemistry, 75:54-63.

Hartz, T.K., Johnstone, P.R.; Nitrogen Availability from H-nitrogen containing organic fertilizers; 2006; Horttechnology, January-March 16:1, p. 39-42.

Hijbeek, R. M.; 2017; Do organic inputs matter - a meta-analysis of additional yield effects for arable crops in Europe; Plant Soil, 411:293-303.

Kramer, S. B, Reganold, J. P., Glover, J. D., et al.; 2006; Reduced nitrate leaching and enhanced denitrifier activity and efficiency in organically fertilized soils; Proceedings of the National Academy of Sciences 103, April p. 4522-4527.

Lazicki, P., Geisseler, D., Lloyd, M.; 2020; Nitrogen mineralization from organic amendments is variable but predictable; Journal of Environmental Quality, March/April, 49:2, p. 483-495.

Lori, M. S.; 2017; Organic farming enhances soil microbial abundance and activity - A meta-analysis and meta-regression; PLoS One, 12:e0180442.

Magdoff, F., Van Es, H.; 2021; Building soils for better crops – ecological management for healthy soils; SARE Handbook Series Book 10, Fourth Edition.

Miner, G. L., Delagado, J. A., Ippolito, J. A., et al.; 2020; Assessing manure and inorganic nitrogen fertilization impacts on soil health, crop productivity, and crop quality in a continuous maize agroecosystem; Journal of Soil and Water Conservation, July, 75:4, p. 481-498.
Ozlu, E., Sandhu, S. S., Kumar, S., et al.; 2019; Soil health indicators impacted by long-term cattle manure and inorganic fertilizer application in a corn-soybean rotation of South Dakota; Scientific Reports, 9:1, p. 11776.

Phelan, P. L., Mason, J. F., Stinner, B. R.; 1995; Soil-fertility management and host preference by European corn borer, Ostrinia nubilalis (Hiibner), on Zea mays L.: A comparison of organic and conventional chemical farming; Agriculture, Ecosystems and Environment, 56, p. 1-8.

Sharaf, H., Thompson, A. A., Williams, M. A., et al.; 2021; Functional change in bacterial communities to fertilizer and rootstock; Soil Science Society of America Journal, July/August, 85:4, p. 1105-1121.

Wang, X., Junliang, F., Guoce, X., et al.; 2018; The Effects of Mulch and Nitrogen Fertilizer on the Soil Environment of Crop Plants; Article *in* Advances in Agronomy, Chapter 3, October.

The following are to be added at § 205.602 – non-synthetic substances prohibited for use in organic crop production as a new subsection , (j) ammonia fertilizers. Each type of ammonia fertilizer would be a separate subsection under ammonia fertilizers. For example:

§205.602
- (j) ammonia fertilizers
  - (i) Stripped ammonia
  - (ii) Concentrated ammonia

Stripped ammonia is intended to encompass a wide variation of novel thermo-mechanical derivations of steam stripping technology that result in ammonia-containing condensate, aqua ammonia, ammonium-compound solutions, or any products thereof, such as further isolation of ammonium compounds into a solid by precipitation or solvent evaporation, and/or treatment with nitrifying bacteria.

Concentrated ammonia is intended to focus on products with substantial levels of Am N and avoids products with minimal N. The limit on % ammoniacal nitrogen (greater than 3%) aligns with the OMRI category description for “Fertilizers with High Ammoniacal Nitrogen.” If both definitions are passed, the NOP could combine them into a single listing during rulemaking.

Classification Motion:
Motion to classify ammonia extracts as nonsynthetic
Motion by: Steve Ela
Seconded by: Jerry D’Amore
Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National List Motions:
Motion to add at §205.602, non-synthetic substances prohibited for use in organic crop production: Stripped Ammonia – created by separating, isolating and/or capturing ammonia or ammonium from an agricultural feedstock or other natural source using methods such as, but not limited to, steam stripping, pressurized air, heat, condensation, and/or distillation.

Motion by: Steve Ela
Seconded by: Jerry D'Amore
Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Motion to add at §205.602, non-synthetic substances prohibited for use in organic crop production: Concentrated Ammonia – contains greater than 3% ammoniacal nitrogen <u>and</u> the total nitrogen content is predominately (i.e., >50%) in the ammonia or ammonium form.

Motion by: Steve Ela
Seconded by: Asa Bradman
Yes: 7 No: 1 Abstain: 0 Absent: 0 Recuse: 0

Motion to add at §205.203(f): Nitrogen products with a C:N ratio of 3:1 or less, including those that are components of a blended fertilizer formulation, are limited to a cumulative total use of 20% of crop needs.

Motion by: Steve Ela
Seconded by: Logan Petrey
Yes: 7 No: 1 Abstain: 0 Absent: 0 Recuse: 0

Approved by Rick Greenwood, Crop Subcommittee Chair, to transmit to NOP August 13, 2021.

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Kasugamycin for Plant Disease Control
July 20, 2021

Summary of Petition:

Kasugamycin is an antibiotic that inhibits bacterial protein synthesis and has been approved by the U.S. Environmental Protection Agency (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 of 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.

Summary of Review:
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.

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 was there 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 in Acidovorax sp. occurred in 1990 and in B. glumae in 2001. In Florida, rapid field resistance to bacterial spot of tomato caused by 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).

The TR contractor was asked to answer the question, "is kasugamycin susceptible to development of resistance with normal (labeled) use?" It was reported (TR 1152) that some level of resistance has occurred, and this is why 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 *Aureobasidium pullulans* products during bloom time, and bio-control antagonists such as *Bacillus subtilis* products later in the blooming period. Other organic procedures are also available to control fire blight, but they are more effective on the West Coast.

Summary of Review:

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.

   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.

2. Reference to appropriate OFPA category:

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

   The National Organic Standards Board (NOSB) was petitioned to add kasugamycin as an allowed synthetic to the synthetic substances National List at 7 CFR §205.601. Kasugamycin does contain an active synthetic ingredient: toxins derived from bacteria, as it is isolated from bacterial fermentation.

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)]

Kasugamycin is an antibiotic that inhibits bacterial protein synthesis and would not be expected to have chemical interactions with other materials used in organic farming.

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)]

   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 (2021 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.

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

   The probability of environmental contamination during manufacture is low because it is confined within a facility as a fermentation product. Kasugamycin is characterized as moderately persistent to persistent (U.S. EPA 2013). A major source of degradation is aerobic microbial metabolism in soil with a half-life of 43-73 days. About four percent remains after a year. Because laboratory studies used only one soil type, the EPA uses a 219-day soil half-life in persistence calculations (U.S. EPA 2013). Both aerobic and anaerobic degradation occurs. Aerobic degradation is faster than anaerobic. Typical aerobic half-life in water is seven days and half-life in sediment is 108 days. Anaerobic half-life was 32 days in water and 141 days in sediment (NYS 2015; U.S. EPA 2013). Hydrolysis in water is very slow, especially in acidic conditions (NYS 2015). Kasugamycin moves freely in sandy soil, less so in clay soils. It is likely to move both into surface water and ground water, but movement into ground water is less likely (U.S. EPA 2013). Because of soil movement, field dissipation is faster than molecular degradation seen in the laboratory. Field dissipation half-life in soil is 5.7 to 12.3 days. It does not volatilize readily from water or soil. Half-life of Kasugamycin in the gas phase is 1.6 hours (NYS 2015) (TR 264).

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

   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 was there 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 <u>Magnaporthe grisea</u> and resistance was noticed in 1971. Field resistance in <u>Acidovorax</u> sp. occurred in 1990 and in <u>B. glumae</u> in 2001. In Florida, rapid field resistance to bacterial spot of tomato caused by <u>Xanthomonas perforans</u> 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. (2021 TR 805).

The TR contractor was asked to answer a question about kasugamycin's susceptibility to development of resistance with normal (labeled) use. It was reported (2021 TR 1152) that some level of resistance has occurred, and this is why 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 (Two in California).

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)]

   Up to five percent of applied amounts of kasugamycin move into surface water. Kasugamycin had the largest harmful effect on aquatic plants, especially blue-green algae. For duckweed, *Lemna gibba*, frond count was reduced with EC50 = 86 ppm. For green algae, *Pseudokirchneriella subcapitata*, 96-hour cell density was reduced with EC50 of 3.9 ppm. For blue-green algae, Anabaena flos-aquae, 96-hour cell density was reduced with EC50 of 0.65 ppm (NYS 2015). The most sensitive plant tested was blue-green algae, *Anabaena sp.*, with EC50 0.65 ppm and a no-observed-adverse-effect concentration (NOAEC) of 0.08 ppm (U.S. EPA 2013). Kasugamycin water contamination measured in rice paddy irrigation water was <2 ppm (Sheu et al. 2010). Huang et al. (2010) noted bacterial population changes when adding kasugamycin at high rates to river water microcosms in the laboratory. The EPA states that Kasugamycin is classified as practically non-toxic to freshwater and estuarine/marine fish and invertebrates on an acute exposure basis (U.S. EPA 2013).

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

   Yes. There are subtle changes in the microbial population as some bacterial species develop kasugamycin resistance. As was stated in an earlier section, 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. It is also postulated that the microbial flora of animals that have grazed in orchards sprayed with kasugamycin could develop resistance as has been shown for other aminoglycoside antibiotics. Negative changes in the soil microflora are not in concordance with OPFA criteria for listing on the National List.

Category 3: Alternatives/Compatibility

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

The 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 *Aureobasidium pullulans* during bloom time, and bio-control antagonists such as *Bacillus subtilis* later in the blooming period. Other organic procedures are also available to control fire blight, but they are more effective on the West Coast.

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

   Kasugamycin has been in agricultural use since 1965. It has been used against a number of plant pathogens. In every instance, some level of resistance has occurred (Vallad et al. 2010; Yoshii et al. 2012). The EPA believes that resistance of the fire blight pathogen *Erwinia amylovora* to kasugamycin is possible, and the Kasumin label requires a resistance management plan. This plan includes use of kasugamycin as part of an IPM program and less than four applications per year (U.S. EPA 2018). (2021 TR 1145

   Given the history that antibiotics used in agriculture create microbial resistance, and that the NOSB has voted to remove other antibiotics in the same family, such as streptomycin, from the National List, the Crops Subcommittee finds that kasugamycin, is not compatible with a system of sustainable agriculture under OPFA criteria.

Classification Motion:
Motion to classify kasugamycin as synthetic
Motion by: Rick Greenwood
Seconded by: Steve Ela
Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National List Motion:
Motion to add kasugamycin to the National List at §205.601(j)(4) for plant disease control
Motion by: Rick Greenwood
Seconded by: Amy Bruch
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

Approved by Rick Greenwood, Crop Subcommittee Chair, to transmit to NOP July 22, 2021.

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Stabilized Hydronium used as a processing aid in organic crop production
July 23, 2021

Summary of Petition:
Hydronium is being petitioned for use as a processing aid for pH adjustment not below 5.0 and as a stabilizer in the production of animal manures. It would be used to reduce malodorous properties of manures.

Summary of Review:
A survey of regulations for organic production from a number of countries and international organizations indicates that hydronium is not included within the Canadian Organic Standards as an allowed material. CODEX Alimentarius does not include a listing for hydronium nor is there a listing in the Japan Agricultural Standard (JAS) for Organic Production. Based on data submitted by the manufacturer, hydronium acts as a biocide but has not been approved by the EPA for that use.

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.

   Hydronium is a mixture of sulfuric acid and calcium hydroxide. The sulfuric acid is produced from sulfur dioxide collected in pollution control scrubbers and the calcium hydroxide is produced by hydrating calcium oxide. Hydronium is a manufactured compound.

2. Reference to appropriate OFPA category:

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

   Hydronium was petitioned as an allowed synthetic substance for addition to the National List at 7 CFR §205.601 (j) 7. Hydronium is used as a production aid and although it contains sulfur, very little sulfur is left in the final product.

Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

   As described in the petition, hydronium would be used in small amounts as an addition to manures during processing and would not be expected to cause detrimental chemical interactions.

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

   The compounds used to produce hydronium are listed as "food grade" and the company states that there are no hazardous compounds generated as by-products.

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

   The technology used to produce hydronium is rated as "non-hazardous" as rated by 3rd party testing and EPA 6-pack testing. There is no discharge waste material or air emissions during production. The probability of environmental contamination during production is low.

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

   Based on EPA 6-pack testing hydronium is rated as non-hazardous, has a corrosivity rating similar to distilled water and does not induce amide hydrolysis on plant, animal, or human tissue.

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)]

   Hydronium is used in very small quantities and would not be expected to have any physiological effects on soil organisms or interact with chemicals in the agroecosystem.

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

   Data submitted in the proposal demonstrates that hydronium has biocide properties, and the petitioner has requested that designation of the product from the EPA. To date, it has not been approved by the EPA. Because hydronium is a biocide it is expected to have an impact on the biodiversity of soil microorganisms with unknown effects.

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)]

OMRI lists over 2,000 pH adjustment aids/acidic compounds. Although many of them would probably not be applicable to the process of odor control of manure many organic acids could probably perform as hydronium is described.

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

   No. Based on OPFA criteria and improving soil health, the biocide activity of this product and the lack of EPA approval make it incompatible with a system of sustainable agriculture.

Classification Motion:
Motion to classify hydronium as synthetic
Motion by: Rick Greenwood
Seconded by: Amy Bruch
Yes: 8 No: 0 Abstain: 0 Absent: Recuse: 0

National List Motion:
Motion to add hydronium to the National List at 205.601(j)(7) as an organic processing aid
Motion by: Rick Greenwood
Seconded by: Steve Ela
Yes: No: 8   Abstain: 0 Absent: 0 Recuse: 0

Approved by Rick Greenwood, Crop Subcommittee Chair, to transmit to NOP July 31, 2021.

National Organic Standards Board
Crops Subcommittee Petitioned Material Proposal
Carbon Dioxide
August 3, 2021

Summary of Petition:
The NOSB received a petition requesting the addition of synthetic carbon dioxide at §205.601 Synthetic substances allowed for use in organic crop production as (a) algicide, disinfectants, and sanitizer, including irrigation system cleaning systems and (j) As plant or soil amendments.

Carbon dioxide is currently allowed for use as an ingredient in organic labeled processed food products: §205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." (b) Synthetic allowed: - Carbon dioxide.

This petition requests the allowance of carbon dioxide in organic crop production.

Subcommittee Review:
Carbon dioxide is understood to be a material with inherently low risk and is approved as a processing aid. Because carbon dioxide is a synthetic material, the Subcommittee discussions focused on the need and benefits of using carbon dioxide over other allowed alternatives?

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.

   Carbon dioxide (empirical formula CO2, CAS Reg. No. 124-38-9) occurs as a colorless, odorless, noncombustible gas at normal temperatures and pressures. The solid form, dry ice, sublimates under atmospheric pressure at a temperature of −78.5 °C.

   Carbon dioxide is prepared as a byproduct of the manufacture of lime during the "burning" of limestone, from the combustion of carbonaceous material, from fermentation processes, and from gases found in certain natural springs and wells.

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

   Carbon dioxide falls under the category of production aid.

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)]

   Carbon dioxide is already allowed as an organic processing substance. It occurs naturally in the atmosphere, has little chemical interactions with other substances, and has no apparent negative effect on other materials used in organic farming systems.

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

   The action to dissolve carbon dioxide (CO_2) in water (H_2O) makes carbonic acid (H_2CO_3): H20 + CO_2 -> H_2CO_3. Carbonic acid is dissociated in water to: HCO_3^- + H^+. This hydrogen lowers water pH. This is a common, naturally occurring reaction in the soil ecosystem from CO_2 in the atmosphere.
   In soils with high pH, applying water with a reduced pH can increase nutrient availability and increase plant health. Additionally, the activity of carbon dioxide in water can help prevent clogging of irrigation systems by algae and other plant contaminants.
   CO_2 can also be used for pest control in storage areas, however, that is not the subject of this petition.

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

   As a basic component of the atmosphere, carbon dioxide has a high environmental persistence. This is not a negative, except to the overarching concern of global warming. At the rates occurring in the atmosphere, it is completely non-toxic and is exempt from having a lethal dose. The water pH adjustment process can be manually controlled, as well as automatically controlled, by adding a pH probe and controller that adjusts the carbon dioxide (CO_2) injection to maintain target pH values in the water. Water cannot drop below pH 5.0 when carbonic acid (dissolved CO_2) is used in the acidification process. This characteristic makes the use of carbonic acid the safer and most secure process for water pH adjustment when compared to alternatives.

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

   Suffocation can occur in pure carbon dioxide but is due to the lack of oxygen not toxicity of carbon dioxide. There are no other direct effects of human health from the substance.

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

   The use of dissolved carbon dioxide to reduce water pH is an acidifying method that occurs naturally, i.e.- atmospheric carbon dioxide from biological processes enters water through equilibrium. It dissolves in water, including water in soil solution, to form carbonic acid. Carbon acid breaks down into carbon dioxide.

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

   Carbon dioxide is a greenhouse gas and can contribute to climate change. Its increase in the atmosphere has altered the biodiversity in many ecosystems. However, the use of this product in accordance with the petition will not add to the increase of carbon dioxide. The petitioned use is for carbon dioxide produced as a byproduct of other processes. The carbon dioxide would be released to the atmosphere regardless of the petitioned use.

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)]

   Alternatives used in organic production to lower pH levels in irrigation water are sulfur "burners" and citric acid. Because water pH cannot drop below 5.0 when carbon dioxide is used as an acidifier, this method may be considered more secure as a pH adjustment compared to alternatives.

   Sulfur burners create sulfurous acid by dissolving the fumes of burning sulfur in irrigation water. Sulfur is an odorless, tasteless, light-yellow solid usually sold in blocks or pellets. Sulfurous acid is slightly irritating to the skin, and strongly irritating to the eyes of rabbits. Under acidic conditions, sulfurous acid may liberate sulfur dioxide, which is known to induce respiratory irritation in humans.

   Citric acid is a non-synthetic widely used in food processing. It is used as an ingredient, acidulant, pH control agent, flavoring, and as a sequestrant. It is used as a dispersant in flavor or color additives. Citric acid has GRAS status (generally recognized as safe) by the FDA

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

   Because carbon dioxide is approved as an organic processing substance, is already being produced, and its listing at §205.601 would be considered a recycling process, the Crops Subcommittee finds it compatible with a system of sustainable agriculture.

Classification Motion:
Motion to classify carbon dioxide as synthetic
Motion by: Logan Petrey
Seconded by: Rick Greenwood
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

National List Motion:
Motion to add carbon dioxide at §205.601
Motion by: Logan Petrey
Seconded by: Brian Caldwell
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Rick Greenwood, Crop Subcommittee Chair, to transmit to NOP August 3, 2021

National Organic Standards Board
Crops Subcommittee Proposal
NOP Request to Review *Lithothamnion* Classification
August 3, 2021

I INTRODUCTION:

Lithothamnion is a genus of coralline marine red algae containing 103 species, some of which have calcareous deposits within their cell walls. It is sometimes considered a plant in the botanical classification *Rhodophyta* within *Archaeplastida*, but other times is not included in the stricter definition of "plant", *Viridiplantae* [https://en.wikipedia.org/wiki/Plant]. In common usage, seaweeds such as *lithothamnion*, kelp, etc. are called plants.

Biology and use

According to The Seaweed Site https://www.seaweed.ie/uses_general/corallinealgae.php :
"A number of crustose, calcareous red algae (Corallinaceae) grow detached in shallow waters and accumulate to form large beds of stone-like algae on the coasts of north western Europe and in the western Mediterranean, México (Baja California), and Brazil. These are collectively known as "maërl", "coral" or "coral sand" in north-western France, Britain and Ireland (Blunden, Binns & Perks 1975). Scientifically, they are also known as "rhodoliths".
"The two most common species in the north-eastern Atlantic are *Phymatolithon calcareum* [apparently a synonym for *L. calcareum*] and *lithothamnion corallioides*, growing from 0-8 m (occasionally to 32 m) in the subtidal of quiet bays with clear Atlantic water off the coasts of Spain, France, England, Scotland, and Ireland, and in the Mediterranean. Similar species form such beds in clear waters throughout the world, such as the Gulf of Mexico, Arctic Canada, Indonesia. The algal thallus is made up of successive layers of calcium (and some magnesium) carbonates, which may account for up to 80% of the wet weight.

Maërl is dredged off the coast of Brittany, at Falmouth in England, in Bantry Bay, Ireland, and in Iceland, dried, ground, and sold as a soil additive, for animal feed supplements, as a water filtration agent, and as a natural anti-osteoporosis remedy. Over 500,000 t are harvested each year from live and dead deposits, although annual amounts are declining, mainly due to the exhaustion of resources, particularly in France.
In Ireland, about 20,000 tonnes of subfossil maërl is harvested from a site in Bantry Bay".

The species *Lithothamnium calcareum* is, besides tricalcium phosphate, often used as food fortification in plant-based milk substitutes to achieve a similar calcium content as a cow milk.
https://en.wikipedia.org/wiki/Lithothamnion

A U.S. Food and Drug Administration (FDA) generally recognized as safe (GRAS) notice has been published for seaweed-derived calcium for the intended use: "in foods in general as a source of dietary calcium for food enrichment and fortification purposes at various levels that range up to 4.0 percent." [https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=28&sort=GRN_No&order=DESC&startrow=1&type=column&search=GRN%20No%2E%C2%A4DECIMAL%C2%A428]

Harvest
Lithothamnion superpositum [=*lithothamnion crispatum*] is a species found off the coast of South America and is used in calcium-enrichment food products and supplements. It's typically a kiwi- or lemon-sized ball of purplish calcified algae that attaches to seaweed on the ocean floor. According to a manufacturer, "At a certain point, it's washed onto shore in a protected eco-marine park and sustainably hand-harvested."

Certifiers that the NOP consulted provided the following additional information:

- *Lithothamnion superpositum [sic] [should be L. calcareum]* algae species have life spans between 50-100 years and appear to favor the volcanic sand/gravel deposits along the coastline shelves near to the shore of Iceland, most concentrated in the West Fjords. During their life span, the algae fronds accumulate seawater minerals, calcifying the fronds. Calcified pieces of the algae break off the live plants, and currents move this material to lower shelves further offshore.
- Harvesting in Brazil is done by dredging dead calcareous skeleton sediment material of *lithothamnion* algae (algae shells), that has detached and accumulated in deposit areas by tide movements, from deep waters off the continental shelf of Brazil. Harvesting in Iceland is done by dredging calcified marine algae from (dead) *lithothamnion sp.* from mines in the sea (100 yards or more offshore, avoiding the live plants) in fjords.
- After harvest, lithothamnion is washed/heat treated, dried, milled, and packaged.

II BACKGROUND:
A *lithothamnion* product was petitioned to be added to the National List in February 2007 (see "Calcium, Seaweed Derived" on the USDA Petitioned Substances webpage). [The petition and NOSB recommendation can be found under "calcium, seaweed derived" at:
https://www.ams.usda.gov/sites/default/files/media/Calcium%20Seaweed%20Petition.pdf]
In 2008, the NOSB recommended that "calcium, seaweed derived" did not need to be considered for addition to §205.605(a) "since use of this material is currently allowed through the existing listing of Nutrient Minerals on the National List §205.605(b)."

Since the 2008 NOSB recommendation, the NOP has received questions about whether USDA organic regulations allow the certification of *lithothamnion*. Organic certification allows organic handlers to use ingredients in organic products without the content counting as part of the 5 percent nonorganic ingredient component. The NOP previously informed a certifier that *lithothamnion* is a nonagricultural product and therefore cannot be certified organic. Since then, the NOP has learned that two certifiers certify *lithothamnion* under the wild crop portion of the USDA organic regulations. Additionally, seven operations are certified to handle organic *lithothamnion,* identified in the Organic Integrity Database as: "*Lithothamnium*," "*Lithothamnion superpositum,*" "*Lithothamnion sp*.," "*Lithothamnion,*" and "*Lithothamnion calcareum.*" Certifiers did not clarify how an agricultural determination was made.

In March 2021, the NOP sent a memo to the NOSB requesting that the NOSB address the classification of collected l*ithothamnion* as "agricultural" or "nonagricultural" and if it may be certified as a "wild crop" under the USDA organic regulations.

III RELEVANT AREAS OF THE RULE:
Related definitions from section 205.2 of USDA organic regulations:

Agricultural product. Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption.

Nonagricultural substance. A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.

Wild crop. Any plant or portion of a plant that is collected or harvested from a site that is not maintained under cultivation or other agricultural management.

According to NOP Guidance 5033, the decision tree 5033-2 should be used to determine whether a substance is classed as Agricultural or Nonagricultural under the NOP. In this case, the substance is collected *lithothamnion*; that is, *lithothamnion* as harvested, before any processing.

IV DISCUSSION:
The Decision Tree for Classification of Agricultural and Nonagricultural Materials for Organic Livestock Production or Handling (NOP 5033-2), step 1, asks, “Is the substance a mineral or bacterial culture as included in the definition [above] of nonagricultural substances in section 205.2 of USDA organic regulations?”

The answer is not simple. Harvested *lithothamnion* consists of dead parts of an algae, harvested for their mineral content. Further, it is not a product of agriculture. Note that an example in decision tree 5033-2 classifies kelp, which is somewhat similar, as agricultural. However, the NOSB feels that the classification turns on the fact that kelp is harvested live, whereas dead parts of *lithothamnion* are harvested as a mineral. Thus, the answer is yes, thereby classifying *lithothamnion* as nonagricultural.

Can a nonagricultural substance be classified as organic? Perhaps, if it is a wild crop.

Is *lithothamnion* a wild crop? Guidance 5022 (National Organic Program wild-crop harvesting practice standard) states, “Eligible species can be plant or other non-animal species, such as mushrooms, kelp, or seaweed, that are fixed to a defined location by a species part, such as a root, holdfast, mycelial thread, rhizoid, or stolon.” Based on the definition and guidance above, and allowing for common usage of the word, “plant”, the NOSB determines that *lithothamnion* is not a wild crop, because it is not a live plant or part of a live plant, and is not fixed to a defined location.

Lithothamnion is similar to diatomaceous earth, peat, or limestone—originally living tissues that after death are accumulated into deposits that can be mechanically harvested.

V RECOMENDATION:
Based on the above considerations, *lithothamnion* is classified as a nonagricultural substance. According to NOP Guidance 5022 lithothamnion is not a wild crop since it is not fixed to a defined location by a species part, therefore it cannot be certified organic.

Vote in Crops Subcommittee:
Motion to classify *lithothamnion* as a nonagricultural substance
Motion: Brian Caldwell
Seconded by: Amy Bruch
Yes:- 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Motion that *lithothamnion* does not meet wild crop criteria and is not eligible to be certified to the wild crop standard.
Motion: Brian Caldwell
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 August 6, 2021.

National Organic Standards Board
Crops Subcommittee Proposal
Biodegradable Biobased Mulch Film
August 13, 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 consider reducing the biobased content requirement. The Crops Subcommittee is now planning to vote on an annotation at the Fall 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. The vast majority of mulch films in this category contain 20% or less of biobased materials (i.e., carbon sources are ~80% petroleum derived). There are some products that might meet the biobased aspect of this material's definition on at **§**205.2, but they 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 fossil fuel-derived 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, and likely fuel, 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. Despite the lack of products meeting the annotation, the NOSB reviewed this material for its five-year sunset renewal in 2017 and decided to relist it as written, with the understanding that there were no products on the market that were commercially viable made from 100% biobased materials. The Crops Subcommittee felt more information was needed that addressed the key questions above before considering a change to the annotation. The Crops Subcommittee also felt that if biodegradable mulch remained on the National List manufacturers would be able to develop a product that met the 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 Report, 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 …. 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, the majority 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. Figures 2 and 3 show examples of relatively complete biodegradation after less than one year and another case where visible material after 2 months “burial” (source: https://eorganic.org/node/8260).

Figure 2. (a) Starch-based biodegradable plastic mulch (BioAgri®) in experimental field plots during harvest, 135 days after laying mulch. (b) 9 months post-harvest on soil surface, 348 days after laying mulch. (c) 9 months post incorporation, 348 days after laying mulch. Photo Credits: J. Cowan (2a) and C. Miles (2a, 2b), Washington State University. From Corbin et al., 2013.

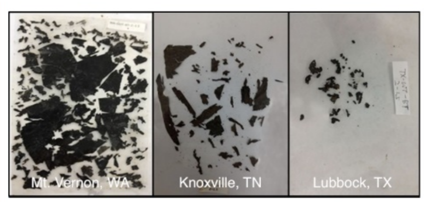


Figure 3. Samples of starch based biodegradable plastic mulch (BioTELO®) recovered after twenty four months burial in the field at three experimental locations. Photo credit: J. Moore-Kucera, Texas Tech University.

Organic Strawberry PE Film Plasticulture (Source: https://ucanr.edu/blogs/blogcore/postdetail.cfm?postnum=31015&)

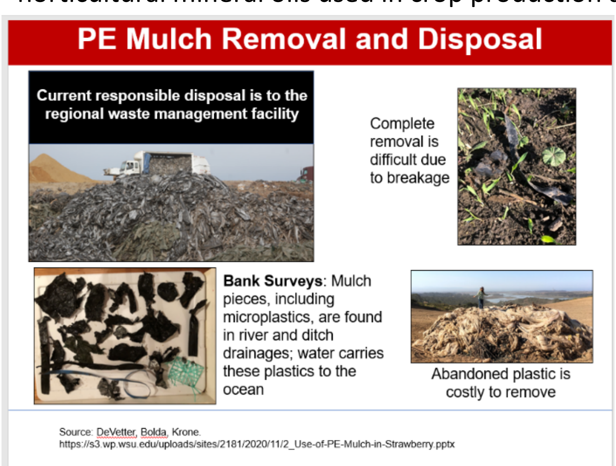
Monterey County Agriculture Plastic Waste – Organic and Conventional. Source: P. Krone, NOAA

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. Use of plastic in organic production is increasing rapidly. Many 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 to essentially containerize soil, resulting in enormous amounts of plastic waste and agricultural soil and general environmental contamination (see figures). For example, the Monterey County Regional Waste Management District in California receives 5,700 tons (11.4 million lbs.) of agricultural plastic annually. Based on the acreage of organic strawberries, (approximately 20%), up to ~1-2 million lbs. is likely from organic fields each year. 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 petroleum-derived products on organic soils. For example, horticultural mineral oils used in crop production are 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.



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 with less than 100% biobased content, if they are approved. 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.

Public commenters at the April 2021 meeting remain divided, although many farmers and certifiers agreed reducing the requirement of 100% biobased content by a small margin is reasonable. Groups supporting the change included, Oregon Tilth, OWPC, MOSA, PCO, QCS, VOF, NOFA. Many farmers also supported the change. Those opposed included NOC, BP, MOGFA, Cornucopia, and OEFFA, raising concerns about the product being “not ready for prime time”, the potential for environmental contamination, the replacement of plant-based mulches, and that use may not reduce use of PE film-based plasticulture on soils.

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 recommends that use of >80% biobased material be required if and when these materials become available, The CS also recommends ongoing monitoring of new research on BDM and other plastic films and that the NOSB should consider changes to this annotation as information and new products 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.

§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) Must be **at least 80%** biobased with content determined using ASTM D6866 (incorporated by reference; see § 205.3).

Vote in Crops Subcommittee
Motion to accept the biodegradable biobased mulch film annotation recommendation.
Motion by: Asa Bradman
Seconded by: Brian Caldwell
Yes: 7 No: 1 Abstain: 0 Absent: Recuse: 0

Approved by Rick Greenwood, Crop Subcommittee Chair, to transmit to NOP August 15, 2021.

National Organic Standards Board
Crops Subcommittee Proposal
National List Technical Correction for Sodium Nitrate
July 27, 2021

Background:
The NOSB seeks to make a technical correction to the listing for sodium nitrate. While sodium nitrate still appears on the National List of Allowed and Prohibited Substances (National List) with an annotation limiting its use (7 CFR 205.602(g) – prohibited nonsynthetic), the sunset review of sodium nitrate has been suspended. The current listing reads:

> Sodium nitrate – unless use is restricted to no more than 20 percent of the crop's total nitrogen requirement; use in spirulina production is unrestricted until October 21, 2005.

According to the sunset provision in OFPA, sodium nitrate was supposed to sunset from the National List on October 21, 2012. At that time, the sunset process required the NOSB to vote to relist a substance for it to remain on the National List. If the NOSB voted to not renew a substance, it would be referred to the NOP for rulemaking to remove it from the List. The current process differs in that the NOSB must vote to remove a substance from the list, otherwise the substance remains on the List.

As part of the 2012 sunset review, the NOSB reviewed sodium nitrate at its April 2011, meeting and recommended that it be relisted, but without the annotation limiting its use. In other words, the NOSB voted to keep sodium nitrate on the National List with a complete prohibition on its use. During the rulemaking process, the NOP received comments about the economic significance of complete prohibition, which delayed rulemaking. While that rulemaking was supposed to be forthcoming, it was never developed nor passed.

Currently the listing for sodium nitrate is in limbo. It was never renewed on the National List as a prohibited substance with or without the annotation limiting its use. While the wording remains on the National List, the listing is considered invalid. Therefore, sodium nitrate use is not restricted to 20% of a crop's total N needs since the listing was not renewed during the 2012 sunset process. It can also be argued that at this time sodium nitrate should not even appear on the National List since it was never officially renewed.

Subcommittee Review:
In order to remedy and clarify this technical issue, stakeholders have asked the NOSB to formally reinstate the listing for sodium nitrate. This proposal is not intended to be a review about whether sodium nitrate should be listed with a 20% cap or be completely prohibited. While this Board notes that the previous NOSB voted for a complete prohibition, in order to ensure that sodium nitrate isn't allowed for unlimited use, this Board recommends a formal motion to recognize the current listing and have it reviewed every five years as part of the sunset cycle. A future Board, or petitioner, can submit a petition for a complete prohibition and that can be debated separately from the resolution of the technical issue that is at currently at hand.

Subcommittee Vote:
Motion to reinstate the listing of sodium nitrate at 7 CFR 205.602(g) - prohibited nonsynthetic: Sodium nitrate - unless use is restricted to no more than 20 percent of the crop's total nitrogen requirement; use in spirulina production is unrestricted until October 21, 2005.

Motion by: Steve Ela
Seconded by: Brian Caldwell
Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Rick Greenwood, Crop Subcommittee Chair, to transmit to NOP July 27, 2021.

Sunset 2023
Meeting 2 - Review
Crops Substances § 205.601 & § 205.602
October 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 scheduled for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the Petitioned Substances Database.

Request for Comments

Written public comments will be accepted through September 30, 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
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 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.

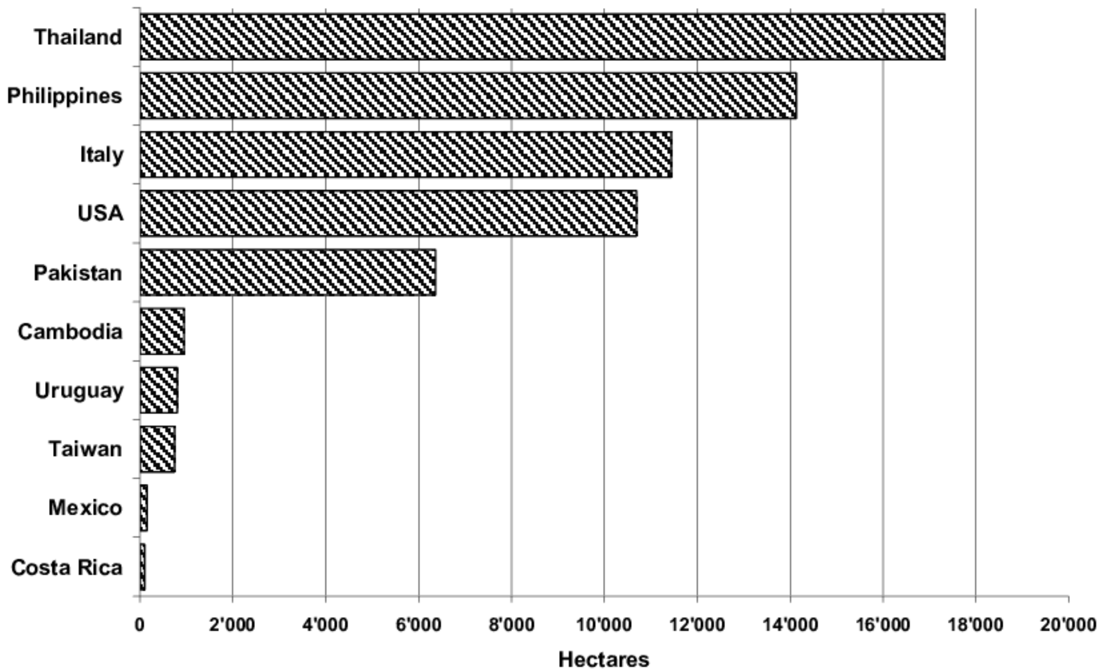


Figure 1. Top producers of organic rice globally (Willer and Yuseffi 2007).

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 Abbottsford 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 and Human Health 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 can 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 known to be toxic to native amphibian species.

In the soil, copper concentrates heavily in the topsoil and over time, leads to resistant fungal strains, 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 is called into question.

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 of bees (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 issue to clarify. The role that bees play in the pollination of commercial crops globally should make the use of copper sulfate 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, its use has repeatedly been 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 copper sulfate use in rice paddies to control tadpole shrimp, it appears that there may be 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 seedings 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.

It may be time to research alternate algicides and other means of controlling tadpole shrimp. It appears that to date there is sufficient evidence to conclude that:

1) use of copper sulfate in rice fields can cause environmental damage,
2) alternative seeding practices could eliminate the need for copper sulfate 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.

Despite these points, public comment, and interviews with organic rice farmers, certifying agencies, and former board members have all highlighted the ongoing need for copper sulfate until alternative herbicides/insecticides are available. According to these sources, abrupt de-listing would have a tremendous negative impact on US-grown organic rice.

Subcommittee Review
Much of the Crops Subcommittee's review of copper sulfate centered on public comments and on interviewing stakeholders after the Spring 2021 NOSB meeting. There were in excess of twenty-five written and oral comments with the overwhelming majority in favor of keeping copper sulfate on the National List. Two of the organizations most opposed to the use of copper sulfate did not advocate immediate delisting, but rather, strongly urged the program to: Get serious about "Continuous Improvement" and to put some real effort into finding alternative methods or materials that would limit or end its use.

The Crops Subcommittee recommends re-listing copper sulfate and has called for a comprehensive review of copper sulfate as part of its Research Priorities for 2021.

References

- Buzio L, Tondel M, De Palma G, et al. (2002) Occupational risk factors for renal cell cancer. An Italian case-control study. La Medicina del Lavoro. 93(4):303-309.
  Rodrigues C, Krüger A, Barbosa W, Guedes R (2016) Leaf fertilizers affect survival and behavior of the Neotropical Stingless Bee Friesella schrottkyi (Meliponini: Apidae: Hymenoptera) , Journal of Economic Entomology, 109(3):1001–1008.
- Tindall K, Fothergill K (2012) Review of a new pest of rice, Tadpole Shrimp (Notostraca: Triopsidae), in the midsouthern United States and a winter scouting method of rice fields for preplanting detection. Journal of Integrated Pest Management 3 (3):B1–B5.
- Van Assche F, Clijsters H (1990) Effects of metals on enzyme activity in plants. Plant Cell Environ. 13:195-206.
- Willer, Helga & Yussefi, Minou. (2007). The World of Organic Agriculture - Statistics and Emerging Trends 2007.

Justification for Vote
The Subcommittee proposes removal of copper sulfate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove copper sulfate from the National List at 205.601(a)(3) and 205.601(e)(4)
Motion by: Jerry D'Amore
Seconded by: Rick Greenwood
Yes: 2 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Ozone gas

Reference: §205.601(a)(5) Ozone gas—for use as an irrigation system cleaner only.
Technical Report: 2002 TAP; 2021 TR
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 gas 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 disinfect water and to oxidize color and taste contaminants in water. Ozone is found in the atmosphere at levels of 0.05 ppm but at levels of 0.5 ppm in cities with smog.

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 the 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
The 2021 TR of ozone noted the following:

Canadian General Standards Board Permitted Substances List - not listed

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
- ozone not listed.

International Federation of Organic Agriculture Movements (IFOAM) Norms
- listed as an equipment cleanser and equipment disinfectant.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999) - not listed

Japan Agricultural Standard (JAS) for Organic Production - ozone is not listed for water treatment.

Human Health and Environmental Issues
When ozone gas is used for water treatment it oxidizes or disinfects many components that impact water quality and could result in crop iron deficiencies. It will oxidize iron and manganese, which precipitate as ferric and manganese hydroxides. Ozone partially oxidizes organic matter to forms that are more easily biodegradable. It is also germicidal against many types of pathogenic organisms including viruses, bacteria,

and protozoa. It is rated as a strong irritant via inhalation, and irritating 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 that ozone is listed in 50 organic system plans (OSPs). The users include wineries, mushroom operations, and grain handlers. There were 17 public comments at the 2021 Spring NOSB meeting, and all were in favor of relisting ozone gas on the National List.

Justification for Vote
The Subcommittee proposes removal of ozone gas from the National List based on the following criteria in the Organic Foods Production Act (OPFA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove ozone gas from the National List
Motion by: Rick Greenwood
Seconded by: Amy Bruch
Yes: 0 No: 6 Abstain: 0 Absent: 2 Recuse: 0

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 that 6%, for use in organic crop production. Peracetic acid was relisted during the 2016 sunset review for Handling and the 2017 sunset review for Livestock. Peracetic acid is an unstable oxidizing agent, which makes it an effective sanitizer.
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 as a seed treatment to inactivate fungi or other plants 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.

Manufacture
According to the 2016 Technical Report (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.
PAA 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.

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 - Not listed.

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.

IFOAM - The 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).

Human Health and 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 which year? 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, it works well in cold conditions, it does not give off chlorine into the environment, it is used as part of a rotation process in fire blight disease control, and it 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 information was provided during public comment and can be found in the 2016 TR.

Concerns about the various forms of peracetic acid mentioned in the 2016 TR were raised during public comment submitted for the Spring 2016 NOSB meeting. 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 mentioned that all sanitizers and disinfectants should be looked at to determine need and to prioritize allowed uses. The NOSB determined this request was outside of the scope of this specific sunset review and would need to be addressed as a separate issue/topic.

Other public comments mentioned that the implementation of the Food Safety Modernization Act (FSMA), which oversees an enhanced approach to food safety at the farm and 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, the NOSB 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 review for Livestock.

Summary of Public Comments
There is widespread use of peracetic acid by many stakeholders, and it is generally considered to be critical to the sanitizer, cleaner, and disinfectant toolkit as one of the most benign and effective materials available for crop-specific uses. Many certifiers report that it is a sanitizer in increasingly widespread use.

Organic producers consider peracetic acid essential to ensure food safety and compliance with food safety regulations under FSMA. Stakeholders broadly support the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized "by specific use or application" with clear identification of the hazards to humans and the environment (NOC, 2020). Further, restructuring the National List so that cleaners, sanitizers, and disinfectants have a designated category would help to ensure certified operations understand which cleaners, sanitizers, and disinfectants may be used, and it would facilitate better organic education. Overall, a unique category on the National List could help the NOSB in its review of cleaners, sanitizers, and disinfectants, and it could support the use of alternative, less toxic materials, when their use can meet strict food safety standards (OTA, 2021). Establishing a separate sanitizer listing on the National List is beyond the scope of this sunset review but the Crops Subcommittee – in coordination with the Handling Subcommittee -- will recommend a work agenda item to advance these suggestions.

Justification for Vote
The Subcommittee proposes removal of peracetic acid from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove peracetic acid from the National List
Motion by: Wood Turner
Seconded by: Jerry D'Amore
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

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
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987); Sunset Review 10/09/2008 (73 FR 59479); Sunset Review 10/03/2013 (78 FR 61154); Sunset renewal notice effective 5/29/2018 (83 FR 14347).
Sunset Date: 5/29/2023

Subcommittee Review

Use
The annotation for EPA List 3 inerts limits their use in organic crop production to passive pheromone dispensers. The dispensers are generally manufactured as either tubes that contain pheromones or as an

impregnated substance containing the pheromone. Passive pheromone dispensers 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 design 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 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 (GXG 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.

Human Health and Environmental Issues

Passive pheromone dispensers used to monitor 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, insecticides may be needed for control of a specific pest insect. 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, 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 pheromone dispensers containing List 3 inerts used per acre. Often maximum applications are in the range of 400 dispensers per acre. Information from the package of one manufacturer lists 8% other ingredients which may include List 3 inerts, 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 is very low when compared to the amounts of allowed List 4 inerts applied in spray materials or the amount of synthetics applied in allowed newspaper mulch. While 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 crop 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 noted in the 2020 review of List 4 inerts, the List 3 inerts listing is also outdated because EPA no longer maintains these lists. Thus, the process 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 the NOSB supported the recommendation that inerts be moved into a separate listing, containing all inert ingredients, with a subheading for inert ingredients used in passive pheromone dispensers. However, the process recommended by the NOSB in that review was not initiated, therefore the current 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 the 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 pheromone dispensers, have a history of use in organic farming, and 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 the 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 pheromones in organic production was a common theme in the public comments.

Subcommittee Review
Comments received at the Spring 2021 NOSB meeting were similar to the comments received for the List 4 inerts review in 2020. The prohibition of List 3 inerts prior to establishment of a new system would cause significant disruption to the availability of essential pest control tools for organic production. Removing List 3 inerts from the National List would severely limit the ability of organic growers to control and monitor a number of crop-threatening pests. There are no natural control alternatives to control these pests. Comments noted that only the pheromones, not the List 3 inerts, are released from the dispensers and that the pheromones themselves do not have direct contact with the organic crop.

While these pheromone products with their accompanying List 3 inerts are critical to organic growers, strong concern was expressed by stakeholders regarding the reference to a defunct EPA list. As with List 4 inerts, a new, current, reference system must be developed for the List 3 inerts. This is critical so that the inerts can be reviewed, new materials can be added to this category, and problematic materials can be removed. Stakeholders and the NOSB implore the NOP to move forward on a current method of listing these inerts in a parallel process to List 4 inerts.

Other stakeholders had concerns about possible health effects from some List 3 inerts and that it is difficult to establish what inerts are being used. One group suggested that it is quite likely that at least some of the List 3 substances would be found to be acceptable if they were individually reviewed by the NOSB, but the broad listing does not the support the integrity of the organic label.

Justification for Vote
The Subcommittee proposes removal of EPA List 3 from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove EPA List 3 from the National List
Motion by: Steve Ela
Seconded by: Asa Bradman
Yes: 1 No: 7 Abstain: 0 Absent: 0 Recuse: 0

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: Added to National List 2/20/2001 (65 FR 80547), 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 Environmental Protection Agency (EPA)-registered pesticide (PC Code 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. 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 Cl_2).

Calcium hypochlorite is an "indirect" food additive approved by the Food and Drug Administration (FDA). Calcium hypochlorite may be used as a final sanitizing rinse on food-processing equipment (21 CFR 178.1010). Calcium hypochlorite 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 FDA or the EPA 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, calcium hypochlorite separates into 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 3-phosphate 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 hydrated (slaked) lime. It is then separated from the coproduct, calcium chloride, and air dried or vacuum dried.

International Acceptance

Canadian General Standards Board Permitted Substances List

International Federation of Organic Agriculture Movements (IFOAM) Norms - Equipment cleaner/disinfectant

Human Health and 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. Chlorine compounds are dermal, respiratory, ocular, and mucous membrane irritants. In addition, 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 chemical properties and mechanisms of action, other chlorine-based oxidant sanitizers are also likely to 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 deemed 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 chlorine 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.

Summary of Public Comments
Many organic stakeholders commented that chlorine materials are essential to ensure food safety and compliance with food safety regulations under the FSMA. Public comment and Board discussions reflect concerns about the use of chlorine materials in organic crop production due to potential impacts on human health and the environment. Some public comments outline the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized "by specific use or application" with clear identification of the hazards to humans and the environment (NOC, 2020). Further, restructuring the National List with a designated category for cleaners, sanitizers and disinfectants would help to ensure certified operations understand which cleaners, sanitizers and disinfectants may be used, and would facilitate better organic education. Overall, a unique category on the National List could help the NOSB in its review of sanitizers, cleaners, and disinfectants, and could support the use of alternative, less toxic, materials when their use can meet strict food safety standards (OTA, 2021). Establishing a separate sanitizer listing on the National List is beyond the scope of this sunset review but the Crops Subcommittee – in coordination with the Handling Subcommittee -- will recommend a work agenda item to advance these suggestions.

Justification for Vote
The Subcommittee proposes removal of calcium hypochlorite from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove calcium hypochlorite from the National List
Motion by: Wood Turner
Seconded by: Logan Petrey
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

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: Added to National List 2/20/2001 (65 FR 80547), 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 (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 (FDA) or the Environmental Protection Agency (EPA) 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 (Cl-H-O3) 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]

[International Federation of Organic Agriculture Movements (IFOAM) Norms] - Equipment cleaner/disinfectant

Human Health and 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. Chlorine 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 chemical properties and mechanisms of action, other chlorine-based oxidant sanitizers are also likely to 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 deemed 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 chlorine 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.

Summary of Public Comments
Many organic stakeholders commented that chlorine materials are essential to ensure food safety and compliance with food safety regulations under the FSMA. Public comment and Board discussions reflect concerns about the use of chlorine materials in organic crop production due to potential impacts on human health and the environment. Some public comments outline the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized “by specific use or application” with clear identification of the hazards to humans and the environment (NOC, 2020). Further, restructuring the National List with a designated category for cleaners, sanitizers and disinfectants would help to ensure certified operations understand which cleaners, sanitizers and disinfectants may be used, and would facilitate better organic education. Overall, a unique category on the National List could help the NOSB in its review of sanitizers, cleaners and disinfectants, and it could support the use of alternative, less toxic, materials when their use can meet strict food safety standards (OTA, 2021). Establishing a separate sanitizer listing on the National List is beyond the scope of this sunset review but the Crops Subcommittee – in coordination with the Handling Subcommittee -- will recommend a work agenda item to advance these suggestions.

Justification for Vote
The Subcommittee proposes removal of chlorine dioxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove chlorine dioxide from the National List
Motion by: Wood Turner
Seconded by: Logan Petrey
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

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. 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 (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 (FDA) or the Environmental Protection Agency (EPA) 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 3-phosphate 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 hydrochlorite 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

International Federation of Organic Agriculture Movements (IFOAM) Norms - Equipment cleaner/disinfectant

Japan Agricultural Standard (JAS) for Organic Production

Human Health and 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).

When formulated via electrolyzed water, hypochlorous acid is effective as a sanitizer at lower chlorine concentrations 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 deemed 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 chlorine 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.

Summary of Public Comments
Many organic stakeholders commented that chlorine materials are essential to ensure food safety and compliance with food safety regulations under the FSMA. Public comment and Board discussions reflect concerns about the use of chlorine materials in organic crop production due to potential impacts on human health and the environment. Some public comments outline the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized "by specific use or application" with clear

identification of the hazards to humans and the environment (NOC, 2020). Further, restructuring the National List with a designated category for cleaners, sanitizers and disinfectants would help to ensure certified operations understand which cleaners, sanitizers and disinfectants may be used, and would facilitate better organic education. Overall, a unique category on the National List could help the NOSB in its review of sanitizers, cleaners, and disinfectants, and could support the use of alternative, less toxic, materials when their use can meet strict food safety standards (OTA, 2021). Establishing a separate sanitizer listing on the National List is beyond the scope of this sunset review but the Crops Subcommittee – in coordination with the Handling Subcommittee -- will recommend a work agenda item to advance these suggestions.

Justification for Vote

The Subcommittee proposes removal of hypochlorous acid from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote

Motion to remove hypochlorous acid from the National List
Motion by: Wood Turner
Seconded by: Logan Petrey
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

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: Added to National List 2/20/2001 (65 FR 80547), 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 Environmental Protection Agency (EPA)--registered pesticide (PC Code 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. 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 (currently 4mg/L expressed as Cl_2).

Sodium hypochlorite is an "indirect" food additive approved by Food and Drug Administration (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). Sodium hypochlorite 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 FDA or the EPA 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 hypochlorite separates into sodium 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 3-phosphate 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 (Na_2CO_3).

International Acceptance
Canadian General Standards Board Permitted Substances List

International Federation of Organic Agriculture Movements (IFOAM) Norms - Equipment cleaner/disinfectant. An intervening event or action must occur to eliminate risks of contamination.

European Economic Community (EEC) Council Regulations 834/2007 and 889/2008
Products for cleaning and disinfection referred to in Article 23 (4).

Japan Agricultural Standard (JAS) for Organic Production

Human Health and 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. Chlorine 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 chemical properties and mechanisms of action, other chlorine-based oxidant sanitizers are also likely to 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 deemed 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 chlorine 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.

Summary of Public Comments
Many organic stakeholders commented that chlorine materials are essential to ensure food safety and compliance with food safety regulations under the FSMA. Public comment and Board discussions reflect concerns about the use of chlorine materials in organic crop production due to potential impacts on human health and the environment. Some public comments outline the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized “by specific use or application” with clear identification of the hazards to humans and the environment (NOC, 2020). Further, restructuring the National List with a designated category for cleaners, sanitizers and disinfectants would help to ensure certified operations understand which cleaners, sanitizers and disinfectants may be used, and it would facilitate better organic education. Overall, a unique category on the National List could help the NOSB in its review of sanitizers, cleaners, and disinfectants, and could support the use of alternative, less toxic, materials when their use can meet strict food safety standards (OTA, 2021). Establishing a separate sanitizer listing on the National List is beyond the scope of this sunset review but the Crops Subcommittee – in coordination with the Handling Subcommittee -- will recommend a work agenda item to advance these suggestions.

Justification for Vote
The Subcommittee proposes removal of sodium hypochlorite from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove sodium hypochlorite from the National List
Motion by: Wood Turner
Seconded by: Logan Petrey
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

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
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 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 with 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 an aqueous solution. Buffering agents are materials that create an effective resistance to change in pH of an aqueous solution when a strong acid or base is added.

Manufacture
Magnesium oxide is a naturally occurring compound that is found in the mineral periclase. There are several manufacturing processes used to produce MgO. However, most commercially available magnesium oxide is formed by calcinating magnesium carbonate–containing minerals (e.g., magnesite, hydro-magnesite).

Magnesium can also be sourced from other mineral sources in the form of magnesium chlorides and silicates, which can be converted to magnesium hydroxide via acid-base and metathesis reactions. Magnesium hydroxide sourced as brucite or by the chemical processing of other magnesium-containing minerals is calcined to form magnesium oxide.

Magnesium oxide is also produced from seawater and salt lake brine sources. While magnesium is a common elemental component of brine, magnesium oxide is not present in brine sources due to its water insolubility. Magnesium chloride is the primary source of magnesium within brine and is converted to magnesium hydroxide using the same reactions used to process mineral sources of magnesium chloride. Additionally, brine may be treated with sulfuric acid to remove carbonates, reducing calcium in the final product. Magnesium oxide from brine is also obtained by calcination of magnesium hydroxide.

NOP guidelines classify substances produced by the "heating or burning of non-biological matter (e.g., minerals) to cause a chemical reaction" as synthetic (NOP 5033). Based on this classification, all commercial sources of magnesium oxide are considered synthetic, formed by calcination (heating) to liberate carbon dioxide (Equation 3) or water (Equation 8). (TR 2021)

International Acceptance
Canadian General Standards Board Permitted Substances List
The CAN/CGSB-32.311-2015 lists magnesium oxide as a "mineral" for use in "feed, feed additives, and feed supplements" and in "health care products and production aids." (TR 2021)

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Magnesium oxide is listed in ED No. 889/2008 as a "feed material of mineral origin." Magnesium oxide is not listed in EC. No 834/2007.

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
TR2021 states that, at the time of publication, the author found no studies on magnesium oxide's environmental persistence or toxicity. The insoluble nature of magnesium oxide makes it unlikely to contaminate water systems, and its insolubility results in low bioavailability within terrestrial environments. Moreover, when used as approved within organic agriculture, magnesium oxide is applied in limited quantities as a viscosity control additive, making environmental contamination unlikely (NOSB 2013).

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 for other materials because it is considered 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
- nontoxic 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. A previous technical report covered the uses of magnesium oxide in livestock production, and the petitioner noted that aspects from that report were relevant to the listing for crop use. In addition, the NOSB requested and received a technical report in the summer of 2021 specifically for this material to be used in crops.

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 the 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 with 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.

In advance of the Spring NOSB meeting, stakeholders submitted a few comments, primarily in favor of permitting magnesium oxide for this particular use. Based on the current review, and stakeholder support, the Subcommittee proposes magnesium oxide remain on the National List.

Justification for Vote
The Subcommittee proposes removal of magnesium oxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove magnesium oxide from the National List
Motion by: Amy Bruch
Seconded by: Logan Petrey
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

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
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 11/03/2013 (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.

Summary of Public Comments:
Relisting calcium chloride as a prohibited non-synthetic material was widely supported in the public comments. Calcium chloride is a material needed to combat physiological disorders of many commodities that typically cannot be resolved with other calcium products. Many commenters stated that calcium chloride is necessary to ensure quality of many crops and significant losses would occur if the substance were not relisted. The current annotation restricting the use to "foliar sprays to treat a physiological disorder associated with calcium uptake" is also supported to prevent soil buildup of chloride.

Justification for Vote
The Subcommittee proposes removal of calcium chloride from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove calcium chloride from the National List
Motion by: Logan Petrey
Seconded by: Brian Caldwell
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

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.

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
In the U.S. rotenone is only registered for piscicidal (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. In the December 27, 2018 Federal Register rotenone was added to §205.602 as a non-synthetic substance that is prohibited for use in organic crop production. The UK banned the sale of rotenone in 2009 and it is also banned in the EU.

Human Health and 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 registrations, except for piscicidal uses.

Discussion
Rotenone was found to have adverse environmental and health impacts, a lack of essentiality, and an incompatibility with organic principles, and therefore, the NOSB unanimously passed a recommendation in October 2012 to add rotenone to the National List at §205.602 as a non-synthetic substance prohibited for use in organic crop production.

There were only five public comments at the 2021 Spring meeting about rotenone and all were in favor of the continued listing as a prohibited natural substance in organic crop production.

Justification for Vote
The Subcommittee proposes removal of rotenone from the National List based on the following criteria in the Organic Foods Production Act (OPFA) and/or 7 CFR 205.600(b): Not recommending removal from the prohibited list, based on adverse environmental and health impacts, a lack of essentiality, and an incompatibility with organic principles.

Subcommittee Vote
Motion to remove rotenone from the National List
Motion by: Rick Greenwood
Seconded by: Amy Bruch
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Zein
August 3, 2021

Summary:
This document reviews 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 2021 technical review. While the petitioner asked for the material to be allowed as a nonorganic agricultural substance, the NOSB disagrees with this classification. In reviewing the petition, TR, NOP Classification of Materials guidance decision tree (NOP 5033), and past NOSB decisions, it was determined that this is a nonagricultural substance and that it should be classified as non-synthetic.

Introduction:
The NOSB was petitioned in February of 2020 to consider zein, otherwise known as "maize protein", "protein coating" or "confectioner's glaze", as an 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.

Regulatory background:
This is the first time that zein has been petitioned for inclusion on the National List.

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].*"

As 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. The corn gluten meal (CGM) that zein is made from is a different product created during the same wet-milling process used to make CSL. The bulk of the corn gluten meal is produced via wet-milling with sulfur dioxide. 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 product, 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*"

Use:
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 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.

Manufacture:
According to the petitioner, *"Flo Chemical Corporation manufactures (isolates) zein utilizing a proprietary process (Freeman Process), which was developed in 1976 by the company's founders. The 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.

International use:
Canadian General Standards Board Permitted Substances List
Zein is not included in the Canadian General Standards Board—CAN/CGSB-32.311-2020, Organic Production Systems Permitted Substances List.

CODEX Alimentarius Commission
Zein does not appear in the CODEX Alimentarius Commission—Guidelines for the Production, Processing, 130 Labelling and Marketing of Organically Produced Foods (GL 32-1999). 131 132

European Economic Community (EEC) Council Regulation
Zein does not appear in the European Economic Community (EEC) Council Regulation—EC No. 834/2007 135 and 889/2008.

Japan Agricultural Standard (JAS) for Organic Production
Zein is not listed in Table 1 "Additives" of the JAS for Organic Processed Foods Notification No. 1606.

International Federation of Organic Agriculture Movements (IFOAM) Norms Zein is not included in the IFOAM Norms

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.

Combining both written and oral stakeholder comments from the 2021 Spring Meeting, there were about ten total responses with none in favor of adding zein to the National List. With that said, there were only two comments against the material itself with the remainder simply challenging the need of "another coating" or "preservatives" on fresh fruits and vegetables. During three subsequent Handling Subcommittee meetings this question of "need" was thoroughly debated with the eventual consensus being that the petitioned substance should be limited to very specific uses where its "unique" hydrophobic properties appear to be "preferred". The petition is therefore annotated as follows:

Annotation of zein for inclusion on the National List at §205.606: "Only for use in nutraceuticals or pharmaceuticals as a micro encapsulation acting as a moister barrier and taste masker."

Category 1: Classification

1. Substance is for: __X__ **Handling** _______ **Livestock**

2. For HANDLING and LIVESTOCK use:
    a. Is the substance ___ **Agricultural** or __X__ **Non-Agricultural?**

    b. If the substance is **Non-agricultural**, is the substance ____**X**_ **Non-synthetic** or __**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.

According to the Decision Tree for Classification of Agricultural and Nonagricultural Materials for Organic Livestock Production or Handling (NOP 5033-2), an agricultural substance that undergoes a chemical change becomes non-agricultural. This then brings up the question as to whether zein should be considered nonsynthetic 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 non-synthetics.

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

N/A

Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

   The substance will be used solely as a coating for nutraceutical and pharmaceutical capsules and as an inert, hydrophobic substance, will have no potential for detrimental chemical reactions.

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)]

   Zein has been deemed GRAS since 1960 and is fully biodegradable and edible. It contributes no toxicity or detrimental breakdown products to the environment.

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

   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 out of 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. 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.

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

   Zein is a fully edible protein layer that contributes an incomplete amino acid profile to the consumer. While it therefore should not be a major protein source in the human diet, its proposed use as a coating for pills represents no impact 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 and solubility of the soil), crops and livestock. [§6518(m)(5)]

   In its proposed role as a coating in organic nutraceuticals and pharmaceuticals, zein will have no role in the agroecosystem. As previously mentioned, the only environmental concerns come from the corn-wet milling process that is used to create the corn gluten meal that is the starting material for zein production.

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

   The TR states: " Zein is extracted from CGM. In its evaluation of CGM as an herbicide ((Office of Pesticide Programs 2003)), stated:

   "All required toxicology data for this biochemical pesticide are waived. No additional toxicological data are needed. The decision to waive these data are based on: 1) the product is naturally occurring, 2) possesses a non-toxic mode of action, 3) corn gluten meal is considered GRAS (Generally Recognized As Safe) by FDA under 21 CFR §184.1321, and can be used without limitations, other than current Good Manufacturing Practices, and 4) under 40 CFR §180.1164, corn gluten is exempted from the requirements of a tolerance on food when used as a herbicide; and under 40 CFR §180.1001 (d), corn gluten meal is exempted from the requirement of a tolerance when used as an attractant on crops. Further, the registrant's request for data waivers was appended with abstracts from scientific journals discussing the use of corn gluten meal as a food and/or feed for dairy and beef cattle, cats, minks, foxes, sheep, horses, swine, poultry, trout, salmon, catfish, guinea pigs, hamsters, monkeys, mice, rats, rabbits, and dogs."

   Zein itself has been considered GRAS (generally recognized as safe) since about 1960 and this status was confirmed in 1981 (Select Committee of GRAS Substances (SCOGS) 1981).

   Zein is a fully biodegradable, edible protein extracted from corn milling byproducts (primarily corn gluten, a GRAS substance) with an alcohol and applied to food as an alcoholic solution. The alcohols involved are isopropyl alcohol (a major ingredient in hand sanitizers) and ethyl alcohol (grain alcohol). Zein manufacturing processes are designed to recover and reuse the alcohol for both economic and environmental reasons. An analogous substance is the purified protein gelatin, extracted from animal processing waste products.

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 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 unique functionality comes in 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 a hypoallergenic option. The final other option, carnauba wax, can be sourced and grown only in Brazil, making it outside of the US jurisdiction for regulating how its grown and produced. However, for the annotated use in micro-encapsulation for pharmaceuticals and nutraceuticals, it appears to be the preferred option.

2. **For Livestock substances, and Nonsynthetic substances used in Handling**: In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

   The substance is compatible with a system of sustainable agriculture, as it would serve solely as an encapsulation method for organically produced substances being made into pills. It would therefore have no impact on the sustainability of the agriculture that produced the substance. Zein itself would be both created and applied in a laboratory setting.

   Zein is created from a renewable resource (corn gluten meal), it is fully biodegradable, and it presents no threat to human health. As the substance is created and applied in the laboratory, it has no impact on the agroecosystem beyond serving as a vehicle for ingesting organic pharmaceutical and nutraceutical products.

Classification Motion:
Motion to classify zein as nonsynthetic
Motion by: Jerry D'Amore
Seconded by: Steve Ela
Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National List Motion:
Motion to add zein at §205.605(a), annotated as: "Only for use in nutraceuticals or pharmaceuticals as a micro encapsulation acting as a moisture barrier and taste masker."
Motion by: Jerry D'Amore
Seconded by: Steve Ela
Yes: 4 No: 3 Abstain: 0 Absent: 0 Recuse: 0

Approved by Jerry D'Amore, Handling Subcommittee Chair, to transmit to NOP August 18, 2021.

National Organic Standards Board
Crops Subcommittee
Fish Oil Annotation Proposal
August 13, 2021

Summary:
In May 2019, the NOSB requested a work agenda to annotate fish oil to address environmental concerns. Specifically, The NOSB request stated:

> During the sunset review of Fish Oil at the Spring NOSB 2019 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 (HS) would like to request a work agenda item to propose an annotation to Fish Oil to address environmental concerns.

In August 2019, the 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 [sic *(National Institute of Environmental Health Sciences)*], 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:

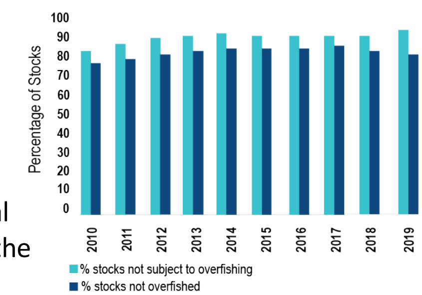
Fish oil was added to the National List in 2007, based on a petition from a manufacturer. At that time the NOSB did not request a Technical Report (TR) or Technical Advisory Panel Report (TAP). The 2007 NOSB recommendation indicated that the OFPA criteria were met in all categories but provided no scientific rationale or citations to support such findings. However, the final NOSB 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. NOAA fisheries manages 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 slight 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 stocks 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), Friends 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 Handling Subcommittee presented a discussion document for 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 standards 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 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.

The Handling Subcommittee originally suggested adding three elements to the current fish oil annotation. The first element would state that fish oil should be sourced from fishing industry by-product only. This annotation would prevent the use of fish caught solely for oil production. Note, 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 are 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.

Earlier discussion documents proposed an annotation limiting fish oil production from fisheries that were harvested such that, when the fisheries were within National Oceanic and Atmospheric Administration (NOAA)’s or Food and Agriculture Organization (FAO)’s jurisdiction, they must not be unsustainably exploited.

These suggested annotations received substantial public comment which raised 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. Others were concerned that while NOAA and FAO standards were similar in objectives, they were not directly comparable because they used different timeframes and population assessment methods, including different data sources and populations modeling techniques. Thus, application of standards based on NOAA and FAO classifications would likely not be uniform across producers or verifiable by organic certifiers and would introduce regulatory inconsistency, and therefore would not be a practical bar to set for 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.

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.

However, there are also advantages to relying on third-party certification programs for non-agricultural products that derive from natural resources. According to MSC and other scientists consulted, "certification schemes are complex and, within seafood, cover varying issues related to environmental sustainability and social responsibility … 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…"

Three examples of a possible annotation were discussed at the April 2021 NOSB meeting (see box). Overall, public comment leaned to Option 2. Fish oil producers generally preferred Option 1 but would accept Option 2. Dairy and other groups producing products containing fish oil leaned toward Option 2 and were not concerned about impacts product availability. Option 3 utilizing the Seafood Watch program was also supported, but concerns were raised about the size and reach of the program.

Option 1 Discussed April 2021:

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 Discussed April 2021:

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 Discussed April 2021:

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/).***

Option 2 in particular has several advantages according to MSC because the "… International Social and Environmental Accreditation and Labeling (ISEAL) and Global Seafood Sustainability Initiative (GSSI)… [are]… 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..." These "… organizations … are highly respected globally as leaders in science-based sustainability certifications. There are established processes, quality controls and quality assurances already in place for GSSI recognized and ISEAL compliant certification programs. GSSI and ISEAL help to define and ensure programs demonstrate their continual compliance in upholding best practice for seafood sustainability certifications and sustainability systems at a global level. Further information on the rigor and process of becoming GSSI benchmarked or an ISEAL Code Complaint member can be found on the respective organizations' website" and the requirements would be clear and enforceable.

Based on public comments and consultation with MSC, the Handling Subcommittee modified Option 2 and recommends adoption of the following annotation.

Fish oil annotation: §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.***

In the future, listing of fish oil at §205.606 and the annotation can be reevaluated when organic aquaculture standards are approved.

Subcommittee Vote:
Motion to accept the proposed fish oil annotation
Motion by: Asa Bradman
Seconded by: Kyla Smith
Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Citations:

- Fish oil annotation discussion document, April 2021 NOSB meeting
- 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

Approved by Jerry D'Amore, Handling Subcommittee Chair, to transmit to NOP August 14, 2021.

Sunset 2023
Meeting 2 - Review
Handling Substances § 205.605(a), § 205.605(b), § 205.606
October 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 scheduled for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the Petitioned Substances Database.

Request for Comments
Written public comments will be accepted through September 30, 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. A useful characteristic of agar-agar is its 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 genera harvested being *Gelidium* and *Gracilaria*, the second of which can be cultivated. After harvesting, the algae are cleaned with water, dried in the sun, pressed into bales, and shipped to processors for agar-agar extraction. Prior to extraction, the *Graciliara* 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 *Graciliara* species would be too weak for most food applications (2011 TR lines 165-176). After pretreatment, the algae are placed in tanks for extraction via hot water and pressure, followed by filtration. Water is removed from the gel 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.

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 if the harvesting of agarophytes, in particular, is harmful to the biodiversity of nearby beaches or algae beds. Agar-agar manufacture produces alkaline wastewater, but there were no documents found that show this to be a current problem to the environment.

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 *Graciliara* species 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-L-galactose), increasing the gel strength of the agar-agar. Data indicate 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.

There were several comments during the Spring 2021 meeting supporting the relisting of agar-agar. It is an essential tool in the development and innovation of organic foods. Several commentors noted there is a distinct difference between synthetic and non-synthetic forms based on species of red algae. However, commercial availability of non-synthetic agar-agar is insufficient and may not be effective for some applications.

Justification for Vote
The Subcommittee proposes removal of agar-agar from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove agar-agar from the National List
Motion by: Kim Huseman
Seconded by: Jerry D'Amore
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

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 of calves or goat kids is 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.

There was overwhelming support during the comment period of the 2021 Spring meeting to relist animal enzymes on the National List. Comments addressed the non-existence of organic animal enzymes and the inability to achieve a reliable organic supply; cost was listed as a barrier as well. Several mentioned the lack of adequate alternatives in order to produce the type(s) of cheese being manufactured. There was one opposing comment suggesting more research needs to be done regarding the essentiality of catalase, animal lipase, pancreatin, pepsin, and trypsin.

Justification for Vote
The Subcommittee proposes removal of animal enzymes from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove animal enzymes from the National List
Motion by: Kim Huseman
Seconded by: Jerry D'Amore
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

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 11/03/2013 (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 [use] 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
The Handling Subcommittee received several comments 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.

Subcommittee review
At the Spring 2021 NOSB meeting, the Subcommittee heard from several certifiers about somewhat limited use of the material among their members, although despite limited use, their support for relisting was clear. One non-profit stakeholder shared concern flagged by the Subcommittee about potential negative impacts from mining for the substance in sensitive areas. That group also asked that the material be annotated to limit its use as a coagulant only.

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?

Justification for Vote
The Subcommittee proposes removal of calcium sulfate-mined from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove calcium sulfate-mined from the National List
Motion by: Wood Turner
Seconded by: Jerry D'Amore
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

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 11/03/2013 (78 FR 61154); Sunset renewal notice effective 5/29/2018 (83 FR 14347).
Sunset Date: 5/29/2023

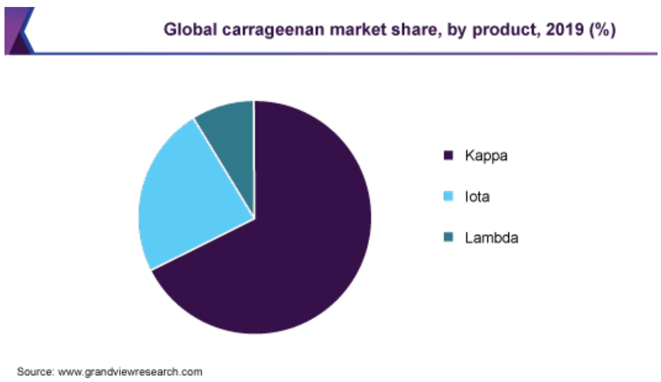
Subcommittee Review

Use
Carrageenan 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 centrifugation and the remaining gel-like solution is the carrageenan, which can be evaporated and dried into a powder for addition to foods.

There are three main kinds of carrageenan (kappa, iota, and lambda 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.

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

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.

Canadian General Standards Board Permitted Substances List
Canada allows carrageenan as a food additive under their organic standard with no limits on usage.

Japan Agricultural Standard (JAS) for Organic Production. JAS allows carrageenan as an additive to organic dairy products.

International Federation of Organic Agriculture Movements (IFOAM) Norms IFOAM allows carrageenan as a food additive with no annotations.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 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).

The 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. The turnover to harvest is quite short, at only 6 weeks. However, increased demand for seaweed has resulted in the establishment of some farms that 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 can be positive. It has been hypothesized that carefully placed seaweed aquaculture can help increase oxygenation in near-shore waters, remove impurities from the water, buffer against wave action, help stabilize marine pH and otherwise help mitigate against some 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. It did not become broadly used in industrial food preparation until the 1930s. It is currently a $500 million dollar industry.

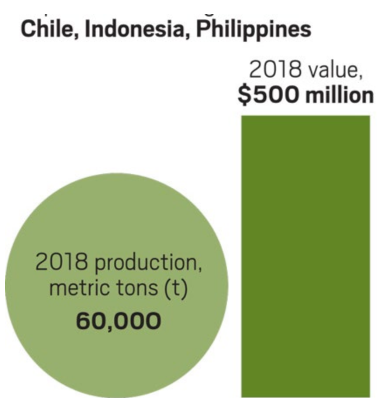


Figure 2. Carrageenan production in 2018 (Taylor, 2019)

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 gelatin were singled out as difficult to produce without carrageenan.

Eliminating carrageenan may be achievable through the elimination of many processed foods where it is considered 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 based on lack of essentiality (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 implement the NOSB recommendation to remove carrageenan from the National List, and carrageenan is currently allowed in organic production.

Stakeholder Input
There were fourteen stakeholder thoughts and/or concerns (both oral and written) registered during the 2021 Spring NOSB meeting. Eight were in favor of keeping carrageenan on the National List and four were opposed. The remaining two indicated that carrageenan was not used within their community. While there was general support within the stakeholder community to keep carrageenan on the National List, it was deemed an unnecessary addition by the NOSB as there are alternative products that serve the same functionality.

Justification for Vote
The Subcommittee proposes removal of carrageenan from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Availability of alternatives.

Subcommittee Vote
Motion to remove carrageenan from the National List
Motion by: Jerry D'Amore
Seconded by: Kyla Smith
Yes: 5 No: 1 Abstain: 0 Absent: 1 Recuse: 0

References:

Bagla, P. (2008) Seaweed invader elicits angst in India. Science. 320:1271

Bixler, HJ (2017) The carrageenan controversy. Journal of Applied Phycology 29:2201–2207

Duarte CM., Wu J, Xiao X, Bruhn A, Krause-Jensen D (2017) Can seaweed farming play a role in climate change mitigation and adaptation? Frontiers in Marine Science 4

Kelly EL, Cannon AL, Smith, JE (2020) Environmental impacts and implications of tropical carrageenophyte seaweed farming. Conservation Biology 34(2): 326-337

Matthee, M. (2007) *The Codex Alimentarius Commission and its standards*. Maastricht University.

Taylor, A (2019) Seaweed farming for food and fuels. Chemical and Engineering News, 97(34)

Tobacman JK, Bhattacharyya S, Borthakur A, Dudeja PK. (2008) The carrageenan diet: not recommended. Science 321(5892):1040-1041.

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
Glucono delta-lactone (GDL) is produced by crystallization from an aqueous solution of gluconic acid. There are a variety of ways gluconic acid 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 fermentation and acid base reactions (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 the use of 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 (CXG 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, which is also listed as nonsynthetic at §205.605(a). 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. Citric 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 requested public comment regarding the use of GDL in organic processed foods other than tofu production. 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 firmer tofu and that GDL is critical for 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.

Subcommittee review
At the Spring 2021 NOSB meeting, the Subcommittee received limited commentary from stakeholders about GDL. However, one commenter did indicate that the misalignment between the current annotation – which prohibits GDL made from bromine water and ensures only nonsynthetic GDL is used in organic – and the 2016 TR which suggests GDL can be made from a variety of different chemical means leaves the listing exposed to synthetic GDL production and some excluded methods. That comment suggests a clarification of the annotation may be needed.

The Handling Subcommittee heard from several certifiers about somewhat limited use of the material among their members, although despite limited use, support for relisting was clear. One non-profit stakeholder shared a concern flagged by the subcommittee about potential negative impacts from mining for the substance in sensitive areas. That group also asked that the material be annotated to limit its use as a coagulant only. Another stakeholder suggested GDL is nonessential, though several certifiers reported that a number of their members and clients are currently using GDL.

At this time, 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?

Justification for Vote

The Subcommittee proposes removal of glucono delta-lactone from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote

Motion to remove glucono delta-lactone from the National List
Motion by: Wood Turner
Seconded by: Jerry D'Amore
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

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 11/03/2013 (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 acid, 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 ($C_4H_6O_6$; 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 (CXG 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 GFSA 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 impart a different taste 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 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.

Subcommittee Review
A number of public comments supported relisting of this material. Commenters highlighted that tartaric acid is essential in wine production and that organic wines rely on this material. However, several stakeholders questioned whether there could be an adequate supply of tartaric acid made from organic grape wine. The listing could discourage the development of an organic tartaric acid. The sale of tartaric acids made from organic wines could also provide additional revenue for organic vintners. This is an open-ended question and the answer to it was not resolved in public comments. Since the question is not resolved, relisting at this point in time is prudent. However, as the organic wine market continues to grow, the Board encourages the inclusion of an analysis of the availability of tartaric acid from organic grapes during the next sunset review, and also encourages the organic wine industry to move towards production of tartaric acid from organic grapes.

Justification for Vote
The Subcommittee proposes removal of tartaric acid from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove tartaric acid from the National List.
Motion by: Steve Ela
Seconded by: Jerry D'Amore
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

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 11/03/2013 (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 enacting 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 Generally Regarded as Safe GRAS under 21 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).

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).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999). No specific listing

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
Cellulose remains essential to organic handling for a few products. The NOSB asked the stakeholders whether there were other ancillary substances (beyond those listed above) that might be used in the production of cellulose. In the April 2021 meeting comments, stakeholders identified glycerin/glycerol as another ancillary substance.

A notable comment by a stakeholder was that sourcing cellulose should be done in a way that minimizes environmental impact. This concern echoes public comments from earlier sunsets of cellulose, as mentioned in the previous section (Environmental Issues) of this document.

Overall, based on the written and oral comments prior to the April 2021 meeting, there continues to be support for relisting cellulose.

Justification for Vote:
The Subcommittee proposes removal of cellulose from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote:
Motion to remove cellulose from the National List at §205.605(b)
Motion by: Kyla Smith
Seconded by: Jerry D'Amore
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recused: 0

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: Added to National List 2/20/2001 (65 FR 80547); 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 Environmental Protection Agency (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. 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 Cl_2).
Calcium hypochlorite is an "indirect" food additive approved by Food and Drug Administration (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 FDA or the EPA 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 triosphosphate 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 vacuum dried.

International Acceptance
Canadian General Standards Board Permitted Substances List
Allowed for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage, or transport units—application to crops or fields is permitted.

European Commission Directorate-general for Agriculture and Rural Development
Production Rules - The current EU regulation on organic production does not state a specific list of substances authorised in the cleaning of food processing facilities dealing with organic food (the only exception concerns milking facilities: Annex VII of Regulation 889/2008). However, operators have to comply with the rules set out in Article 26(4) (b) of Regulation 889/2008, notably, they have to implement suitable cleaning measures, monitor their effectiveness and record these operations. In addition, any food processing operator has to comply with the "hygiene package" regarding products that are allowed for cleaning and disinfection of food processing facilities and equipment.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Equipment cleaner/disinfectant: An intervening event or action must occur to eliminate risks of contamination.

Human Health and 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.

Summary of Public Comments

Public comment and Board discussions reflect concerns about the use of chlorine materials in organic food processing and handling because of their potential impacts on human health and the environment, but as noted above, many organic stakeholders judge these materials essential to ensure food safety and compliance with food safety regulations under FSMA. Very thoughtful public comments outline the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized "by specific use or application" with clear identification of the hazards to humans and the environment (NOC 2020). Further, "Restructuring the National List so that cleaners, sanitizers and disinfectants have a designated section… would generally help certified operations understand the cleaners, sanitizers and disinfectants that may be used, and it would help organic outreach and education… Overall, a designated list could help NOSB in its review of sanitizers, cleaners and disinfectants and it could support the use of alternative, less toxic materials, when their use can meet strict food safety standards (OTA 2021)." Establishing a separate sanitizer listing on the National List is beyond the scope of this sunset review but the HS will recommend a work agenda item to advance these suggestions.

Justification for Vote

The Subcommittee proposes removal of calcium hypochlorite from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote

Motion to remove calcium hypochlorite from the National List
Motion by: Asa Bradman
Seconded by: Jerry D'Amore
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

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: Added to National List 2/20/2001 (65 FR 80547); 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 Cl_2).

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 (FDA) or the Environmental Protection Agency (EPA) 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 ($NaClO_3$) and sulfuric acid (H_2SO_4) are reacted with sulfur dioxide (SO_2), or chloric acid is reacted with methanol (CH_3OH) (HSDB, 2005). Alternatively, chlorine dioxide can be formed with chlorine (Cl_2) 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
Allowed for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage, or transport units—application to crops or fields is permitted.

European Commission Directorate-general for Agriculture and Rural Development
Production Rules - The current EU regulation on organic production does not state a specific list of substances authorised in the cleaning of food processing facilities dealing with organic food (the only exception concerns milking facilities: Annex VII of Regulation 889/2008). However, operators have to comply with the rules set out in Article 26(4) (b) of Regulation 889/2008, notably, they have to implement suitable cleaning measures, monitor their effectiveness and record these operations. In addition, any food

processing operator has to comply with the "hygiene package" regarding products that are allowed for cleaning and disinfection of food processing facilities and equipment.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Equipment cleaner/disinfectant: An intervening event or action must occur to eliminate risks of contamination.

Human Health and 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.

Summary of Public Comments
Public comment and Board discussions reflect concerns about the use of chlorine materials in organic food processing and handling because of their potential impacts on human health and the environment, but as noted above, many organic stakeholders judge these materials essential to ensure food safety and compliance with food safety regulations under FSMA. Very thoughtful public comments outline the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized "by specific use or application" with clear identification of the hazards to humans and the environment (NOC 2020). Further, "Restructuring the National List so that cleaners, sanitizers and disinfectants have a designated section… would generally help certified operations understand the cleaners, sanitizers and disinfectants that may be used, and it would help organic outreach and education… Overall, a designated list could help NOSB in its review of sanitizers, cleaners and disinfectants and it could support the use of alternative, less toxic materials, when their use can meet strict food safety standards (OTA 2021)." Establishing a separate sanitizer listing on the National List is beyond the scope of this sunset review but the HS will recommend a work agenda item to advance these suggestions.

Justification for Vote
The Subcommittee proposes removal of chlorine dioxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove chlorine dioxide from the National List
Motion by: Asa Bradman
Seconded by: Jerry D'Amore
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

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 to add
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. 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 (SWDA) (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 (FDA) or the Environmental Protection Agency (EPA) 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 triosphosphate 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
Allowed for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage, or transport units—application to crops or fields is permitted.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Not listed

Human Health and 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.

Summary of Public Comments
Public comment and Board discussions reflect concerns about the use of chlorine materials in organic food processing and handling because of their potential impacts on human health and the environment, but as noted above, many organic stakeholders judge these materials essential to ensure food safety and compliance with food safety regulations under FSMA. Very thoughtful public comments outline the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized "by specific use or application" with clear identification of the hazards to humans and the environment (NOC 2020). Further, "Restructuring the National List so that cleaners, sanitizers and disinfectants have a

designated section… would generally help certified operations understand the cleaners, sanitizers and disinfectants that may be used, and it would help organic outreach and education… Overall, a designated list could help NOSB in its review of sanitizers, cleaners and disinfectants and it could support the use of alternative, less toxic materials, when their use can meet strict food safety standards (OTA 2021)." Establishing a separate sanitizer listing on the National List is beyond the scope of this sunset review but the HS will recommend a work agenda item to advance these suggestions.

Justification for Vote
The Subcommittee proposes removal of hypochlorous acid from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove hypochlorous acid from the National List
Motion by: Asa Bradman
Seconded by: Jerry D'Amore
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

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: Added to National List 2/20/2001 (65 FR 80547); 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. 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).

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 FDA or the EPA 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 triosphosphate 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
Allowed for wash water in direct contact with crops or food; b) in flush water from cleaning irrigation systems, equipment, storage, or transport units—application to crops or fields is permitted.

European Commission Directorate-general for Agriculture and Rural Development
Production Rules - The current EU regulation on organic production does not state a specific list of substances authorised in the cleaning of food processing facilities dealing with organic food (the only exception concerns milking facilities: Annex VII of Regulation 889/2008). However, operators have to comply with the rules set out in Article 26(4) (b) of Regulation 889/2008, notably, they have to implement suitable cleaning measures, monitor their effectiveness and record these operations. In addition, any food processing operator has to comply with the “hygiene package” regarding products that are allowed for cleaning and disinfection of food processing facilities and equipment.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Equipment cleaner/disinfectant: An intervening event or action must occur to eliminate risks of contamination.

Human Health and 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.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.

Summary of Public Comments
Public comment and Board discussions reflect concerns about the use of chlorine materials in organic food processing and handling because of their potential impacts on human health and the environment, but as noted above, many organic stakeholders judge these materials essential to ensure food safety and compliance with food safety regulations under FSMA. Very thoughtful public comments outline the need for a comprehensive technical review of sanitizers and listing of sanitizers on the National List itemized "by specific use or application" with clear identification of the hazards to humans and the environment (NOC 2020). Further, "Restructuring the National List so that cleaners, sanitizers and disinfectants have a designated section… would generally help certified operations understand the cleaners, sanitizers and disinfectants that may be used, and it would help organic outreach and education… Overall, a designated list could help NOSB in its review of sanitizers, cleaners and disinfectants and it could support the use of alternative, less toxic materials, when their use can meet strict food safety standards (OTA 2021)." Establishing a separate sanitizer listing on the National List is beyond the scope of this sunset review but the HS will recommend a work agenda item to advance these suggestions.

Justification for Vote
The Subcommittee proposes removal of sodium hypochlorite from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove sodium hypochlorite from the National List
Motion by: Asa Bradman
Seconded by: Jerry D'Amore
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

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 'nixtamilization' - 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 (CXG 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, as 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 commercial processing methods used for peaches, the NOSB 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.

Subcommittee Review
Stakeholder comments on potassium hydroxide were mixed, with some supporting relisting and others asking for a more thorough review and a possible annotation change for this listing.

Proponents of relisting noted that there are no management practices that would eliminate the need for this material, that it is needed for pH adjustment and potassium fortification, and there are differences in solubility as compared to possible alternatives. Delisting of this material would lead to difficulties with product stability and increased manufacturing losses. One commenter noted that if this product were delisted they would leave the organic category.

Opponents to relisting noted the human health hazards from the corrosivity of potassium hydroxide, the environmental concerns from the disposal of large amounts of water with soluble potassium and alkali ions, and whether it continues to be essential for organic peach processing. Others noted that the annotation is problematic in that it lists uses that are not allowed rather than uses that are allowed. Annotations that list allowable uses are very specific in that other uses are definitively prohibited. Annotations that only list methods that are prohibited allow for any other uses, including those that were not anticipated at the time of listing. However, annotation changes cannot be done during the sunset review and would need to be the reviewed as a separate work agenda item.

While the Subcommittee recognizes the arguments of the opponents to this material, the removal of this material would be disruptive to organic handlers and at this point in time it is still essential for organic handling.

Justification for Vote
The Subcommittee proposes removal of potassium hydroxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove potassium hydroxide from the National List.
Motion by: Steve Ela
Seconded by: Asa Bradman
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

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 do not appear to be any human health concerns associated with potassium lactate as provided by the 2015 TR. There was an environmental issued 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 National List 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 National List. 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. Potassium lactate was added to the National List effective January 28, 2019. The Handling Subcommittee finds significant merit to keep potassium lactate on the National List at § 205.605 (b) with the annotation: for use as an antimicrobial agent and pH regulator only.

Summary of Public Comments
A majority of public commenters was in support of relisting potassium lactate. A review of the "use tables" supplied by several associations indicate that potassium lactate is a widely used material. Some stakeholders asked why both potassium and sodium lactates are on the National List as they appear to be used nearly interchangeably. It was noted that there are certain uses, such as "low sodium" meat alternatives, that require potassium lactate specifically.

Justification for Vote
The Subcommittee proposes removal of potassium lactate from the National List based on the following criteria in the Organic Foods Production Act (OPFA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove potassium lactate from the National List
Motion by: Jerry D'Amore
Seconded by: Steve Ela
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

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 filtered 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. 834/2007 and 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 (CXG 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 disbursed 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.

Summary of Public Comment
Most stakeholders were in favor of relisting based on essentiality. Public comments noted that alternatives, such as organic rice hulls, are not able to be used to achieve suitable functionality in all applications. There were a few comments that suggested the NOSB review the current annotation against the original annotation passed by the Board to ensure the intent of the original annotation is accurately conveyed.

Justification for Vote
The Subcommittee proposes removal of silicon dioxide from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove silicon dioxide from the National List
Motion by: Kyla Smith
Seconded by: Kim Huseman
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

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. Lactic acid is allowed.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
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 National List 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 National List. 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. Sodium lactate was added to the National List effective January 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.

Summary of Public Comments
A majority of public comments were supportive of relisting sodium lactate. A review of the "use tables" supplied by several associations indicate that sodium lactate is a widely used material. Some stakeholders asked why both sodium and potassium lactates are on the National List as they appear to be used nearly interchangeably. It was noted that there are certain uses, such as "low sodium" meat alternatives that require potassium lactate specifically.

Justification for Vote
The Subcommittee proposes removal of sodium lactate from the National List based on the following criteria in the Organic Foods Production Act (OPFA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove sodium lactate from the National List
Motion by: Jerry D'Amore
Seconded by: Kim Huseman
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Sunset 2023
Meeting 2 - Review
Livestock Substances § 205.603 & § 205.604
October 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 scheduled for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the Petitioned Substances Database.

Request for Comments

Written public comments will be accepted through September 30, 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
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 overdosage 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. The resulting charcoal may be chemically activated using a variety of acids, bases, and salts, usually under pressure and elevated temperature. Activation agents include acetic acid, hydrochloric acid, potassium hydroxide, sodium hydroxide, zinc chloride, and several others. According to the 2021 TR, these chemical activation agents are usually collected and reused. The charcoal may also be activated through exposure to oxygenated gas or steam. Activated charcoal can also be produced from animal by products or coal, but these sources are not allowed under this listing.

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."

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.

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.”

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.

Because of concern regarding the use of certain acids in manufacture, during a 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. The recent TR indicates that this concern is lessened by re-use of the activation agents.

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.

Comments on activated charcoal received for the Spring 2021 NOSB meeting were strongly in favor of its continued listing as an approved synthetic substance for use in livestock care. It is used infrequently in relatively small amounts and has little environmental impact. Furthermore, its use can reduce or prevent livestock distress and death.

Justification for Vote
The Subcommittee proposes removal of activated charcoal from the National List based on the following criteria in the Organic Foods Production Act (OPFA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove activated charcoal from the National List
Motion by: Brian Caldwell
Seconded by: Kim Huseman
Yes: 0 No: 3 Abstain: 0 Absent: 2 Recuse: 0

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 the treatment of hypocalcemia (also called parturient paresis or 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 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 a number of methods, including the reaction of gluconic acid with calcium hydroxide. Calcium hydroxide was also reviewed by the NOSB for processing and was voted 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."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 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.

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."

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 from November 2000 to 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. Due to the listing of calcium borogluconate as a stand-alone substance and the inclusion of the substance under the listing for electrolytes, the Subcommittee sought feedback on the separate listings and clarity from the FDA on the status of the substance as a livestock treatment. The NOP conferred with the FDA on the proposed additions and amendments to § 205.603. During this conference, the FDA indicated that their process involves reviewing formulated products for medical treatment approval. FDA indicated they do not review for medical treatment approval of generic materials, as included in this rule. Therefore, individual substances cited in this rule would not be reviewed as medical treatments under the FDA process. Based upon this consultation, NOP believes these substances are not in conflict with FDA regulations.

Stakeholders reflected a general acceptance of calcium borogluconate under separate listings to facilitate consistency amongst certifiers. One comment noted that the majority of certifiers would allow calcium borogluconate as an injectable electrolyte but having the separate listing assures this is the case. One certifier commented the listing is redundant, another certifier adding that having the separate listings does not cause differences in decision making.

Producers support the re-listing of calcium borogluconate, stating that it is a common, inexpensive, and traditional treatment for ketosis in ruminates. A producer group noted that a variety of treatments for ketosis are necessary for organic producers as they perform and are administered in different ways. Two veterinarians commented that the substance is essential for livestock treatment.

Justification for Vote
The Subcommittee discussed stakeholder feedback, the additional listing of the substance on the National List as an electrolyte and the regulatory clarity established by NOP with the FDA. As the substance provides relief from unnecessary animal suffering, it is compatible with a sustainable system of agriculture.

The Subcommittee proposes removal of calcium borogluconate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove calcium borogluconate from the National List
Motion by: Kim Huseman
Seconded by: Mindee Jeffery
Yes: 0 No: 3 Abstain: 0 Absent: 2 Recuse: 0

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 an electrolyte that is used in organic livestock to treat metabolic conditions such as hypocalcemia, scours, dehydration, milk fever, erratic heartbeat, loss of muscle control, mastitis, ketosis, alkalosis, acidosis, and difficulty in labor and prostration. Lack of treatment often results in death. Although the FDA considers electrolyte formulations to be animal drugs, many of the formulations have not been

formally approved by the FDA; often because they are non-proprietary, general use materials. No company has applied for a New Animal Drug Approval (NADA) for calcium propionate.
Milk production is very closely related to the total glucose supply at the udder. Propionate is used by the liver to make the glucose used by the cow to make lactose, the sugar in milk. 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. The fats are 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, creating acetone, acetoacetate, and beta-hydroxybutyrate. These products are released from the liver into the cow's bloodstream, causing 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, an intravenous injection is needed. Oral doses of calcium chloride can be effective, but it is caustic, causing ulcerations and acidosis. Calcium propionate is less caustic, does not cause acidosis, and the propionate fatty acid is glucogenic. One dose of calcium propionate 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.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 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."

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."

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, 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 extra stress on 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 treatment of hypocalcemia and the prevention of milk fever 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.

Public comments on calcium propionate received for the Spring 2021 NOSB meeting were generally in favor of continuing its listing on the National List as an approved synthetic substance for use in livestock care. A majority of livestock dairy producers, veterinarians, and the organic industry at large stated it was an essential treatment for milk fever. It was noted that calcium propionate products present little opportunity for environmental or human health issues, stating that the calcium propionate is metabolized by the livestock to achieve normal electrolyte balances. One commenter stated that they have not seen new, non-synthetic products available for the treatment of milk fever.

There were a few commenters who noted that the listing for calcium propionate is redundant, as the listings for electrolytes at §205.603(a)(11) and nutritive supplements at§205.603(a)(21) together allow for calcium propionate for the treatment of milk fever, but other commenters stated that having the separate listings does not cause differences in decision making.

Justification for Vote
The Livestock Subcommittee proposes removal of calcium propionate from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.603(a) if applicable: N/A. Not recommending removal.

Subcommittee Vote:
Motion to remove calcium propionate from the National List
Motion by: Kim Huseman
Seconded by: Sue Baird
Yes: 0 No: 4 Abstain: 0 Absent: 1 Recuse: 0

Chlorine materials Calcium hypochlorite, chlorine dioxide, Hypochlorous acid generated from electrolyzed water, sodium hypochlorite

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
(iii) Hypochlorous acid - generated from electrolyzed water
(iv) Sodium hypochlorite

Petition(s): 2016 (Hypochlorous Acid)
Technical Report: 2006 TR (Chlorine materials); 2017 Limited Scope TR (Hypochlorous Acid)
Past NOSB Actions: 10/1995 NOSB minutes and vote; 05/2006 NOSB sunset recommendation; 10/2010 NOSB recommendation; 10/2015 sunset recommendation; 04/2016 Recommendation to add hypochlorous acid; 11/2017 sunset recommendation
Recent Regulatory Background: Added to National List 2/20/2001 (65 FR 80547); Sunset renewal notice 3/15/2017 (82 FR 14420); Hypochlorous acid added to NL effective 1/28/2019 (83 FR 66559); Sunset renewal notice effective 10/30/2019 (84 FR 53577).
Sunset Date: 1/28/2024 (hypochlorous acid); 10/30/2024 (Calcium hypochlorite, chlorine dioxide, sodium hypochlorite)

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).

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.

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 hydrated (slaked) lime. It is then separated from the coproduct, calcium chloride, and air dried or vacuum dried. 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.

Hypochlorous acid: 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 hydrochlorite 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
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.

Public comment was consistently in favor of relisting chlorine materials including (i) Calcium, hypochlorite, (ii) Chlorine dioxide, (iv) Sodium hypochlorite. Due to its efficacy as a sanitizer and the overall lack of suitable alternatives, livestock producers and other stakeholders in the livestock product supply chain cited chlorine materials as a critical tool to maintain hygiene.

Justification for Vote
The Subcommittee proposes removal of chlorine materials from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove chlorine materials from the National List
Motion by: Kim Huseman
Seconded by: Nate-Powell-Palm
Yes: 0 No: 4 Abstain: 0 Absent: 1 Recuse: 0

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 Technical Advisory Panel (TAP), the FDA has declared kaolin to be generally recognized as safe (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
Kaolin pectin is a formulated mixture of kaolin and pectin. Both kaolin and pectin occur naturally. Kaolin is a mineral dust formed by weathering of aluminum silicates. Pectin may be obtained from appropriate edible plant material, usually citrus fruits or apples, by extraction into an aqueous medium. No organic precipitants are used other than methanol, ethanol, and isopropanol. In some pectin products, a portion of the methyl esters are 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 is 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 the environment.
- In the manner in which kaolin is to be used, in kaolin pectin, there is an 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.

Public comment during the 2021 spring meeting overwhelmingly supported the relisting of kaolin pectin; it is a vital tool used for gastrointestinal disorders in livestock production. Kaolin pectin does not seem to be overused, but rather being used on an as-needed basis. The TAP on kaolin pectin is from 2002, and the Livestock Subcommittee requested a new TR in 2021. The TR was not available before the Subcommittee voted on this document.

Justification for Vote
The Subcommittee proposes removal of kaolin pectin from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove kaolin pectin from the National List
Motion by: Sue Baird
Seconded by: Mindee Jeffery
Yes: 0 No: 4 Abstain: 0 Absent: 1 Recuse: 0

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
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
Mineral oil was petitioned in 2002 to be used for treatment of intestinal compaction and topical

application, and as a dust suppressant. After reviewing the 2003 TAP review, NOSB recommended adding mineral oil for treatment of intestinal compaction only. The scope of this sunset review is for mineral oil, approved in 205.603(a)(20) for administering internally to lubricate the intestinal tract and dislodge intestinal obstructions in cattle and other ruminants. The National Organic Program (NOP) final rule currently permits the use of mineral oil in organic livestock production for treatment of intestinal compaction, prohibited for use as a dust suppressant in 7CFR 205.603(a)(20).

Mineral oil is used as an internal lubricant in livestock production. 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 failure of omasal transport, which develops because of a condition that prevents ingested material from passing through the omasal canal into the abomasum, the fourth and final stomach compartment in the ruminants' stomachs. 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 until the viscous mineral oil treatment lubricates the impaction.

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). Ruminants such as cattle produce large volumes of gas during the digestive process, and natural foaming agents in legumes and some rapidly growing grasses cause stable foam to form in the rumen. The animal is therefore unable to pass the gas trapped as small bubbles in the foam. Severe cases may require insertion of a wide-boar trocar and cannula into the rumen to relieve the pressure followed by direct addition of an anti-bloat preparation (e.g., mineral oil, vegetable oils, or dioctyl sodium sulfosuccinate) into the rumen through the cannula. Sudden death is commonly observed in cattle that are not closely observed. As a preventative measure, veterinary specialists suggest that cattle producers drench each animal twice daily with an anti-bloat preparation when the pasture is considered risky.

Manufacture

The industrial production of highly refined, food-grade mineral oils involve chemical processing and refinement using various chemical reagents and/or catalysts. To produce mineral oil, the chemical composition of natural crude oil is altered through physical separation (distillation) followed by reactions/combination with synthetic substances and reagents (aromatic solvents, strong acids, 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.

Because of the complexity of the mineral oil mixtures, refined mineral oils are identified using several CAS numbers depending on the treatment processes utilized and the intended use pattern of the mineral oil product. Mineral oils used in organic livestock production are hydrocarbon molecules containing 34 carbon atoms. These untreated mineral oils may also contain small amounts of nitrogen- and sulfur containing compounds. As such, the NOSB classified mineral oil as "synthetic" since initially recommending addition of the substance to the National List.

International Acceptance

Canadian General Standards Board Permitted Substances List

Canadian regulations permit numerous uses for mineral oils of varying purity. Mineral oils are 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).

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 oils are 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."

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 oils are 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 oils 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."

International Federation of Organic Agriculture Movements (IFOAM) Norms
The IFOAM Norms permit the use of "light mineral oils (paraffin)" under Appendix 3 (crop protectants and growth regulators). There are no approved uses for mineral oils 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.

Human Health and Environmental Issues
Because of their complexity, it is not possible to separate mineral oil mixtures into individual components for quantification. Indeed, an enormous number of individual components are constituents of crude and refined mineral oil mixtures. Mineral oils may be classified as highly refined or mildly treated/untreated.

Testing in laboratory animals has demonstrated that mineral oils are slightly to practically non-toxic to mammals on an acute exposure basis. Mineral oils are mild irritants, classified as Toxicity Category IV (lowest toxicity) for skin irritation and Category III for eye irritation. Highly refined "white" mineral oils produced no sensitization reactions in guinea pigs repeatedly exposed to the substance.

The carcinogenicity and genotoxicity potential for mineral oils is generally dependent upon the degree of refinement and presence of PAHs in the mixture. White mineral oils, which have 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 oils are practically non-toxic to birds and honeybees via acute oral and contact exposure, respectively. Refined mineral oils are generally characterized as minimally toxic to aquatic organisms on an acute exposure basis.

The white mineral oils that are likely to be used for lubrication and external parasite control in organic livestock production are highly refined oils that contain negligible quantities of toxic contaminants compared to untreated and mildly treated oils.

Discussion

During the 2015 review of mineral oil some livestock producers indicated that failure to regularly treat for omasal impaction often results in the need for surgery. Mineral oil products are considered unapproved animal drugs according to FDA regulations. Animal drugs containing mineral oils 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.”

Accordingly, the NOP was unable to accept the 2015 NOSB recommendation to allow the use of mineral oil as a livestock medication. Mineral oil remains prohibited for use in organic livestock production as an orally administered treatment of constipation in cattle and other ruminants. The NOP currently permits the use of mineral oil in organic livestock production for topical use and as a lubricant at §205.603(b)(6)).

Best management practices may prevent the development of omasal impaction and parasite infestation in cattle, sheep, and other livestock under certain conditions. 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. Like bloat, 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.

Public comments received during the Spring 2021 NOSB meeting overwhelmingly supported relisting mineral oil. Commenters stated that mineral oil is used infrequency but when it is needed, there is no alternative that is sufficient because natural oils do not work, as they get digested and do not move or break up the compaction. Other commenters stated that other than invasive surgery, mineral oil was the best option. One livestock producer stated that you can take good care of your animals, but compaction can still happen in rare cases. If the material were prohibited, there would be huge negative effects on cow health. Animal welfare would be impacted, because the animal would either die, or would have to be sold if nonorganic treatments are used. One livestock veterinarian commented that, “Mineral oil has the property of not being absorbed by the gut and thus can coat the gut so there is no absorption and possible reabsorption downstream of toxins. It can be used for frothy bloat. It is indispensable to me as a practitioner to quickly reverse digestive upsets.”

Subcommittee Justification
The Subcommittee proposes removal of mineral oil from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove mineral oil from the National List
Motion by: Kim Huseman
Seconded by: Brian Caldwell
Yes: 0 No: 3 Abstain: 0 Absent: 2 Recuse: 0

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 fermentation 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 Agricultural Standard (JAS) for Organic Production
The Japan Agricultural Standard (JAS) for Organic Production 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 (JAS, 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-needed basis, provide valuable support to an animal's immune system and work to assist livestock health, well-being, and animal welfare.

Public comments consistently highlighted the need for effective health supplements that can address acute illnesses in livestock. Overall, commenters agreed that the removal of nutritive supplements would hobble organic livestock producers' ability to effectively manage their stock and provide the best care in acute illness scenarios.

Justification for Vote
The Subcommittee proposes removal of nutritive supplements from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove nutritive supplements from the National List
Motion by: Nate Powell-Palm
Seconded by: Brian Caldwell
Yes: 0 No: 4 Abstain: 0 Absent: 1 Recuse: 0

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
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 allowed for use in organic production only as a treatment for ketosis in ruminants [21 CFR 205.603(a)(27)]. Propylene glycol is typically administered in an oral drench to animals showing signs of clinical ketosis or to animals that a producer suspects of having subclinical ketosis. Propylene glycol is generally recognized as safe (GRAS) by the U.S. FDA (21 CFR 184.1666).

Ketosis is a metabolic disease that can result from energy imbalance in early lactation. According to the most recent technical report, the majority of a dose of propylene glycol is not fermented in the rumen. Instead, it is directly absorbed and metabolized by the liver to form glucose.

Manufacture
Propylene glycol is commercially produced through the hydrolysis of propylene oxide. The original source of the propylene oxide is typically propylene, generated either through the steam cracking of hydrocarbons or through the dehydrogenation of propane, both of which are non-renewable sources.

The 2021 technical report notes that researchers and manufacturers are improving methods to produce propylene glycol on a commercially viable scale via two additional routes:

- Catalytic hydrogenolysis of glycerol, a method that is becoming more economically feasible with the increased production of glycerol through biomass-produced ethanol.
- Microbial fermentation through a number of different microorganisms.

Many of the fermentation methods in development rely on genetically modified microorganisms for the efficient production of propylene glycol.

International Acceptance

Canadian General Standards Board Permitted Substances List

The Canadian General Standards Board includes propylene glycol on CAN/CGSB 32.311-2020 Table 5.3 (Health Care Products and Production Aids) with the annotation, "May only be used as an ingredient in foot baths." Table 5.3 also includes a listing for "Formulants (inerts, excipients)," allowing propylene glycol as an excipient used along with a permitted active ingredient.

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

The CODEX guidelines state in Annex 1, Part B "Health Care" clauses that producers must first prevent disease through species selection and management approaches. If prevention practices are insufficient to keep an animal healthy, a producer may use allopathic veterinary drugs if other homeopathic or phytotherapeutic products are insufficient. Propylene glycol is not explicitly mentioned for livestock health care input materials, but it would fall into the category of "veterinary drug" as defined in Section 2.2 of the 261 Guidelines.

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

Title II, Chapter 2, Section 4 of the EC No. 889/2008 focuses on disease prevention and veterinary treatment in organic livestock production. Article 24, paragraph 3 indicates that if preventive methods and phytotherapeutic and homeopathic products are not effective at combating illness, a producer may use chemically synthesized veterinary medical products. In this case, propylene glycol would be considered a "veterinary medicinal product" under the definition at Article 1(2) of Directive 2001/82/EC of the European Parliament and of the Council concerning the Community code relating to veterinary medicinal products. A 48-hour withdrawal period between the last administration and the production of organically produced milk or meat is noted.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Section 5.6 of the IFOAM Standard for Organic Production and Processing describes the requirements for the use of veterinary medicine in organic livestock production. Section 5.6.1 requires that producers establish preventive practices, including good quality feed and access to the outdoors, to avoid illness in their livestock before using synthetic allopathic veterinary medical products. Propylene glycol, when used to address ketosis symptoms in livestock, would be considered a synthetic allopathic veterinary medical product, and Exception (c) would allow its use under veterinary supervision with a minimum withdrawal period of at least 14 days. Prophylactic use of synthetic allopathic veterinary drugs is prohibited.

Japan Agricultural Standard (JAS) for Organic Production.

Article 4 of the Japanese Agricultural Standard for Organic Livestock, last revised in April 2018, includes the "Health control" section, specifying practices for organic livestock production. The Standard requires that producers implement preventive practices before using veterinary drugs, and veterinary drugs may only be used for therapy purposes. A withdrawal period of 48 hours between last use and milking or slaughter is noted.

Environmental Issues
The technical report on propylene glycol notes that the substance is widely used throughout many U.S. and global economic sectors, with most of the production capacity through propane as part of the petrochemical reduction process. Production of propane can lead to significant environmental impacts, including greenhouse gas emissions, pollution of waterways, water use issues, and petrochemical spills.

In the treatment of ketosis, propylene glycol is used in small volumes and is virtually non-toxic to vertebrates and invertebrates (with the exception of cats). Its use on organic dairy farms presents a very low risk for environmental contamination. Beyond mishandling or leakage from packages, less than 1 percent of the propylene glycol used in a dose is excreted in milk, manure, or urine when used to treat ketosis. Contamination resulting from on-farm use is likely to be minimal.

Based on currently available information, propylene glycol is:

- Not acutely toxic and it has a high lethal concentration in both mammals and aquatic species.
- Readily decomposed into carbon dioxide and water by microorganisms in water and soil, and breaks down in air through reaction with hydroxyl radicals.
- Able to move rapidly through the environment with water and shows little to no bioaccumulation.
- Efficiently retained and consumed as energy for animals so that it will not be applied to soils through manure incorporation.

Discussion
Propylene glycol 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. This is the first sunset review of propylene glycol at this listing.

Public comments were received for the Spring 2021 meeting in written formats. One industry group reported that propylene glycol is a sensible replacement for the administration of bottles of dextrose intravenously, which is a subpar treatment and can be dangerous for the farmer and the cow. According to the written submission, propylene glycol is the easiest route to rehabilitating ruminants suffering from ketosis, as cows can be aggressive when ketotic, making IV administration difficult and dangerous.

Dairy producers noted that there are natural alternatives like oral administration of apple cider vinegar and molasses. In addition to natural and preventative solutions to ketosis, producers provided information that propylene glycol is commonly available in farm stores and veterinary clinics and supported the continued listing of the substance. Additionally, a large animal veterinarian commented that propylene glycol is the gold standard for treatment of ketosis in ruminants.

The USDA organic regulations specify that producers shall not administer any drug in the absence of illness [7 CFR 205.238(c)(2)], limiting the use of propylene glycol to after the onset of ketosis symptoms, both clinical and subclinical, in ruminants.

According to the technical report, many of the available fermentation methods rely on genetically modified microorganisms for the efficient production of propylene glycol. These new methods offer the potential to produce propylene glycol without relying on petrochemical byproducts but are not economically competitive or available at commercial scale at the time of this review.

Subcommittee Recommendation
Despite concerns about the environmental impacts from the manufacturing practices identified in the technical report, and the potential future risk of excluded methods in the manufacture of propylene glycol,

the Subcommittee has determined that the limited use of the substance as a medical treatment for ketosis is necessary and recommends relisting.

Justification for Vote
The Subcommittee proposes removal of propylene glycol from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove propylene glycol from the National List
Motion by: Mindee Jeffery
Seconded by: Nate Powell-Palm
Yes: 0 No: 4 Abstain: 0 Absent: 1 Recuse: 0

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)(10) 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., Na_2O_2 or an alkaline solution of hydrogen peroxide, H_2O_2) 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 (CXG 32-1999) 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.

Public comments during the 2021 spring meeting were supportive of relisting sodium chlorite, acidified (ASC) as an approved teat dip for livestock. It was stated a few times that it is not used frequently but key when necessary to prevent mastitis. During the subcommittee review, there was discussion about the two listings at §205.603(a) and §205.603(b), and whether they were redundant. It appears the listings are not redundant. At §205.603(a) Sodium chlorite is allowed as a pre-milking sanitizer while at §205.603(b) it is used for post-milking as a preventative topical treatment.

Justification for Vote

The Subcommittee proposes removal of sodium chlorite, acidified from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote

Motion to remove sodium chlorite, acidified from the National List
Motion by: Kim Huseman
Seconded by: Nate Powell-Palm
Yes: 0 No: 3 Abstain: 0 Absent: 2 Recuse: 0

Zinc sulfate

Reference: §205.603 (b)(12) 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). Zinc ash is produced from zinc ore mined from underground or open pit mines (TR line 60).

International Acceptance
Canadian General Standards Board Permitted Substances ListOperators 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 may be relaxed under veterinary supervision if listed substances fail to work. TR lines 216 – 221.

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. TR lines 231-238.

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
Production of zinc sulfate results in significant local production of tailings in large volumes and lesser amounts of particulates, heavy metals, and gases, which can be filtered out or captured, but may not be depending on where the zinc is mined and processed. The amount of zinc sulfate used for foot rot control is a small proportion of its total use. However, its disposal on farm fields with manure can result in soil zinc buildups beyond desirable levels.

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 accumulate in soils, its persistence is less certain due to its mode of attachment to soils. Zinc sulfate is therefore considered a more benign material compared to copper sulfate.

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.

Discussion
According to the 2015 TR, "Peracetic acid and hydrogen peroxide foams are also used in the treatment and control of footrot, although the efficacy of these treatments is controversial (Bergstein et al., 2006). It is important to note that antibiotics are increasingly used in treatment of pododermatitis, due to the bacterial nature of its etiology. However, good evidence is available for increased microbial antibiotic resistance in *Dichelobacter nodosus* and other bacteria present during infection (Lorenzo, et al., 2012). Antibiotics are prohibited in organic livestock production (7CFR §205.237, §205.238).These same bacteria have not demonstrated resistance to zinc sulfate treatment…. Some vaccines have been shown to be effective in treating footrot. Because several bacteria are involved in the infection and these are represented by multiple serogroups, the effectiveness of using a monovalent vaccine in treating another serogroup is likely to be limited. Programs are ongoing to address vaccination, but a complete vaccine has not yet been described for footrot in cattle or sheep (Bennett and Hickford, 2010)."

Copper sulfate and zinc sulfate are two of the most accepted treatments and are comparable in efficacy. Formalin can also be used for this purpose but is not approved for use on organic farms. 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.

Copper compounds are toxic to sheep and goats, so the presence of zinc sulfate on the National List allows for its use for these species as an alternative to copper sulfate.

Comments from stakeholders were strongly in favor of retaining zinc sulfate on the national list as an approved synthetic material. Some proposed adding an annotation specifying that its use be curtailed if soil zinc levels become excessive. Zinc sulfate is considered less environmentally damaging than copper sulfate, which is on the National List for the same use. Since zinc sulfate has only been on the National List for a short time, it is not clear whether its presence there will reduce the use of copper sulfate for hoof disease.

Based on this information, including stakeholder comments, the Livestock Subcommittee proposes that zinc sulfate be retained on the National list.

Justification for Vote
The Subcommittee proposes removal of zinc sulfate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A. Not recommending removal.

Subcommittee Vote
Motion to remove zinc sulfate from the National List
Motion by: Brian Caldwell
Seconded by: Kim Huseman
Yes: 0 No: 3 Abstain: 0 Absent: 2 Recuse: 0

National Organic Standards Board
Materials Subcommittee Proposal
2021 Research Priorities
August 12, 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 systems 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 Proposal
2021 Research Priorities
August 12, 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 more accurately reflect the existing need 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 Systems 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 chorine is the best material to use.
- Could the rotation of materials for cleaning and disinfecting help lower the risks from chlorine materials and still be effective in providing the desired control of pathogens?
- Research on the absorption of chlorine by produce from its 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. Comments were limited in the previous two comment cycles.

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 2021 NOSB Research Priorities proposal
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, August 13, 2021

National Organic Standards Board
Materials/GMO Subcommittee Discussion Document
Excluded Methods Determinations
August 12, 2021

Introduction and background
Cell fusion and protoplast fusion have a nuanced history in the context of the USDA's National Organic Program and the work of the National Organic Standards Board. Cell fusion is included under terms defined at §205.2 as an excluded method. In 2013, the NOP clarified its position on both techniques in Policy Memo 13-1 allowing for both techniques to be used solely within taxonomic plant families. As work by the NOSB progressed in this area, cell fusion and protoplast fusion continue to be included as techniques to be evaluated on the excluded methods "TBD list" with notes indicating follow-up work by the NOSB.

Goals of this document
The Materials Subcommittee is seeking feedback on the TBD list terms 'cell fusion' and 'protoplast fusion.' This document will outline the history and explore context towards determining if more discussion is necessary on the issues of cell fusion and protoplast fusion as excluded methods in organic systems.

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.

The NOSB previously recommended the use of the following definitions to determine whether or not a method should be/is excluded.

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.

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)

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

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

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.

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 assess phenotypes more accurately, however the emphasis must be on whole plant selection.

Criteria

Below are the criteria listed in the 2016, 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.
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.

Method and synonyms	**Types**	**Excluded Methods**	**Criteria Applied**	**Notes**
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.
Agro-infiltration		YES	1, 3, 4	*In vitro* 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		*TBD*		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		*TBD*		Subject of an NOP memo in 2013. The Crops Subcommittee will continue to explore the issue.
TILLING	Eco-TILLING	*TBD*		Stands for "Targeted Induced Local Lesions in Genomes." It is a type of mutagenesis.

Doubled Haploid Technology (DHT)		*TBD*		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		*TBD*		Induced mutagenesis developed through exposure to UV light, chemicals, irradiation, or other stress.
Transposons		*TBD*		Produced from chemicals, ultraviolet radiation, or other synthetic activities.

Discussion

Under the NOP organic regulation, cell fusion is by definition an excluded method at §205.2. In 2013, NOP Policy Memo 13-1 provided further context for the use of cell fusion in organic systems which included protoplast fusion. Both were deemed to be excluded methods except when either technique was employed within taxonomic plant families. The policy memo defends this assertion that this limited use mimics natural phenomenon and is therefore allowed.

In February 2013, the NOSB discussion document on Excluded Methods Terminology references the policy memo explaining "that cell fusion techniques are considered an 'excluded method' when the donor cells/protoplasts do not fall within the same taxonomic family. Cell fusion is also an 'excluded method' when the donor or recipient organism is derived using techniques of recombinant DNA technology and techniques involving the direct introduction into the organism of hereditary materials prepared outside of the organism."

As the NOSB continued its work around issues of excluded methods, both cell fusion and protoplast fusion were included on a list of techniques that needed consideration for allowance/prohibition (see Appendix for NOSB proposal and discussion document April 2016). This "TBD list" included cell fusion with the note column giving the explanation "[s]ubject of an NOP memo in 2013. The Crops Subcommittee will continue to explore the issue." Protoplast fusion was included in the TBD list with the note "[t]here 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." The Materials Subcommittee is exploring whether its work is complete with cell/protoplast fusion, and by extension, the need for additional criteria to approach future TBD list determinations.

Questions for our Stakeholders

1. Should the NOSB prioritize developing additional criteria for excluded methods determinations before continuing to work on the remaining TBD list techniques?

2. Is Policy Memo 13-1 complete and applied consistently in organic systems, i.e., do cell fusion and protoplast fusion need to remain on the TBD list or can they be moved to the excluded method section with the notes that allowance is made for these techniques when employed within taxonomic plant families?

3. As the NOSB makes excluded methods determinations on the remaining TBD list techniques, should this organic system include allowance for historical use and a time frame for phasing out excluded uses?

Appendix

National Organic Program (February 2013).
Policy Memorandum Cell Fusion Techniques used in Seed Production. AMS.USDA.GOV
https://www.ams.usda.gov/sites/default/files/media/NOP-PM-13-1-CellFusion.pdf

National Organic Standards Board. Materials/GMO Proposals. (April 2013).
Discussion Document on Excluded Methods Terminology. AMS.USDA.GOV
https://www.ams.usda.gov/sites/default/files/media/GMOSCTrmnlgyExclddMthdsApril%202013.pdf

National Organic Standards Board. Materials/GMO Proposals. (April 2016).
Excluded Methods Terminology – Third Discussion Document. AMS.USDA.GOV
https://www.ams.usda.gov/sites/default/files/media/MSDDExcludedMethodsApr2016.pdf

National Organic Standards Board Materials/GMO Proposals. (April 2016).
Excluded Methods Terminology – Proposal. AMS.USDA.GOV
https://www.ams.usda.gov/sites/default/files/media/MSPrpslExcldMethTerminologyApr2016.pdf

Motion to accept the Fall 2021 excluded methods discussion document
Motion by: Mindee Jeffery
Seconded by: Brian Caldwell
Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Wood Turner, Materials Subcommittee Chair, to transmit to NOP August 12, 2021.

National Organic Standards Board
Policy Development Subcommittee Discussion Document
Oral and Written Comment Submissions
August 10, 2021

Introduction and background

The National Organic Standards Board is bound by regulation to conduct open meetings in accordance with the Federal Advisory Committee Act (FACA) along with the provisions of the Policy and Procedures Manual (PPM). Stakeholder submissions of written and oral comments are the backbone of community engagement, providing invaluable perspectives on the many issues that arise in organic systems. In the interest of maintaining fair and equal access to the Board by the stakeholder community, the Policy Development Subcommittee (PDS) is reviewing procedures on written and oral comments. PDS seeks to review the framework for written and oral comment submissions through engaging the organic community in a dialogue on best practices.

Goal of this Document

The Policy Development Subcommittee seeks to hear feedback on how it might modify established procedures to maximize community engagement practices that facilitate fair and equal access to National Organic Standards Board members by all stakeholders.

Discussion

The Policy Development Subcommittee is considering the submission process of oral and written comments to the Board for in person and/or virtual meetings. Governing policies and procedures from FACA, Federal Register Notices, and the PPM are listed and linked in the Appendix of this document.

Written Comments:

In regard to written comments in advance of NOSB meetings, the PPM states, "All members of the public are encouraged to submit public comment in writing according to the Federal Register Notice. Written submissions allow NOSB members the opportunity to read comments in advance, eliminate or decrease the need for paper copies to be distributed during the meeting, and allow each NOSB member to review and analyze data and information well ahead of the public meeting and possible voting."

The NOSB has an established 30-day comment period prior to each of its public meetings. The comment period opens approximately 45 days prior to the meeting, and closes 30 days later, giving Board members approximately 2 weeks to read, analyze, and incorporate written comments into their proposals. The Federal Register Notice states that written comments submitted after the deadline may not be considered by the Board before they deliberate and vote during the meeting. The PDS is strengthening the language to indicate that the NOSB will not consider comments submitted after the deadline.

Written comments are sometimes submitted to NOP and/or individual Board members after the comment period closes, along with the urgent request that the information be forwarded to the entire Board. Balancing the need to engage with stakeholders and ensuring all stakeholders have equal access to the Board creates pressure on Board members' attention during meetings. PDS sees the forwarding of written comments to the Board after the closure of the comment period as an issue of fairness.

Stakeholders should not expect written comments submitted after the deadline to be posted to the Federal Register or forwarded to the Board during the public meeting. The defined comment period exists for a reason.

Oral Comments:

Announcements in the Federal Register illuminate the process and deadline for submitting oral comment requests before each meeting. Given the sea change in meeting processes as informed by the pandemic, oral comments are under consideration in two areas. In the first, the Policy Development Subcommittee is considering the importance of in-person oral comments during in-person Board meetings versus moving to an all-virtual pre-meeting oral comment process. Further, PDS is exploring access/fairness issues that can arise when organizations schedule multiple individuals for oral comments that can effectively advantage that organization over other commenters.

Oral comments are foundational to the NOSB's informed decision-making process. The NOSB receives feedback that the scheduling of NOSB meeting in the Spring and Fall conflicts with the planting and harvest schedules for some stakeholders and is a barrier to attendance at the in-person meetings. Virtual oral comments allow those without time or resources to travel, the opportunity to engage in the process and provide information to the Board. Given the shift and emergence of virtual resources, the PDS is considering making the virtual, pre-meeting format for oral comments the standard. Board members have noted that oral comments received the week before the meeting allow more consideration before deliberation and voting. Alternatively, Board members do not want to discourage in-person attendance by stakeholders, acknowledging the value of stakeholder information presented orally during the context of the in-person meeting. The PDS is trying to balance the need to provide opportunity for expansive participation by the stakeholder community within a framework that also aides the Board's digestion of information.

Oral comment registration procedures are outlined in the Federal Register Meeting Notice and the Policy and Procedures Manual. Oral commenters are generally scheduled in the order in which they register. The NOP makes an effort to accommodate scheduling requests for special circumstances if possible. Scheduling accommodations, while possibly increasing engagement, can lead to a lack of fairness in time given to a single organization or subject, and also increases the workload of the NOP. The PDS does not intend to be overly prescriptive when it comes to scheduling oral comments but does want to explore best practice for remaining open and flexible while maintaining a level playing field for all stakeholders.

Questions

1. Should the Board move to an entirely virtual format for oral comments the week before in-person meetings or maintain the pre-pandemic format of hearing oral comments, both virtually prior to the in-person meeting as well as in-person at the public NOSB meeting?
2. If NOSB meetings move to a model wherein all oral comments are heard virtually the week before the meeting, would it reduce the attendance of stakeholders at the Board meeting?
3. Restrictions due to the pandemic aside, would the availability of a live-stream meeting discourage in-person attendance?
4. Is the practice of scheduling multiple oral comments by a single organization (such as a business/company/non-profit/trade group) inherently unfair? Is there a path by which the Board can field multiple areas of expertise from a single organization, while balancing the limits of time, fairness, and the importance of receiving a wide range of stakeholder feedback?

Appendix:

A. Policy and Procedure Manual (PPM) rev. October 25, 2019 (https://www.ams.usda.gov/sites/default/files/media/NOSB-PolicyManual.pdf)

VIII. NOSB PROCEDURES

E. PUBLIC COMMENT

The NOP and NOSB encourage public comment and work collaboratively to increase opportunities for greater participation by a broad range of people, employing various modes of communication and modern technology whenever possible. Individuals may present oral comment at either a pre-meeting electronic webinar or at the in-person NOSB meeting.

Before Public Meetings:

Written comment: All members of the public are encouraged to submit public comment in writing according to the Federal Register Notice. Written submissions: allow NOSB members the opportunity to read comments in advance, eliminate or decrease the need for paper copies to be distributed during the meeting and allow each NOSB member to review and analyze data and information well ahead of the public meeting and possible voting.

Oral Comments

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

Comments at In-Person Public Meetings:

- All persons wishing to comment at NOSB meetings during public comment periods must, in general, sign-up in advance per the instructions in the Federal Register Notice for the meeting. Persons requesting time after the closing date in the Meeting Notice, or during last minute sign-up at the meeting, will be placed on a waiting list and will be considered at the discretion of the NOP working closely with the NOSB Chair and will depend on availability of time.
- All presenters are encouraged to submit public comment in writing according to the Federal Register Notice. Written submissions allow NOSB members the opportunity to read comments in advance electronically, and decreases the need for paper copies to be distributed during the meeting.
- Persons will be called upon to speak according to a posted schedule. However, speakers should allow for some flexibility. Persons called upon who are absent from the room could potentially miss their opportunity for public comment.
- Time allotment for public comment per person will be four (4) minutes, with the options of reducing to a minimum of three (3) and extending to a maximum of five (5) minutes at the discretion of the NOP, working closely with the NOSB Chair in advance of the meeting.

- Persons must give their names and affiliations for the record at the beginning of their public comment.
- Proxy speakers are not permitted.
- Public comments may be scheduled according to topic.
- Individuals providing public comment shall refrain from making any personal attacks or remarks that might impugn the character of any individual.
- Members of the public are asked to define clearly and succinctly the issues they wish to present before the Board. This will give NOSB members a comprehensible understanding of the speaker's concerns.

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

- The NOSB and NOP seek public communication outside of Board biannual meetings and public comment periods to inform the NOSB and NOP of stakeholders' interests, and to comment on the NOSB's and NOP's work activities year around.
- The NOSB may post draft discussion documents and proposals between public meetings for review and public comment. Timely submission of comments will assist the NOSB and its Subcommittees in revising such documents for subsequent NOSB review.

B. Federal Register Notice Example: https://www.regulations.gov/document/AMS-NOP-20-0089-0001

C. Requirements regarding FACA meetings: (https://www.gsa.gov/policy-regulations/policy/federal-advisory-committee-management/advice-and-guidance/the-federal-advisory-committee-act-faca-brochure)

Open Access to Committee Meetings and Operations
Under the provisions of the Federal Advisory Committee Act, federal agencies sponsoring advisory committees must:

- Arrange meetings that are reasonably accessible and at convenient locations and times;
- Publish adequate advance notice of meetings in the *Federal Register*;
- Open advisory committee meetings to the public (with some exceptions-see the section on "Government in the Sunshine Act" below);
- Make available for public inspection, subject to the Freedom of Information Act, papers and records, including detailed minutes of each meeting; and
- Maintain records of expenditures.

D. Sample and Example of FACA Bylaws (https://www.gsa.gov/policy-regulations/policy/federal-advisory-committee-management/advice-and-guidance/sample-and-example-of-faca-bylaws**)**

NOSB doesn't have bylaws – we instead have a combination of OFPA and the PPM.

Open Meetings. Unless otherwise determined in advance, all meetings of the Government Procurement Advisory Board (GPAB) will be open to the public. Once an open meeting has begun, it will not be closed for any reason. All materials brought before, or presented to, the Board during the conduct of an open meeting, including the minutes of the proceedings of an open meeting, will be available to the public for review or copying at the time of the scheduled meeting.

Members of the public may attend any meeting or portion of a meeting that is not closed to the public and may, at the determination of the Chairman, offer oral comment at such meeting. The Chairman may decide in advance to exclude oral public comment during a meeting, in which case the meeting announcement published in the Federal Register will note that oral comment from the public is excluded and will invite written comment as an alternative. Members of the public may submit written statements to the PAB at any time.

Subcommittee Vote:
Motion to accept the discussion document on Public Comments
Motion: Jerry D'Amore
Seconded: Nate Powell-Palm
Yes: 4 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Mindee Jeffery, Policy Development Subcommittee Chair, to transmit to NOSB August 10, 2021