National Organic Standards Board Meeting
April 18 & 20 (Comment webinars), and April 25 - 27, 2023 (NOSB meeting)

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National Organic Standards Board
Certification, Accreditation and Compliance Subcommittee
Proposal: Organic Is Climate-Smart Agriculture
February 18, 2023

Introduction:

Dear Dr. Tucker,
With the announcement of the Partnerships for Climate-Smart Commodities funding, the organic community celebrated how many of the award projects included certified organic companies and organic serving non-profit organizations. The certified organic community has been involved in 20 years of consensus-making in a public-private partnership with the United States Department of Agriculture (USDA) National Organic Program (NOP) and the National Organic Standards Board (NOSB). The NOSB process represents countless hours of research, stewarding innumerable acts implementing a voluntary regulatory program through which producers are paid a premium for their systems-based approach (collection of climate-smart practices), and by which consumers can be assured of climate-smart decision-making with transparency and the force of law.

While organic community members live and breathe the NOP standards every day, it's possible to forget that the USDA oversees the "Certified Organic" seal and has (very successfully) shepherded the marketplace to its current retail market size of $62 billion. Indeed, to be clear, the market program that is the goal of the funding offered by the Partnership for Climate-Smart Commodities has already been created in the form of the National Organic Program (NOP).

While all certified organic production is climate-smart, not all "climate-smart" production is certified organic. Therefore, this proposal aims to articulate why, if an agriculture producer is certified organic, they should be automatically considered climate-smart and made eligible for all climate-smart funding, buying, and other programmatic opportunities administered by the USDA.

Per the February 2022 memo, the NOSB was tasked with addressing the questions to help articulate why classifying certified organic farming "climate-smart" is a sensible evolution of the hard work and resources that have gone into building the wildly successful NOP.

We expect this document to be a clear signal to the greater USDA that certified organic production should be automatically considered "climate-smart" and therefore eligible for any and all funding opportunities and support through relevant USDA programs. We consider this an ongoing discussion and look forward to the dialogue and future clarifications the USDA might request.

Throughout the remainder of this proposal, the NOSB responds in detail to the seventeen questions outlined in the memo.

1) What existing data or research support the link between organic practices and climate change mitigation?

For an excellent summary of the scientific literature, we encourage you to read the report: Schonbeck, M., D. Jerkins, and L. Snyder. 2017. Soil health and organic farming. Organic Farming Research Foundation: Santa Cruz, CA, USA. While the Schonbeck et al. report focuses on soil health in organic farming systems, we remind the NOP that, by not using prohibited synthetic nitrogen fertilizers, herbicides, or pesticides, organic farms inherently emit fewer greenhouse gas emissions.

The following USDA scientists are working on organic-specific agronomy research and can add their nuanced scientific perspectives to this question. The researchers are Michel Cavigelli and Eric Brennan at the Agricultural Research Service (ARS), and Sharon Raszap Skorbiansky at the Economic Research Service (ERS). It would be helpful to have USDA researchers (or an interdisciplinary team of university researchers) assess the state of the literature on climate change and organic farming. Important points to consider in such a review include:

- The climate footprint of energy-intensive input production.
- Synthetic inputs' role in soil's capacity to hold carbon.
- Differences in nitrous oxide and methane emissions on farms under organic and conventional management.
- Farm resiliency of different systems.

2) What research should USDA prioritize to demonstrate the efficacy of organic farming as climate-smart agriculture?

1. Climate benefits of zero synthetic fertilizer use. The NOP standards prohibit crop production using synthetic fertilizers, herbicides, and pesticides. As a carbon-intensive input, synthetic nitrogen fertilizer represents one of the focal areas' researchers aim to minimize and use effectively. From a manufacturing carbon footprint to synthetic nitrogen's role in volatilizing soil organic matter to fertilizer runoff issues affecting water quality, organic agriculture has addressed or eliminated the impact of synthetic fertilizer on the environment by eliminating its use. To comprehensively understand certified organic production's impact on soil and water quality, research quantifying the per-acre impact of organic agriculture's elimination of synthetic nitrogen in the following categories should be prioritized: carbon not emitted in the manufacturing process, the carbon sequestered in the soil by not volatilizing soil organic matter through concentrated nitrogen application, and finally, the nitrogen kept from contaminating ground and surface water.

2. Life cycle analysis of the major organic commodities, including corn, soybeans, wheat, dairy, eggs, and chicken meat, should be conducted across the continental United States. Organic producers must use most of the climate-smart practices listed on the Partnerships for Climate-Smart Commodities announcement webpage. By quantifying the impact of NOP regulations on the crops' carbon footprint, producers will be well positioned to communicate precisely to consumers the climate implications of being certified organic.

3. Economic resiliency analysis: Organic is the solution to mitigating climate change *and* responding to it. In a global economy where supply chain disruption is the norm, conventional crop yields are erratic, and farm viability is highly susceptible to shocks, certified organic production offers a solution by relying on the ecological potential of land rather than relying on off-farm inputs imported from thousands of miles away. As of the writing of this document, we have evidence that organic yields are more resilient to drought due to increased organic matter in the soil (Rodale, 2017) however, we need more data on quantifying the potential. Organic farms rely on fertilizers either produced on the farm (via crop rotation, cover crops, or animal manures) or regionally sourced fertility (chicken litter, cattle manure, compost, etc.).

3) What key practices that support climate-smart agriculture are already codified in the USDA organic regulations?

The following climate-smart practices are codified in the USDA organic regulations. These practices are highlighted in the Partnership for Climate-Smart Commodities announcement.

- Cover crops - **[205.203(b) and 205.205]** - Certified organic crop producers were the original leaders in integrating cover crops.
- Low-till or no-till – Organic producers are required to select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion **[205.203(a)]**
- Nutrient management-Certified organic producers must not use any fertilizer or composted plant and animal material that contains a synthetic substance not included on the National List of synthetic substances allowed for use in organic crop production **[205.203(e)1]**
- Manure management-Certified organic producers must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances **[205.203(d)]**
- Buffers, wetland and grassland management, and tree planting on working lands **[205.202(c)]**
- Climate-smart pasture practices, such as prescribed grazing or legume inter-seeding- **[205.240(b)]**
- Planting for high carbon sequestration rate- **[205.203(a-c)]**
- Enhanced efficiency fertilizers - **[205.203(b)]**
- Alternate wetting and drying on rice fields- **[205.206]**
- Soil amendments, like biochar and compost- Organic growers actively embrace progressive soil amendments like biochar, compost, and other approved materials which build soil biology and physical structure; indeed, the USDA organic regulations allow the use of biochar **[205.105]**

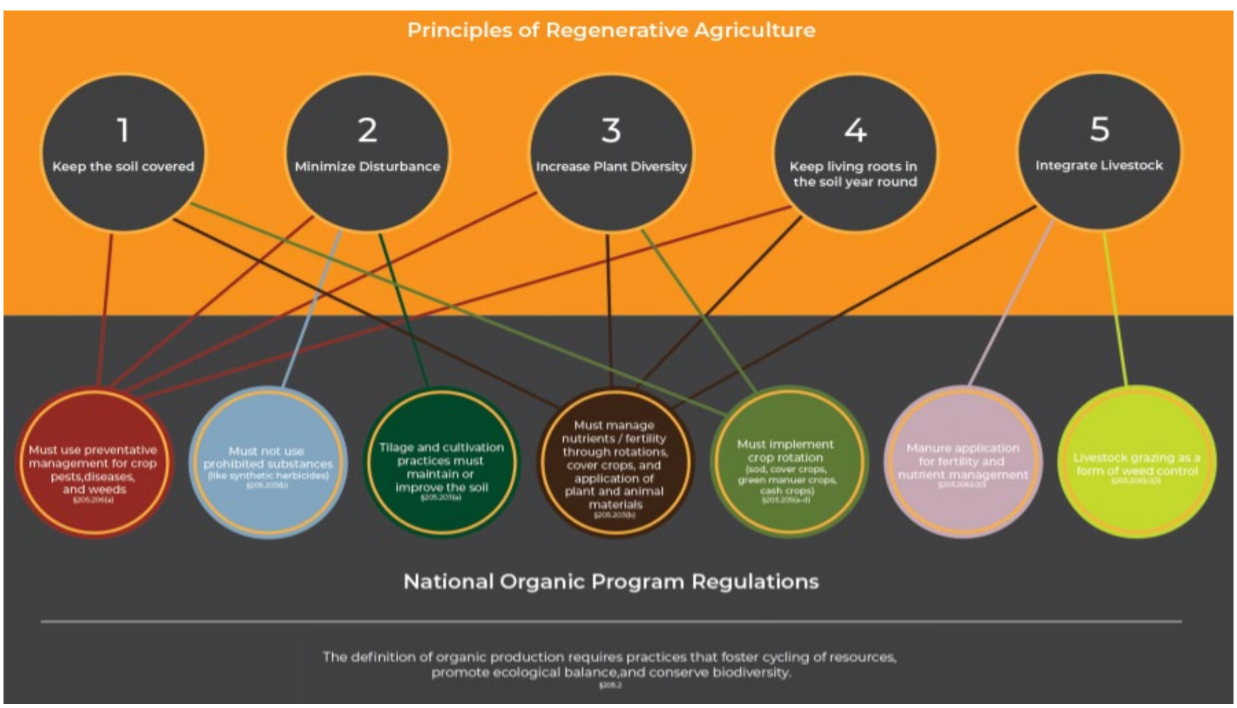


Figure -1: - Organic Agronomy Training Service (OATS).

4) **What climate-smart organic practices should new/transitioning farmers be made aware of?**

- Organic farming can require less tillage (Figure 1: Moldboards and Dust Clouds: Organic Has a Tillage, OATS 2021) than conventional agriculture due to crop rotations. The yield gap (Figure 1: Double the Acres Half the Yield: Organic Can't Feed the World, OATS 2021) between organic and conventional production is closing (i.e., corn) or has closed (i.e., wheat).
- Certified organic farming prohibits synthetic nitrogen use, which is positive for soil health and farmers' pocketbooks.
- Crop insurance for organic is improving (attention is still needed).
- Certified organic rotations incorporating perennial crop phases such as clover or alfalfa or annual crop phases such as small grains and pulses can lead to less tillage than conventional systems.
- Organic crop rotations can fix nearly all of the fertility necessary to have robust crop yields when proactively managed.
- Organic prohibits the use of synthetic fertilizers, yet rapidly realizes yields that are consistent with conventional.

5) **What specific practices already documented in organic system plans (OSPs) support climate-smart agriculture?**

- Cover crops **[205.203(b) and 205.205]** Certified organic crop producers were the original leaders in integrating cover crops.
- Low-till or no-till practices: all tillage practices, including equipment and timing, are recorded in the OSP **[205.203(a)]**
- Nutrient management plan: OSP requires applicant farmers to document and receive approval for all material fertility inputs, fertility monitoring, and application practices, including approval for each material by the certifier **[205.203(e)1]**
- Manure management practices on crop and livestock operations **[205.203(d)]**
- Buffers, wetland and grassland management, and tree planting on working lands **[205.202(c)]**
- Climate-smart pasture practices: Grazing practices are extensively documented to show that all ruminants receive 30% or more of their dry matter intake from pasture **[205.240(b)]**
- Planting for high carbon sequestration rate: Crop rotation is extensively documented in the OSP, showing between 3 and 5 years of history on each **[205.203(a-c)]**
- Enhanced efficiency fertilizers: **[205.203(b)]**
- Alternate wetting and drying on rice fields: **[205.206]**
- Soil amendments, like biochar: Organic growers actively embrace progressive soil amendments like biochar; indeed, the USDA organic regulations allow the use of biochar **[205.105]**

6) **How could organic system plans and other organic recordkeeping more clearly demonstrate that organic farmers' practices support climate-smart agriculture?**

Organic certifiers could work with other federal agencies who are working on climate-smart agriculture to adopt a common language for the:

- Guidance on soil testing procedures to prove soil organic matter is being maintained or increasing
- Guidance on soil testing showing that soil fertility is maintaining or increasing
- Guidance on whether nitrogen auditing should be done on organic operations during inspections. Guidance to help understand what nitrogen sources are allowed. Guidance on how to assess if a farm has a growing dependence on off-farm fertility or if they are building their soil fertility

- Guidance on soil testing procedures to prove soil water holding capacity is being maintained or increasing

7) How can NOP better communicate to new and transitioning farmers that organic supports climate-smart agriculture?

Clearly communicate to new and transitioning farmers that the organic standards completely incorporate the five pillars of soil health as identified by the Natural Resources Conservation Service (NRCS) as codified into law via the NOP standards (Figure 1).

8) What are the barriers to capturing and reporting on organic farming benefits?

Organic system plans maintained by farmers and reviewed by certifiers vary from certifier to certifier. A universal OSP that requires annual reporting of key data including soil organic matter content of the soil, fertility levels of Nitrogen, Phosphorus, Potassium (NPK) in the soil, and other key soil health indicators could enable farmers to use their OSP as a multi-purpose reporting form. To this end, a universal OSP that is designed to ask questions in a way that complies with other federal programs (NRCS, Risk Management Agency (RMA), Farm Service Agency (FSA) etc.) could enable farmers to perform less duplicative reporting when seeking access to other programs administered by the USDA.

9) What changes would increase the efficiency and effectiveness of organic reporting of climate-smart agriculture data? What federal, state, or local climate-smart programs could organic farmers apply for?

The following list is not comprehensive but shows how organic producers could easily qualify without additional reporting: This list is not exhaustive.

- Through the USDA Natural Resources Conservation Service (NRCS)
  - Environmental Quality Incentives Program (EQIP)
  - Conservation Stewardship Program (CSP)
  - Regional Conservation Partnership Program (RCPP)
  - Conservation Innovation Grant (CIG)
- Through the USDA Risk Management Agency (RMA)
  - Pandemic Cover-Crop Program (PCCP)

10) What types of crosswalk tools would most help farmers in making connections between the Organic Systems Plan and any documentation required for other climate-smart and/conservation programs?

Making the Organic System Plan (OSP) a universal document consistent across certifiers would allow certified operations to enter into climate-smart and conservation programs more efficiently.

11) How can organic farmers better market their current practices as climate-smart?

The NOSB is eager to hear suggestions from the organic community about this question.

As a baseline understanding: certified organic farmers lead the way with the implementation of climate-smart practices and should automatically qualify for any climate-smart label when the USDA codifies the term's use.

Marketing is about messaging, and as the agricultural solution to climate change, Organic has a story to tell. To realize the full potential of the public-private partnership we need USDA-Agricultural Marketing Services' (AMS) help. The organic seal is trusted and venerated but it's also static. As consumers look to their food as a means of combatting climate change with their dollars, they need the organic label to clearly make the connection between organic and climate-smart.

As organic stakeholders, including farmers, processors, and retailers, coalesce around the most impactful practices to combat climate change, the following practices could be elevated to improve consumer awareness of the climate smart benefits of organic:

- Certified organic producers are prohibited from using synthetic fertilizers, making organic an obvious climate-smart option.
- Organically farmed soils have been found to sequester 13% more soil organic matter than conventional farms (Ghabbour, et al., 2017).
- Under organic certification, ruminant livestock are required to be on pasture, thus reducing the amount of manure stored on organic farms, which in turn reduces potential nutrient leaching.

12) What organic practices and attributes should organic farmers highlight to help them qualify for climate-smart programs?

- The use of crop rotation and cover crops to build soil fertility.
- Zero use of synthetic fertilizers.
- Buffers around field edges.
- The requirement to maintain riparian areas.
- The use of animal manures and judicious tillage to increase soil biology.
- Reduced tillage by considering the entire crop rotation on a field.

13) How can organic farmers talk about their practices so they can benefit from the variety of federal, state, and private sector climate-smart agriculture programs? i.e., reducing duplication of reporting?

Organic agriculture is a dynamic systems-based approach to solving production barriers and mitigating environmental concerns. Standardizing the language regarding climate-smart agriculture will be a step in the right direction allowing for a reduction of duplication with reporting.

The USDA should focus on streamlining and consistency of reporting so organic producers could automatically be qualified to be endorsed for the non-GMO project, climate-smart agriculture, Farm Service Agency (FSA), NRCS, Risk Management Agency (RMA) programs.

14) USDA already supports climate-smart agriculture through many technical assistance and incentive programs. What can be done to ensure those resources reach organic farmers?

Producers would be aware of the availability of programs that support climate-smart practices if they were listed in the OSP or as cover pages to the OSP. This outreach technique has proven effective for the organic cost-share program (FSA). Most certifiers ask organic farmers if they would like to participate in organic cost-share during the application process. Standardization of communication and forms will be key. Farmers need to know where to look for these resources, and if they can always be found as an annual update from their certifier, filling out the OSP would be a one-stop shop for communication.

Furthermore, delivering streamlined, standardized communication to each certifier for circulation in the OSP and then cross-posting the same standardized communication in the USDA Organic Insider, with FSA and NRCS staff, and agents that sell RMA policies.

15) What types of technical assistance do organic farmers need to transition? Is this assistance available now? What type of assistance may be missing?

- Technical assistance for record keeping and organic farming principles knowledge.
- Orientation on weed mitigation equipment and techniques.
- Building robust rotations that tackle agronomic concerns.
- Soil health and nutrient management strategies for organic farming.
- Navigating non-standardized contracts for crop sales.
- Technical guidance on how to join a crop marketing cooperative and organic marketing in general, which is typically executed through a different type of supply chain than conventional agriculture.
- Risk management programs. Currently risk management opportunities are a deterrent to farmers considering transition to organic because coverage levels decline when transitioning from conventional to organic.

Several groups, including state organic programs, select certifiers, Organic Agronomy Training Service, Practical Farmers of Iowa, Montana Organic Association, California Certified Organic Farmers (CCOF) Foundation, Oregon Tilth, NRCS, etc., offer farmers some form of technical assistance.

Missing assistance: Expert organic agronomy advisors with localized/regional knowledge. We are missing experts who know how to help organic farmers grow and expand at scale in their region, increasing profitability.

Additional missing expertise: the banking/lending community is not well versed in how to support organic farmers.

16) How can USDA better connect organic farmers with the tools, expertise, and networks they need to successfully promote themselves as climate-smart?

Organic farmers are deploying multiple climate-smart practices already, as many are fundamental for creating a successful foundation in organic agriculture. Promoting these practices is where the organic program and organic farmers have fallen short.

17) What are the most critical research needs organic farmers could benefit from?

The NOSB annually presents a list of organic food and agriculture research priorities. The NOSB requests that integrated research be undertaken considering the whole farm system, recognizing the interplay of agroecology, the surrounding environment, and native and farmed species of plants and animals. These priorities are essential to the community, and the NOSB recommends attention to the following summarized list:

Livestock

1. Determine the efficiency of natural parasiticides and methodologies, including but not limited to, nutritional programs, use of herbs, essential oils, homeopathic remedies, diatomaceous earth, and the genetic pool of laying hens in controlling *A. galli* and *H. gallinarum* in laying and replacement chickens intended to become hens.
2. Evaluate natural alternatives to dl-methionine in a system approach for organic poultry feed programs.
3. Evaluate ways to prevent and manage internal parasites in livestock, examining breeds, geographical differences, alternative treatments, and pasture species.
4. Develop a dairy program to address climate change mitigation strategies where milking capabilities are not hindered, and effective forage rotations are maximized.
5. Develop balanced organic livestock rations that incorporate high percentages of diverse, regionally adapted feed grain and forage crops to reduce the reliance on corn and soybeans and allow farmers to realize more marketing opportunities for a robust crop rotation.

Crops

1. Examination of decomposition rates, the effects of residues on soil biology, and the factors that affect the breakdown of biodegradable biobased mulch films.
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 (including specific considerations related to copper use in organic rice production) 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 problem insects and weeds.
8. Factors impacting organic crop nutrition, and organic/conventional nutrition comparisons.
9. Side-by-side trials of approved organic inputs, both synthetic and natural, and cultural methods, with a request for collaboration with the USDA IR-4 project (Interregional Research Project No. 4), a specialty crops research program.
10. Impartial evaluation of microbial inoculants, soil conditioners, and other plant and soil amendments is needed as there is little objective evidence upon which to assess their contribution to soil health.
11. More research, extension services, and education are needed to fully understand the relationship between on-farm biodiversity and pathogen presence and abundance.
12. Clarify practices that reduce greenhouse gas emissions and that contribute to farming systems resilience in the face of climate change.

Food Handling and Processing

1. Sanitizers: Effective alternatives of sanitizers, effect on occupational human health and environment, effectiveness of rotational use strategies with the sanitizers currently on the National List.

2. Effect of various types of food packaging on organic products, including suitable alternatives to BPA (Bisphenol-A) for linings of cans used for various products, plastic use, antimicrobial nanoparticle surface coatings of packaging.
3. Research on the creation of an overarching ancillary ingredient review process for materials used in processing and handling vs reviewing ancillaries as part of the petition or sunset review process, including cost/benefit of each process.
4. Alternatives to conventional celery powder for curing organic meat.
5. Research on best practices for identifying potential vectors of heavy metal contamination in organic systems, including strategies for effective testing in soils, water, organic processing, etc. that could lead to the identification and prevention of heavy metals transgression in organic systems.
6. Evaluation of the essentiality of §§ 205.605(a), 205.605(b), and 205.606 substances and the suitability of organic alternatives in applicable food formulations via laboratory testing, sensory evaluation, and/or market analysis.

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 GMO/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/GE seed.
4. Techniques for preventing unintended presence of GMO/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 consumer access to organically produced foods.
2. Production and yield barriers to transitioning to organic production to help growers successfully complete the transition.

Subcommittee Vote

Motion to accept the proposal on Organic IS Climate-Smart Agriculture
Motion by: Nate Powell-Palm
Second: Amy Bruch
Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 2

References:

Schonbeck, M., D. Jerkins, and J. Ory. 2017. *Soil Health and Organic Farming: Building Organic Matter for Healthy Soils: An Overview.* Organic Farming Research Foundation (www.ofrf.org), 39 pp.

Elham A. Ghabbour, Geoffrey Davies, et al., 2017. *Advances in Agronomy: Chapter One - National Comparison of the Total and Sequestered Organic Matter Contents of Conventional and Organic Farm Soils*

Rodale Institute, 2021. *The Farming Systems Trial.*

National Organic Standards Board
Certification, Accreditation, Compliance Subcommittee
Climate Induced Farming Risk and Crop Insurance Discussion Document
February 14, 2023

The reality of organic crop insurance: Not meeting organic farmer needs and not meeting actuarial mandate.

Summary
As USDA begins the process of implementing the Transition to Organic Partnership Program (TOPP), there is heightened urgency to help transitioning and existing organic farmers manage their risk. Transitioning farmers face challenges regarding farming methods, yields, on-farm production practices, and marketing. Existing organic farmers face increasing risk as climate change creates on-farm problems such as flooding, drought, and hail. As USDA enters a new era, promoting climate-smart practices, the NOSB notes that the best climate-smart production system is one that is certified organic.

The new Transition to Organic Partnership Program strives to greatly increase the amount of farmland under organic management in the near term. This program, in conjunction with climate-smart farming methods and climate change induced risk, highlights the need to improve the existing policy tools offered to help farmers manage their risk, namely crop insurance.

This discussion document provides background information for the evolution of crop insurance, organic crop insurance, and a synthesis of the existing related literature and available data. Anecdotal evidence is strongly suggestive that crop insurance, in its current iteration, does not work as well as it could for organic farmers and, consequently, does not adequately help organic farmers manage their risk. While the extant body of literature has made great strides in pointing out problems with organic crop insurance, at the time of this writing there is an insufficient body of evidence documenting the shortfalls of organic crop insurance. Through this discussion document, we aim to fill this knowledge gap.

Through the public comment process, we seek your responses to the following six questions. In your comment, please indicate your crop and region when applicable.

1. What has been your experience (or your members’ experience) with crop insurance, including the type purchased?

2. What do you see as the most significant obstacle to organic farmer adoption of crop insurance?

3. What benefit do organic producers receive from crop insurance (on other words, what is working for them?)

4. What problems have farmers experienced with their crop insurance policies?

5. What recommendations would you make to improve the functioning of crop insurance for organic producers?

6. In your view, are there other, perhaps better, mechanisms for organic farmer risk mitigation?

Introduction

Crop insurance is currently the primary federal policy available to help farmers manage their risk from production (low yields) or price (as reflected by uncertainty of input and output prices). Overseen by the Risk Management Agency of USDA, the Federal Crop Insurance Program is a market-based insurance program (USDA RMA, undated). Producers of crops that lack insurance programs are eligible to enroll in the noninsured crop disaster payment program under the purview of the Farm Service Agency, which targets losses due to natural disasters (USDA FSA, undated).

Prior to 2014, crop insurance was one of many federal programs that supported farm income. With the passage of the 2014 Farm Act, crop insurance became the dominant method of federal support for farmers, by insuring losses caused by low prices or low yields. The statute requires that payouts for crop insurance plus a small reserve are equal to the premiums paid, so premiums are meant to be actuarially fair. In addition to pricing the insurance correctly, crop insurance policies need to be designed to attract enough farmers so that the program effectively pools risk (Hamilton, 2020). Adverse selection, where only the highest risk individuals opt for insurance, is a well-known problem for insurance, and crop insurance is not exempt from this undesirable possible outcome. An analysis of crop insurance data for the state of Iowa finds that premiums are too high for highly productive land and too low for less productive land (Price et al. 2019).

Prior to 2002, organic farming was not considered a 'good farming practice,' which effectively made organic farming excessively risky from an actuarial standard (Morris et al., 2019). While producers were able to buy crop insurance, it was likely that they would not receive payment for their losses. Despite the switch to defining organic methods as good farming practices, organic producer use of crop insurance is relatively low (Raszap Skorbiansky et al., 2022). Morris et al. challenge that concept, and argue that comparisons of crop insurance adoption should be based on crop type. When compared to the rest of agriculture, the organic farm sector has more specialty crops and fewer field crops (Dimitri, 2010), in terms of value of sales, and crop insurance is more available for field crops. In 2016, between 50-100 percent of the value of organic corn, almonds, rice, wheat, and soybean crops were insured, which is roughly in line with the insurance coverage for agriculture as a whole (Morris et al., 2019).

Moreover, as Morris et al. (2019) report, organic farming systems and crop insurance are not, in many ways, incentive compatible. Organic farmers manage their risks through improving soil organic matter, rotating crops, and diversifying their operations (Hanson et al., 2004). Improving soil health is viewed as on-farm risk management by many organic producers (Snyder et al., 2022). Another form of risk is price risk related to market access and other market factors. Some producers, especially those who raise specialty crops, manage their market risk by creating a CSA, or by marketing their production to multiple outlets (Snyder et al., 2022).

Crop insurance addresses only risks created by yield or price variability (although a few policies address quality) and furthermore, decisions to purchase insurance are part of a broader set of farmer actions. For example, crop insurance may be a requirement for producers seeking financing. DeLay et al. (2022) found that highly leveraged producers are also more likely to purchase crop insurance. Grain growers are more likely to use crop insurance (Belasco, 2013).

Implications of low adoption of crop insurance by organic farmers are many, including preventing RMA from collecting data on organic production outcomes (Delbridge and King, 2018). At the same time, in

2021, for nine of the ten top organic crops the payouts exceeded the premiums received.[1] For every year between 2012 and 2021, for all crop insurance policies, the payouts exceeded the premiums received (RMA USDA, 2022). Thus, the organic crop insurance program is not meeting its mandate to be actuarially fair. A simulation of the 2014 shift to using organic specific yields (referred to as t-yield) indicates that the use of organic t-yields did improve the actuarial fairness, but farmers might have responded by not purchasing crop insurance (Delbridge and King, 2018).

The work by Morris et al. (2019), funded by OREI, suggests that if more farmers transitioned their operations to organic, farm level risk would be reduced, which would translate to lower public expenditures on crop insurance. However, this conclusion is based on the potential for organic farmers to reduce or manage their on-farm risks through their farming practices in addition to purchasing crop insurance. If all of the farmers able to manage risk through their farm practices opt not to purchase crop insurance, those buying crop insurance would be riskier producers. And, at the time of this writing, the evidence points to the need to change the parameters of organic crop insurance to meet the mandate for actuarial fairness, unless the Risk Management Agency agrees to place organic and conventional farmers in the same insurance pools.

Since crop insurance is the primary instrument for sharing producer risk, improving the product to better meet the needs of organic producers is an important next step. A question that remains outstanding is how to design the crop insurance program in a way that is sound and provides the correct incentives to organic farmers. Another, related, question is whether it is essential to assess organic products separately and requiring them to be actuarially fair on their own. As Morris et al. (2019) explain, creating a strong crop insurance product for the organic sector has been problematic.

The creation and evolution of crop insurance

Crop insurance was created in the 1938 Farm Bill, through the Federal Crop Insurance Act. The history of the Farm Bill over time provides important context for understanding the shape of today's farm policy, including the design of crop insurance. In the earliest years of farm policy, competing needs of the primary crops – cotton, wheat, and corn – repeatedly created conflict among House members during Farm Bill negotiations (Coppess, 2018). Those negotiating the 1938 Farm Bill struck a deal that consisted of acreage reductions in cotton, mandatory loans for corn, and crop insurance for wheat. During this first iteration farmers were allowed to pay crop insurance premiums with cash or wheat, and only yield insurance was available (Coppess, 2018). The tensions among crops, and then later between urban and rural areas, remain important forces in the Farm Bill debates.

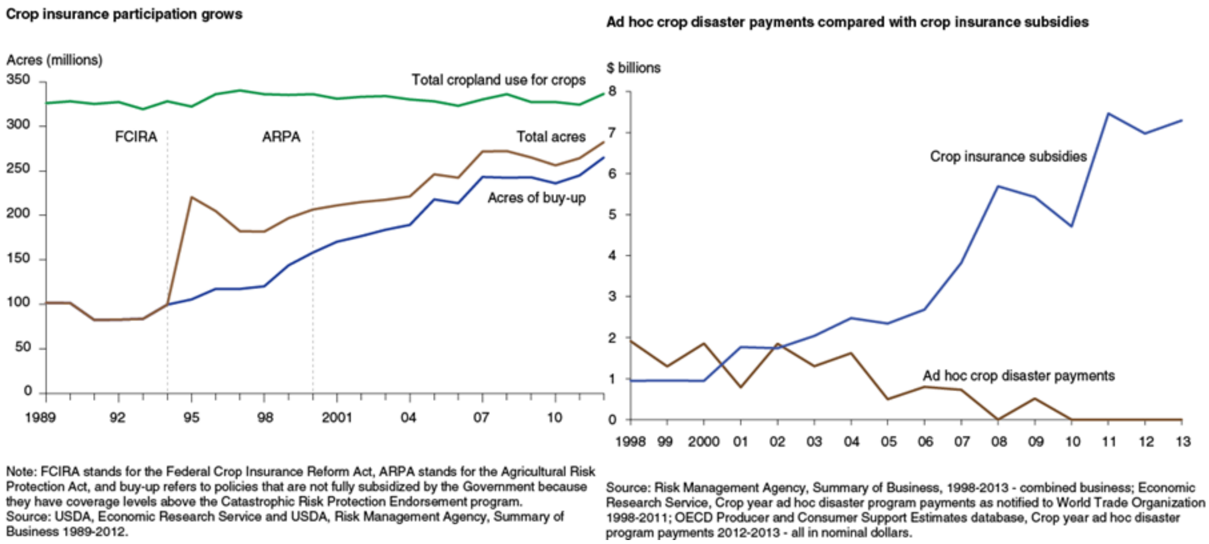
In 1980, the Farm Bill specified that the federal government could subsidize crop insurance premiums, and also transferred control of the insurance policies to private sector agents (Coppess, 2018). The subsidy amount was increased in 1994, and simultaneously, purchasing crop insurance became a requirement for participating in other farm programs (O'Donahue, 2014). Premium subsidies were increased again in 2000, and revenue insurance became eligible for subsidies (Coppess, 2018) which led to farmers selecting higher levels of insurance coverage (O'Donahue, 2014).

The following two diagrams (see figure 1) show changes in crop insurance adoption since 1998. The first shows that insured acres, and the number of acres with higher coverage levels, increased while total

[1] The ten top organic crops, in terms of liability, are corn, apples, soybeans, wheat, blueberries, potatoes, grapes, citrus fruit, tomatoes and peanuts (RMA, USDA 2022).

acres in production remained stable. The second diagram shows how subsidies increased over time, while disaster payments declined (O’Donahue, 2014).

Figure 1. Crop insurance use and subsidies over time



Source: O’Donahue, 2014.

Adoption of crop insurance by organic producers

Crop insurance adoption by organic farmers ranged from 20-27 percent of certified organic farms during the years 2008, 2014, 2019 and 2021 (see table 1). While the number of organic farms with crop insurance rose over the 13 years, the percent of farms increased only slightly suggesting that adoption rates remain fairly constant. For 2014, 2019 and 2021, approximately 60 percent of those using crop insurance chose to cover all of their farmland.

Table 1. Organic farm crop insurance adoption: 2008, 2014, 2019, 2021

Year	Operations			Share of farmland insured				
	Insured farms	Total certified farms	Percent of farms insured	Less than .25	.25 to .49	.50 to .74	.75 to .99	All
	number			*Percent of farms in each category*				
2008	2,141	10,903	20	n/a	n/a	n/a	n/a	n/a
2014	2,781	11,715	24	8	11	14	10	58
2019	4,255	15,548	27	5	10	16	12	56
2021	4,501	16,194	26	5	7	14	15	60

Note: Share of farmland insured presents the percent of operations in each category of farmland insured for those choosing crop insurance.
Source: Organic Surveys, 2014, 2019 and 2021.
A different perspective on the use of crop insurance by organic farmers is provided by the Risk Management Agency, through their annual report on the number of organic crop insurance policies purchased (RMA, USDA 2022). The average number of organic policies per farm (for those using crop insurance), shown in Table 2, increased from 2.18 policies per farm in 2014 to 2.46 in 2021. One notable

trend is the decrease in the number of whole farm revenue protection crop insurance policies purchased between 2017 and 2021.

Table 2. Crop insurance policies 2012-2021

Year	Organic policies	Policies per organic farm	Organic Specialty Crop policies	Whole Farm Revenue Protection
	Number			
2012	5,152		na	*
2013	5,716		na	*
2014	6,073	2.18	na	*
2015	6,827		1,789	1,122
2016	7,936		1,922	2,204
2017	8,442		1,984	2,722
2018	9,161		2,213	2,490
2019	9,815	2.30	2,429	2,156
2020	10,763		2,608	2.029
2021	11,078	2.46	na	1,934

Notes: Policies per farm are calculated by dividing the number of organic policies in this table by the number of farms opting for crop insurance in Table x.
*Whole Farm Revenue Protection was created in the 2014 Farm Act, and thus not available prior to 2015. na = data not publicly available.
Sources: Raszap Skorbiansky et al., 2022; RMA USDA, 2022.

For farmers who do not use crop insurance, the primary reason for not adopting it is they don't need it or want it (see table 3). In 2021, the next most often given reason for not using crop insurance is lack of familiarity with crop insurance, followed by the cost of insurance.

Table 3. Organic farmer reasons for not buying crop insurance

Year	Too expensive	Farmer unfamiliar	Agent unfamiliar	Not available for crop	No organic price elections	Don't need or want	Other
				percent of farms			
2014	22	24	na	na	na	na	na
2019	11	15	1	9	1	53	10
2021	11	18	1	8	1	50	11

Note: na = not available
Source: Organic Surveys, 2014, 2019 and 2021

Recent work using primary data shows that the greater the number of commodities grown on the organic farm operation, the less likely a farmer is to adopt crop insurance (Belasco and Fuller, 2022). Similarly, farms with more years of experience in the organic sector are less likely to adopt crop insurance, while organic farms with higher gross sales are more likely to adopt crop insurance (Belasco and Fuller, 2022). In contrast, research using USDA's Agricultural Resource Management Survey (ARMS) data finds that relatively more diverse organic farms are more likely to adopt crop insurance, but Belasco and Fuller argue this may result from the ARMS data, which includes farms with relatively low levels of crop diversity. The ARMS data also suggest that the higher the share of farmland that is organic, the lower the likelihood of purchasing crop insurance. Network effects may be present, as well, given that the more organic farms in a county, the higher the likelihood of buying crop insurance. Also supporting the idea of network effects is the result from Morris et al. (2019), which indicates that peer use is related to a producer's interest in crop insurance.

Qualitative data indicates that organic farmers who do not buy crop insurance indicate their decision to pass on crop insurance results from their belief that their farms are too diversified or too small to make crop insurance worthwhile (Belasco and Fuller, 2022). Other research, conducted by USDA's Economic Research Service (ERS), suggests that organic producers believe that crop insurance and other USDA programs benefit large scale operations, and furthermore, completing the paperwork tracking yields for each crop is prohibitive (Raszap Skorbiansky et al., 2022). The same study found that producers prefer to manage risk through their production practices, rather than purchasing crop insurance (Raszap Skorbiansky et al., 2022).

Organic farmers who purchase insurance based on organic t-yields tend to have higher losses, when compared to organic farmers who have a long enough history to base insurance on their actual production history (Delbridge and King, 2018). The use of t-yields may be a barrier to organic insurance adoption by beginning farmers. This is especially problematic since, in 2021, 54 percent of organic farmers were farming organically for less than 10 years (USDA NASS, 2022).

Crop insurance payouts

The Environmental Working Group's (EWG) Farm Subsidy database includes aggregated data on crop insurance. Note that organic specific insurance information is not included in the EWG database. Insurance payouts for the period 1995 - 2020 totaled $144 billion, and four crops accounted for 77 percent of these payouts: corn, soybeans, wheat, and cotton (EWG, 2022). For organic crop insurance, for the years from 2012-2021, $1.4 billion of indemnity payments were made to farmers (USDA RMA, 2022). Four crops – corn, soy, wheat, and rice – accounted for 53 percent of the total payments to farmers.

For the years 1995-2020, 61 percent of indemnity payments were for losses farmers realized due to drought (34 percent) and excessive moisture (27 percent) (EWG, 2022). Payments for hail damage made up 7 percent of payouts (EWG, 2022). Changing climate conditions and an increase in the number of adverse weather events suggests this trend will continue. The high cost of farm losses due to drought and excess moisture similarly suggests that it would be more cost effective to take a different approach to risk management. The Intergovernmental Panel on Climate Change (IPCC) recommends, with high confidence, that resilience to climate change would be increased by using ecosystem based agricultural methods (IPCC, 2022).

Key problems that impact adoption of and efficacy of crop insurance (preliminary list; this will be improved after public comment)

1. Farmer lack of knowledge about crop insurance

    a. The Organic Farming Research Foundation 2022 national research agenda reports that one-third of organic farmer survey respondents list the need for technical support for crop insurance (Snyder et al., 2022).

2. Organic crop insurance is too expensive

    a. When organic premiums are too high, adverse selection may cause the pool to become riskier. Eventually the insurance program becomes unsustainable (Belasco and Fuller, 2021).

3. Whole Farm Revenue Program (WFRP)

    a. Previous qualitative work finds that farmers believe WFRP provides disincentives for incorporating crop diversity and new management practices, such as cover cropping on farms. As a result, crop insurance–which should be encourage farmers to become more resilient and diverse–is driving specialization, according to an organic producer (Looser et al. 2023).
    b. WFRP insurance is not available for new and beginning producers.
    c. Farmers seeking to expand their operations indicate that WFRP insurance does not work well.

4. Insufficient organic price information, including quality specification in insurance

    a. Improving organic price data.
    b. While contract price addendum is available, specifications need to be reexamined.
    c. Organic crops would benefit from specific adjusting standards for their crops. For example, organic #1 food grade corn is adjusted on #5 feed grade conventional corn, which results in organic corn crops having a wide gap of uninsurable quality.

5. Organic specific t-yields are problematic for farmers without an actual organic production history.

    a. Researchers have suggested using a producer's conventional yields as the basis for insurance, rather than the t-yield (Delbridge and King, 2018).
    b. Another suggestion is that organic producers use the t-yields they acquired during their transition time period for their organic t-yields.
    c. What is the justification for organic farmers receiving new t-yields for transition and then restarting the process once the transition to organic is complete?

Other questions

1. Is the requirement for actuarial fairness reasonable? The initial impetus for crop insurance – in 1938 – was to provide farmers with social insurance, to help them cope with the ups and downs of farm production (Hamilton, 2021). It is interesting to note that, historically, farmers were much less interested in crop insurance than the policymakers were (Hamilton, 2021).

Questions for organic stakeholders (these are the same questions from the beginning of this document.

1. What has been your experience (or your members' experience) with crop insurance?

2. What do you see as the most significant obstacle to organic farmer adoption of crop insurance?

3. What benefit do organic producers receive from crop insurance (on other words, what is working for them?)

4. What problems have farmers experienced with their crop insurance policies?

5. What recommendations would you make to improve the functioning of crop insurance for organic producers?

6. In your view, are there other, perhaps better, mechanisms for organic farmer risk mitigation?

Motion to accept the discussion document on Climate Induced Farming Risk and Crop Insurance
Motion by: Nate Powell-Palm
Seconded by: Kim Huseman
Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 2

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National Organic Standards Board
Certification, Accreditation, Compliance Subcommittee
Oversight Improvements to Deter Fraud: Consistent Location Identification
Discussion Document
February 14, 2023

Challenge:
The location of certified organic operations, including fields is inconsistently recorded and managed across certifiers. This challenges the industry, leading to a gap in certifiers' ability to accurately cross-check the operations and fields they certify with other certifiers. Furthermore, some certifiers cannot conduct independent verification or unannounced inspections of fields because they don't have mapping capabilities of all field locations.

Solution:
Certifiers located both domestically and internationally can seamlessly harmonize the data intake of their clients when producers request to certify new fields for organic certification. By requesting the geolocation of certified operations , certifiers will be able to receive consistent data that is easily managed while also allowing the inspectors to confirm the accuracy of the data during the inspection and use it as a cross-check.

Background:
the new Strengthening Organic Enforcement (SOE) rule will make supply chain tracebacks and mass balances mandatory. Complete supply chain tracebacks will require many certifiers to work bi-directionally up and down the supply chain in cooperation with other certifying bodies.

In addition to the SOE, the Federal Transition Initiative currently being rolled out across the US discusses ways to improve existing programs that support organic transition and markets. Consistency with certified operation location identification and verification of land eligibility is important and can be accomplished through requiring geolocation for all certified operation.

According to several certifiers interviewed for this document, the data requested when receiving an application for certification for a new field typically includes the name of the field and the number of acres. Some certifiers request the address or driving locations. Still, many certifiers confirmed that if asked, they would be unable to locate each field they certify via google maps or other interactive GPS databases. This lack of data cripples certifiers' ability to act quickly in the case of aggregated mass balance investigations across their clients or in the case of a major contamination event.

Consistent Location Identification:
Consistency in field identification should be required to comply with the soon-to-be SOE-mandated supply chain traceback since a method for consistent field identification exists worldwide.

In the Fall of 2021, the NOSB received the following comment/question regarding the proposed rule on Strengthening Organic Enforcement (SOE), "Will the final rule require mandatory data reporting to NOP by crop type, acreage, and location; and a number of animals by livestock type and location, at least on an annual basis to the Organic Integrity Database (OID)? A requirement for certifying agents to report production area certified by crop/livestock and location, on at least an annual basis, to the OID is one of the most impactful single actions that can be taken to increase integrity in the global organic control systems." This commenter's question provided a road map for CACS.

1. At the Fall 2022 NOSB meeting, the proposal, "Oversite Improvements to Deter Fraud: Acreage Reporting", was unanimously passed by the Board.
    a. That recommendation's importance was to balance and cross-check that the volume of certified acres (under the NOP) ultimately supports the volume of organic products produced and sold (under the NOP).

2. At the Spring 2023 NOSB meeting, the discussion document "Oversite Improvements to Deter Fraud: Consistent Location Identification" will receive public comment and be discussed by the NOSB.
    a. The discussion document's purpose is to establish the structure and system for universal field location identification for organic producers, certifiers, inspectors, and the NOP, to register, verify, and cross-check the location of all acres certified under the NOP, both domestically and internationally.

The Strengthening Organic Enforcement (SOE) Rule:
The SOE states, "Certifying agents must be able to conduct unannounced inspections of any operation they certify. Therefore, AMS requires that certifying agents only accept applications for certification or continue certification from operations for which the certifying agent is able to conduct unannounced inspections. To ensure consistency, transparency, and accountability, certifying agents are expected to describe the areas where they operate in the written materials they provide to both applicants and certified operations, and review the locations of all operations during their application review or annual review. A certifying agent that cannot conduct unannounced inspections in an applicant's or certified operation's location due to logistical challenges, staffing, security, or other reasons, is considered to not have the administrative capacity for certification activities in that area, consistent with § 205.501(a)(19)."

A consistent process for locating certified organic operations, including fields, would aid in executing parts of the SOE, including cross-checking and supply chain verification.

History, Evolution, and Benchmarking of Geo-Referencing Information:

1. **Global Navigation Satellite Systems (GNSS) and Global Positioning Systems (GPS)** - In the 1970s, the United States military began using a form of GNSS called GPS for navigation, which became publicly available in the early 2000s.
    a. GPS allows for navigation to any point of interest, anywhere in the world.

b. According to GPS.gov, "GPS is a U.S. - owned utility that provides users with positioning, navigation, and timing (PNT) services.....24 operating satellites are transmitting one-way signals that give current GPS satellite position and time." GPS is generally expressed as specific latitude and longitude coordinates
c. Russia, China, and the European Union also have a GNSS similar to GPS.
    i. Japan and India have regionally based systems.
d. The GPS is the oldest of all the GNSS.
    i. GPS.gov states, "the American taxpayer pays for the GPS service enjoyed throughout the world. All GPS program funding comes from general U.S. tax revenues….there are no plans to privatize GPS, as US Law and policy require the civil GPS service to be provided free of direct user fees."

2. Keyhole Markup Language (KML) and Keyhole Markup Language Zipped (KMZ)

a. KML is a file responsible for storing map locations that can be viewed with the following:
    i. Geographical Information Systems (GIS) such as ArcGIS
    ii. Geospatial Tools such as Google Earth Pro
b. KMZ is a Zip-compressed version of a KML

The precedence of geo-referenced data is found within the USDA Currently:

1. Risk Management Agency (RMA):

a. Having exact location information provides enhanced transparency and oversight. The Risk Management Agency's General Standards Handbook Section 1.c. of the Maintaining Organic Records states, "a requirement for organic producer's record keeping is that "insured must have, e.g., aerial or GIS (Geographical Information System) maps, from the organic farming operation that show the exact location of each field for certified organic, transitional, buffer zone, and conventional acreage not maintained under an organic practice."

2. Certifier Community:

a. Several Certifiers are already collecting town, range, and section (TRS) data with others using "GPS Coordinates." How can those certifiers share with other ACAs their intake process?
b. One certifier creates a KMZ, in Google Earth Pro, for every "site" (synonymous with field), collecting location information (latitude/longitude) from the middle of each site. The business provides location and latitude/longitude; inspectors verify that info and create a KMZ file.

Low Burden - One-Time Collection:
By requiring a consistent method of location identification information through GPS coordinates, it will be easy and low-burden to achieve consistency across all geographic locations, domestic and international.

For organic operations that do not have access to this information, the information can be easily obtained once and then used from that point forward. GPS is free and accessible globally and can serve as the logical path forward for consistently capturing location information domestically and internationally.

GPS proposed framework for location information:

1. One GPS coordinate (including latitude and longitude) for location identification of each location, such as a certification office, brokerage or importer office, manufacturing facility, handling facility, field, production unit - a field in a grower group, etc.
    a. A GPS coordinate in the center of the field can be a best practice.

In Summary:

There has been a lot of positive momentum for increased continuous improvement within the Organic Community with special attention given to the recent finalization of the SOE Rule and the introduction of the Federal Transition Initiative. In the spirit of this effort, the NOP can help certifiers make the information collected as part of the requirement to verify land eligibility consistent by requiring certifiers to collect the geolocation for all operations including the fields they certify. Consistency within the organic community is essential.

CACS has two specific recommendations for discussion:

1. Consistency amongst all accredited certifiers to use a universal system, the GPS, to obtain specific location data information of all certified operations (fields, production units - grower groups, handling locations, importers, brokers, certifiers, etc.).
2. Previous land affidavits include and are reconciled with GPS location information - which is essential for both domestic and international.

Questions for our stakeholders:

1. Are you currently collecting field-level location information? If so, what method are you using to collect this information?
2. Which certifiers currently request GPS coordinate information to identify locations of organic fields?
3. Certifiers: Are you able to locate every field you certify via the information provided solely by your client (e.g., maps, field history, OSPs), or would you need the certified client to show you where the field is located?
4. What would be the best GIS or Geospatial Tool for certifiers and inspectors to view aggregated location data via maps?

Motion to accept the discussion document on Modernizing Organic Infrastructure - Consistent Location Identification
Motion by: Amy Bruch
Seconded by: Carolyn Dimitri
Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 1

National Organic Standards Board
Crops Subcommittee
Petitioned Material Discussion Document
Potassium Sorbate as an active ingredient for plant disease and insect control/suppression
February 7, 2023

Summary of Petition:

Potassium sorbate, referred to as KS throughout the report, is being petitioned for use as an active ingredient for plant disease and insect control/suppression in field and greenhouse applications. The petition states that potassium sorbate will be an effective tool in a crop disease-resistance program with its contact mode of action, and that it is not suspected to contribute to the phytotoxicity of crops.

The petition identifies the substance as 100% food-grade KS with no ancillary substances. The proposed end-use fungicide/insecticide contains 45% KS, with the remaining 55% comprised of the inert ingredients' urea and citric acid, both of which appear on the 2004 EPA List 4A: Inerts of Minimal Concern. With KS as an active ingredient, the end-use product would be used to target crop disease and insects such as powdery mildew, downy mildew, and whiteflies on many crops, including grapes, cucurbits, roses, stone fruit, pome fruit, nuts, solanaceae vegetables, and cannabaceae plants.

Summary of Review:

KS is petitioned for addition to the National List at 7 CFR 205.601(e) for use as an insecticide and at § 205.601(i) for use as a plant disease control. KS currently is on FIFRA's (Federal Insecticide, Fungicide Rodenticide Act) list 25(b), which is for active and inert ingredients (of chemicals) that are considered a minimum risk, and therefore, do not require an EPA registration number and are exempt from EPA regulations on efficacy and toxicity. KS is generally recognized as safe (GRAS) by FDA.

KS has been petitioned unsuccessfully three additional times for inclusion on the National List. KS is not internationally approved for the petitioned use.

1. 1995, seed treatment, production aid 7 USC 6517(c)(1)(B)(1)
    a. Petitioned (sorbic acids and its salts) for use in food processing
    b. Conclusion: sorbic acid was synthetic and not compatible with organic processing or handling

2. 2002 Crops, 205.601:
    a. Petitioned for use in seed film coating as a preservative.
        i. Potassium sorbate is a weak acid antimicrobial known to cause resistance and is used in the food industry.
        ii. Conclusion: potassium sorbate was not allowed as a synthetic substance for use as a preservative, as more information was needed for justification.

3. 2002 Livestock, 205.603:
    a. Petitioned for use in organic livestock production as a mold inhibitor (preservation in aloe vera - aloe vera can be used as an alternative for antibiotics when treating livestock)
        i. Conclusion: Additional information on the ingredients in the manufacturing of potassium sorbate is questioned.

KS, used as an active ingredient, would function in a contact mode of action form. Many alternative products and cultural practices exist. The petition states that the degradation products (sorbic acid and potassium hydroxide) are more hazardous than the product itself.

In food additives, sorbic acid interacts negatively with nitrite and is known to create direct-acting mutagens and genotoxic agents. The extent of these interactions in field conditions is unknown. The TR indicates that limited information on KS, as petitioned, exists. Thus, there needs to be more available information regarding the potential interactions of KS with other crop production inputs. (TR 579-583).

In addition, the TR indicates that there was little to no information on KS as petitioned to understand its chemical interactions or its use in conventional crop pesticide application (TR 579-581), how KS interacts with soil organisms, the use of KS as a foliar spray on growing crops (TR758-759), and persistence of KS in the environment or its by-products (TR 468-470), thus in many cases the TR leverages information that was available regarding KS as a post-harvest treatment and/or as a conventional food additive (TR 74, 470-472, 857-862).

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.

Potassium sorbate is not explicitly listed anywhere in the Organic Foods Production Act of 1990 (OFPA) nor the USDA organic regulations CFR part 205. It is implicitly on the National List as an inert ingredient of minimal concern on the National List at 205.601 (m) (i) and 206.603 (e)(1).

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 potassium sorbate be used as an active ingredient for plant disease and insect control/suppression under the following conditions:

1. § 205.601(e): Synthetic substances allowed for use in organic crop production – as insecticides
2. § 205.601(i): Synthetic substances allowed for use in organic crop production – as plant disease control

Note: The TR states that KS is one of the most common food preservatives; In contrast, most food preservation with KS occurs as part of food processing; it is the application during crop production and post-harvest handling of raw agricultural commodities that are considered within the scope of the current petition. Post-harvest use would have to be annotated explicitly for any KS listed at 205.601 according to the National Organic Program (NOP) Guidance 5023. (TR 99-103)

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)]**

Potassium sorbate, due to its antimicrobial properties, has been historically used in the food processing industry as a preservative and is used in a wide range of food products, including meats, cheeses, baked goods, fresh and fermented vegetables, dried fruit, fish, processed food, and carbonated beverages. There is little historical use of KS in organic agricultural production.

The TR notes that before receiving the 25(b) exemption, potassium sorbate was used as an active ingredient in several EPA-registered pesticides. The last of these registrations was canceled in 1989. KS is also on the 2004 EPA List 4A – Minimal risk inert ingredients. Thus, it is currently permitted as an inert ingredient in combination with permitted active ingredients in pesticide formulations used in organic crop production according to 205.601 (m) (1) (TR 206-213).

Two notable points were brought up in the TR relating to KS (and/or sorbic acid used to make KS):

1. Processed food products with sorbate and nitrite preservatives may form mutagens and genotoxic agents under certain conditions.
    a. In vitro studies on bone marrow chromosomes of mice showed that the combination of sorbic acid and nitrite creates a synergistic effect, severely affecting the spindle apparatus and chromosomal structure.
    b. Research on how these two substances would interact with humans and the field environment is unavailable.
2. Ames test and rec-assay mutagenicity found DNA-damaging activity when combined with KS, ascorbic acid, and iron salts. (TR 585-597).

2. What is the toxicity and mode of action of the substance, its breakdown products or any contaminants, and their persistence and areas of concentration in the environment?

Few studies in the literature report on using KS as a crop fungicide. Thus, information regarding its persistence or that of its by-products in the environment is limited. (TR 467-468).
The TR states that crystalline KS is relatively stable; its behavior in solutions and foods depends on factors like temperature, pH, food combination, water activity, packaging, and various metals and other additives. (TR474-477). The presence of KS in natural environments after its commercial use is considered safe. KS has a contact mode of action.
The TR notes that since KS inhibits microorganisms from colonizing a “new” substrate, KS is an effective antimicrobial. However, this bacteriostatic effect is likely to be overwhelmed in a natural community, where microorganisms can quickly degrade KS into readily metabolized compounds such as sorbitol, potassium, and sorbic acid. (TR 454-457). In general, sorbic acid and its salts have been considered compounds of low ecotoxicity.

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

KS is a potassium salt of sorbic acid. Sorbic acid (synthetically manufactured using ketene and crotonaldehyde) is neutralized with potassium hydroxide (manufactured through chemical synthesis) to yield potassium sorbate, the petitioned substance. Several methods are described for isolating the KS solid, including filtration, centrifugation spraying, or crystallization of KS and subsequent distillation. The petition states that the source of potassium sorbate is food grade and manufactured in a closed system, waste disposal certified, and chlorine-free production with multiple accreditations such as Food Safety System Certification, HACCP, and ISO 9001.

Potassium hydroxide (KOH) is considered a category-one hazardous substance under the Clean Water Act due to its impact on pH and potassium levels in wastewater. Although KOH itself may be corrosive in solid form and is listed as a hazardous substance under the Clean Water Act, it is considered a GRAS substance when produced with good manufacturing practice and currently appears on the National List at 205.605(b)(26) for use in processed products.

KS and its by-products are disposed of by landfilling in closed containers or incarceration. The TR states that KS has no potential for environmental accumulation.

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

Potassium sorbate is listed as Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration (US FDA) at 183.3640, with the only specification being that it be used according to good manufacturing practices (GMPs). The TR states that KS and its residues are exempt from the requirement of a tolerance in food per 40 CFR 180.1233.

Since minimal data is available on potassium sorbate as petitioned, the TR provides information regarding other uses of KS (food preservation, cosmetic, personal care products, washing and cleaning products, pharmaceuticals, and other manufactured industrial products) and not necessarily for the petitioned use.

The current TR discusses the consumption of processed products that use KS as a food additive. Most of the KS is dispelled when consumed…however, 12.6% is retained (studies on rats) by internal organs, skeletal muscles, and other body parts (TR 516-519). An increased KS intake (>25mg/kg) may lead to cytotoxic and genotoxic effects by producing mutagenic compounds and inducing chromosome aberrations and DNA breakage (cancers and diabetes mellitus). Wide use of KS in food, cosmetics, cleaners, etc., could lead to higher-than-normal buildup.

On the contrary, the petition references the 2002 Technical Advisory Panel Review (TAP) that was contracted to support earlier reviews of KS. The TAP states that potassium sorbate is the potassium salt of an unsaturated fatty acid, which participates in the normal fat metabolism in the human body and will be oxidated into carbon dioxide and water finally. It will not be accumulated in the human body. The 2002 TAP states that KS is safe and has the lowest allergenic potential of all food preservatives.

The petition states that although allergic reactions to KS can be described as unusual, there was a reported incident of severe rashes by a worker in a dairy plant who had repeated occupational exposure. The petition also states that KS is a category 2B serious eye damage/eye irritation health hazard with a WARNING signal word. As petitioned to be used in the OR-159-B end-use product with KS at 45%, KS is classified by OSHA Hazard Communication Standards as not hazardous.

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)].

Few studies are found in the literature that report on the use of KS as a crop fungicide, thus, information regarding its persistence or that of its by-products in the environment resulting from this use is limited. No studies on KS used to control the target organism identified on the petitioned product's label were found to expound on its potential effects on soil microbial communities. (TR 467-470).

For crops: The TR mentions KS being tested for phytotoxicity in cotton in the 1970s. The treatments caused a reduction in the primary root elongation at three different concentrations and showed that the KS severely affected the dry weight of cotton seedling shoots and roots. (TR 606-608). The TR mentions that further field research is needed on any possible adverse effects that KS could have on the bacterial communities necessary for healthy soil and optimal microbe-plant interactions, as early testing demonstrated that KS addition slightly increased the pH of the soil and soil pH is essential in bacterial community structure and diversity (TR 618-620).

For Livestock: The TR mentions that when KS was petitioned for use in livestock in 2002, one reviewer in the TAP stated that one should determine directly at what level KS, as an anti-bacterial, will interfere with ruminant metabolism. The TR noted that future research that identifies the concentrations of KS affecting the ruminant microbiome is needed (TR 633-637).

6. Are there any adverse impacts on biodiversity? (§205.200)
KS antimicrobial properties and characteristics could alter the microbiome in the soil, The petition states that it is reasonable to expect that it would inhibit the growth of soil microorganisms, and additionally, that a significant number of organisms regarded as beneficial are suppressed.

The TR mentions that further field research is needed on any possible adverse effects that KS could have on the bacterial communities necessary for healthy soil and optimal microbe-plant interactions (TR618-620), as early testing demonstrated that KS addition slightly increased the pH of the soil and soil pH is essential in bacterial community structure and diversity.

In general - sorbic acid and KS are considered compounds of low ecotoxicity. However, the TR states that high concentrations of KS can impair photosynthetic functions in algae, negatively affect the microbiome of fishes, inhibit mycelial growth in fungi, and affect the soil pH (TR 615, 617, 669).

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 petition states that KS is necessary as an organic input pesticide active ingredient because it has a contact mode of action where organic crop farmers in the US can use the petitioned product in a disease resistance management program rotating with fungicides with different modes of action. The petition includes testing data showing efficacy on powdery mildew, downy mildew, and white fly, and observed no phytotoxicity even at double the use rate on the crops tested. Other trials of the effectiveness of KS, as petitioned, were not found.

The petition discusses efficacy, indicating that KS is comparable to conventional pesticides and carries a higher efficacy rate than other allowed organic or natural actives. The petition included research regarding in vitro efficacy of eight food additives as possible alternatives to synthetic fungicides for controlling soil-borne pathogens. Also included in the petition is a breakdown of a comparison study of the efficacy of potassium salts against soil-borne and air-borne fungi reviewing KS and potassium bicarbonate (active ingredient listed on 7 CFR 205.601i(9)). According to the petition, in tests done at Michigan State, KS significantly outperformed potassium bicarbonate and sulfur in controlling downy mildew, an important, difficult-to-control grape disease. Few other published pesticide trials have been done with this material. However, the petition also notes that there are currently non-synthetic and natural substances that could be used in place of potassium sorbate.

A literature review for KS uncovered limited information on use as a foliar spray for growing crops. (TR 758-759). The TR indicates that over 750 biological controls were approved for use as crop pests, weeds, and disease controls under NOP standards on the OMRI Products List (OMRI 2022) (TR 764-765). The petition states that searching in the OMRI database under the "Crop Pest, Weed, and Disease Control" keyword "fungicide" yields 464 fungicide products that are OMRI approved. The TR indicated that there were over 500 pesticides formulated with plant-derived active ingredients on the OMRI Products List (OMRI, 2022). Fixed coppers and copper sulfate, potassium silicate, lime sulfur, hydrogen peroxide, horticultural oils, potassium bicarbonate, and polyoxin D zinc salt are all alternative products.

In terms of cultural practices, applying a systems-based approach and deploying preventive practices and ecological processes to promote beneficial microbial diversity in the soil and biodiversity to attract beneficial insects, as well as cover cropping, crop rotations, and cropping schedules, are examples of management practices that can also assist in insect and disease mitigation.

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

KS is already used in organic production as it is an allowed substance for use in organic crop production at 205.601 (m) - As synthetic inert ingredients as classified by the EPA.

As petitioned, KS is not approved to be used internationally. However, it is permitted under the European Economic Community Council Regulations as a preservative in organic livestock feed. KS has been petitioned two other times, in crops as a seed treatment and in livestock as a mold inhibitor, and was not added to the national list due to reasons discussed in the summary of the review section. In addition, KS is not made from renewable resources, the materials used to produce KS are not recyclable, do not complement the use of natural and biological controls, and many alternative substances and practices exist currently.

As the TR states in several places, more research is needed to understand the impacts of allowing KS to be used as an active ingredient for insect and plant disease control, therefore, an abundance of caution needs to be considered.

Questions for stakeholders:

1. Is there a need for potassium sorbate (KS) for use as an insecticide or plant disease control?
2. Is there any additional known research available to understand KS's potential and efficacy if used as an insecticide or plant disease control?

Subcommittee Vote:
Motion to accept the discussion document on potassium sorbate
Motion by: Amy Bruch
Seconded by: Jerry D'Amore
Yes: 4 No: 0 Abstain: 0 Recuse: 0 Absent: 3

Sunset 2025
Meeting 1 - Request for Public Comment
Crops Substances § 205.601 & § 205.602
April 2023

Introduction

As part of the Sunset Process, the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List which must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, annotation, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, it is noted in this list. Substances included in this document may also be viewed in the NOP's Petitioned Substances Index.

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2023 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2023 public meeting. Written public comments will be accepted through April 5, 2023 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

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

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

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

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

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

For Comments that Do Not Support the Continued Use of §205.601 Substances in Organic Production:
If you provide comments that do not support a substance at §205.601, you should provide reasons why the use of the substance should no longer be allowed in organic production. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

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

For Comments that Support the Continued Prohibition of §205.602 Substances in Organic Production:
If you provide comments supporting the prohibition of a substance on the §205.602 section of the National List, you should provide information demonstrating that the substance is:

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

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

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

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

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

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

Written public comments will be accepted through April 5, 2023, 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:

- Alcohols: Ethanol
- Alcohols: Isopropanol
- Sodium carbonate peroxyhydrate
- Newspaper or other recycled paper, without glossy or colored inks (§205.601(b) - mulch)
- Newspaper or other recycled paper, without glossy or colored inks (§205.601(c) - compost feedstock)
- Plastic mulch and covers
- Aqueous potassium silicate (§205.601(e) - insecticide)
- Aqueous potassium silicate (§205.601(i) - plant disease control)
- Elemental sulfur (§205.601(e) - insecticide; §205.601(i) - plant disease control; §205.601(j) - plant or soil amendment
- Lime sulfur (§205.601(e) - insecticide)
- Lime sulfur (§205.601(i) - plant disease control)
- Hydrated lime
- Liquid fish products
- Sulfurous acid
- Ethylene gas
- Microcrystalline cheesewax

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

- Potassium chloride

Alcohols: Ethanol

Reference: 205.601(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (1) Alcohols. (i) Ethanol.
Technical Report(s): 1995 TAP; 2014 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 17-18); 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Ethanol is used in organic crop production as an algicide, disinfectant, and sanitizer, including irrigation system cleaning.

Manufacture
Ethanol can be produced by fermentation and chemical synthesis through direct or indirect hydration of ethylene. Fermentation to produce ethanol can use starch, sugar, or cellulose using either natural or genetically engineered strains of bacteria or yeast.

International Acceptance

Canadian General Standards Board Permitted Substances List
Ethanol is listed as a synthetic for organic crop and livestock production.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Ethanol is listed as a synthetic for organic crop and livestock production.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Ethanol is listed as a synthetic for organic crop and livestock production.

International Federation of Organic Agriculture Movements (IFOAM)
Ethanol is listed as a synthetic for organic crop and livestock production.

Japan Agricultural Standard (JAS) for Organic Production
Ethanol is listed as a synthetic for organic crop and livestock production.

Environmental Issues
According to the United States Environmental Protection Agency (EPA), the agency that regulates all non-food applications of ethanol, ethanol is practically non-toxic based on acute oral and inhalation

toxicity tests. Ethanol is biodegradable in air, soil, and water. Ethanol can contribute to smog but would be minimal in the quantities used.

Discussion
The Crops Subcommittee noted there is little to no environmental or human health impacts associated with the use of ethanol.

In the 2017 sunset review, the NOSB voted unanimously to keep ethanol on the National List. Public comments during 2017 were mainly in favor of keeping ethanol on the National List, but one commenter did suggest that organic ethanol sources should be investigated.

Questions to our Stakeholders
1. Should there be an annotation requiring organically produced ethanol if sufficient quantities are available for organic production?

Alcohols: Isopropanol

Reference: 205.601(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (1) Alcohols. (ii) Isopropanol.
Technical Report(s): 1995 TAP; 2014 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 17-18); 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/20 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Isopropanol is used for a variety of industrial and consumer uses. In organic crop production, isopropanol can be used as an algicide, disinfectant, and sanitizer. Isopropanol has broad-spectrum antimicrobial activity against vegetative bacteria, viruses, and fungi.

Manufacture
Isopropanol is a synthetic compound that is manufactured by hydration of petroleum-derived propylene. Acetone can also be used as a hydrated base chemical over a metal catalyst.

International Acceptance
Canadian General Standards Board Permitted Substances List
Canadian organic production standards permit the use of isopropanol for a number of agricultural applications.

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

Alcohols, presumably including isopropanol, may be used for cleaning and disinfecting livestock building installations and utensils.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
"Need recognized by certification body or authority"

International Federation of Organic Agriculture Movements (IFOAM)
No information found

Japan Agricultural Standard (JAS) for Organic Production
No information found

Environmental Issues
The United States Environmental Protection Agency (EPA) considers isopropanol slightly toxic to practically non-toxic on acute oral and inhalation toxicity tests. The alcohol can contribute to smog and ozone formation, but large-scale releases are unlikely based on prescribed use in organic agriculture.

Discussion
The Crops Subcommittee reviewed the use, manufacturing, and environmental concerns of isopropanol, and previous NOSB reviews.

When isopropanol was reviewed for the 2017 sunset, the vote by the NOSB was unanimous in retaining it on the National List. Public comments from stakeholders were mainly in favor of keeping it on the National List as an example of why multiple sanitizers and disinfectants are needed and listed for organic use.

Questions to our Stakeholders
None

Sodium carbonate peroxyhydrate

Reference: 205.601(a) As algaecide, disinfectants, and sanitizer, including irrigation system cleaning systems. (8) Sodium carbonate peroxyhydrate (CAS #-15630-89-4)—Federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.
Technical Report: 2006 TR; 2014 TR
Petition(s): 2005
Past NOSB Actions: 11/2007 NOSB recommendation; 10/2014 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 12/13/2010 (75 FR 77521); Sunset renewal notice published 06/19/2015 (80 FR 35177); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use

According to the 2014 TR and previous reviews by the Board, sodium carbonate peroxyhydrate has been used in organic production as an algaecide in rice fields, ponds, ditches, and irrigation lines. It was added to the National List in 2007 as an alternative to materials such as copper and chlorine; it has been registered for use in rice since 2010. In wider legal uses of the substance, "In its primary registration by the US Environmental Protection Agency (EPA) as a biopesticide, use sites for sodium carbonate peroxyhydrate include ornamental plants, turf grasses, terrestrial landscapes, commercial greenhouses, garden centers, nurseries, and storage areas. Target pests included algae, moss, liverworts, slime molds and their spores. There was no food use authorized." (TR 104-107)

Manufacture

According to the 2014 TR, "Sodium carbonate peroxyhydrate is the chemical name for an addition product produced by drying hydrogen peroxide in the presence of sodium carbonate (CAS No. 497-19-8). The pure substance contains 32.5 % hydrogen peroxide and 67.5 % sodium carbonate (based on weight)" (TR 51-53).

The TR lists three common manufacturing processes via drying, crystallization, and a spray granulation process. "The dry process involves spraying an aqueous stabilized hydrogen peroxide solution on solid sodium carbonate with continuous agitation. A solid-liquid reaction yields sodium carbonate peroxyhydrate" (TR 232-33). "In the spray granulation process, solutions of sodium carbonate and aqueous stabilized hydrogen peroxide are sprayed onto a bed of sodium carbonate peroxyhydrate nuclei in a fluid-bed granulator. The product bed is kept in movement by a stream of heated air. Product is continuously withdrawn from the dryer and the desired grain-size fraction is obtained by classification" (TR 235-238). "The crystallization process takes advantage of the high solubility of sodium carbonate peroxyhydrate. In this method, sodium carbonate peroxyhydrate is salted out of aqueous solutions with sodium chloride. A sodium carbonate/NaCl suspension is reacted with stabilized hydrogen peroxide under stirring and cooling. The crystallized sodium carbonate peroxyhydrate is separated from the mother liquor by centrifugation, and drying in a fluid-bed dryer" (TR 240-244).

International Acceptance

Canadian General Standards Board Permitted Substances List

As per the 2014 TR: "Hydrogen peroxide is on the Canadian Organic Production Systems Permitted Substances Lists (CAN/CGSB-32.311-2006). It is listed for use as a fungicide. Sodium carbonate (soda ash) is considered a natural substance in the Canadian system. Sodium carbonate peroxyhydrate is not included in any of the Canadian permitted substance lists" (TR 168-171).

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

As per the 2014 TR: "Sodium carbonate peroxyhydrate is not listed as a permitted substance for organic production"(TR 187)

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

As per the 2014 TR: "Although Codex Alimentarius permits the use of sodium carbonate peroxyhydrate as an anti-bactericide in raw milk, it is not included in any list for organic use" (TR 176-77).

International Federation of Organic Agriculture Movements (IFOAM) Norms

As per the 2014 TR: "Sodium carbonate peroxyhydrate is not listed or discussed for use in the IFOAM norms" (TR 201).

Japan Agricultural Standard (JAS) for Organic Production
As per the 2014 TR: "Sodium carbonate peroxyhydrate, hydrogen peroxide and sodium carbonate are not specifically listed in the Japanese Agricultural Standard for Organic Plants" (TR 195-196).

Environmental Issues
An emission of sodium carbonate peroxyhydrate to the environment could occur during production, formulation, and use of the substance (TR lines 323-24). Sodium, carbonate, and hydrogen peroxide do not adsorb to sediment (TR line 333). No new concerns were raised about human health or environmental effects since the earlier review in 2006; however, the substance can have negative impacts on fish, birds, and bees. "Aquatically, toxic effects of sodium carbonate peroxyhydrate on fish have been reported, but the sensitivity of different fish species depends on final hydrogen peroxide concentration, water temperature, and life stage" (TR 395-397). "Undissolved sodium carbonate peroxyhydrate is toxic to birds when ingested. However, once applied and dissolved in water, sodium carbonate peroxyhydrate is not expected to be toxic to birds. Sodium carbonate peroxyhydrate is also highly toxic to bees and it should not be allowed to drift to flowering plants or used when contact with bees might occur" (TR 404-407).

Discussion
The Crops Subcommittee considered previous reviews of this substance. In the last review, the Subcommittee sought input comparing this material with copper sulfate for control of algal scum in rice production and asked if it could replace copper sulfate for that use. Limited and conflicting comments were received. Points raised in favor of renewing the substance stated that it provides better control of algae, and its breakdown components of water and oxygen are more favorable than the accumulation of elemental copper associated with copper sulfate. Additionally, when utilized in irrigation ponds sodium carbonate peroxyhydrate has fewer corrosion issues with irrigation equipment than copper sulfate.

The Subcommittee recognizes the value in the continued presence of the substance on the National List, even if it is not a commonly used material. Additionally, the potential for inadvertent use as a fungicide in branded products marketed for both uses was discussed by the Subcommittee.

Questions to our Stakeholders
1. Is there potential for misuse as a fungicide when sodium carbonate peroxyhydrate is applied as an algaecide? Additionally, should the NOSB consider expanding the listing to an allowance for use as a fungicide?
2. Is this substance being used as an effective alternative to copper sulfate in rice production to control algae?

Newspaper or other recycled paper, without glossy or colored inks

Reference: 205.601(b) As herbicides, weed barriers, as applicable. (2) Mulches. (i) Newspaper or other recycled paper, without glossy or colored inks.
Technical Report: 1995 TAP; 2006 TR; 2017 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 19); 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation

Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/20 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Newspaper and other recycled paper is commonly used in organic agriculture as a non-chemical means of weed management and soil moisture retention, soil temperature moderation, and boosts to soil organic matter. It is also used to shade out plant growth; it then degrades into the soil.

Manufacture
A 2017 TR on this material reports that one-third to one-half of all paper in the United States is recycled into other paper products, and reports EPA figures from 2013 data that paper is recycled at a rate of 63% in the United States.

Recycled paper comes from a number of different sources that affect the grade of the recycled paper product; old corrugated containers, mixed paper, old newspapers, high grade de-inked paper, and pulp substitutes. These larger categories are further segmented into as many as 50 different sub-grades of recycled paper. Paper recovered for recycling is ultimately shredded and pulped to produce new paper products.

Some recycled paper cannot be made into other paper products but can become a feedstock for compost products, while some recycled paper carries too many contaminants – some of it toxic -- including plastics, motor oil, paint, glass, and other non-paper materials.

An important consideration of newspaper and recycled paper in organic production relates to the inks that are printed onto the paper. Black ink has historically been derived from vegetable- or petroleum-based sources that involve the use of solvents that can damage the environment in a variety of ways. Increasingly, black inks have become water-based, though not 100% solvent-free. The use of various heavy metal compounds in colored ink has been an important consideration in excluding colored inks from use in organic production. Similarly, while glossy inks can gain their functional components from nonsynthetics like bentonite or kaolinite, those functions can also come from petrochemical synthetic polymers like acrylonitrile, polyethylene (LDPE), styrene, butadiene, vinyl acetate, and polyvinyl chloride, excluding them from any use in organic production.

Adhesives, glues, waxes, and resins are also among the materials that could be found in newspaper and recycled paper products and raise similar questions to those posed during prior reviews of biodegradable biobased mulch film.

Paper mulches are not regulated as an herbicide by the EPA and are considered inert.

It is worth noting that virgin, or non-recycled paper, comes from a variety of plant materials, including wood, trees, straw, hemp, sugarcane bagasse, bamboo, reeds, and kenaf, with the majority coming from wood fibers. As noted in the 2017 TR , most of the wood fibers derived from trees used for paper production do not incorporate methods considered to be excluded from organic production. However, some genetically modified trees are being produced that could potentially be used in paper production in the future. Some sources have reported that as many as 200 different chemicals can be used to make it possible to use tree fiber as a feedstock for paper production (Discover Magazine, April 4, 2014).

International Acceptance
Canadian General Standards Board Permitted Substances List
Permitted for use but only "without glossy paper and coloured ink."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Not specified as permitted for use.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Not specified as permitted for use.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Not specified as permitted for use.

Japan Agricultural Standard (JAS) for Organic Production
Not specified as permitted for use.

Environmental Issues
While recycled paper production is assumed to have fewer environmental impacts than virgin paper production, it still presents issues. Sodium hydroxide and other chemical additives and surfactants may be introduced into the process. The de-inking sludge – or wastewater byproduct – that is produced from paper recycling can contain a number of synthetic materials and is typically landfilled, burned, or co-composted with sewage and poultry litter.

That said, the use of recycled paper ensures that trees are not harvested for the production of paper, a process that has much more far-reaching impacts including the loss of habitat, disturbance or destruction of soils, and the destabilization of carbon sinks.

Discussion
At the 2015 NOSB sunset review, it came to the attention of both the NOSB and the public that there are new, less toxic materials used in production of newspaper and other recycled paper products which could stimulate the NOSB to consider a change to the annotation for this material. A technical report (TR) was requested and subsequently completed in summer 2017. The TR revisited the ingredients and colored inks in newspaper as well as their effect on the environment.

While there has been progress towards less toxic materials used in inks, and more recycling of paper products since the original listings and annotation of newspaper and recycled paper, it is difficult-to-impossible to determine if the inks present in the newspaper are ones that are less problematic. There is no methodology to distinguish between color inks that might be more acceptable for direct application to organic land and those that are not. When reviewing the 2017 TR, the Crops Subcommittee decided the current annotation for newspaper and recycled paper, which prohibits glossy or colored inks, should remain. This conclusion was presented as an update to the full NOSB at the Fall 2017 NOSB meeting. The NOSB unanimously voted to continue this listing at 205.601(b) in 2018.

There was continued support for this material to remain on the National List with the current annotation. Certifiers, grower groups, and individual growers all submitted comments in favor of retaining this material in both locations on the National List. While some stated there was currently not much use of this material in organic crop production, they also stated it should continue to be allowed for those who wish to continue using it. One certifier noted that newspaper could be included in manure that is cleaned out of livestock barns, supporting the relisting as a compost feedstock.

Questions to our Stakeholders

1. Should there be an annotation for this listing that attempts to further clarify what uses are acceptable within organic production?
2. How widely used are these materials in organic production?

Newspaper or other recycled paper, without glossy or colored inks

Reference: 205.601(c) As compost feedstocks—Newspapers or other recycled paper, without glossy or colored inks.
Technical Report: 1995 TAP; 2006 TR; 2017 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 19); 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Newspaper and other recycled paper is commonly used in organic agriculture as a compost feedstock. Effectively, the newspaper or recycled paper is a carbon source – or food -- for active compost processing.

Manufacture
A 2017 TR on this material reports that one-third to one-half of all paper in the United States is recycled into other paper products, and reports EPA figures from 2013 data that paper is recycled at a rate of 63% in the United States.

Recycled paper comes from a number of different sources that affect the grade of the recycled paper product: old corrugated containers, mixed paper, old newspapers, high grade de-inked paper, and pulp substitutes. These larger categories are further segmented into as many as 50 different sub-grades of recycled paper.

Some recycled paper cannot be made into other paper products but can become a feedstock for compost products, while some recycled paper carries too many contaminants – some of it toxic -- including plastics, motor oil, paint, glass, and other non-paper materials.

An important consideration of newspaper and recycled paper in organic production relates to the inks that are printed onto the paper. Black ink has historically been derived from vegetable- or petroleum-based sources that involve the use of solvents that can damage the environment in a variety of ways. Increasingly, black inks have become water-based, though not 100% solvent-free. The use of various heavy metal compounds in colored ink has been an important consideration in excluding colored inks from use in organic production. Similarly, while glossy inks can gain their functional components from nonsynthetics like bentonite or kaolinite, those functions can also come from petrochemical synthetic polymers like acrylonitrile, polyethylene (LDPE), styrene, butadiene, vinyl acetate, and polyvinyl chloride, excluding them from any use in organic production.

Adhesives, glues, waxes, and resins are also among the materials that could be found in newspaper and recycled paper products and raise similar questions to those posed during prior reviews of biodegradable biobased mulch film.

Composting is not federally regulated therefore, neither is the use of paper as a compost feedstock. However, components of paper feedstock, such as heavy metals, could be regulated at the state level.

It is worth noting that virgin, or non-recycled paper, comes from a variety of plant materials, including wood, trees, straw, hemp, sugarcane bagasse, bamboo, reeds, and kenaf, with the majority coming from wood fibers. As noted in a 2017 TR, most of the wood fibers derived from trees used for paper production do not incorporate methods considered to be excluded from organic production. However, some genetically modified trees are being produced that could potentially be used in paper production in the future. Some sources have reported that as many as 200 different chemicals can be used to make it possible to use tree fiber as a feedstock for paper production (Discover Magazine, April 4, 2014).

International Acceptance

Canadian General Standards Board Permitted Substances List
Permitted for use but only “without glossy paper and coloured ink.”

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Not specified as permitted for use.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Not specified as permitted for use.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Not specified as permitted for use.

Japan Agricultural Standard (JAS) for Organic Production
Not specified as permitted for use.

Environmental Issues
While recycled paper production is assumed to have fewer environmental impacts than virgin paper production, it still presents issues. Sodium hydroxide and other chemical additives and surfactants may be introduced into the process. The de-inking sludge – or wastewater byproduct – that is produced from paper recycling can contain a number of synthetic materials and is typically landfilled, burned, or co-composted with sewage and poultry litter.
That said, the use of recycled paper ensures that trees are not harvested for the production of paper, a process that has much more far-reaching impacts including the loss of habitat, disturbance or destruction of soils, and the destabilization of carbon sinks.

Discussion
At the 2015 NOSB sunset review, it came to the attention of both the NOSB and the public that there are new, less toxic materials used in production of newspaper and other recycled paper products which could stimulate the NOSB to consider a change to the annotation for this material. A technical report (TR) was requested and subsequently completed in summer 2017. The TR revisited the ingredients and colored inks in newspaper as well as their effect on the environment.

While there has been progress towards less toxic materials used in inks, and more recycling of paper products since the original listings and annotation of newspaper and recycled paper, it is difficult to impossible to determine if the inks present in the newspaper are ones that are less problematic. There is no methodology to distinguish between color inks that might be more acceptable for direct application to organic land and those that are not. When reviewing the 2017 TR, the Crops Subcommittee decided the current annotation for newspaper and recycled paper, which prohibits glossy or colored inks, should remain. This conclusion was presented as an update to the full NOSB at the Fall 2017 NOSB meeting. The NOSB unanimously voted to reinstate continue this listing at 205.601(c) in 2018.

There was continued support for this material to remain on the National List with the current annotation. Certifiers, grower groups, and individual growers all submitted comments in favor of retaining this material in both locations on the National List. While some stated there was currently not much use of this material in organic crop production, they also stated it should continue to be allowed for those who wish to continue using it. One certifier noted that newspaper could be included in manure that is cleaned out of livestock barns, supporting the relisting as a compost feedstock.

Questions to our Stakeholders
1. Should there be an annotation for this listing that attempts to further clarify what uses are acceptable within organic production?
2. How widely used are these materials in organic production?

Plastic mulch and covers

Reference: 205.601(b) As herbicides, weed barriers, as applicable. (2) Mulches. (ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)).
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 20); 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Plastic mulches and covers provide multiple functions in organic production including, but not limited to, weed barrier, soil, nutrient and water retention, soil warming, soil solarizing, high and low tunnels, and reflective barriers for insect pests.

Manufacture
Plastic mulches and covers are thermoplastic resins of high melt viscosity, usually polyethylene. Resin pellets are melted into an extruder and pumped or blown through a die or tube to form the plastic in the desired shape.

International Acceptance
Canadian General Standards Board Permitted Substances List
Plastic mulches: non-biodegradable and semi-biodegradable materials shall not be incorporated into the soil or left in the field to decompose. Use of polyvinyl chloride as plastic mulch or row cover is prohibited.

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

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
No reference

Japan Agricultural Standard (JAS) for Organic Production
Plastic mulch (limited to those to be removed after use)

Environmental Issues
Although there is significant support for its relisting, plastic mulch has many environmental concerns, most of which are related to disposal after each season. The recycling of plastic mulch seems to be a diminishing option. The product is easily damaged and contaminated, which makes recycling a less viable option. Other concerns include the breakdown of microplastics and litter from damaged product remaining in the field. These pieces are considered foreign materials and contaminate organic soils. The labor cost to remove plastic is very expensive and often is a challenge for growers. Because of this, many growers are excited for the development of biodegradable mulches.

Discussion
The Crops Subcommittee discussed the use, manufacturing, and environmental issues with plastic mulches. The expansiveness of the listing and annotations were reviewed, and it was noted that the term, "covers," can be in reference to high and low tunnels as well as ground coverings. Members of the subcommittee discussed the significance of recycling as a diminishing option and reviewed the social concerns about recycling of plastic mulches not being a viable option. The subcommittee also discussed § 205.206(c)(6) that requires plastic mulches to be removed at the end of the growing or harvest season and how it is applied with this listing.

Questions to our Stakeholders
1. Please describe in detail how this listing for plastic mulches is being applied in conjunction with the § 205.206(c)(6) requirement for removal, and specifically, how is the provision being applied in all areas of organic cropping systems?

Aqueous potassium silicate

Reference: 205.601(e) As insecticides (including acaricides or mite control). (2) Aqueous potassium silicate (CAS #-1312-76-1)—the silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.
Technical Report: 2003 TAP; 2014 TR; 2022 Limited Scope TR Pending
Petition(s): 2002; 2006 (Addendum #1)
Past NOSB Actions: 11/2007 NOSB recommendation; 10/2014 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 12/13/2010 (75 FR 77521); Sunset renewal notice published 06/19/2015 (80 FR 35177); Sunset renewal notice published 05/07/2020 (85 FR 27105).
Sunset Date: 6/22/2025

Subcommittee Review

Use
Aqueous potassium silicate is used as an insecticide for insects and mites. Formulations of aqueous potassium silicate are either sprayed on the foliage of plants or incorporated in the soil with the goal of plant uptake across root and leaf boundaries. The silica tetrahedra are purported to be incorporated in boundary cells (in roots and leaves) inhibiting insect feeding and the onset of plant disease infection. The action of applying potassium silicate in a foliar spray serves to induce production of phytoalexins, chitinases and that in turn strengthen stroma and cell walls.

Manufacture
Aqueous potassium silicate is manufactured by combining high purity silica sand and potassium carbonate (both mined materials) and heating to a high temperature (2000 degrees F). The potassium carbonate and silicon dioxide fuse to form a molten potassium silicate glass with the evolution of carbon dioxide gas. This glass can either be 1) cooled and ground into a powder or 2) dissolved in water to form a potassium silicate solution. The solution may subsequently be spray dried to form hydrous powder granules of potassium silicate.

International Acceptance

Canadian General Standards Board Permitted Substances List
Potassium silicate is listed as approved for crop protection.

European Economic Community (EEC) Council Regulation, EC No. *834/2007* *and* *889/2008*
No silicates were listed at this website.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Silicates allowed only as ground powders.

International Federation of Organic Agriculture Movements (IFOAM)
Silicates are allowed as plant protectants

Japan Agricultural Standard (JAS) for Organic Production
No information found

Environmental and Health Issues
The 2014 TR states that

- "Potassium silicate will not adversely affect birds."
- It is "practically non-toxic to fish."
- "Potassium silicate is not toxic to honeybees at the concentration administered for the foliar spray."
- "The overall toxicological risk from human exposure to potassium silicate is negligible."
- "Risks from aggregate exposure via oral, dermal and inhalation exposure are … considered negligible."

Discussion
Written comments in 2018 were heavily in favor of relisting. As an example, the Organic Produce Wholesalers Coalition wrote—

- The substance is taken up by plants and reinforces the plant's ability to defend itself against diseases and pests through enhanced activation of specific immune responses.
- The [TR] cites many articles and reviews that support positive and beneficial effects of soluble silicates in protecting plants from abiotic and biotic stresses. The most significant effect on plants, besides improving their fitness and increasing plant productivity, is the suppression of insect feeding and impacts from plant diseases.

- Aqueous potassium silicate is approved by the EPA as a biopesticide for use on agricultural crops, fruits, nuts, vines, turf, and ornamentals, making it useful for producers of many of the fruit and vegetable crops distributed by OPWC members.
- EPA notes that there is minimal potential for concern about exposure of insects, fish, and other non-target wildlife as a result of using potassium silicate for pest control. At the recommended concentration for potassium silicate foliar spray, reactivity with other substances used in organic crop, livestock or handling is not expected.

Based on information in the 2014 technical report (TR), concerns were raised in the 2018 sunset review regarding skin irritation from handling aqueous potassium silicate, effects on farmworkers making the foliar application, effects on human or animal consumers because of its reported effect of making forage plants less digestible, its reported effect of elongation and thickening of stems, delayed antithesis and flower deformation in some plant species, and whether it is essential to and compatible with organic production.

Following up on these concerns:

- Investigation of the effect of aqueous potassium silicate on flowers showed that the articles cited were greenhouse studies in soilless media. One study showed that applications of potassium silicate "either increased or decreased height, diameter, fresh weight, dry weight, flower diameter, and leaf thickness." The other study found that drenches with higher rates of potassium silicate resulted in stunted plants with deformed flowers. However, substrate pH was not carefully controlled with the addition of such high-pH drenches. These studies have little to do with use of aqueous potassium silicate as a foliar spray in organic agriculture.
- Similarly, the study showing that aqueous potassium silicate could make forages "more difficult to chew and digest" was unrelated to the use pattern of aqueous potassium silicate in organic agriculture. The study looked at forages harvested at different growth stages and showed that overmature grass forages contained high levels of silicon and were less digestible.
- A new, limited scope TR currently in review says that aqueous potassium silicate does not present an inhalation hazard to farmworkers.
- Aqueous potassium silicate products are used by some organic fruit and vegetable growers. They have not reported adverse effects on their produce, on the contrary, they advocated for its relisting. One grower reported that two early sprays of aqueous potassium silicate eliminated several late sprays of sulfur.

Questions to our Stakeholders

1. What is the efficacy of aqueous potassium silicate relative to available alternatives?
2. How would the removal of this product impact organic growers?
3. To what extent does listing aqueous potassium silicate result in reductions in use of sulfur-based products for pest management?

Aqueous potassium silicate

Reference: 205.601(i) As plant disease control. (1) Aqueous potassium silicate (CAS #-1312-76-1)—the silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.
Technical Report: 2003 TAP; 2014 TR; 2022 Limited Scope TR Pending
Petition(s): 2002; 2006 (Addendum #1)
Past NOSB Actions: 11/2007 NOSB recommendation; 10/2014 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 12/13/2010 (75 FR 77521); Sunset renewal notice published 06/19/2015 (80 FR 35177); Sunset renewal notice published 05/07/2020 (85 FR 27105).
Sunset Date: 6/22/2025

Subcommittee Review

Use
Aqueous potassium silicate is used as a crop protectant for disease control and suppression. Formulations of aqueous potassium silicate are either sprayed on the foliage of plants or incorporated in the soil with the goal of plant uptake across root and leaf boundaries. The silica tetrahedra are purported to be incorporated in boundary cells (in roots and leaves) inhibiting insect feeding and the onset of plant disease infection. The action of applying potassium silicate in a foliar spray serves to induce production of phytoalexins, chitinases and that in turn strengthen stroma and cell walls.

Manufacture
Aqueous potassium silicate is manufactured by combining high purity silica sand and potassium carbonate (both mined materials) and heating to a high temperature (2000 degrees F). The potassium carbonate and silicon dioxide fuse to form a molten potassium silicate glass with the evolution of carbon dioxide gas. This glass can either be 1) cooled and ground into a powder or 2) dissolved in water to form a potassium silicate solution. The solution may subsequently be spray dried to form hydrous powder granules of potassium silicate.

International Acceptance

Canadian General Standards Board Permitted Substances List
Potassium silicate is listed as approved for crop protection.

European Economic Community (EEC) Council Regulation, EC No. *834/2007* *and* *889/2008*
No silicates were listed at this website.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Silicates allowed only as ground powders.

International Federation of Organic Agriculture Movements (IFOAM)
Silicates are allowed as plant protectants

Japan Agricultural Standard (JAS) for Organic Production
No information found

Environmental (and Health) Issues
The 2014 TR states that

- "Potassium silicate will not adversely affect birds."
- It is "practically non-toxic to fish."
- "Potassium silicate is not toxic to honeybees at the concentration administered for the foliar spray."
- "The overall toxicological risk from human exposure to potassium silicate is negligible."
- "Risks from aggregate exposure via oral, dermal and inhalation exposure are … considered negligible."

Discussion
Written comments in 2018 were heavily in favor of relisting. As an example, the Organic Produce Wholesalers Coalition wrote—

- The substance is taken up by plants and reinforces the plant's ability to defend itself against diseases and pests through enhanced activation of specific immune responses.
- The [TR] cites many articles and reviews that support positive and beneficial effects of soluble silicates in protecting plants from abiotic and biotic stresses. The most significant effect on plants, besides improving their fitness and increasing plant productivity, is the suppression of insect feeding and impacts from plant diseases.
- Aqueous potassium silicate is approved by the EPA as a biopesticide for use on agricultural crops, fruits, nuts, vines, turf, and ornamentals, making it useful for producers of many of the fruit and vegetable crops distributed by OPWC members.
- EPA notes that there is minimal potential for concern about exposure of insects, fish, and other non-target wildlife as a result of using potassium silicate for pest control. At the recommended concentration for potassium silicate foliar spray, reactivity with other substances used in organic crop, livestock or handling is not expected.

Based on information in the 2014 technical report (TR), concerns were raised in the 2018 sunset review regarding skin irritation from handling aqueous potassium silicate, effects on farmworkers making the foliar application, effects on human or animal consumers because of its reported effect of making forage plants less digestible, its reported effect of elongation and thickening of stems, delayed antithesis and flower deformation in some plant species, and whether it is essential to and compatible with organic production.

Following up on these concerns:

- Investigation of the effect of aqueous potassium silicate on flowers showed that the articles cited were greenhouse studies in soilless media. One study showed that applications of potassium silicate "either increased or decreased height, diameter, fresh weight, dry weight, flower diameter, and leaf thickness." The other study found that drenches with higher rates of potassium silicate resulted in stunted plants with deformed flowers. However, substrate pH was not carefully controlled with the addition of such high-pH drenches. These studies have little to do with use of aqueous potassium silicate as a foliar spray in organic agriculture.
- Similarly, the study showing that aqueous potassium silicate could make forages "more difficult to chew and digest" was unrelated to the use pattern of aqueous potassium silicate in organic agriculture. . The study looked at forages harvested at different growth stages and showed that overmature grass forages contained high levels of silicon and were less digestible.

- A new, limited scope TR currently in review says that aqueous potassium silicate does not present an inhalation hazard to farmworkers.
- Aqueous potassium silicate products are used by some organic fruit and vegetable growers. They have not reported adverse effects on their produce, on the contrary, they advocated for its relisting. One grower reported that two early sprays of aqueous potassium silicate eliminated several late sprays of sulfur.

Questions to our Stakeholders

1. What is the efficacy of aqueous potassium silicate relative to available alternatives?
2. How would the removal of this product impact organic growers?
3. To what extent does listing aqueous potassium silicate result in reductions in use of copper and sulfur-based products for pest management?

Elemental sulfur

Reference: 205.601(e) As insecticides (including acaricides or mite control). (5) Elemental sulfur.
Reference: 205.601(i) As plant disease control. (10) Elemental sulfur.
Reference: 205.601(j) As plant or soil amendments. (2) Elemental sulfur.
Technical Report: 1995 TAP; 2018 TR
Petition(s): 2017 (slug or snail bait, separate sunset review)
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 345); 11/2005 NOSB sunset recommendation; 04/2010 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Approved legal uses of the substance (TR 67-75): Elemental sulfur is currently on the National List of Allowed and Prohibited Substances as a synthetic substance allowed for use in organic crop production for the following categories:

1. For uses as an insecticide, including acaricides or mite control (7 CFR)) 205.601 (e)(5).
2. For plant disease control (7 CFR 205.601(i)(10)).
3. As plant or soil amendments (7 CFR 205.601(j)(2)).

The current sunset review includes all three listings of sulfur, used as an insecticide, plant disease control, and as a plant or soil amendment.

Sulfur is an essential plant nutrient, naturally present in our food and soil, and is part of normal human biochemistry. When sulfur is used as a soil amendment it can have a strong acidifying effect by replacing sodium with calcium in high pH alkali soils. Sulfur is considered the fourth major plant nutrient after nitrogen, phosphorus, and potassium-. Sulfur can also be used to control insects and/or diseases. It is approved for use on conventional and organic crops to help control fungi and other pests and is commonly used on farms domestically and internationally.

Manufacture
Sulfur is one of few elements found in its elemental form in nature, typically in limestone/gypsum formations, limestone/anhydrite formations associated with salt domes, or volcanic rock (d'Aquin 2007).

Currently, elemental sulfur is produced as a by-product from natural gas or petroleum operations and refinery processes. The latter is the primary source of most elemental sulfur currently being used.

International Acceptance
Canadian General Standards Board Permitted Substances List
Sulfur is allowed by the Canadian Organic Standards. The Canadian General Standards Board (CGSB) includes non-synthetic elemental sulfur as a permitted substance for organic production systems (CAN/CGSB-32.311-2015) for use as a soil amendment and as a foliar application. The CGSB also permits using sulfur to control external parasites and sulfur smoke bombs in conjunction with other methods used for rodent control when a pest control program is temporarily overwhelmed.

European Economic Community (EEC) Council Regulation, EC No. *834/2007 and 889/2008*
European Economic Community (EEC) Council Regulation (EEC No 2092/91), carried over by Article 16(3)(c) of Regulation No 834/2007, permits the use of sulfur as a fungicide, acaricide, and repellent in organic food production.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Codex Alimentarius Commission (CAC GL 32-1999) permits the use of sulfur for pest and disease control when the certification body or authority recognizes the need for plant protection (Codex, 2013).

International Federation of Organic Agriculture Movements (IFOAM)
The International Federation of Organic Agriculture Movements (IFOAM) lists sulfur as an approved substance for use as pest and disease control, fertilizer/soil conditioner, and crop protectant and growth regulator.

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

Environmental Issues
Elemental sulfur is relatively innocuous in the environment when used according to the product label. It is also low in toxicity. It should not be used within one month of any horticultural oil product, as currently stated on most sulfur labels.

An updated Technical Report (TR) was completed on April 19, 2018. There was no new information contradicting historical information that characterizes sulfur as an important and relatively safe material for organic agriculture.

Although low in acute toxicity, sulfur is a respiratory, ocular, and dermal irritant that can significantly impact farmworker health. Farmworker exposures can be mitigated if label recommendations and proper PPE recommendations are followed.

Discussion
2018 NOSB Review: Historically, there has been strong support for the continued listing of sulfur, particularly for use against various bacterial and fungal diseases, insects, and as a plant and soil amendment. It was noted that several agricultural commissioners in California had encouraged a shift to wettable formulations in vineyard applications, and anecdotal information suggests fewer drift and regulatory problems.

Based on the extensive public comment and discussions, new technical reviews, previous committee votes & discussions, and historical public comment, the 2018 NOSB review concluded that elemental sulfur still appears to be necessary in organic crop production. The NOSB should continue to monitor sulfur use in organic agriculture and respond to any new information raising environmental or, in particular, public health concerns.

The current Subcommittee reviewed the use, manufacture, environmental concerns, and previous board reviews and research. The Subcommittee also discussed the Spring 2018 recommendation to add a new use for sulfur: as a molluscicide. The subcommittee reviewed a journal article, and a study completed at Oregon State University to further discuss the effects on children's respiratory health.

Questions to our Stakeholders

1. How often are wettable formulations used for the application of sulfur?

Lime sulfur

Reference: 205.601(e) As insecticides (including acaricides or mite control). (6) Lime sulfur—including calcium polysulfide.
Technical Report: 2014 TR
Petition(s): N/A
Past NOSB Actions: Actions: 04/1995 NOSB minutes and vote (pg. 341); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Lime sulfur is on the National List at §205.601(e)(6) as an insecticide (including acaricide or mite control) and at §205.601 (j)(6) for plant disease control. As an insecticide, lime sulfur is used to control mites (spider mites and rust mites), aphid, and San Jose scale in tree fruit and other organic crops.

Manufacture
Lime sulfur is often referred to by its chemical name, calcium polysulfide. It is considered to be synthetic and is produced by reacting boiling calcium hydroxide [$CaOH2_2$] and ground sulfur (2014 TR).

International Acceptance
Canadian General Standards Board Permitted Substances List
Allowed as a production aid

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Permits the use of lime sulphur (calcium polysulfide) as a fungicide, insecticide, acaricide.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Does not appear on this listing

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as a crop protectant

Japan Agricultural Standard (JAS) for Organic Production
Lime sulfur powder allowed as Substances for Plant Pest and Disease Control

Environmental Issues
Residues of lime sulfur are exempt from the requirement of a tolerance under 40 CFR 180.1232 as determined by the U.S. EPA because the calcium polysulfides found in lime sulfur products rapidly degrade to calcium hydroxide and sulfur in the environment and human body.

Discussion
The vast majority of public commenters during the previous review were in favor of relisting lime sulfur for control of fungal and bacterial diseases as well as its uses for various insects. It has widespread and historical use across many crops and regions. Many comments note that there are not viable alternatives for its various uses. The few comments against lime sulfur primarily referenced the 2014 Technical Report (TR), noting that later-season use of the material may have a negative impact on beneficial insects and that large scale releases of the material could have environmental impacts.
Lime sulfur can cause phytotoxicity in some crops, however, rates and timings can be used to avoid this problem. In fact, lime sulfur pesticide applications during and shortly after bloom can have a desirable crop-thinning effect on apples. The TR notes that lime sulfur may impair some beneficial insects, but timing of use can minimize the negative effects. It also noted potential human health concerns from lime sulfur primarily due to its high alkalinity or the release of hydrogen sulfide. In New York State, , lime sulfur is classed as a restricted use pesticide because of potential hazards handling the concentrated product. This concern can be mitigated if proper safety procedures are followed during manufacture

and label directions including personal protective equipment (PPE) are followed. The TR also provided an extensive list of alternative materials and practices, however, if an outbreak of mites or scale occurs, lime sulfur is an effective option.

Questions to our Stakeholders

1. Is lime sulfur a necessary organic pesticide?

Lime sulfur

Reference: 205.601(i) As plant disease control. (6) Lime sulfur.
Technical Report: 2014 TR
Petition(s): N/A
Past NOSB Actions: Actions: 04/1995 NOSB minutes and vote (pg. 341); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Lime sulfur is on the National List at §205.601(e)(6) as an insecticide (including acaricide or mite control) and at §205.601 (j)(6) for plant disease control. As a fungicide, it is used to control powdery mildew, anthracnose, scab, peach leaf curl, fire blight, and several other plant diseases in tree fruit and berry crops.

Manufacture
Lime sulfur is often referred to by its chemical name, calcium polysulfide. It is considered to be synthetic and is produced by reacting boiling calcium hydroxide [$CaOH2_2$] and ground sulfur (2014 TR).

International Acceptance

Canadian General Standards Board Permitted Substances List
Allowed as a production aid

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Permits the use of lime sulphur (calcium polysulfide) as a fungicide, insecticide, acaricide.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Does not appear on this listing

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as a crop protectant

Japan Agricultural Standard (JAS) for Organic Production
Lime sulfur powder allowed as Substances for Plant Pest and Disease Control

Environmental Issues
Residues of lime sulfur are exempt from the requirement of a tolerance under 40 CFR 180.1232 as determined by the U.S. EPA because the calcium polysulfides found in lime sulfur products rapidly degrade to calcium hydroxide and sulfur in the environment and human body.

Discussion
The vast majority of public comments during the previous review were in favor of relisting lime sulfur for control of fungal and bacterial diseases as well as its uses for various insects. It has widespread and historical use across many crops and regions. Many comments note that there are not viable alternatives for its various uses, especially as part of an integrated fire blight control program. The few comments against lime sulfur primarily referenced the 2014 Technical Report(TR) in noting that later season use of the material may have a negative impact on beneficial insects and that large scale releases of the material could cause environmental impact.
Lime sulfur can cause phytotoxicity in some crops, however, rates and timings can be used to avoid this problem. In fact, lime sulfur pesticide applications during and shortly after bloom can have a desirable crop-thinning effect on apples. The TR notes that lime sulfur may impair some beneficial insects, but, once again, timing of use can minimize the negative effects. It also noted potential human health concerns from lime sulfur primarily due to its high alkalinity or the release of hydrogen sulfide. In New York state, lime sulfur is classed as a restricted use pesticide because of potential hazards handling the concentrated product. This concern can be mitigated if proper safety procedures are followed during manufacture and label directions including personal protective equipment (PPE) are followed. The TR also provided an extensive list of alternative materials and practices; however, an important benefit of lime sulfur is that it can be effective even after a fungus infection has taken place. Almost all other organic alternatives have only preventative action.

Questions to our Stakeholders
1. Is lime sulfur a necessary organic pesticide?

Hydrated lime

Reference: 205.601(i) As plant disease control. (4) Hydrated lime.
Technical Report: 1995 TAP; 2001 TAP; 2002 TR (calcium hydroxide); 2015 TR (Livestock)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 345); 04/2006 sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Technical correction annotation change published 10/31/2003 (68 FR 61987); Sunset renewal notice published

10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Hydrated lime is a synthetic substance limited for use in organic crop production for plant disease control and as an external pest control in organic livestock production (7 CFR §205.603(b)(6)). Regarding livestock applications, hydrated lime may not be used to cauterize physical alterations (medical treatment) or deodorize animal wastes. Hydrated lime, also known as calcium hydroxide, is listed for handling as an allowed synthetic, nonagricultural substance which may be used as an ingredient in or on processed products (7 CFR 205.605(b)(8)).

Manufacture
According to the 2015 Technical Review for Livestock, the "industrial production of hydrated/slaked lime involves two elementary reactions beginning with naturally occurring limestone deposits. In the first step, ground limestone—which contains predominantly calcium carbonate (CaCO3) with smaller amounts of magnesium, silicon, aluminum, and iron oxide compounds—is thermally transformed into quicklime (Oates, 2010). Specifically, heating raw or minimally processed limestone to temperatures in excess of 900 ºC results in conversion of the calcium carbonate content of limestone to calcium oxide (CaO) in a material known as quicklime (equation 1). This thermal transformation occurs with liberation of carbon dioxide (CO2) gas. In the slaking process, quicklime reacts exothermically (releases heat) with two equivalents of water to produce hydrated/slaked lime consisting primarily of calcium hydroxide [Ca(OH)2] (equation 2). The normal hydration process is carried out at atmospheric pressure and temperatures of approximately 100 ºC (Kenny & Oates, 2007). A variation of the normal hydration process involves reaction of quicklime and water under a high steam pressure of up to 1 MPa and at temperatures approaching 180 ºC to form hydrates. After hydration, the hydrated lime product is dried, milled, and air classified" (TR 231-243).

International Acceptance

Canadian General Standards Board Permitted Substances List
Hydrated lime is listed in Section 4.3—Crop Production Aids and Materials—for use as a plant disease control agent only (CAN, 2011). Canadian organic regulations also permit the use of hydrated lime as a health care product and/or production aid in organic livestock production under Section 5.3 of the Permitted Substances Lists. According to this rule, hydrated lime is not allowed for use to cauterize physical alterations (medical treatment) or deodorize animal wastes. (2015 TR 177-181)

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

Annex I of the European regulations allow "industrial lime from sugar production"—a byproduct of sugar production from sugar beet—as a fertilizer or soil conditioner. Calcium hydroxide may be used as a fungicide on fruit trees to control Nectria galligena in organic crop production under Annex II and as a processing aid in the production of processed organic foods of plant origin under Annex VIII (EC, 2008). European Union Organic regulations do not permit the use of hydrated lime/calcium hydroxide as an external parasiticide in livestock production. (TR 188-93)

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 Foods (CAC/GL 32-1999) do not list hydrated lime/calcium hydroxide for use in organic livestock or crop production. However, calcium hydroxide is included in the list of "processing aids which may be used for the preparation of products of agricultural origin referred to in Section 3 of these guidelines" (Codex, 2013). (TR 183-86)

International Federation of Organic Agriculture Movements (IFOAM)

Permits the use of "milk of lime" (i.e., hydrated/slaked lime, calcium hydroxide) for pest and disease control and disinfection in livestock housing and equipment (Appendix 5). Likewise, calcium hydroxide (slaked lime) is included in the "Indicative List of Equipment Cleansers and Equipment Disinfectants" (Appendix 4 – Table 2) for organic handling/processing. Calcium hydroxide is also listed as an approved food additive for maize tortilla flour and processing aid for sugar (Appendix 4 – Table 1). Lastly, application of calcium hydroxide (hydrated lime) is allowed on aerial plant parts only for plant disease control according to Appendix 3 of the IFOAM Norms (IFOAM, 2014). Hydrated lime is not explicitly listed as an approved miticide according to IFOAM. (TR 201- 208).

Japan Agricultural Standard (JAS) for Organic Production

Calcium hydroxide derived from calcium oxide (slaked lime) is listed in Table 1 of the standard as an approved fertilizer and soil improvement substance (JMAFF, 2012). Hydrated lime is not explicitly approved as a miticide according to Japanese organic regulations. (TR 195-199)

Environmental Issues

Hydrated lime is released to the environment through various industrial waste streams and according to its use in agricultural production. Both calcium and hydroxide—the principal atomic/molecular subunits of hydrated lime—are abundantly present in natural waters; therefore, it is unlikely that small to moderate releases will adversely affect the aquatic or terrestrial environment. Large-volume accidental releases, however, could significantly raise the pH of receiving waters and soils, resulting in toxic effects to non-target organisms. Hydrated lime is considered practically non-toxic to slightly toxic to freshwater fish and invertebrates when added in quantities that do not lead to significant changes in water pH. While certain strains of soil bacteria can tolerate extreme pH levels (e.g., pH 1.0 or 11.0), larger soft-bodied soil organisms are significantly more sensitive to changes in soil pH. Earthworms, for example, can only survive in the physiological pH range of 4.0 to 8.0. Changes in soil pH due to application of alkaline hydrated lime can also affect the bioavailability of toxic heavy metal contaminants as well as essential micronutrients. It is highly unlikely that hydrated lime from livestock treatments will be released to nearby soils in sufficient quantities to adversely impact the environment. Industrial production of the chemical precursor, quicklime (CaO), uses considerable amounts of energy and may release dust into the atmosphere. The use of more efficient modern kilns and bag filters can minimize the environmental impact of this process.

Discussion

The Crops Subcommittee discussed this substance and its use across all areas of the National List, including Crops, Livestock, and Handling (listed as calcium hydroxide). Two Technical Advisory Panels (TAPs) and two Technical Reports (TR) were compiled in 1995, 2001, 2002, and 2015, respectively. The use of hydrated lime (as has been practiced in organic production) is known to be an effective disease suppression practice. A previous sunset review noted that the use of hydrated lime in Bordeaux mix to make copper available for disease suppression is highly effective and widely used by fruit and vegetable growers. The Subcommittee discussed the history of hydrated lime and expressed a desire to receive further information on the current extent of use.

Questions to our Stakeholders

1. Is there any new information that would warrant the need for a new TR for this substance?
2. Please provide information on the extent to which hydrated lime is used in organic cropping systems.

Liquid fish products

Reference: 205.601(j) As plant or soil amendments. (8) Liquid fish products —can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

Technical Report: 1995 TAP; 2006 TR (fish-based fertilizers); 2019 TR (liquid fish products)

Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 346); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation

Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)

Sunset Date: 6/22/2025

Subcommittee Review

Use

Liquid fish products are used as fertilizers in the production of organic crops. Liquid fish products contain fundamental nutrients and many trace minerals critical for use in organic farming. Liquid fish foliar application can deliver important nutrients that can reduce certain nutrient stresses which can, in turn, improve crop yields.

Manufacture

Liquid fish products are fish hydrolysates that are made from chopped fish byproducts that are (1) enzymatically digested and heated, or (2) enzymatically processed without heat (cold processing). Liquid fish products are then stabilized with an acid, such as phosphoric, sulfuric, or citric acid, to prevent microbial growth. The use of formic acid is prohibited due to phytotoxicity. A third method of liquid fish product manufacture utilizes fermentation by bacteria that produce lactic acid, which preserves the fish. All three methods of liquid fish product manufacture cannot result in a pH below 3.5.

International Acceptance

Canadian General Standards Board Permitted Substances List

The Canadian Organic Standard allows for the use of liquid fish products. Acids are permitted to lower the pH to 3.5, but no prohibited preservatives can be used.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Liquid fish is not on the EU Annex I list of approved fertilizers, but the EU does allow fish meals.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Contingent upon recognition from a certification body or authority.

International Federation of Organic Agriculture Movements (IFOAM)
The International Federation of Organic Agriculture Movements (IFOAM) permits using fish and shell products and food processing of animal origin.

Japan Agricultural Standard (JAS) for Organic Production
The Japanese Organic Standard permits the use of food industry byproducts of fish origin if they are derived from natural sources.

Environmental Issues
Nutrient runoff from excessively or improperly applied fertilizers can cause eutrophication of surface waters, potentially harming fish, and other aquatic animals.

Global impacts of commercial fisheries on marine ecosystems include documented fish population decline (and in some cases, ecosystem collapse) due to overharvesting. Liquid fish products are derived from several sources, including fish waste and bycatch/mortalities. To a lesser extent, fish are harvested for meal, oil, and solubles (also known as the wet reduction process). Large-scale population declines have occurred, with at least three fish species harvested for meal, oil, and soluble production. Considering this information, during the previous sunset review, conducted in 2018, the Crops Subcommittee added a work agenda item regarding liquid fish products. At the October 2020 meeting, the Board proposed, approved, and recommended to the NOP to add an annotation to liquid fish products at § 205.601(j)(8) to limit the use to fish sourced from waste left over aftermarket food fish are processed for human consumption, bycatch, and invasive species.

Discussion:
Previous NOSB sunset review summary: Historically, there has been strong support for keeping liquid fish products on the National List, and public comment at the October 2018 NOSB meeting reiterated the strength of that support. Many farmers considered liquid fish products essential for many crops, including foliar and other applications. Concerns about the sustainability of source fish, including the possible use of wild fish harvested for the sole purpose of producing liquid fertilizers, were raised by the Crops Subcommittee, and extensive discussion during the October 2018 NOSB meeting focused on production methods and sources of raw fish material for the production of fish-based fertilizers. These discussions resulted in a work-agenda request to assess the environmental impact of harvesting wild, native fish for all fertilizer purposes, to protect natural fish populations, and to ensure that liquid fish and other fish-based fertilizer products used in organic production are not harmful to the environment. Information from this review could inform future policy recommendations regarding the use of wild fish for organic fertilizers but is beyond the scope of review for this sunset review.

The current Crops Subcommittee discussed the uses of liquid fish products as a plant or soil amendment, the manufacturing process, and environmental issues. The Subcommittee also reviewed the October 2020 NOSB recommendation on Wild, Native Fish for Liquid Fish Products, which the NOP has not implemented; it is currently listed as “On Hold” in the NOSB Recommendations Library.

Questions to our Stakeholders

1. Is the liquid fish products annotation "- can be pH adjusted with sulfuric, citric, or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5." clear and able to be enforced?

Sulfurous acid

Reference: 205.601(j) As plant or soil amendments. (11) Sulfurous acid (CAS # 7782-99-2) for on-farm generation of substance utilizing 99% purity elemental sulfur per paragraph (j)(2) of this section.

Technical Report: 2010 TR; 2014 TR; 2023 Limited Scope TR (pending)

Petition(s): 2008

Past NOSB Actions: 05/2009 NOSB recommendation; 10/2014 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation

Regulatory Background: Added to National List 07/07/2010 (75 FR 38693); Sunset renewal notice published 06/19/2015 (80 FR 35177); Sunset renewal notice published 05/07/2020 (85 FR 27105)

Sunset Date: 6/22/2025

Subcommittee Review

Use

The primary use of sulfurous acid is as an acidifying agent to neutralize and reduce excessive alkalinity in soil and/or water. The resulting acidic irrigation water can be helpful with nutrient deficiencies that arise when saline or alkaline conditions tie up essential micronutrients. This use supports improved crop yields and can help to reduce soil degradation from salinity build up.

Manufacture

The primary ingredients used in the preparation of sulfurous acid are water and elemental sulfur. Almost all elemental sulfur is produced as a byproduct of coal, natural gas, and petroleum refinement. Sulfurous acid is manufactured by spraying water through smoke and fumes created by burning elemental sulfur. Several substances are created in this process, including sulfur dioxide, hydrogen sulfide, and hydrogen sulfite.

International Acceptance

Canadian General Standards Board Permitted Substances List

Sulfurous acid can be used in the production of Canadian Organic Products as a preservative in alcoholic beverages made from grapes or other fruit, although minimum use is recommended. No mention is made of sulfurous acid as a soil amendment (CGSB, 2011a,b).

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

Sulfurous acid is allowed in wine production only.

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

Sulfurous acid is allowed in wine production only.

International Federation of Organic Agriculture Movements (IFOAM)
Sulfurous acid is allowed by IFOAM in wine production, as a pH adjuster in sugar production, and is a permitted soil amendment.

Japan Agricultural Standard (JAS) for Organic Production
JAS does not mention sulfurous acid but allows sulfuric acid as a pH adjuster in sugar production.

Environmental Issues

Sulfurous acid appears on the EPA non-food inert list and does not require a tolerance or an exemption from tolerance. According to a sulfurous acid manufacturer (and noted in the 2014 TR, lines 229-232) sulfur dioxide released into the atmosphere by a sulfurous acid generator is minimal. The EPA does not regulate this emission. Sulfurous acid contains no persistent substances of record. Hydrogen sulfite present in the solution is metabolized by sulfite-reducing bacteria and plants that recycle sulfurous acid into bioavailable sulfur compounds. Water and other dissolved compounds leach into the soils. Functionally sulfurous acid serves to condition soils by adjusting pH.

Regarding human health concerns and per the 2014 TR, sulfurous acid is not expected to be carcinogenic (2014 TR, lines 370-371). Sulfur dioxide is approved by the US Food and Drug administration for use as a food preservative and food colorant (2014 TR, lines 371-372).

Discussion

During the Fall 2018 meeting, the NOSB voted unanimously to keep sulfurous acid on the National List. Most of the written comments at the Fall 2018 meeting supported the relisting, several indicated "no reported use" and one commented that no synthetic fertilizers should be permitted.

A limited scope TR was received by the Crops Subcommittee in early February 2023 and was declared "sufficient" during the Subcommittee meeting held on February 9th, 2023. The TR authors did a seemingly complete job of listing potential alternatives and then evaluating these alternatives as being less effective than sulfurous acid. This limited scope 2023 TR is in the process of being posted online.

Questions to our Stakeholders

None.

Ethylene gas

Reference: 205.601(k) As plant growth regulators. (1) Ethylene gas—for regulation of pineapple flowering.

Technical Report: 1999 TAP; 1999 TAP (handling) (pg. 14-54); 2000 TAP (supplemental information); 2007 TAP; 2011 Limited Scope TR; 2023 TR (Crops, Handling) - pending

Petition(s): N/A

Past NOSB Actions: 10/1999 NOSB recommendation (handling) (pg. 443); 10/2001 recommendation (handling) (pg. 2); 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation

Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Technical correction annotation change published 10/31/2003 (68 FR 61987); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal

notice published and was effective 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Ethylene gas is on the National List for use as a plant growth regulator, for organic pineapple production only. Ethylene gas is used to induce uniform flowering in pineapples and is applied 7-15 months after planting. Application can be repeated two to three times after the initial application (2011 TR lines 53-56). Ethylene gas is made from hydrocarbon feedstocks, such as natural gas liquids or crude oil. Operators should be well trained and prepared. However, the safety concern to workers is limited when correctly used and monitored (2007 TAP, pg. 4).

Manufacture
Ethylene gas is produced almost exclusively from the pyrolysis of hydrocarbons in tubular reactor coils installed in externally fired heaters. Ethylene may also be made from ethanol in fixed or fluid-bed reaction systems (2007 TAP).

International Acceptance

Canadian General Standards Board Permitted Substances List
Allowed for use in Canadian organic production for post-harvest ripening of tropical fruit and de-greening of citrus and to control sprouting of potatoes post-harvest in holding bins.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Allowed for use in Europe organic production in the degreening of bananas, kiwis, and kakis; Degreening of citrus fruit only as part of a strategy for preventing fruit fly damage in citrus; Flower induction of pineapple; sprouting inhibition in potatoes and onions.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
CODEX indicates:
"For degreening of citrus for fruit fly prevention and as a flowering agent for pineapples. As sprouting inhibitor for potatoes and onions: Need recognized by the certification body or authority for sprout inhibition of stored potatoes and onions where varieties that have long dormancy characteristics are not available, or these varieties are not suited to local growing conditions. Must be used in a manner that minimizes exposure to operators and workers."

International Federation of Organic Agriculture Movements (IFOAM)
Ethylene gas is allowed in organic production by IFOAM for the de-greening and ripening of citrus.

Japan Agricultural Standard (JAS) for Organic Production
JAS limits the allowed use of ethylene gas to the ripening of bananas, kiwifruits, and avocados after harvest.

Environmental Issues
Public testimony during the last sunset review indicated that the current level of organic pineapple production is dependent on the availability of this material. No new issues of human health or environmental concerns were raised that had not been addressed in previous NOSB Sunset review cycles. The main safety concern in relation to ethylene use has been the explosive nature of the gas in the air. Operators should be well trained and prepared, though the safety concern to workers is low when correctly used and monitored (2007 TAP, pg. 4).

Discussion
The Crops Subcommittee discussed the use, manufacturing, and the environmental issues, and previous NOSB reviews of ethylene gas. The Crops Subcommittee will incorporate information from the 2022 Technical Report into the Sunset proposal document for the Fall 2023 meeting.

As part of the Spring 2018 public meeting, the Crops Subcommittee requested additional information regarding the issue of scale and the use of ethylene and alternative technologies. Written and oral commenters expressed continued support for this material, stating that it is an essential tool for the commercial production of pineapples for the export market. Commenters stated that no viable alternatives exist. Without ethylene, commenters said, it would be impossible to achieve the uniform ripening necessary for timing the harvest for fruit shipment. Others commented that the material does not fit any OPFA criteria, and it is not essential for the production of the crop but rather is employed for economic reasons.

Questions to our Stakeholders
1. Have any alternatives become available?
2. Based on the international acceptances, is there a need to expand the use of ethylene?

Microcrystalline cheesewax

Reference: 205.601(o) As production aids. (1) Microcrystalline cheesewax (CAS #'s 64742-42-3, 8009-03-08, and 8002-74-2)-for use in log grown mushroom production. Must be made without either ethylene-propylene co-polymer or synthetic colors.
Technical Report: 2018 TR
Petition(s): 2007; 2008 (Addendum #1)
Past NOSB Actions: 05/2008 NOSB recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 03/15/2012 (77 FR 8089); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Microcrystalline cheesewax has been used in organic agriculture as a production aid in log-grown shiitake mushrooms since the 1980s. Microcrystalline cheesewax is used to seal holes in hardwood logs (commonly oak) after the shiitake spawn is inserted.

Manufacture
Microcrystalline cheesewax is a food-grade product made up of a mixture of microcrystalline wax, paraffin wax, and petroleum. All three of these materials come from refining crude oil, where these petroleum waxes are separated by fractional distillation followed by fractional crystallization.

International Acceptance

Canadian General Standards Board Permitted Substances List
CAN/CGSB-32.311 "Table 6.5 Processing aids" prohibits microcrystalline wax "either alone or in formulation with paraffin wax."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Neither microcrystalline cheesewax, nor its components, are listed in EC No. 834-2007 nor EC No.889/2008.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Neither microcrystalline cheesewax, nor its components, are listed in the CODEX (GL 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)
Neither microcrystalline cheesewax, nor its components are listed in IFOAM.

Japan Agricultural Standard (JAS) for Organic Production
Neither microcrystalline cheesewax, nor its components, are listed in the JAS for organic food production.

Environmental Issues (and human health concerns)
Per the 2018 TR and referenced studies: "There have been no reports that indicate the likelihood of the bioaccumulation of either microcrystalline cheesewax or its breakdown products, nor any reports of associated ecotoxicity." Microcrystalline cheesewax is widely regarded as "readily biodegradable" [232-239].
Also per the 2018 TR, "...microcrystalline cheesewax, its components, and its breakdown products are chemically stable and are not known to be health risks." [308-309]. Microcrystalline cheesewax is sometimes heated just before being used as a sealant, at which time caution should be used to avoid inhaling the vapor as this could cause respiratory irritation [317].

Discussion
At the Fall 2018 meeting, the NOSB voted unanimously to keep microcrystalline cheesewax on the National List. Some of the written comments reviewed during the Fall 2018 meeting focused on the current need for microcrystalline cheesewax, saying that the production method (inoculated logs) was no longer used. This notion was countered by the assertion that there was still wide use by small growers.

Questions to our Stakeholders
1. Is there now an effective natural or approved synthetic replacement for the microcrystalline cheesewax that is not derived from petroleum by-products?
2. Should an annotation be added that requires the removal of residues of the microcrystalline cheesewax that remains in the environment once the logs are finished fruiting?

Potassium chloride

Reference: 205.602(e) Potassium chloride—unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.
Technical Report: 1995 TAP; 2023 TR pending
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 22); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review
Use
Potassium is required for health in humans, plants, and microorganisms (1995 TAP pg. 4, 14). Potassium is an essential element for plants as they use it to regulate movement of water and nutrients within the plant, photosynthesis regulation, and enzyme activation. While potassium is found in many soils, it may not exist naturally in a high enough concentration for optimal plant growth, and/or it may be present but in a bound format rendering it unavailable. Potassium is commonly used by growers either alone, as a complex in potassium chloride, or as an ingredient in a fertilizer blend for soil supplementation. Chloride is also an essential element for plants (TAP pg. 12); however, monitoring of chloride use is required to assure soil salinity is managed appropriately. The current annotation in the NOP regulations stipulates chloride monitoring when potassium chloride is used to prevent chloride accumulation in soils.

Manufacture
Potassium chloride is a mineral that occurs naturally and is a product of potash mining where water is forced into the ground to dissolve potassium chloride deposits (1995 TAP, pg. 3). Brine is brought back to the surface where the water is evaporated off to isolate the potassium chloride. Potassium chloride can similarly be produced from sea water extraction via solar evaporation.

International Acceptance

Canadian General Standards Board Permitted Substances List
Permitted for use from mined sources such as sylvite, carnalite, and potash.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Not specified as permitted for use.

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

International Federation of Organic Agriculture Movements (IFOAM)
Permitted for use.

Japan Agricultural Standard (JAS) for Organic Production
Permitted as “fertilizers and soil improvement substances.”

Environmental Issues
Potassium chloride is derived from mining activities, and there are impacts associated with its extraction. There has not been widespread concern about significant impacts.

Discussion
At the Fall 2018 meeting, the NOSB unanimously voted to relist potassium chloride at 7 CFR 205.602

During 2018 meetings, public commenters were also unanimously supportive of continued listing with the current annotation, and there were no other non-chloride types reported by the public. At the time, one certifier recommended that the NOSB request a technical report (TR) on potassium chloride to thoroughly consider the use of synthetic dust suppressants or other synthetic additives.

A draft TR was provided to the Crops Subcommittee on December 2, 2022 and was deemed sufficient, although the Subcommittee requested additional information on effective organic alternatives to potassium chloride. This 2023 TR is pending.

The Crops Subcommittee has had anecdotal discussions about whether or not potassium chloride (per this listing) is being used by organic growers. Subcommittee members have acknowledged that potassium chloride is an inexpensive means of dealing with potassium deficiencies in the soil and is likely very geographically specific in its application (potassium is prevalent in high mineral soils, for example, and thus minimal need for supplemental potassium), but also noted that potassium sulfate may be another good cost-effective alternative with adverse effect. Subcommittee members also discussed the nature of the annotated listing itself and whether it has been successful in reducing chloride leaching – and associated environmental impact -- where it is applied, and also noted that if chloride buildup in the soil is an issue that merits monitoring, there are likely other problematic accumulations in the soil in such contexts as well. The Crops Subcommittee discussed the wide use of potassium chloride in conventional agriculture and the fact that conventional growers are able to mitigate salt concerns by virtue of the conventional toolkit.

Questions to our Stakeholders
1. Is potassium chloride widely used by producers of organic crops?

Sunset 2025
Meeting 1 - Request for Public Comment
Livestock Substances § 205.603 & § 205.604
April 2023

Introduction

As part of the Sunset Process, the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List which must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, annotation, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, it is noted in this list. Substances included in this document may also be viewed in the NOP's Petitioned Substances Index.

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2023 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2023 public meeting. Written public comments will be accepted through April 5, 2023 via www.regulations.gov.

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

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

For Comments that Support the Continued Use of §205.603 Substances in Organic Production:

If you provide comments supporting the allowance of a substance at §205.603, you should provide information demonstrating that the substance is:

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

For Comments that Do Not Support the Continued Use of §205.603 Substances in Organic Production:
If you provide comments that do not support a substance at §205.603, you should provide reasons why the use of the substance should no longer be allowed in organic production. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

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

For Comments that Support the Continued Prohibition of §205.604 Substances in Organic Production:
If you provide comments supporting the prohibition of a substance on the §205.604 section of the National List, you should provide information demonstrating that the substance is:

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

For Comments that Do Not Support the Continued Prohibition of §205.604 Substances in Organic Production:
If you provide comments that do not support the prohibition of a substance at §205.604, you should provide reasons why the use of the substance should no longer be prohibited in organic production. Specifically, comments that support the removal of a substance from the §205.604 section of the National List should provide new information since its last NOSB review to demonstrate that the substance is:

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

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

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

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

Written public comments will be accepted April 5, 2023, via [www.regulations.gov.](http://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:

- Alcohols: Ethanol
- Alcohols: Isopropanol
- Aspirin
- Biologics—Vaccines
- Electrolytes
- Glycerin
- Phosphoric acid
- Lime, hydrated
- Mineral oil

§205.604 Sunsets: Nonsynthetic substances prohibited for use in organic livestock production:

- None

Alcohols: Ethanol

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (1) Alcohols. (i) Ethanol - disinfectant and sanitizer only, prohibited as a feed additive.
Technical Report: 1995 TAP; 2014 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 23); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
The United States Environmental Protection Agency (US EPA) regulates all non-food applications of ethanol, including its use as a pesticide and plant growth regulator. According to the Reregistration Eligibility Decision for Aliphatic Alcohols, ethanol and isopropanol were registered in the US as early as 1948 as active ingredients in indoor disinfectants (US EPA, 1995). Approximately 48 ethanol products were registered for use as hard surface treatment disinfectants, sanitizers and mildewcides as of 2012 (US EPA, 2012a). Ethanol is also the active ingredient in certain plant growth regulator products [2014 TR 118-123].

Manufacture
Both fermentation and chemical synthesis procedures are used in the commercial production of ethanol for the preparation of disinfectant solutions, spirits, and industrial fuel sources. A variety of methods are available for the fermentative production of ethanol from carbon sources such as starch, sugar and cellulose using natural and genetically engineered strains of yeast or bacteria. Ethanol can also be produced synthetically through the direct or indirect hydration of ethylene and as a by-product of certain industrial operations [2014 TR 43-48].

International Acceptance

Canadian General Standards Board Permitted Substances List
Canadian organic production standards permit the use of ethanol for a number of agricultural applications.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Alcohols, presumably including ethanol, may be used for cleaning and disinfecting livestock building installations and utensils.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Ethanol is allowed when mechanical, physical and biological methods are inadequate for pest control.

International Federation of Organic Agriculture Movements (IFOAM)
Synthetic ethanol is an approved additive and processing/post-harvest handling aid when organic and natural sources are not available.

Japan Agricultural Standard (JAS) for Organic Production
Ethanol may be used in the processing, cleaning, storage, packaging, and other post-harvest processes when physical or methods using naturally derived substances are insufficient.

Environmental Issues
Aside from accidental spills, the risk of environmental contamination from released ethanol is minimal. The release of strong acids and bases used in the production of ethanol due to improper handling/disposal could lead to serious environmental impairments and ecotoxicity in both terrestrial and aquatic environments. However, no incidents involving the release of these chemical feedstocks from ethanol production facilities have been reported. Further, lesser amounts of ethanol are constantly released to the environment from animal wastes, plants, insects, forest fires, and microbes without causing environmental impairment (HSDB, 2012). It is therefore unlikely that large-scale spills and associated environmental contamination will occur under the allowed use of ethanol as a sanitizer and disinfectant in organic livestock production [2014 TR 586-594].

Discussion
The Subcommittee highlighted the fact that to maintain efficacy, producers need a range of sanitizers so as to not have any one sanitizer lose its efficacy. Additionally, the benign manufacturing process of this material further confirms it as being aligned with OFPA.

Questions to our Stakeholders
None

Alcohols: Isopropanol

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (1) Alcohols. (ii) Isopropanol-disinfectant only.
Technical Report: 1995 TAP; 2014 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 23); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Isopropanol is used for a variety of industrial and consumer purposes, ranging from chemical and solvent applications to medical and consumer usage [2014 TR 54-55]. Agricultural uses of isopropanol

include the disinfection of production tools and surfaces and topical antisepsis during medical treatments. Livestock producers may use alcohol (i.e., isopropanol and/or ethanol) solutions for sanitizing and disinfecting surfaces (e.g., production implements, troughs, and floor drains) and during medical treatments as a topical disinfectant (Jacob, 2013; Dvorak, 2008) [2014 TR 60-63].

Manufacture
Chemical synthetic procedures are used in the commercial production of isopropanol that is used in the preparation of consumer-use disinfectants, industrial solvents, and specialty chemicals. Specifically, indirect, and direct methods for the hydration of petroleum-derived propylene are the two primary commercial processes to produce isopropanol. In addition, smaller amounts of industrial isopropanol are generated through the hydration of acetone over transition-metal catalysts (Papa, 2011; Merck, 2006). A variety of methods are also available for the fermentative production of isopropanol from carbon sources, such as starch, sugar, and cellulose, using genetically engineered yeast and bacteria (Papa, 2011) [2014 TR 37-44].

International Acceptance

Canadian General Standards Board Permitted Substances List
Canadian organic production standards permit the use of isopropanol for a number of agricultural applications.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Alcohols, presumably including isopropanol, may be used for cleaning and disinfecting livestock building installations and utensils.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Isopropanol is allowed when mechanical, physical and biological methods are inadequate for pest control.

International Federation of Organic Agriculture Movements (IFOAM)
Isopropanol is an approved synthetic equipment cleaner and equipment disinfectant. Isopropanol is also an allowed synthetic substance for pest and disease control and disinfection in livestock housing.

Japan Agricultural Standard (JAS) for Organic Production
Isopropanol may be used in the processing, cleaning, storage, packaging, and other post-harvest processes when physical or methods using naturally derived substances are insufficient.

Environmental Issues
Although isopropanol is a volatile organic compound and potentially contributes to the formation of ozone and photochemical smog, large-scale releases of isopropanol under the prescribed use pattern in organic crop production are unlikely [2014 TR 362-364]. Isopropanol may enter the environment because of its manufacture in addition to its solvent and chemical intermediate uses [2014 TR 366-367]. According to US EPA, isopropanol is slightly toxic to practically non-toxic based on acute oral and inhalation toxicity tests as well as primary eye and dermal irritation studies (EPA, 410 1995) [2014 TR 413-415].

Discussion
The Subcommittee highlighted the fact that to maintain efficacy, producers need a range of sanitizers so as to not have any one sanitizer lose its efficacy. Additionally, the benign manufacturing process of this material further confirms it as being aligned with OFPA.

Questions to our Stakeholders
None

Aspirin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (2) Aspirin-approved for health care use to reduce inflammation.
Technical Report: 1994 TAP; 2017 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 347-348); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
The following information and data was taken from the 2017 TR.

Aspirin is considered a pain reliever and fever reducer in the over-the counter, tentative final monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use by the U.S. Food and Drug Administration (FDA) (53 Federal Register 46204, Nov. 16, 1988 and 21 CFR 343). Aspirin is included under 21 CFR 343.12 and 343.13 for the prevention of cardiovascular events and the treatment of rheumatologic disorders. Aspirin is also listed at 7 CFR 205.603 as a synthetic substance allowed for the use in organic livestock production and is approved for health care use to reduce inflammation. Its half life is short in cattle, and it is not as beneficial in reducing pain as Flunixin. However, aspirin is usually given orally, which makes it easier and more usable for farmers in an emergency. Additionally, Flunixin must be administered under written orders of a licensed veterinarian, and it has a restriction annotation for a withdrawal time. A second pain medication approved for pain relief in organic livestock is Butorphanol (7 CFR 205.603(a)(5) and 21 CFR 522.246). Butorphanol is a synthetic opioid partial agonist analgesic; however, it also must be administered under a veterinarian's written orders, and it too is restricted by annotation to a withdrawal time. Aspirin inhibits the biosynthesis of certain hormone-like substances called prostaglandins, which accounts for most of its clinical effects. Depending on where in the body these prostaglandins are produced, they may trigger pain, inflammation, fever, or blood clotting. Following absorption, aspirin is hydrolyzed to salicylic acid, which is the active metabolite for its major clinical effects. Aspirin also inhibits platelet aggregation by irreversibly inhibiting prostaglandin cyclooxygenase.

Manufacture

The most prevalent method of synthesizing aspirin is via esterification. Salicylic acid is treated with acetic anhydride, an acid derivative, causing a quantitative chemical reaction that turns salicylic acid's hydroxyl group into an ester group (R-OH → R-OCOCH3; Figure 2). This process yields aspirin and acetic acid, which are considered byproducts of this reaction. Small amounts of sulfuric acid (and occasionally phosphoric acid) are almost always used as a catalyst. The chemical feedstocks for synthesizing aspirin are also manufactured through a chemical process. Salicylic acid is produced commercially via the Kolbe-Schmitt process. Here, phenol and sodium hydroxide react to make sodium phenoxide. The phenoxide comes into contact with CO2 to form sodium salicylate. The salicylate is acidified to give salicylic acid. The acid is usually crystallized from an aqueous solution to give a technical grade 99.5% salicylic acid product. For a pharmaceutical grade product, salicylic acid is further purified by sublimation. The commercial process for acetic anhydride was developed by Wacker Chemie in 1922 and uses a chemical reaction between acetic acid and ethenone at a low temperature and pressure.

International Acceptance

Canadian General Standards Board Permitted Substances List

The Canadian General Standards Board includes aspirin as a permitted substance for organic production 82 systems under CAN/CGSB-32.311-2015 for pain mitigation and inflammation reduction in livestock 83 84 Aspirin was not found to be listed under any other international standard for organic livestock production.

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

Aspirin was not found to be listed.

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

Aspirin was not found to be listed under CODEX for organic livestock production.

International Federation of Organic Agriculture Movements (IFOAM)

Aspirin was not found to be listed under IFOAM for organic livestock production.

Japan Agricultural Standard (JAS) for Organic Production

Aspirin was not found to be listed under JAS for organic livestock production.

Environmental Issues

Due to the rapid biodegradation/hydrolysis of aspirin and its active metabolite, salicylic acid, and the effectiveness of sewage treatment, there are no known reports of aspirin causing appreciable harm to surface or groundwater, soil, or agro-ecosystems. The background levels present in drinking water would result in the average exposure of approximately 0.05% of a typical daily dose over an average 70-year lifetime in humans. There is some evidence that acetylsalicylic acid (and/or active metabolites) can be toxic to aquatic invertebrates; however, current research into the impact of aspirin and pharmaceuticals in wastewater and aquatic ecosystems is not sufficient for definite conclusions.

Discussion

Aspirin is important to the humane treatment of organic animals and is commonly used to reduce inflammation. It is the only real-time responsive form for inflammation and fever management available. There are other products that are available but do not offer the same type of timely response to ensure animal health and wellbeing. This is also a proven remedy and is critical in organic livestock production.

This material satisfies the OFPA evaluation criteria.

Questions to our Stakeholders
None

Biologics—Vaccines

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (4) Biologics - Vaccines.
Technical Report: 2011 TR (GMO vaccines); 2014 TR (§205.611 aquaculture)
Petition(s): 2012 (§205.611 aquaculture)
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 3-4); 11/2005 NOSB sunset recommendation; 11/2009 NOSB recommendation (§205.105 excluded methods); 10/2010 NOSB sunset recommendation; 10/2014 NOSB recommendation (§205.105 excluded methods); 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation; 10/2019 NOSB recommendation (§205.105 excluded methods)
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
The Organic Foods Production Act (OFPA) specifically allows vaccines to be used in the absence of illness, while prohibiting all other medications from this use. Vaccination against bacterial or viral infections is a cost effective and efficient method or lessening animal suffering and disease. A vaccine contains, or produces in the vaccinated individual, an antigen that stimulates an immune response and enables protection from the disease and/or future infection. In the case of a disease outbreak, administration of vaccines may be required by government agencies.

Manufacture
Vaccines are produced through a variety of methods that use natural or genetically modified pathogens grown in a culture (yeast, bacteria, or cell), separation and purification of the vaccine, and addition of other materials that may enhance the efficacy of the vaccine. These methods will result in a live, modified live, or killed vaccine.

International Acceptance

Canadian General Standards Board Permitted Substances List
From 2011 Technical Review (TR), which focuses on GMO vaccines:
It appears that GMO vaccines are allowed in organic agriculture in Canada if other vaccines are not commercially available or are ineffective. CAN/CGSB-32.311-2020 table 5.3.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
From 2011 Technical Review (TR), which focuses on GMO vaccines:
EU standards (EU 2018/848) do not explicitly discuss GMO vaccines. GMOs are not allowed.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
From 2011 Technical Review (TR), which focuses on GMO vaccines:
According to the Codex Alimentarius Commission's guidelines for organic agriculture, "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." The standards do not clarify whether vaccines should be free of GMO organisms; however, it is noted in the guidelines that anything contained in animal feed must be from non-biotechnology-derived sources (Codex Alimentarius Commission, 1999).

International Federation of Organic Agriculture Movements (IFOAM)
From 2011 Technical Review (TR), which focuses on GMO vaccines:
According to the International Federation of Organic Agriculture Movements (IFOAM) draft 2010 standards, while "the deliberate use or negligent introduction of genetically engineered organisms or their derivatives is prohibited" for animals, seeds, fertilizers, and other materials, IFOAM makes an exception for vaccines (IFOAM, 2010).

Japan Agricultural Standard (JAS) for Organic Production
From 2011 Technical Review (TR), which focuses on GMO vaccines:
Recombinant technology is generally prohibited in the production of livestock products under the Japan Agricultural Standard (JAS) for Organic Production; however, a discussion of vaccines derived with GMO organisms is not provided (JMAFF, 2005).

Environmental Issues

Relevant sections of 7 U.S.C. 6518:
Questions 1-7 below. The responses inserted to questions 1-6 are from the 2011 TR. The response for #7 is based on the 2019 NOSB formal recommendation to the NOP.

(1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;
Vaccine additives may interact with other additives/adjuvants; however, reactions are limited due to the generally small amounts of chemical constituents present in vaccines. Furthermore, preservative/adjuvant combinations such as thimerosal [a mercury-based preservative] and aluminum salts are common, and generally any vaccines causing adverse reactions would not be allowed on the market unless risks were mitigated (Roth and Henderson, 2001)

(2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;
All vaccines (conventional and GMO) can be shed in the animal's feces and other secretions, although not all animals will shed vaccine DNA. This shed DNA could potentially infect other animals and spread the virus or bacteria in the environment. However, vaccines cannot survive in the environment for long periods of time. Vaccines contain aluminum salts and other chemical

adjuvants or additives; however, it is unclear if these substances are released in high quantities or whether they may impact the environment. Moreover, for both conventional and GMO vaccines, regulatory authorities consider additives when licensing them, establishing residue limits and withdrawal periods (required time between vaccination and slaughtering or milking) when necessary (OIE, 2010).

(3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;

Although accidental spills may occur during vaccination and some environmental contamination may occur during proper use (e.g., in coarse spray vaccine administration), extensive contamination of the environment with vaccine organisms is not anticipated due to low rates of shedding and the low survival rate of many pathogens in the environment (CFIA 2007 and 2008a). If manufacturers/livestock farmers do not correctly dispose of unused or expired vaccine materials, there is a potential for contamination of the environment with vaccine additives such as mercury-containing thimerosal (MDH, 2011). The impact of this contamination would depend on the specific circumstances of the manufacturing process or disposal.

(4) the effect of the substance on human health;

Regulators have noted that farmers or vaccine applicators could become infected during care of vaccinated animals that shed viral or bacterial organisms (CFIA, 2007 and 2008a). However, many of the diseases for which food animals are vaccinated cannot reproduce in either the target animal or humans (CFIA, 2007 and 2008a). For example, the vector for the porcine circovirus vaccine is Baculovirus, which is an insect virus not associated with disease in humans or animals. Risk assessments for GMO vaccines conducted by the Canadian Food Inspection Agency (CFIA) predicted that human health effects in workers would be minimal, as long as handlers took the necessary safety precautions to protect themselves (e.g., safety equipment such as gloves).

Some regulators and scientists have questioned whether the meat from GMO vaccinated animals may be harmful to humans who consume it (CFIA, 2006; Traavik, 1999). This issue is examined before licensure of a GMO vaccine. For example, the risk assessment report from the CFIA (2006) indicates that the Salmonella typhurium vaccine (live culture GMO vaccine) has a low health risk to humans exposed through spills or shedding by vaccinated animals. The vaccine strain is entirely eliminated before the broiler chickens are sold, so salmonella exposure to humans consuming vaccinated animals is unlikely. If any viral DNA is left in meat from vaccinated animals, it is expected to be broken down in the human gastrointestinal tract, thus, health problems are not anticipated from consumption (CFIA, 2010).

(5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;

GMO vaccines are meant to improve immunity to disease in vaccinated livestock animals.
All vaccines, including GMO vaccines, can cause unwanted side effects in vaccinated animals including swelling and irritation at the site of injection, fever, coughing (after nasal administration), respiratory distress, and reduced fertility (Morton, 2007). However, there is no difference in these symptoms between GMO and traditional vaccines, and all vaccines are evaluated for side effects by manufacturers.

(6) the alternatives to using the substance in terms of practices or other available materials;

Homeopathic remedies may be used to supplement or replace vaccines. For example, nosodes are a homeopathic remedy made from a pathological product (e.g., blood, saliva, or diseased tissue) that are administered orally (ECCH, 2008). Nosodes act similarly to vaccines by facilitating natural resistance mechanisms and increasing the cure rate of existing infections in animals. However, some studies have indicated that nosodes are not highly efficacious in preventing disease (McCroy and Barlow, in Morris and Keilty, 2006). Nosodes may be more effective if combined with conventional vaccines or if other homeopathic remedies are used. Natural herbal supplements like dandelion and chicory may also be used, but these are usually used to treat infection once it occurs, rather than to prevent infection (Morris and Keilty, 2006).

According to the European Council for Classical Homeopathy (ECCH), nosodes are "homeopathic remedies of biological origin that are derived from pathologically modified organs or parts of organs that are of human or animal origin, or from cultured micro-organisms that have been killed, or from products of the decomposition of animal organs, or from body liquids containing pathogens or pathological products" (ECCH, 2008). Nosodes act similarly to vaccines by facilitating natural resistance mechanisms and increasing the cure rate of existing infections in animals. Nosodes have been used to treat bovine mastitis, or inflammation of the mammary glands, in dairy cows. This condition is usually caused by bacteria entering the udder. Vaccines have been shown to be ineffective in preventing most cases of mastitis.

A study by Werner et al. (2010) found no difference between the cure rates of homeopathic treatments versus antibiotic treatments (allowed in conventional livestock only) for mild to moderate mastitis at the end of a 56-day treatment period. However, authors reported that the homeopathic remedy significantly increased the cure rate compared to placebo treatments. Despite the improvements compared to placebo-treated animals, authors noted that both homeopathic and antibiotic treatments had a relatively low cure rate, suggesting low efficacy for these two treatments (Werner et al., 2010).

(7) its compatibility with a system of sustainable agriculture.

The NOSB recognizes that vaccines play an important role in a sustainable agriculture system, from animal health to farm financial viability.

> *"The [NOSB] recognizes the importance vaccines play in the prevention of livestock disease. When an organic livestock producer loses one or more of their animals, there is the loss of the animal's production capability, as well as a loss of time and resources associated with the breeding and selection that resulted in that specific animal. Breeding and selection often take years or even decades. When an animal is lost, all of those years of breeding and their unique genetics are also lost. The use of vaccines as a preventative can protect this long-term investment in genetic improvement, and vaccines remain an important tool in the organic livestock producer's toolbox to protect the investments that producers have in individual animals as well as their herds or flocks." (2019 NOSB recommendation: Use of Excluded Method Vaccines in Organic Livestock Production)*

Discussion

The Livestock Subcommittee recognizes that use of vaccines can be critical to the success of organic livestock farms.

During the 2018 sunset review, there was universal agreement among producers, certifiers, and organic advocacy groups that vaccines are an important health maintenance tool on organic livestock farms, with agreement to relist with no other annotation.

However, there have been inconsistencies between certifiers about allowable vaccines. Two areas in the organic regulations address use of vaccines; one on the National List (NL) of allowed and prohibited substances at §205.603(a)(4), and one at § 206.105 (e). that details excluded methods.
In the past, some certifiers did not allow the use of excluded method vaccines, relying on the NOP regulation at §206.105 (e) which only allows use of this type of vaccine if it has gone through NOSB review and NOP placement on the National List. Other certifiers allowed any type of vaccine to be used, and may or may not have inquired if the vaccine has been produced through excluded methods. These certifiers relied on the presence of vaccines on the National List at § 205.603(a)(4) without any restriction or clarifying annotation.

In 2019, the NOSB passed a formal recommendation on this issue. It requested the NOP change the USDA organic regulations at § 205.105(e), from

(e) Excluded methods, except for vaccines: *Provided,* That, the vaccines are approved in accordance with §205.600(a).

to:

(e) Excluded methods, except for vaccines: Provided, That**, vaccines produced through excluded methods may be used when an equivalent vaccine not produced through excluded methods is not commercially available.**

The 2019 recommendation also directed stakeholders on how to determine whether a vaccine was produced with excluded methods, offered a list from the 2011 TR of those produced with and without excluded methods, and requested that the NOP and stakeholders enhance and update that list. At this date, the 2019 recommendation has not been adopted by the NOP.

This sunset review encompasses the entire class of synthetic livestock vaccines, including those made with excluded methods. The NOSB encourages the NOP to adopt the 2019 recommendation. In the meantime, our interpretation is that this listing fulfills the requirement at § 206.105 (e) for all livestock vaccines.

Questions to our Stakeholders
1. What are the most up to date organic regulations on GMO vaccines in other countries?
2. Are there concerns about components of vaccines besides the active ingredients?
3. Are certifiers interpreting the provisions at § 205.603(a)(4) and § 205.105(e) consistently, even though the 2019 NOSB recommendation has not been officially adopted?
4. Is the yellow highlighted wording above an acceptable interpretation of § 205.105(e)?

Electrolytes

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (11) Electrolytes - without antibiotics.
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 23); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Electrolytes should more properly be called veterinary electrolyte formulations. They are mixtures of multiple synthetic ingredients used to restore ionic balance, especially in oral rehydration solutions to correct dehydration and in oral and injectable formulations for the correction of milk fever. Key electrolyte ingredients include calcium, potassium, magnesium, and sodium salts, plus phosphates, dextrose, and other additives.

Electrolytes are considered animal drugs by the FDA. In USDA organic production, they may only be used when preventative practices are inadequate to prevent illness and may not be given in absence of illness. Electrolytes are used to restore ionic balance, treating a variety of metabolic conditions such as hypocalcemia, scours, milk fever, dehydration, mastitis, ketosis, acidosis, and more. Electrolyte balance is essential to maintain the normal physiology and health of livestock. When there is an imbalance of cations such as sodium, potassium, calcium, or magnesium, either too low or high, the health and life of the animal are at risk. Stages of life, environmental stresses, and stages of production, such as birthing an animal, are all conditions that can throw the electrolyte balance off and would necessitate the use of this material to restore health and well-being to the animal.

Manufacture
Electrolytes are produced through industrial processes and fermentation or may be mined. The major component of electrolyte formulations are salts and would have a variety of carriers or other ingredients (i.e., excipients) that enhance their properties, such as dextrose, citric acid, glucose, glycine, and more. The 2015 Technical Report (TR) has a detailed description of the various manufacturing processes.

International Acceptance
Canadian General Standards Board Permitted Substances List
Allowed as a livestock health care product.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Electrolytes are not mentioned specifically in 834/2007. However, 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).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Veterinary-prescribed drugs or antibiotics are approved if not used preventatively. Withdrawal periods must be doubled.

International Federation of Organic Agriculture Movements (IFOAM)
Veterinary-prescribed drugs or antibiotics are approved if not used preventatively. Withdrawal periods must be doubled, with a minimum of 14 days. Only three courses of drug use are allowed within a 12-month period.

Japan Agricultural Standard (JAS) for Organic Production
Electrolytes for organic animal production were not mentioned; therefore, it is unknown whether they are specifically allowed or prohibited (JAS 2007).

Environmental Issues
From the 2015 TR: "In summary, electrolytes used in treatment formulations for livestock operations are either non-toxic, slightly toxic, GRAS, or FDA-approved food additives." And "individual animals treated infrequently with injectable electrolytes to correct ionic imbalance should cause no unusual pollution compared to a normal, untreated animal."

Discussion
Commenters from the previous sunset review universally agreed that electrolytes are essential and should remain on the National List with no changes to the annotation. Organic certification agencies noted they certify many organic producers who use electrolytes to maintain healthy livestock, both mammals and poultry. Environmental and consumer groups, as well as companies that market organic livestock products, also supported the relisting of these materials.
The Livestock Subcommittee believes that electrolytes satisfy the OFPA evaluation criteria. They are used regularly and found to be essential by a large number of organic livestock producers.

Questions to our Stakeholders
None

Glycerin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (14) Glycerin - allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.
Technical Report: 2010 TAP
Petition(s): N/A
Past NOSB Actions: 10/1999 NOSB minutes and vote (pg. 441); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Technical correction (changed to "glycerine") published 12/12/2007 (72 FR 70479); Sunset renewal notice published 06/06/2012 (77 FR 33290); Technical correction (changed back to "glycerin") published 02/05/2015 (80 FR 6429); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use

Glycerin has over 1,000 uses; however, its use in organic livestock is limited to an ingredient in teat dips (§205.603(a)(11)). As an ingredient in teat dips it prevents teat irritation and improves skin conditioning. Glycerin does have some germicidal activity (Fox et al., 1990) [2010 TAP p. 1].

Manufacture

Glycerin is a byproduct of the soap manufacturing process. The oldest method of manufacture is by hydrolysis of natural fats & oils (either animal or vegetable): heat, steam, and pressure "split" the glycerin from the oil. The glycerin is concentrated in multistage evaporators and refined. Purification is achieved through either an ion exchange process or a distillation system, but it can also be produced synthetically from propylene. If only heat, steam or pressure is used to split the ester bonds to liberate free glycerol from fat (i.e., triglycerides), then this is a hydrolysis reaction catalyzed by physical forces and is compatible with organic criteria. However, if glycerol is formed by the chemical reaction of sodium hydroxide, then glycerol is produced by a chemically catalyzed hydrolysis reaction and may be considered synthetic [2010 TAP pgs. 1, 3].

International Acceptance

Canadian General Standards Board Permitted Substances List

Glycerin or other synthetics used as a teat dip are not addressed, but it does not appear to be prohibited.

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

Glycerin or other synthetics used as a teat dip are not addressed, but it does not appear to be prohibited.

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

Glycerin or other synthetics used as a teat dip are not addressed, but it does not appear to be prohibited.

International Federation of Organic Agriculture Movements (IFOAM)

Glycerin or other synthetics used as a teat dip are not addressed, but it does not appear to be prohibited.

Japan Agricultural Standard (JAS) for Organic Production

Glycerin or other synthetics used as a teat dip are not addressed, but it does not appear to be prohibited.

Environmental Issues

Glycerin breaks down to glucose which in turn readily breaks down in the environment to CO2 and H2O; there are no concerns with persistence or toxicity in the environment [2010 TAP pgs. 2].

Discussion
Glycerin falls under section 6517(1)(B)(i) of the OFPA code that describes livestock medicines.

Natural alternatives include castor oil and vegetable oils. There are some management tools for controlling mastitis, which include wiping debris from the teats, massaging the teat to loosen debris and stimulate milk letdown, wiping off the teat dip using individual cloths or paper towels, and applying the milking unit without air admission. None of the management tools seem to be effective alone. The public comments from 2018 were supportive of continued listing of glycerin as a livestock teat dip.

Questions to our Stakeholders
1. Are natural alternatives sufficient to remove glycerin from the National List?
2. What protocol is followed to determine if the glycerin used is produced through the hydrolysis of fats or oils instead of synthetically from propylene?

Phosphoric acid

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (25) Phosphoric acid - allowed as an equipment cleaner, *Provided*, That, no direct contact with organically managed livestock or land occurs.
Technical Report: 1999 TAP (pg. 25-34); 2003 TAP (pg. 21-24); 2023 Limited Scope TR pending
Petition(s): N/A
Past NOSB Actions: 10/1999 NOSB minutes and vote (pg. 441); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Phosphoric acid (H_3PO_4) has many uses. As a cleaner, it is generally used to remove rust and mineral deposits found on metal equipment such as boilers and steam-producing equipment. In dairy operations, it is used to remove calcium and phosphate salt deposits from processing equipment. Phosphoric acid is a hazardous substance.

In livestock facilities, phosphoric acid is used in Clean-In-Place (CIP) and non-CIP systems to remove encrusted surface matter and mineral scale found on metal equipment. The chemical reaction of the acid with minerals found in deposits makes them water soluble and thus easier to remove. For cleaning purposes, phosphoric acid is often combined with a surfactant, usually a detergent.

Phosphoric acid is sometimes used to remove resistant biofilms, colonies of microorganisms that attach to a surface and are protected by a self-generated protective film of polysaccharides (Muhammad et al., 2020).

Surfaces covered with mineral scale are particularly susceptible to biofilm attachment. It is important to note that when the mineral scale is dislodged, the biofilm is also dislodged. Smooth

Manufacture
There are two ways to create phosphoric acid.

1. Wet Process – Mined phosphate ore is treated with sulfuric acid, and the resulting phosphoric acid is separated from the calcium sulfate crystals produced. Many ore impurities exist; therefore, they can be further purified to obtain technical or food-grade phosphoric acid.

2. Thermal (furnace process) – Pure phosphorus is burned in excess air, and the resulting phosphorus pentoxide is then hydrated, cooled, and the acid mist is collected. It is considered purer than phosphoric acid achieved via the wet process and is considerably more expensive.

International Acceptance

Canadian General Standards Board Permitted Substances List
Phosphoric acid is listed as a "cleaner, disinfectant and sanitizer permitted on organic product contact surfaces for which a removal event is mandatory [for use] on dairy equipment." TR 2021

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Not listed – TR 2021

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Not listed – TR 2021

International Federation of Organic Agriculture Movements (IFOAM)
Phosphoric acid is listed in organic production and processing as an "equipment cleanser and equipment disinfectant only for dairy equipment" and as a "substance for pest and disease control and disinfection in livestock housing and equipment [for] dairy equipment." TR 2021

Japan Agricultural Standard (JAS) for Organic Production
Not Listed – TR 2021

Environmental Issues
The TR states that if stored, used, and disposed of properly, phosphoric acid utilized as a cleaning agent for livestock equipment and facilities will not interact very much with the agroecosystem nor come into direct contact with livestock. The acid will dilute quickly in the environment, and there are no toxicity issues directly from its breakdown products.

Effects on Human Health - The exact dangers depend on the solution's concentration strength, with higher concentrations presenting greater hazards. Phosphoric acid, at 85 wt. % is considered a corrosive chemical solution that can cause, through skin exposure and inhalation, severe skin burns, permanent eye damage, sore throat, shortness of breath, and even death—among other things.

Discussion

The Subcommittee reviewed the use, manufacturing process, and environmental concerns. A Limited Scope TR was requested, reviewed, and deemed sufficient for explaining alternative practices and products that can be used in place of phosphoric acid.

Questions to our Stakeholders

1. Is phosphoric acid essential for organic livestock production?
2. Would an annotation be beneficial to clarify when a rinse or purge is or is not required?

Lime, hydrated

Reference: 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable. (6) Lime, hydrated - as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 24); 04/2006 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Technical correction annotation change published 10/31/2003 (68 FR 61987); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use

Information and data was taken from the 2015 TR

Under the USDA organic regulations for livestock production, hydrated lime is only permitted for use as an external parasiticide. Regarding livestock applications, the final rule states that hydrated lime may not be used to cauterize physical alterations (medical treatment) or deodorize animal wastes.

The NOSB sunset review of hydrated lime pertains to applications of the substance for parasitic mite control in sheep, goats, cattle, and other livestock. Mange caused by parasitic mites is highly irritating for animals and can result in economic losses from wool damage (lamb and sheep) and reduced production of meat products (McNeal, 1999). Sheep scab—caused by the parasitic mite Psoroptes ovis—is a contagious, highly pruritic (i.e., itching) disease that results in the development of large, yellowish, scaly, crusted lesions, accompanied by damage to wool and hide. Sarcoptic and demodectic mange are problematic for producers of sheep and goats (CFSPH, 2009). In U.S. cattle production, sarcoptic mange (scabies), psoroptic mange, chorioptic mange, demodectic mange and psorergatic mange (itch mite) continue to be problematic skin diseases. Dips consisting of 2% hot lime sulfur (i.e., hydrated lime, elemental sulfur, and water) are recommended as treatments for parasitic mites associated with these diseases (Losson & Mignon, 2011).

Composition of hydrated or "slaked" lime consists primarily of calcium hydroxide [$Ca(OH)_2$] and magnesium hydroxide [$Mg(OH)_2$] at 50 - 95% and 0 - 50% of the substance, respectively. High purity forms of the substance contain greater than 90% calcium hydroxide.

Manufacture

The industrial production of hydrated/slaked lime involves two elementary reactions beginning with naturally occurring limestone deposits. In the first step, ground limestone—which contains predominantly calcium carbonate ($CaCO_3$) with smaller amounts of magnesium, silicon, aluminum, and iron oxide compounds—is thermally transformed into quicklime. Specifically, heating raw or minimally processed limestone to temperatures in excess of 900 ºC results in conversion of the calcium carbonate content of limestone to calcium oxide (CaO) in a material known as quicklime (equation 1). This thermal transformation occurs with liberation of carbon dioxide (CO_2) gas. In the slaking process, quicklime reacts exothermically (releases heat) with two equivalents of water to produce hydrated/slaked lime consisting primarily of calcium hydroxide [$Ca(OH)_2$] (equation 2). The normal hydration process is carried out at atmospheric pressure and temperatures of approximately 100 ºC. A variation of the normal hydration process involves reaction of quicklime and water under a high steam pressure of up to 1 MPa and at temperatures approaching 180 ºC to form hydrates. After hydration, the hydrated lime product is dried, milled, and air classified. Equations 1 and 2 below provide molecular depictions of the overall synthetic process.

$$CaCO_3 \xrightarrow{heat} CaO + CO_2\,(g) \qquad \text{(equation 1)}$$

$$CaO + H_2O \rightarrow Ca(OH)_2 \qquad \text{(equation 2)}$$

International Acceptance

Canadian General Standards Board Permitted Substances List

Canadian organic regulations permit the use of hydrated lime as a health care product and/or production aid in organic livestock production under Section 5.3 of the Permitted Substances Lists. According to this rule, hydrated lime is not allowed for use to cauterize physical alterations (medical treatment) or deodorize animal wastes. Hydrated lime is also listed in Section 4.3—Crop Production Aids and Materials—for use as a plant disease control agent only (CAN, 2011).

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

Organic regulations from the European Union do not permit the use of hydrated lime/calcium hydroxide as an external parasiticide in livestock production. However, Annex I of the European regulations allow "industrial lime from sugar production"—a byproduct of sugar production from sugar beet—as a fertilizer or soil conditioner. Calcium hydroxide may be used as a fungicide on fruit trees to control *Nectria galligena* in organic crop production under Annex II and as a processing aid in the production of processed organic foods of plant origin under Annex VIII (EC, 2008).

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 Foods (CAC/GL 32-1999) do not list hydrated lime/calcium hydroxide for use in organic livestock or crop production. However, calcium hydroxide is included in the list of "processing aids which may be used for the preparation of products of agricultural origin referred to in Section 3 of these guidelines" (Codex, 2013).

International Federation of Organic Agriculture Movements (IFOAM)
IFOAM Norms permit the use of "milk of lime" (i.e., hydrated/slaked lime, calcium hydroxide) for pest and disease control and disinfection in livestock housing and equipment (Appendix 5). Likewise, calcium hydroxide (slaked lime) is included in the "Indicative List of Equipment Cleansers and Equipment Disinfectants" (Appendix 4 – Table 2) for organic handling/processing. Calcium hydroxide is also listed as an approved food additive for maize tortilla flour and processing aid for sugar (Appendix 4 – Table 1). Lastly, application of calcium hydroxide (hydrated lime) is allowed on aerial plant parts only for plant disease control according to Appendix 3 of the IFOAM Norms (IFOAM, 2014). Hydrated lime is not explicitly listed as an approved miticide according to IFOAM.

Japan Agricultural Standard (JAS) for Organic Production
According to Table 4 of the Japanese agricultural standard for organic livestock products, slaked lime (calcium hydroxide) is an approved agent for cleaning or disinfecting of housing for livestock. Calcium hydroxide derived from calcium oxide (slaked lime) is also listed in Table 1 of the standard as an approved fertilizer and soil improvement substance (JMAFF, 2012). Hydrated lime is not explicitly approved as a miticide according to Japanese organic regulations.

Environmental Issues
Hydrated lime is released to the environment through various industrial waste streams and according to its use in agricultural production(HSDB, 2014). Both calcium and hydroxide—the principal atomic/molecular subunits of hydrated lime—are abundantly present in natural waters (Solvay, 2011; 402 WSDE, 2005); therefore, it is unlikely that small to moderate releases will adversely affect the aquatic or terrestrial environment. Large-volume accidental releases, however, could significantly raise the pH of receiving waters and soils, resulting in toxic effects to non-target organisms. Hydrated lime is considered practically non-toxic to slightly toxic to freshwater fish and invertebrates when added in quantities that do not lead to significant changes in water pH (WSDE, 2005). While certain strains of soil bacteria can tolerate extreme pH levels (e.g., pH 1.0 or 11.0), larger soft-bodied soil organisms are significantly more sensitive to changes in soil pH. Earthworms, for example, can only survive in the physiological pH range of 4.0 to 8.0 (USDA, 2002). Changes in soil pH due to application of alkaline hydrated lime can also affect the bioavailability of toxic heavy metal contaminants as well as essential micronutrients (Delhaize & Ryan, 411 1995; FAO, 2014). It is highly unlikely that hydrated lime from livestock treatments will be released to nearby soils in sufficient quantities to adversely impact the environment. Industrial production of the chemical precursor, quicklime (CaO), uses considerable amounts of energy and may release dust into the atmosphere. The use of more efficient modern kilns and bag filters can minimize the environmental impact of this process (Kenny & Oates, 2007).

Treatment and disposal is a potential complication associated with the use of hydrated lime and other miticide treatments in large volumes. In some cases, operators have discharged spent dip directly into watercourses or allowed the chemicals to soak into the ground near the dip facility (PAN-UK, 1997). Livestock operators using hydrated lime dipping stations for external parasite control should ensure that the resulting highly alkaline waste solutions are properly treated and disposed of to minimize the likelihood of environmental contamination.

Discussion
In the previous sunset review, the majority of public comment supported relisting. Many commenters suggested that hydrated lime was essential for organic production in that it prevents the spread of pests among herds. A few commenters said that there are no alternatives to hydrated lime. In subcommittee

for this review, it was noted that disposal of hydrated lime when treating a herd could be of environmental concern and seek stakeholder input.

Questions to our Stakeholders

1. Is hydrated lime regularly used currently for parasitic control in animal herds?
2. What are typical disposal protocols for spent lime after dipping?
3. Since the material was last reviewed, have additional commercially available natural alternatives emerged?

Mineral oil

Reference: 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(7) Mineral oil - for topical use and as a lubricant.
Technical Report: 2002 TAP; 2015 TR; 2021 Limited Scope TR
Petition(s): 2002 (medical treatment and feed additive)
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 24); 05/2003 NOSB recommendation (feed additive, not recommended) (pg.1443-1444); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review
Use
The USDA organic regulations currently permit the use of mineral oil in organic livestock production for direct topical application and as a lubricant under 7 CFR 205.603(b)(6). Regarding this use pattern, mineral oil acts as an external parasiticide when applied topically to animals infested with mites, lice, and other parasites. External parasites such as lice, mange mites, and various insects can adversely impact the health of individual animals and lead to economic losses for livestock. These parasites do not generally kill their hosts, but they can weaken the animal and, in some cases, transmit diseases to the host animals. Mineral oil is also used as a lubricant during artificial insemination (AI).

Mineral oil is administered internally to lubricate the intestinal tract to treat bloat and dislodge intestinal obstructions in cattle and other ruminants under 7 CFR 205.603(a)(20) Mineral oil—for treatment of intestinal compaction.

Manufacture
Crude petroleum oil is the predominant source of mineral oils used in organic and conventional agriculture, as well as food for human consumption, cosmetic products, and drugs. Refined mineral oils are obtained through physical separation, such as distillation and solvent extraction, and chemical conversion processes, including cracking, hydrogenation, alkylation, isomerization and/or other chemical transformations. The composition of mineral oil is dependent upon the crude oil source (e.g., location of procurement) and the processing that occurs in the refinery, such as physical separations and chemical conversions. Because of the complexity of the mineral oil mixtures, refined mineral 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 well as polycyclic aromatic hydrocarbons (PAHs). PAHs may be toxic, and some are carcinogenic in long-term exposures.

The industrial production of highly refined, food-grade mineral oils involve chemical processing and refinement using various chemical reagents and/or catalysts. Crude oil is desalted, distilled, and subjected to solvent extraction, de-aromatization with fuming sulfuric acid or sulfur trioxide, and/or catalytic hydrocracking treatments to reduce the concentration of polar constituents containing heteroatoms (nitrogen, oxygen, and sulfur atoms) as well as polynuclear aromatic hydrocarbons (PAHs) and other aromatic compounds. Crude oil is considered an economically significant natural resource throughout the world, and would likely be classified as a naturally derived, non-synthetic substance according to NOP definitions. To produce mineral oil however, 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). Thus, the NOSB has classified mineral oil as "synthetic".

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).

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."

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."

International Federation of Organic Agriculture Movements (IFOAM)
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).

Environmental Issues
In the 2007 risk assessment for mineral oils, US EPA indicated that most manufacturers are currently using modified refining and cleanup processes to remove the more toxic components and generate refined minerals largely devoid of PAHs as well as nitrogen and sulfur compounds. Because of their complexity, it is not possible to resolve mineral oil mixtures into individual components for quantification. Indeed, an enormous number of individual components— from compounds of varying carbon chain length to isomers of the same carbon chain length—are constituents of crude and refined mineral oil mixtures (EFSA, 2012).

Mineral oils may be classified as highly refined or mildly treated/untreated. 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 such as PAHs compared to untreated and mildly treated oils. 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.

Discussion
Mineral oil for veterinary use appears to have little negative effect on the animal or the environment, while being critical for humane treatment of some serious animal health issues. The EPA approves pesticides, including the use of mineral oil as an external parasiticide under this listing.

As a veterinary medicine for use in artificial insemination (AI), however, the FDA has jurisdiction. The Livestock Subcommittee is unclear how this would function in practice, given that the FDA does not approve generic materials or ingredients, only complete formulated products. Are only 100% mineral oil products allowed by organic certifiers?

The majority of 2018 commenters considered mineral oil essential for organic agriculture and suggested re-listing. Most commenters indicated that they use mineral oil as a spray, and use it minimally (as little as one cup per animal) to control flies and mites. One commenter suggested de-listing mineral oil citing alternative substances to control pests.

Questions to our Stakeholders

1. Are there products used for artificial insemination and parasite control that are not 100% mineral oil? How are they checked for compliance with the Organic Regulations by farmers, technicians, vets, or certifiers?
2. Is mineral oil essential for livestock parasite control?

National Organic Standards Board
Materials Subcommittee
2023 Research Priorities Discussion Document
Spring 2023

Executive Summary

Overall: The National Organic Standards Board (NOSB) presents an annual list of research priorities for organic food and agriculture, a process originally established by the Board in 2012. 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. Evaluate ways to prevent and manage parasites in livestock, examining breeds, geographical differences, alternative treatments, practices, and pasture species.
2. Determine the efficacy of natural parasiticides and methodologies, including but not limited to, nutritional programs, use of herbs, essential oils, homeopathic remedies, diatomaceous earth, pasture rotation, mixed species grazing, and utilizing the genetic pool within breeds
3. For all livestock species including laying hens to control A. galli and H. gallinarum.
4. Evaluate natural alternatives to DL-Methionine in a system approach for organic poultry feed program.
5. Develop a dairy program to address climate change mitigation strategies where production capabilities are not hindered, and effective forage rotations are maximized.
6. Develop balanced organic livestock rations that incorporate high percentages of diverse, regionally adapted grain crops to reduce the reliance on corn and soybeans and allow farmers to realize more marketing opportunities for a robust crop rotation.

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 (including specific considerations related to copper use in organic rice production) 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 problem insects and weeds.
8. Factors impacting organic crop nutrition, and organic/conventional nutrition comparisons.
9. Side-by-side trials of approved organic inputs, both synthetic and natural, 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.
13. Alternatives to eliminate usage and remediation strategies to mitigate contaminated areas for Per- and Polyfluoroalkyl (PFAS) substances.
14. Assessing the economic impact of GMO contamination on organic crops.
15. The extent and impact of plastic use in organic crop production.

Food Handling and Processing

1. Sanitizers: Effective alternatives of sanitizers, effect on occupational human health and environment, effectiveness of rotational use strategies with the sanitizers currently on the National List
2. Effect of various types of food packaging on organic products, including suitable alternatives to BPA (Bisphenol-A) for linings of cans used for various products, plastic use, antimicrobial nanoparticle surface coatings of packaging.
3. Research on the creation of an overarching ancillary ingredient review process for materials used in processing and handling vs reviewing ancillaries as part of the petition or sunset review process, including cost/benefit of each process.
4. Alternatives to conventional celery powder for curing organic meat.
5. Research on best practices for identifying potential vectors of heavy metal contamination in organic systems, including strategies for effective testing in soils, water, organic processing, etc. that could lead to the identification and prevention of heavy metals transgression in organic systems.
6. Evaluation of the essentiality of 205.605(a), 205.605(b), and 205.606 substances and the suitability of organic alternatives in applicable food formulations via laboratory testing, sensory evaluation, and/or market analysis.

Materials / 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
2023 Research Priorities Discussion Document
Spring 2023

INTRODUCTION

The National Organic Standards Board (NOSB) presents an annual list of research priorities for organic food and agriculture based on a process originally established by the Board in 2012. The NOSB's Livestock, Crops, Handling, and Materials/GMO Subcommittees proposed an updated set of priorities at the Fall 2022 Board meeting. The Board requests input from stakeholders on the 2023 research priorities and will review those comments for the Fall 2023 proposal.

BACKGROUND

The list of priorities is revisited each year by the NOSB. The list is made meaningful by input through the written and oral public comments shared with the Board, through the expertise of the Board itself and through interactions throughout the year with those engaged in some dimension of the organic farm to fork continuum. When the NOSB has determined that a priority area has been sufficiently addressed, it is removed from the list of priorities. Priorities are also edited each year to reflect the existing need more accurately for new knowledge.

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

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

Livestock

1. 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, 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 over time? 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? An area of particular concern is control of *A. galli* and *H. gallinarum* in laying and replacement chickens.

2. Evaluation of Methionine in the Context of a System Approach in Organic Poultry Production - Methionine is an essential amino acid for poultry. Prior to the 1950's, poultry and pigs were fed a plant and meat-based diet without synthetic amino acids such as methionine. One former NOSB member stated, in §205.237(5) (b), “We have seemingly made vegetarians out of poultry and pigs”. As the organic community moves toward reducing, removing, or providing additional annotations to synthetic methionine in the diets of poultry, a heightened need exists for the organic community to rally around omnivore producers to assist in marshaling our collective efforts in finding viable alternatives to synthetic methionine and to help find approaches for making them more commercially available.

Continued research on the use of synthetic methionine in the context of a systems approach (nutrition, genetic selection, management practices, etc.) is consistent with the NOSB unanimous resolution passed at the La Jolla, California, Spring 2015 board meeting. A systems approach that includes industry and independent research by USDA/ARS, on farms, and by agricultural land grant universities is needed for:

A. evaluation of the merits of natural alternative sources of methionine such as herbal methionine, high methionine corn, and corn gluten meal, potato meal, fishmeal, animal by-products, and other non-plant materials in organic poultry production systems. Additional research on the more promising alternatives to bring them into commercial production is also encouraged;
B. 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;
C. management practices impacting the flock’s demand for methionine should be included, such as flock management practices, access to pasture, and pasture management; and
D. 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.

The fruition of these types of research topics could take years to achieve; however, an aggressive and/or heightened research focus could lead to findings that can positively impact the organic poultry industry and the organic brand.

3. Develop a dairy program to address climate change mitigation strategies where production capabilities are not hindered, and effective forage rotations are maximized. - To further acknowledge the central role the certified organic industry will play in the fight against climate change, an opportunity exists to both empower the economic resilience of organic dairy farmers while harnessing the soil building potential of diverse perennial and annual forages, we encourage the research community to dedicate resources to the following need:

A. Identify an index of dairy cattle genetics to which producers could breed their existing herds and achieve a minimum of 12,000 lbs. of milk production per year on 100% forage diets. In considering the genetics selected, also identify animals bred for longevity as the more lactations on a cow, the more spread out the fixed costs of raising her as a heifer becomes.

B. To assist dairy farmers in having the tools to consider a forage-based rotation for their herds, research and identify crop rotations that have three functions: produce high quality forage, maximize soil building, and result in the most profitable outcome for the dairy producer.

4. Develop balanced organic livestock rations that incorporate high percentages of diverse, regionally adapted grain crops to reduce the reliance on corn and soybeans and allow farmers to realize more marketing opportunities for a robust crop rotation. - The US organic livestock demand and consumption of organic corn and soybean meal in feed rations exceeds US production. To help encourage farmers to utilize robust crop rotation programs that are specific to their geographical region, give livestock producers more product availability/flexibility of ingredients, and reduce the dependence on corn and beans, there needs to be proven equitable rations in all livestock segments that include alternative energy and protein sources.

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.

Further research into certain diseases in vegetables (including but not limited to early blight, late blight, downy mildews, etc.), fruits (including, but not limited to, apple scab, fire blight, peach leaf curl, little cherry disease, X-disease, grape botrytis, etc.), and soilborne or other disease affecting organic crops that require mitigations such as approved fungicides or the increased use of copper.

Specifically related to organic rice production and the ongoing concern about copper usage related to that crop (although not exclusive to it), more research is needed on disease management that:

1) supports a systems-based approach to reduce the needs of copper materials;
2) addresses a breeding component for disease resistance (where copper is used);
3) addresses alternate formulations to help reduce elemental copper;
4) speaks to developing biological agents to (hopefully) displace copper with a softer alternative;
5) evaluate plant nutritional strategies to lessen disease impacts.

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 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 of Problem Insects and Weeds - There is a large pool of research on the control of insects and weeds using organic methods. Many controls use a systems approach and are quite effective. However, some arthropod pests including new invasive species, are problematic, and in several cases the organic control options are very limited or nonexistent. The organic community needs more information on their biology, life cycle weak points, and natural enemies to implement targeted and systemic management.

Examples are:

- spotted wing drosophila
- brown marmorated stinkbug
- Spotted lanternfly
- Swede midge
- Leek moth
- Corn rootworm beetle (northern and western)
- Cutworms (army, western bean, etc.)
- and others

Weed management is one of the greatest challenges to successful organic crop production. Development of integrated organic management strategies that effectively control weeds in specific cropping systems without excessive tillage continues to be a top research priority for organic producers. For instance, Canadian thistle, pigweed (including invasive palmer amaranth and waterhemp), wild sunflower, giant ragweed, cocklebur, and other perennial weeds can be very difficult to control in reduced tillage systems.

Research into new technologies such as electroshock weeders, interrow mowers, camera-guided cultivators, laser-weeders incorporating AI (artificial intelligence) and robotics, propane flamers, etc. is critical to success in field crops, whereas tarping, solarization, and a new generation of hand tools have great potential in small- to medium-scale vegetable crops. For large scale vegetable as well as row-crop producers, strip tillage and compatible weed management tools including row cleaners, finger weeders, and high residue cultivators can combine reduced tillage and cover crops into one practice set.

Future cropping systems will utilize multiple elements of soil, crop, pest, and weed management. The integration of tools such as weed-suppressive cover crops and rotations, livestock grazing, flaming, beneficial insect habitat, intercropping, etc. into annual and perennial cropping systems needs more research.

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.

13. Per- and Polyfluoroalkyl (PFAS): Alternatives to eliminate usage and remediation strategies to mitigate contaminated areas

Background: There is a need for increased research examining PFAS substances. PFAS a broad term that contains thousands of chemicals used in consumer, commercial, and industrial products. There is evidence that PFAS substances, also known as "forever chemicals," contaminate farmland, water, food, consumer goods, and more. PFAS substances can negatively impact human health and animal health in direct and indirect ways over time.

Many researchers and scientists are looking into matters related to PFAS substances. The NOSB is requesting additional research on the following:

- To find safe and eco-friendly alternatives so PFAS substances can be eliminated in the production of consumer, commercial, and industrial products to prevent any future contamination.
- To quantify the impact of PFAS substances on the environment, including agricultural land and water, and human and animal health.
- To identify tools to identify, measure, and remediate PFAS contamination that has already occurred in the environment and on organic and non-organic farmland.

14. Assessing the economic impact of GMO contamination on organic crops.

Background: Genetically Engineered Crops and Organic Crops can exist in adjacent fields. There are many risks, including cross-pollination, that are mitigated as best as possible by the growers involved, but much to the expense of the organic producer. Organic growers use borders, at a minimum of thirty feet, off-set planting timeframes to avoid cross-pollination (causing organic crops to be planted sometimes at undesirable times) and change cropping rotations, all to mitigate risk.

Research is needed on the following:

- The total cost of GMO contamination on organic farms for the full range of crops with GMO varieties (including lesser-studied crops like apples, canola, summer squash, sweet corn, etc.).
    - This would include recommended buffer requirements, recommended planting delays windows, testing costs, a variety of pollen receptivity restrictions, loss of sales, etc.
- Are USDA coexistence provisions adequate?
- Drifting chemicals can be considered “chemical trespassing.” Could pollen contamination be considered trespassing as well?

15. The extent and impact of plastic use in organic crop production.

Both consumers and producers are concerned about the use of plastics in organic agriculture.

The Crop’s subcommittee is requesting research and information on the following:

- Statistics on current use (acreage and quantity) of crop production plastics, including mulches, drip tape, containers, row covers, tarps, high tunnels, greenhouses, etc.
- What is the turnover and fate of these plastics?
    - This information is needed for the US and major production areas such as Mexico, Spain, Chile, Holland, Canada, etc.
- What are the economics of alternatives?
- If approved biodegradable biobased mulch films are developed, how many organic farmers would switch to them, and what would impact overall plastic usage?
- Can longer-term mulches such as landscape fabric reduce overall plastic use if allowed to remain in place over several years?

Handling

1. Sanitizers: Effective alternatives of sanitizers, effect on occupational human health and environment, effectiveness of rotational use strategies with the sanitizers currently on the NL

- Can research projects that emphasize and reinforce collaboration between researchers, agencies that regulate sanitizers and food safety, and NOP be designed with the goal of developing an alternative process for evaluating sanitizers and sanitation practices for use by organic operations?
- Is there a measurable transfer of sanitizer residue to organic food following the sanitization of food contact surfaces? If residues are not found, is it even necessary for the National List to regulate surface/environmental sanitizers? (This topic should not be limited to only National List materials and should also include sanitizers such as quaternary ammonia compounds, or QACs.)
- What amount of sanitizer/disinfectant remains on the surface of various organic products after a processing or packing step that includes direct treatment with a sanitizer? That includes a water bath containing water treated with a sanitizer?
- Could the development of robust, post-harvest handling standards better identify which sanitation, disinfectant, or treatment practices have an impact on organic integrity? Could expanded handling standards assist in regulating and enforcing the use of sanitizers instead of, or in addition to, the National List?
- Could restructuring the National List to separate sanitizers from ingredients and processing aids create a pathway to development of an alternative set of evaluation criteria for sanitizers?
- What would the impact on handlers and processors be if any one of the sanitizers were removed from the National List?

2. Effect of various types of food packaging on organic products, including suitable alternatives to BPA (Bisphenol-A) for linings of cans used for various products, plastic use, antimicrobial nanoparticle surface coatings of packaging.

3. Research on the creation of an overarching ancillary ingredient review process for materials used in processing and handling vs reviewing ancillaries as part of the petition or sunset review process, including cost/benefit of each process.

- Full proposal draft language: The topic of ancillary substances contained in substances on 205.605 and 205.606 and how the NOSB should review them has been a topic of discussion since 2013 but has not reached a full resolution. The current process is to review individually during the petition or sunset review process. However, as noted by stakeholder comments this has the potential to result in different decisions due to the gap in time, available information and/or persons responsible for conducting the review being different. It would be beneficial to analyze and compare different strategies for conducting ancillary substance review in a more comprehensive manner as opposed to the current individual review process that includes a cost/benefit analysis of each proposed review strategy.

4. Production of celery for celery powder yielding nitrates sufficient for cured meat applications, and investigation of agriculturally derived alternatives.

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

5. Research on best practices for identifying potential vectors of heavy metal contamination in organic systems, including strategies for effective testing in soils, water, organic processing, etc. that could lead to the identification and prevention of heavy metals transgression in organic systems.

- *[intentionally does not include further detail]*

6. Evaluation of the essentiality of 205.605(a), 205.605(b), and 205.606 substances and the suitability of organic alternatives in applicable food formulations and/or analysis of the barriers to organic production via laboratory testing, sensory evaluation, and/or market analysis

- Full proposal draft language: In review of substances on the National List at 205.605 and 205.606 during the sunset process questions related to essentiality and commercial availability of organically produced substances, and if supplies are lacking knowledge of the barriers to organic production, are often the focus of the review by the Handling Subcommittee and of stakeholder comments. There are often commenters that blanketly state that all items should be removed from 205.606 - inferring that there should be the ability to produce all of these substances organically. Therefore, it would be beneficial to comprehensively understand the current status of essentiality of these substances and if organic alternatives exist; and if not what the barriers are that prevent a vibrant organic market for these substances.

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.

Subcommittee Vote:
Motion to accept the discussion document on the 2023 NOSB Research Priorities
Motion by: Wood Turner
Seconded by: Carolyn Dimitri
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Approved by Wood Turner, Materials Subcommittee Chair, to transmit to NOSB, February 14, 2023

National Organic Standards Board
Materials Subcommittee
Excluded Methods Discussion Document
Plant Breeding Techniques "TBD List"
February 14, 2023

Summary of Request:

The Materials Subcommittee is seeking feedback on the remaining To Be Determined (TBD) List in the Excluded Methods Plant Breeding Techniques discussion document. The goal is to determine whether the techniques are excluded methods under the legal definition at 205.2, OFPA criteria, as well as previous NOSB recommendations. . The Materials Subcommittee has requested a limited scope TR for induced mutagenesis in order to facilitate the work and has included questions for stakeholder feedback in this discussion document.

Summary of Review:

<u>**Draft Definitions**</u>

TILLING (Targeted Induced Local Lesions in Genomes):

This technique has two parts:

First, mutations are induced in seeds by treating them with mutagenic chemicals, or, less commonly, using environmental stresses or radiation. These provide an increased frequency of point mutations distributed randomly in the genome. In Eco-TILLING, mutagens are not used. Genetic diversity is obtained by using diverse seed sources.

Second, samples are taken from seedlings grown out from step one, and tested to find those with mutations in a targeted location within the plant genome. Desired seedlings can then be used for breeding.

Double Haploid (DH):

Double haploid is a genotype of two identical chromosomes from spontaneous or artificial doubling, which produces pure homozygous or inbred lines. This greatly expedites breeding procedures, slimming a 5-or-6-year task to only one generation. To date, maize is the predominant crop bred using this technique.

There are two methods to produce DH plants. In-vivo and in-vitro with the use of synthetic chemicals to double chromosomes.

Firstly, in-vivo methods accomplish double haploidy with cross pollination techniques using irradiated pollen or haploid inductor or inducer lines. Megaspores/ovule cells can be induced with pollen of the inductor lines to develop haploid embryos without recombination of genes. The haploid embryo can spontaneously double its chromosomes to become homozygous double haploid plants. Double haploidy can be obtained all in-vivo.

Secondly, in-vitro methods are plant tissue cultures (often times treated with phytohormones to stimulate growth) of haploid cells from either microspores/pollen in androgenesis or megaspores/ovules in gynogenesis which differentiate into haploid embryos then haploid plants. These haploid plants will duplicate their chromosomes spontaneously or with the application of colchicine, a synthetic chemical resulting in a homozygous double haploid plant.

Induced Mutagenesis:

Mutagenesis is a process by which the genetic information of an organism is changed by the production of a mutation(a). The agents that cause mutation are called mutagens(b). Mutation induced by mutagens is called induced mutation.

> [a]*In biology, a mutation is an alteration in the nucleic acid sequence of the genome of an organism, virus, or extrachromosomal DNA)*
> [b]*In genetics, a* ***mutagen*** *is a physical or chemical agent that permanently changes genetic material, usually DNA, in an organism and thus increases the frequency of mutations above the natural background level.*

Mutagenesis may occur spontaneously in nature, or as a result of exposure to mutagens. It can also be achieved experimentally using laboratory procedures. A mutagen is a mutation-causing agent, be it chemical or physical, which results in an increased rate of mutations in an organism's genetic code. In nature mutagenesis can lead to cancer and various heritable diseases, and it is also a driving force of evolution.

Transposons:

A chromosomal segment that can undergo transposition, especially a segment of bacterial DNA that can be translocated as a whole between chromosomal, phage, and plasmid DNA in the absence of a complementary sequence in the host DNA. Also called jumping gene.

A transposable element (TE, transposon, or jumping gene) is a nucleic acid sequence in DNA that can change its position within a genome, sometimes creating or reversing mutations and altering the cell's genetic identity and genome-size.

Questions:
1. Please provide feedback on the draft definitions along with relevant peer reviewed scientific sources.
2. In the use of each technique, please describe the individual steps and the application of prohibited substances or excluded methods that may be employed in that step towards creating new varieties of plants or animals, if applicable.
3. For each technique, describe/list plant varieties, clones, etc. which may have been developed and are currently being used in organic systems.

To Be Determined "TBD list":

Terminology				
Method and synonyms	**Types**	**Excluded Methods**	**Criteria Used**	**Notes**
TILLING	Eco-TILLING	*TBD*		Stands for "Targeted Induced Local Lesions in Genomes." Standard TILLING includes induced mutagenesis. Eco-TILLING does not.
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.

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; it 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; it 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.
Cell and Protoplast Fusion	Donor and/or recipient cells are outside taxonomic plant family; and/or recombinant DNA technology is employed	YES	Terms Defined 205.2	See NOP Policy Memo 13-1.

Methods Allowed:

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.
Cell and Protoplast Fusion	Recipient and/or donor cells are within the same taxonomic plant family; must be achieved without recombinant DNA technology	NO		NOP Policy Memo 13-1; Definition of Modern Biotechnology

Subcommittee Vote:

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

National Organic Standards Board
Materials/GMO Subcommittee
Discussion Document - Technical Report (TR) Template Update
Spring 2023

Intro/Background:
The Materials Subcommittee (MS) is seeking feedback on an update to the Technical Report (TR) template. The NOSB Policy and Procedures Manual (PPM)[1] defines a Technical Report as:

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

According to the PPM (Appendix A), *"A Subcommittee cannot proceed with a recommendation to list a material if it is determined that there is insufficient valid scientific information on that material's impact on the environment, human health, and its compatibility with organic principles."* The NOSB is presenting this discussion document to provide the community of experts with an opportunity to comment on updates to the format and an opportunity to include relevant questions for materials that are at risk for Excluded Methods. The Materials Subcommittee, with technical assistance from the National Organic Program (NOP) and the Organic Materials Review Institute (OMRI), has included the existing TR template for Handling (Appendix B1) and Crops/Livestock (Appendix C1), along with proposed updated templates for Handling (Appendix B2) and Crops/Livestock (Appendix C2).

Note: the NOSB has within its mandate to add specific questions to the TR template when necessary

Goals:
a. Harmonize the flow of information requested in the TR with the petition template (NOP 3011, 4.2[2]) and the Organic Foods Production Act (OFPA) criteria[3], while reducing redundancy.
b. Add relevant questions/sections for Excluded Methods discovery.

Discussion:
The Materials Subcommittee requests help to try to solve a gap/problem with the scope and format of TRs. The intended use of TRs is for the evaluation of specific substances. However, the Materials Subcommittee would like to request a TR for breeding methods, like induced mutagenesis, which may fall in the class of Excluded Methods. In the course of this work, the Materials Subcommittee discussed the possibility of using the TR process to evaluate many kinds of methods and practices in addition to the evaluation of specific substances. Excluded Methods may include both unique methods and specific materials in the creation/manufacture of a technique that is being evaluated for use in an organic system. The Materials Subcommittee is not advocating for a change in the TR process, but instead has

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[1]National Organic Standards Board Policy and Procedures Manual https://www.ams.usda.gov/sites/default/files/media/NOSB-PolicyManual.pdf
[2]NOP 3011 Procedure - National List Petition Guidelines, 4.2: Items to be Included in a Petition, https://www.ams.usda.gov/sites/default/files/media/NOP3011PetitionProcedures.pdf
[3]Organic Foods Production Act, 7 U.S.C. 6517(c)(1)(B)(i), https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title7-section6517&num=0&edition=prelim

framed several questions around the issue. The Materials Subcommittee asks the community's feedback/ideas on how best to proceed.

Questions to our Stakeholders:

1. Are there other relevant sections of OFPA, or the NOSB PPM, that refer to the TRs that could provide further information on improving the TR process? Is the Materials Subcommittee missing resources outside of OFPA and the NOSB PPM?
2. Where in the TRs is the best places for questions? What questions should be included to help the NOSB identify excluded methods in the organic supply chain?
3. Who uses TRs and for what purposes?
4. Is the TR template functional for all types of materials, methods, and practices? If not, does the NOSB need to develop another report template for methods/practices?

Subcommittee Vote
Motion to accept the discussion document on the TR template updates.
Motion by: Mindee Jeffery
Seconded by: Dilip Nandwani
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Appendix A

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

Steps in the material review process for a new petition:

1. NOP receives a petition, reviews it for completeness and eligibility according to OFPA and the petition guidelines. NOP forwards the petition to the appropriate Subcommittee with a courtesy copy to the Materials Subcommittee.
2. Subcommittee (SC) determines sufficiency of the petition. If found insufficient, the subcommittee will notify the NOP of additional questions or information, and NOP will send that feedback to the petitioner.
3. Subcommittee (SC) determines if a technical review (TR) is needed.
4. SC may develop a discussion document based on the petition and forward that document to the full board for posting, and to solicit public discussion.
5. Technical report is completed and sent to the subcommittee for review.
6. TR sufficiency is determined by SC, and the TR is posted on the NOSB website by the NOP.
7. SC reviews substance, develops proposal, discusses proposal and votes, and submits for posting ~45 days prior to public meeting.
8. The NOSB members analyze comments and vote on the proposal at the public meeting.
9. The NOSB chair delivers the final recommendations to NOP.

Step 1: Receipt of Petition

During this phase the NOP will:

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

Ineligible petitions include:

- Formulated (brand name) products
- Food additive without FDA approval
- Pesticide without EPA tolerance or tolerance exemption
- Requests to add substances already allowed
- Synthetic macronutrient (e.g., NPK) fertilizers
- Materials otherwise prohibited by the USDA organic regulations (e.g., sewage sludge, GMOs, etc.)
- Previously petitioned/rejected materials (if no new information is provided)

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[4] National Organic Standards Board Policy and Procedures Manual https://www.ams.usda.gov/sites/default/files/media/NOSB-PolicyManual.pdf

Upon determination of completeness and eligibility, NOP will:

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

Step 2: Subcommittee (SC) determines sufficiency of the petition

During this phase, the applicable NOSB Subcommittee has 60 days to review the petition and determine if the petition is sufficient for SC review. This decision may be based on the following:

- Is there sufficient information in the petition for the SC to determine why or for what purpose the material is being petitioned?
- what is the petitioners proposed wording for listing the material?
- Is the information presented in the petition clear and consistent so that a proposal may easily be developed?

If the petition is found insufficient, the Subcommittee will notify the NOP of additional questions or information, and NOP will send that feedback to the petitioner.

Step 3: Subcommittee determines whether a Third-Party Technical Review is required

During this phase, which may occur simultaneously with the determination of petition sufficiency, the applicable NOSB Subcommittee has 60 days to review the petition and determine whether a third-party technical review is required. This decision is based on the following:

- Is there sufficient information in the petition that makes a technical review unnecessary?
- Do any previous technical reviews of other materials provide sufficient information?
- Can the Subcommittee reasonably research any needed technical information?
- Can sufficient information be obtained from public comment?
- Does the Subcommittee have the expertise needed to address the questions related to the petition? This includes impact on the environment, impact on human health, and sustainability and compatibility with organic principles.

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

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

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

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

Option for a Technical Advisory Panel (TAP)
OFPA states: "The NOSB shall convene technical advisory panels to provide scientific evaluation of materials considered for the National List."(7 USC 6518 (k)(3))
The NOSB has not convened independent Technical Advisory Panels since 2005. Currently the NOSB is relying on information within the Technical Reports provided by the NOP and public comment to make their final recommendations
In some cases, NOSB may wish to convene a TAP instead of requesting a TR, for review of complex or controversial substances.

Step 4: Subcommittee may develop a discussion document based on the petition and forward that document to the full board and post it for public discussion

At the discretion of the Subcommittee (SC), the SC may develop a discussion document to:

- Solicit public comment about the material prior to a proposal being developed
- Provide opportunity for full board discussion prior to a proposal being written
- Allow the petitioner to hear public and board comments and give them an opportunity to submit petition addendums prior to a Subcommittee proposal and vote

A petition discussion document is optional, but if used, could allow for full board discussion of a material while a technical review is in process or if the SC determines a full board discussion would benefit the writing of the SC proposal on the material.

Step 5: Third Party Technical Review
During this phase the NOP will:

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

Third party experts may consist of contractors, or employees of the USDA, such as AMS

Science and Technology, AMS Agricultural Analytics Division, Agricultural Research Service, or other federal agencies with appropriate expertise, as needed.

Step 6: Technical Review Sufficiency Determination

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

Review the draft TR to ensure that it:

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

The Subcommittee chair will notify the NOP, within 60 days of receiving the TR, that the TR is sufficient. If the TR is not found sufficient, the Subcommittee must provide the NOP with an explanation of why, including a request for additional information or improvements.

If necessary, the NOP will seek improvements or supplemental information from the contractor. Once the Technical Reports are deemed sufficient, the NOP will post on the NOP website.

Step 7: Review by the Subcommittee (Crops, Livestock or Handling)

During this phase the Subcommittee conducting the review will:

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

Step 8: Action by Full NOSB

During this phase the NOP will:

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

At the NOSB meeting:

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

Step 9: The NOSB Chair will review all final recommendations and submit them to the NOP

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

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

- The Subcommittee sends a written request for a new work agenda item to the Executive Subcommittee.
- The request should include a summary of the issue, brief justification for the change, and resources in hand or needed for the project.
- The ES considers the request and determines if it should go forward.
- NOP reviews the item for possible addition to the work agenda, and may propose to add to a future meeting schedule depending on NOSB workload.
- The Subcommittee develops a proposal for consideration that is separate from the sunset review of the substance. NOP will then consider rulemaking action in a timely manner, without constraints due to the sunset timeline.

Additional considerations concerning Technical Reviews

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

- A Subcommittee cannot proceed with a recommendation to list a material if it is determined that there is insufficient valid scientific information on that material's impact on the environment, human health and its compatibility with organic principles.
- The decision to request a third-party expert needs to be made independently of the availability of funds. If there is a lack of funding to secure third party expert advice, the Subcommittee has the option to place the review of new petitions on hold.

- The Subcommittee determines the completeness of the petition and whether a Technical Review is needed.
- The decision to define the expertise of the third-party expert is the responsibility of the Subcommittee reviewing the material or issue.
- To incorporate a diversity of opinions and to minimize the risk of bias, a Subcommittee may seek information from a range of technical experts (individuals or institutions). The Subcommittee may also ask questions in their posted proposals, in order to gain needed information from the public.
  The NOP will seek Technical Reviews from a range of experts. The name of the contracted party will appear on the Technical Review. All Federal contracts, including those issued by USDA/NOP to Technical Report contractors, are governed by the Federal Acquisition Regulations (FAR). The FAR includes a "Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions," which requires contractors to identify and prevent personal conflicts of interest for their covered employees. "Personal conflict of interest" means a situation in which a covered employee has a financial interest, personal activity, or relationship that could impair the employee's ability to act impartially and in the best interest of the Government when performing under the contract.
  Link: https://www.acquisition.gov/far/current/pdf/FAR.pdf

Definitions

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

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

V. Prioritization of Petitions

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

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

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

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

Priority 4: A petition to reconsider adding a material that had previously been rejected by a

Name of Material

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
List all chemical names

Other Name:
List other names

Trade Names:
List trade names

CAS Numbers:
List CAS numbers

Other Codes:
List other codes (e.g., INS number, E number, etc.)

Summary of Petitioned Use

For petitions to add or amend a substance, describe the petitioned use of the substance. For substances currently on the National List, summarize the allowed uses under the USDA organic regulations (7 CFR Part 205).

Characterization of Petitioned Substance

Composition of the Substance:
Describe Composition of the Substance

Source or Origin of the Substance:
Briefly describe the source or origin of the substance (to be addressed in more detail below under Evaluation Questions 1 through 4).

Properties of the Substance:
Describe Physical and Chemical Properties of the Substance

Specific Uses of the Substance:
Describe Specific Uses of the Substance - primary focus should be given to describing the petitioned use of the substance as it relates to organic handling; secondary focus should be given to providing general information on other uses of the petitioned substance in agricultural handling/processing.

Approved Legal Uses of the Substance:
Describe the Status of the Petitioned Substance under applicable Federal Regulations (i.e., EPA, FDA, USDA (including APHIS or FSIS), NIEHS, etc.)

Action of the Substance:
Describe Action of the Substance – focus should be given to describing mode of action of the substance, when used as petitioned.

Combinations of the Substance:
Describe Combinations of the Substance – focus should be given to describing whether the petitioned substance is a precursor to, component of, or commonly used in combination with a substance(s) identified on the National List. Any known synergistic effects (either positive or negative) with other substances on the National List should be identified.

In addition, information should be provided on whether any additional ingredients (e.g., inert ingredients, stabilizers, preservatives, carriers, anti-caking agents, or other materials) are generally added to commercially available forms of the petitioned substance.

Status

Historic Use:
Describe historic use of the substance in organic agricultural production (if no historic use in organic agricultural production, please describe historic use in conventional agricultural production).

Organic Foods Production Act, USDA Final Rule:
Describe whether the Petitioned Substance is Listed anywhere in the Organic Foods Production Act of 1990 (OFPA) or the USDA organic regulations, 7 CFR Part 205.

International

Describe the status of the substance among international organizations. Specifically, the report should address whether the petitioned substance is allowed or prohibited for use in other international organic standards such as:

Canada, Canadian General Standards Board—CAN/CGSB-32.311-2015, Organic Production Systems Permitted Substances List
http://www.inspection.gc.ca/food/organic-products/standards/eng/1300368619837/1300368673172

CODEX Alimentarius Commission—Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
http://www.fao.org/docrep/005/Y2772E/Y2772E00.HTM
Note: For Codex, the reference should be cited as "guidelines," rather than as "standards".

European Economic Community (EEC) Council Regulation—EC No. 834/2007 and 889/2008
http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008R0889

Japan Agricultural Standard (JAS) for Organic Production
http://www.maff.go.jp/e/jas/specific/criteria_o.html

International Federation of Organic Agriculture Movements (IFOAM)
http://www.ifoam.bio/en/ifoam-norms

Evaluation Questions for Substances to be used in Organic Handling

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

Data Required: The response must describe the processes used to manufacture or formulate the substance, including a discussion of all precursors and/or feedstocks. A description of alternate manufacturing methods which are not included in the petition, if any, should be presented. The response must also describe, in detail, any chemical changes effected on any naturally occurring precursor or feedstock by all manufacturing or formulation processes. For the purposes of this response, a chemical change could be the addition or deletion of one atom to the substance's molecular structure or other description of chemical modification.

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

Data Required: For the purposes of this response, chemical processes are processes include, but are not limited to, acid base reactions, calcification, thermal or catalytic cracking, esterification, hydrogenation, mixing of substances or elements, oxidation-reduction, polymerization, etc., obtained through process units such as compressors, cracking towers, heat exchangers, mixers, reactors, pumps, etc.

If the substance is extracted from a natural material, information should be provided on any materials and methods used to extract, separate, isolate, or withdraw the substance, including any solvents used, acid-base extraction methods, or mechanical or physical separation methods.

If the substance is created by a naturally occurring biological process, those process(es) must be described in detail. For the purposes of this response, naturally occurring biological processes are processes that include but are not limited to, aerobic and anaerobic digestion, decomposition, fermentation, various metabolic processes, and photosynthesis.

Information should be provided on whether the substance has been chemically modified from the source or origin of the substance, including whether the substance has been isolated from a natural source in a form that does not occur in nature, and whether any synthetic materials used in the production or extraction of a substance may remain in the final product.

For the purposes of this response, an agricultural source is 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.

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

Data Required: The response must discuss whether non-synthetic or natural sources of the petitioned substance exist and are available. The report contractor should examine the effect, form, function, quality, and quantity of the naturally sourced version of the petitioned substance, in comparison to manufactured versions. The following information on any naturally sourced versions should be provided in the report:

- literature, including product or practice description, on performance and test data;
- name and address of the manufacturer(s), if applicable; and,
- types of products the substance is currently used in.

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

Date Required: The response must indicate whether or not the substance has been determined to be GRAS by FDA. This information may be found in 21 CFR Parts 182, 184, and 186. If not determined to be GRAS by FDA, indicate whether it appears on FDA's "GRAS Notice Inventory" available at http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing.

The response should cite the FDA regulatory citation confirming GRAS status or whether FDA has provided a response letter of no objection to a manufacturer's notification of GRAS status.

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

Data Required: The response must explain why the primary function of the substance is or is not as a preservative.

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

Data Required: When replacement or improvement of nutrients is required or allowed by regulation, the report evaluators should cite the appropriate regulations.

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

Data Required: The response must indicate whether the use of the petitioned substance affects the levels of nutrients (e.g., proteins, carbohydrates, fats, vitamins, and minerals) commonly found in the food product. Effects may include increasing or decreasing the amount and/or bioavailability of the nutrients.

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

Data Required: The response must indicate whether the petitioned substance may contain residues of substances that exceed FDA's Action Levels for Poisonous or Deleterious Substances in Human Food. For the most part, these action levels will relate to residues found in agricultural products. Heavy metals or contaminants are addressed through FDA's action levels. These action levels can be found at https://www.fda.gov/food/guidanceregulation/ucm077969. See the latest edition of Food Chemicals Codex (National Research Council) for accepted reference standards for metals and other contaminants in food ingredients in the U.S.

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

Data Required: In consideration of the petitioned substance, its manufacturing process, and its breakdown products, describe the mode of action of the substance with respect to its effects on biological, chemical and physical effects on the environment or biodiversity. The analysis must include consideration of potential effects on both terrestrial and aquatic systems and effects on arthropod natural enemies (*e.g.*, predators and parasitic hymenoptera), pollinators, bats and birds

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

Data Required: Describe reported health effects and causation that may be attributed to the use of the petitioned substance and/or its breakdown products.

Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518(m)(6)).

Data Required: The response to this request for development of technical information must describe the availability of an alternative practice(s) to the use of the petitioned substance. Many research-based alternative practices may be found at: http://eorganic.info/, https://www.sare.org/, and https://attra.ncat.org/; these resources should be consulted before exhausting search for alternative practices. When assessing alternative practices, the report should address:

- Literature, including practice description, on performance and test data;
- A comparison of the function and effectiveness of the proposed alternative practice to the petitioned substance; and,
- Types of products produced and scope of use of alternative practices.

Evaluation Question #12: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517(c)(1)(A)(ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518(m)(6)).

Data Required: The response must describe the availability of a non-synthetic or natural substance(s) which could be substituted for petitioned substance. Many natural substances may be found at: https://organic.ams.usda.gov/Integrity/default.aspx, http://eorganic.info/, https://www.sare.org/, https://www.omri.org/, www.606organic.com, and https://attra.ncat.org/; these resources should be consulted before exhausting search for alternative practices. The examination should address:

- A comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic (natural) product with the petitioned substance;
- Commercial availability of substitute non-synthetic (natural) products, both domestically and globally.
- A comparison of reported risks to human health associated with the substitute non-synthetic (natural) product to the petitioned substance;
- A comparison of reported environmental effects (both aquatic and terrestrial) associated with the substitute non-synthetic (natural) product to the petitioned substance;
- Literature, including product or practice description, on performance and test data; and
- Types of products and range of uses for the alternative substance; and,

Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR 205.600(b)(1)).

Data Required: The list should be based upon a comparison of the effect, form, function, quality, and quantity of the recommended organic agricultural product with the petitioned substance. Many organic products may be found at: https://organic.ams.usda.gov/Integrity/default.aspx, http://eorganic.info/, https://www.sare.org/, https://www.omri.org/, www.606organic.com, and https://attra.ncat.org/; these resources should be consulted before exhausting search for alternative practices. In developing the list, the following should be considered:

- A comparison of the effect, form, function, quality, and quantity of the substitute organic agricultural product to the petitioned substance;
- Commercial availability of substitute organic products, both domestically and globally
- A comparison of reported risks to human health associated with the substitute organic agricultural product to the petitioned substance;
- A comparison of reported environmental effects (both aquatic and terrestrial) associated with the substitute organic agricultural product to the petitioned substance;
- Any literature, including product description, on performance and test data;
- The name and address of the supplier/manufacturer, if applicable; and
- Types of products and range of uses for the alternative substance.

Report Authorship

The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:

- Name, Title, Organization
- Name, Title, Organization
- Name, Title, Organization

All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

References

All citations listed in the report must be included in references section using MLA format. A minimum of 20 current scientific references must be cited in the report to provide adequate scientific credibility and thorough review. Citation using MLA format must be included appropriately within the text to avoid plagiarism.

Name of Material

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
List all chemical names

Other Name:
List other names

Trade Names:
List trade names

CAS Numbers:
List CAS numbers

Other Codes:
List other codes (e.g., INS number, E number, etc.)

Summary of Petitioned Use

For petitions to add or amend a substance, describe the petitioned use of the substance. For substances currently on the National List, summarize the allowed uses under the USDA organic regulations (7 CFR part 205).

Characterization of Petitioned Substance

Composition of the Substance:
Describe Composition of the Substance

Source or Origin of the Substance:
Briefly describe the source or origin of the substance (to be addressed in more detail below under Evaluation Questions 1 through 4).

Properties of the Substance:
Describe Physical and Chemical Properties of the Substance

Specific Uses of the Substance:
Describe Specific Uses of the Substance - primary focus should be given to describing the petitioned use of the substance as it relates to organic handling; secondary focus should be given to providing general information on other uses of the petitioned substance in agricultural handling/processing.

Approved Legal Uses of the Substance:
Describe the Status of the Petitioned Substance under applicable Federal Regulations (i.e., EPA, FDA, USDA (including APHIS or FSIS), NIEHS, etc.).

Action of the Substance:
Describe Action of the Substance – focus should be given to describing mode of action of the substance, when used as petitioned.

Combinations of the Substance:
Describe Combinations of the Substance – focus should be given to describing whether the petitioned substance is a precursor to, component of, or commonly used in combination with a substance(s) identified on the National List. Any known synergistic effects (either positive or negative) with other substances on the National List should be identified.

In addition, information should be provided on whether any additional ingredients (e.g., inert ingredients, stabilizers, preservatives, carriers, anti-caking agents, or other materials) are generally added to commercially available forms of the petitioned substance.

Status

Historic Use:

Describe historic use of the substance in organic agricultural production (if no historic use in organic agricultural production, please describe historic use in conventional agricultural production).

Organic Foods Production Act, USDA Final Rule:

Describe whether the Petitioned Substance is listed anywhere in the Organic Foods Production Act of 1990 (OFPA) https://uscode.house.gov/view.xhtml?req=granuleid%3AUSC-prelim-title7-chapter94&saved=%7CZ3JhbnVsZWlkOlVTQy1wcmVsaW0tdGl0bGU3LWNoYXB0ZXI5NC1mcm9udA%3D%3D%7C%7C%7C0%7Cfalse%7Cprelim&edition=prelim or the USDA organic regulations, 7 CFR part 205 https://www.ecfr.gov/current/title-7/subtitle-B/chapter-I/subchapter-M/part-205.

International

Describe the status of the substance among international organizations. Specifically, the report should address whether the petitioned substance is allowed or prohibited for use in other international organic standards such as:

Canada

CAN/CGSB-32.310- Organic production systems-General principles and management standards
CAN/CGSB-32.311, Organic Production Systems-Permitted Substances List
http://www.inspection.gc.ca/food/organic-products/standards/eng/1300368619837/1300368673172

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

http://www.fao.org/docrep/005/Y2772E/Y2772E00.HTM
Note: For Codex, the reference should be cited as "guidelines," rather than as "standards".

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

https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021R1165&from=EN#d1e32-48-1

Japan Agricultural Standard (JAS) for Organic Production

https://www.maff.go.jp/e/policies/standard/specific/organic_JAS.html

IFOAM-Organics International

http://www.ifoam.bio/en/ifoam-norms

Evaluation Questions for Substances to be used in Organic Handling

Classification of the substance

Evaluation Question #1: **(A) Describe if the substance is extracted from naturally occurring plant, animal, or mineral sources. (B) Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Include any chemical changes that may occur during manufacture or formulation of the substance. (C) Discuss whether the petitioned substance is agricultural or non-agricultural. If the substance is non-agricultural, is it synthetic or non-synthetic? [7 U.S.C. 6502(22); NOP 5032-1; NOP 5033-2]**

(A) If the substance is extracted from a natural material, information should be provided on any materials and methods used to extract, separate, isolate, or withdraw the substance, including any solvents used, acid-base extraction methods, or mechanical or physical separation methods. If the substance is created by a naturally occurring biological process, those process(es) must be described in detail.

For the purposes of this response, naturally occurring biological processes are processes that include but are not limited to, aerobic and anaerobic digestion, decomposition, fermentation, various metabolic processes, and photosynthesis.

(B) The response must describe the processes used to manufacture or formulate the substance, including a discussion of all precursors and/or feedstocks. A description of alternate manufacturing methods and the extent of their commercial use which are not included in the petition, if any, should be presented. The response must also describe, in detail, any chemical changes effected on any naturally occurring precursor or feedstock by all manufacturing or formulation processes. If any synthetic materials used in the production or extraction of a substance remain in the final product, describe them.

For the purposes of this response, a chemical change involves a process (i.e., chemical reaction) whereby a substance is transformed into one or more other distinct substances. This may include the addition or deletion of one atom to the substance's molecular structure or other description of chemical modification.

Chemical processes include, but are not limited to: acid base reactions, calcification, thermal or catalytic cracking, esterification, hydrogenation, mixing of substances or elements, oxidation-reduction, polymerization, etc., obtained through process units such as compressors, cracking towers, heat exchangers, mixers, reactors, pumps, etc.

(C) Based on the information provided on (A) and (B), the definition of synthetic at 7 U.S.C. 6502(22) NOP Guidance 5033-1 and NOP Guidance 5033-2, describe if the substance can be classified as agricultural or non-agricultural.

Evaluation Question #2: Specify whether the petitioned substance is categorized as Generally Recognized as Safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR 205.600(b)(5)). If not categorized as GRAS, describe the regulatory status.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

Purpose and necessity of the substance

Evaluation Question #3: Describe whether the primary technical function or purpose of the petitioned substance is a preservative (7 CFR 205.600(b)(4)).
The response must explain why the primary function of the substance is or is not as a preservative.

Evaluation Question #4: Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law). If so, how? (7 CFR 205.600(b)(4)).
When replacement or improvement of nutrients is required or allowed by regulation, the report evaluators should cite the appropriate regulations.

Evaluation Question #5*: Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR 205.600(b)(3)).*
The response must indicate whether the use of the petitioned substance affects the levels of nutrients (e.g., proteins, carbohydrates, fats, vitamins, and minerals) commonly found in the food product. Effects may include increasing or decreasing the amount and/or bioavailability of the nutrients.

Environment and human health effects

<u>Evaluation Question #6:</u> List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR 205.600(b)(5)).
The response must indicate whether the petitioned substance may contain residues of substances that exceed FDA's Action Levels for Poisonous or Deleterious Substances in Human Food. For the most part, these action levels will relate to residues found in agricultural products. Heavy metals or contaminants are addressed through FDA's action levels. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed See the latest edition of Food Chemicals Codex (National Research Council) for accepted reference standards for metals and other contaminants in food ingredients in the U.S.

<u>Evaluation Question #7:</u> Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. 6517(c)(1)(A)(i) and 7 U.S.C. 6517(c)(2)(A)(i)).
In consideration of the petitioned substance, its manufacturing process, and its breakdown products, describe the mode of action of the substance with respect to its effects on biological, chemical and physical effects on the environment or biodiversity. The analysis must include consideration of potential effects on both terrestrial and aquatic systems and effects on arthropod natural enemies (*e.g.*, predators and parasitic hymenoptera), pollinators, bats, and birds.

<u>Evaluation Question #8:</u> Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. 6517(c)(1)(A)(i), 7 U.S.C. 6517(c)(2)(A)(i)) and 7 U.S.C. 518(m)(4)).
Describe reported health effects and causation that may be attributed to the use of the petitioned substance and/or its breakdown products.

<u>Alternatives</u>

<u>Evaluation Question #9:</u> Are there alternative natural (nonsynthetic) source(s) of the substance? (7 CFR 205.600(b)(1)).
The response must discuss whether natural (nonsynthetic) sources of the petitioned substance exist and are available. The report contractor should examine the effect, form, function, quality, and quantity of the naturally sourced version of the petitioned substance, in comparison to manufactured versions. Briefly describe any naturally sourced alternatives by summarizing:

- literature, including product or practice description, on performance and test data;
- name and address of the manufacturer(s), if applicable; and
- types of products the substance is currently used in.

<u>Evaluation Question #10:</u> Describe all nonagricultural non-synthetic substances or products which may be used in place of the petitioned substance (7 U.S.C. 6517(c)(1)(A)(ii)). Additionally, identify which of those are currently allowed under the USDA organic regulations (7 CFR 205.605(a)).
The response must describe the availability of a nonagricultural non-synthetic or natural substance(s) which could be substituted for petitioned substance. Briefly describe any nonagricultural nonsynthetically sourced alternatives by summarizing:

- A comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic (natural) product with the petitioned substance.
- Commercial availability of substitute non-synthetic (natural) products, both domestically and globally.
- A comparison of reported risks to human health associated with the substitute non-synthetic (natural) product to the petitioned substance.
- A comparison of reported environmental effects (both aquatic and terrestrial) associated with the substitute non-synthetic (natural) product to the petitioned substance;
- Literature, including product or practice description, on performance and test data; and
- Types of products and range of uses for the alternative substance.

<u>Evaluation Information #11:</u> Provide a list of organic agricultural products that could be alternatives for the petitioned substance.

The list should be based upon a comparison of the effect, form, function, quality, and quantity of the recommended organic agricultural product with the petitioned substance. Many organic products may be found at: https://organic.ams.usda.gov/Integrity/default.aspx, http://eorganic.info/, https://www.sare.org/, https://www.omri.org/, www.606organic.com, and https://attra.ncat.org/; these resources should be consulted before exhausting search for alternative practices. Briefly describe the organic agriculturally derived alternatives by summarizing:

- A comparison of the effect, form, function, quality, and quantity of the substitute organic agricultural product to the petitioned substance;
- Commercial availability of substitute organic products, both domestically and globally.
- A comparison of reported risks to human health associated with the substitute organic agricultural product to the petitioned substance.
- A comparison of reported environmental effects (both aquatic and terrestrial) associated with the substitute organic agricultural product to the petitioned substance;
- Any literature, including product description, on performance and test data;
- The name and address of the supplier/manufacturer, if applicable; and
- Types of products and range of uses for the alternative substance.

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

The response to this request for development of technical information must describe the availability of an alternative practice(s) to the use of the petitioned substance. Many research-based alternative practices may be found at: http://eorganic.info/, https://www.sare.org/, and https://attra.ncat.org/; these resources should be consulted before exhausting search for alternative practices. Briefly describe alternative practices by summarizing:

- Literature, including practice description, on performance and test data;
- A comparison of the function and effectiveness of the proposed alternative practice to the petitioned substance; and,
- Types of products produced and scope of use of alternative practices.

Report Authorship

The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:

- Name, Title, Organization
- Name, Title, Organization
- Name, Title, Organization

All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

References

All citations listed in the report must be included in references section using MLA format. A minimum of 20 current scientific references must be cited in the report to provide adequate scientific credibility and thorough review. Citation using MLA format must be included appropriately within the text to avoid plagiarism.

Name of Material

Crops or Livestock

Identification of Petitioned Substance

Chemical Names:
List all chemical names

Other Name:
List other names

Trade Names:
List Trade Names

CAS Numbers:
List CAS numbers

Other Codes:
List other codes

Summary of Petitioned Use

For petitions to add or amend a substance, describe the petitioned use of the substance. For substances currently on the National List, summarize the allowed uses under the USDA organic regulations.

Characterization of Petitioned Substance

Composition of the Substance:
Describe Composition of the Substance

Source or Origin of the Substance:
Briefly describe the source or origin of the substance (to be addressed in more detail below under Evaluation Questions 2 and 3).

Properties of the Substance:
Describe Physical and Chemical Properties of the Substance

Specific Uses of the Substance:
Describe Specific Uses of the Substance - primary focus should be given to describing the petitioned use of the substance; secondary focus should be given to providing general information on other uses of the petitioned substance in agricultural crop or livestock production.

Approved Legal Uses of the Substance:
Describe the Status of the Petitioned Substance under applicable Federal Regulations (i.e., EPA, FDA, USDA (including APHIS or FSIS), NIEHS, etc.)

Action of the Substance:
Describe the Mode Action of the Substance – focus should be given to describing the mode of action of the substance, when used as petitioned.

Combinations of the Substance:
Describe Combinations of the Substance – focus should be given to describing whether the petitioned substance is a precursor to, component of, or commonly used in combination with a substance(s) identified on the National List.

In addition, information should be provided on whether any additional ingredients (e.g., inert ingredients, stabilizers, preservatives, carriers, anti-caking agents, or other materials) are generally added to commercially available forms of the petitioned substance.

Status

Historic Use:

Describe historic use of the substance in organic agricultural production (if no historic use in organic agricultural production, please describe historic use in conventional agricultural production).

Organic Foods Production Act, USDA Final Rule:

Describe whether the Petitioned Substance is Listed anywhere in the Organic Foods Production Act of 1990 (OFPA) or the USDA organic regulations, 7 CFR Part 205.

International

Describe the status of the substance among international organizations. Specifically, the report should address whether the petitioned substance is allowed or prohibited for use in other international organic standards such as:

Canada - Canadian General Standards Board Permitted Substances List. This list was updated in November 2015.

CAN/CGSB-32.311-2015 — Organic production systems - Permitted substances lists
http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/normes-standards/internet/bio-org/lsp-psl-eng.html

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

Note: For Codex, the reference should be cited as "guidelines," rather than as "standards".

http://www.codexalimentarius.org/standards/list-standards/en/?no_cache=1
http://www.codexalimentarius.org/download/standards/360/cxg_032e.pdf

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

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

Japan Agricultural Standard (JAS) for Organic Production—
http://www.maff.go.jp/e/jas/specific/criteria_o.html

International Federation of Organic Agriculture Movements (IFOAM) –
http://www.ifoam.bio/en/ifoam-norms

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

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

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

Data Required: The response must describe the processes used to manufacture or formulate the substance, including a discussion of all precursors and/or feedstocks. A description of alternate manufacturing methods and the extent of their commercial use which are not included in the petition, if any, should be presented. The response must also describe, in detail, any chemical changes effected on any naturally occurring precursor or feedstock by all manufacturing or formulation processes. For the purposes of this response, a chemical change involves a process (i.e., chemical reaction) whereby a substance is transformed into one or more other distinct substances. This may include the addition or deletion of one atom to the substance's molecular structure or other description of chemical modification.

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

Data Required: For the purposes of this response, chemical processes are processes include, but are not limited to, acid base reactions, calcification, thermal or catalytic cracking, esterification, hydrogenation, mixing of substances or elements, oxidation-reduction, polymerization, etc., obtained through process units such as compressors, cracking towers, heat exchangers, mixers, reactors, pumps, etc.

If the substance is extracted from a natural material, information should be provided on any materials and methods used to extract, separate, isolate, or withdraw the substance, including any solvents used, acid-base extraction methods, or mechanical or physical separation methods.

If the substance is created by a naturally occurring biological process, those process(es) must be described in detail. For the purposes of this response, naturally occurring biological processes are processes that include but are not limited to, aerobic and anaerobic digestion, decomposition, fermentation, various metabolic processes, and photosynthesis.

Information should be provided on whether the substance has been chemically modified from the source or origin of the substance, including whether the substance has been isolated from a natural source in a form that does not occur in nature, and whether any synthetic materials used in the production or extraction of a substance may remain in the final product.

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

Data Required: The response must describe whether and how the petitioned substance and/or the breakdown products are persistent or cumulative when used in organic crop or livestock production as petitioned.

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

Data Required: The response must describe whether the petitioned substance, its contaminants, or any of its breakdown products have been reported to have toxic effects and are capable of causing adverse health and/or environmental effects either present in the substance or arising from the degradation of the substance over time.

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

Data Required: The response must describe the occurrence and severity of environmental contamination during the manufacture, use, misuse, or disposal of the petitioned substance. This data may be available through review of assessments performed per EPA, FDA, and/or NIEHS review. Data or reports from other U.S. or International universities, agencies, independent groups, or other news reports should be included in this response when available.

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

Data Required: The response to this request for development of technical information must describe any known chemical interactions between the petitioned substance and other substances allowed for use in organic production or handling as applicable. Describe any common combinations of materials used with the petitioned substance. Describe any substances resulting from these interactions and whether they may cause adverse health and/or environmental effects either present in the substance or arising from the degradation of the substance over time. Toxicity, mode of action, and persistence of the substance and its breakdown products should be explained.

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

Data Required: The response must describe the substances (the petitioned substance and/or its byproducts in combination with naturally occurring substances over time) that are capable of affecting the agro-ecosystem. The effects of these substances, including toxicity, mode of action and environmental persistence of the substance and its breakdown products should be explained.

The response should describe whether and how the petitioned substance affects the survival and/ or function of soil organisms, such as, but not limited to earthworms, mites, grubs, bacteria, nematodes, algae, and protozoa by changing soil temperature, water availability, pH levels, nutrient availability, salt concentration, solubility or other parameter. For crops, the response should also describe whether and how the substance affects plant physiology by creating changes in plant pH, nutrient or water utilization, or other parameters when used as petitioned. For livestock production, the response should also describe whether and how the substance affects animal physiology by creating changes in behavior, fertility, metabolism or other parameters.

In addition, the response should describe the potential or actual impacts of the substances upon endangered species, population, viability or reproduction of non-target organisms and the potential for measurable reductions in genetic, species or eco-system biodiversity, if possible.

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

Data Required: Drawing upon responses to above questions #2-8, and any other relevant information, describe the biological, chemical and physical agents capable of causing harmful environmental effects and the causation, that may be attributed to the use of the petitioned substance and/or its breakdown products.

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

Data Required: Drawing upon responses to above questions #2-8 and any other relevant information, describe the reported health effects and causation that may be attributed to the petitioned substance and/or its breakdown products.

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

Data Required: The response must describe the availability of non-synthetic or natural substance(s), including organic agricultural products, which could be substituted for petitioned substance. The examination should address:

- a comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic or natural product with the petitioned substance;
- literature, including product or practice description, on performance and test data;
- name and address of the manufacturer(s), if applicable; and
- For livestock (and pet food) feed substances, information on technical barriers to production of organic agricultural products that may serve as alternatives.

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

Data Required: The response to this request for development of technical information must describe the availability of alternative practices, such as cultural, biological, and mechanical controls, to the use of the petitioned substance.

Alternative cultural methods including methods used to enhance crop health and prevent weed, pest, or disease problems without the use of substances. Examples include the selection of appropriate varieties and planting sites; proper timing and density of plantings; irrigation; and extending a growing season by manipulating the microclimate with green houses, cold frames; or wind breaks.

Other alternative practices may include, but are not limited to, crop rotation, mulching with fully biodegradable materials, mechanical cultivation, augmentation or introduction of predators or parasites of the pest species; development of habitat for natural enemies of pests; nonsynthetic controls such as lures, traps, and repellents; sanitation measures and management practices which suppress the spread of disease organisms.

Alternative practices used in livestock production may include, but are not limited to, selection of species and types of livestock with regard to suitability for site-specific conditions, resistance to diseases and parasites; site selection , housing, pasture and sanitation practices that minimize occurrence and spread of disease and parasites; stocking density; and seasonal production practices.

When assessing alternative practices, the report should address:

- Literature, including practice description, on performance and test data;
- A comparison of the function and effectiveness of the proposed alternative practice with the petitioned substance; and,
- Frequency or prevalence of use of alternatives, if known.

Report Authorship

The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:

- Name, Title, Organization
- Name, Title, Organization
- Name, Title, Organization

All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

References

Name of Material
Crops or Livestock

Identification of Petitioned Substance

Chemical Names:
List all chemical names

Other Name:
List other names

Trade Names:
List Trade Names

CAS Numbers:
List CAS numbers

Other Codes:
List other codes

Summary of Petitioned Use

For petitions to add or amend a substance, describe the petitioned use of the substance. For substances currently on the National List, summarize the allowed uses under the USDA organic regulations 7 CFR part 205.

Characterization of Petitioned Substance

Composition of the Substance:
Describe Composition of the Substance

Source or Origin of the Substance:
Briefly describe the source or origin of the substance (to be addressed in more detail below under Evaluation Questions 2 and 3).

Properties of the Substance:
Describe Physical and Chemical Properties of the Substance

Specific Uses of the Substance:
Describe Specific Uses of the Substance - primary focus should be given to describing the petitioned use of the substance; secondary focus should be given to providing general information on other uses of the petitioned substance in agricultural crop or livestock production.

Approved Legal Uses of the Substance:
Describe the Status of the Petitioned Substance under applicable Federal Regulations (i.e., EPA, FDA, USDA (including APHIS or FSIS), NIEHS, etc.).

Action of the Substance:
Describe the Mode Action of the Substance – focus should be given to describing the mode of action of the substance, when used as petitioned.

Combinations of the Substance:
Describe Combinations of the Substance – focus should be given to describing whether the petitioned substance is a precursor to, component of, or commonly used in combination with a substance(s) identified on the National List.

In addition, information should be provided on whether any additional ingredients (e.g., inert ingredients, stabilizers, preservatives, carriers, anti-caking agents, or other materials) are generally added to commercially available forms of the petitioned substance.

Status

Historic Use:
Describe historic use of the substance in organic agricultural production (if no historic use in organic agricultural production, please describe historic use in conventional agricultural production).

Organic Foods Production Act (OFPA), USDA Final Rule:
Describe whether the Petitioned Substance is Listed anywhere in the Organic Foods Production Act of 1990 (OFPA) or the USDA organic regulations, 7 CFR part 205.

International
Describe the status of the substance among international organizations. Specifically, the report should address whether the petitioned substance is allowed or prohibited for use in other international organic standards such as:

Canada
CAN/CGSB-32.310- Organic production systems-General principles and management standards
CAN/CGSB-32.311— Organic production systems - Permitted substances lists
https://inspection.canada.ca/organic-products/standards/eng/1300368619837/1300368673172

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Note: For Codex, the reference should be cited as "guidelines," rather than as "standards."
http://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
834/2007: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32007R0834&from=EN
889/2008: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0889&from=EN

Japan Agricultural Standard (JAS) for Organic Production—
https://www.maff.go.jp/e/policies/standard/specific/organic_JAS.html

IFOAM – Organics International
http://www.ifoam.bio/en/ifoam-norms

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

Classification of the substance

Evaluation Question #1: (A) Describe if the substance is extracted from naturally occurring plant, animal, or mineral sources. (B) Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Include any chemical changes that may occur during manufacture or formulation of the substance. (C) Based on the manufacturing process description, discuss if the substance is classified as synthetic or a nonsynthetic. [7 U.S.C. 6502(22); NOP 5033-1]

- **(A)** If the substance is extracted from a natural material, information should be provided on any materials and methods used to extract, separate, isolate, or withdraw the substance, including any solvents used, acid-base extraction methods, or mechanical or physical separation methods. If the substance is created by a naturally occurring biological process, those process(es) must be described in detail.

For the purposes of this response, naturally occurring biological processes are processes that include but are not limited to, aerobic and anaerobic digestion, decomposition, fermentation, various metabolic processes, and photosynthesis.

(B) The response must describe the processes used to manufacture or formulate the substance, including a discussion of all precursors and/or feedstocks. A description of alternate manufacturing methods and the extent of their commercial use which are not included in the petition, if any, should be presented. The response must also describe, in detail, any chemical changes effected on any naturally occurring precursor or feedstock by all manufacturing or formulation processes. If any synthetic materials used in the production or extraction of a substance remain in the final product, describe them.

For the purposes of this response, a chemical change involves a process (i.e., chemical reaction) whereby a substance is transformed into one or more other distinct substances. This may include the addition or deletion of one atom to the substance's molecular structure or other description of chemical modification.

Chemical processes include, but are not limited to: acid base reactions, calcification, thermal or catalytic cracking, esterification, hydrogenation, mixing of substances or elements, oxidation-reduction, polymerization, etc., obtained through process units such as compressors, cracking towers, heat exchangers, mixers, reactors, pumps, etc.

(C) Based on the information provided on (A) and (B), the definition of synthetic at 7 U.S.C. 6502(22) and NOP Guidance 5033-1, describe if the substance can be classified as synthetic or as a nonsynthetic.

Synthetic substances have been chemically modified from the source or origin or have been isolated from a natural source in a form that does not occur in nature.

<u>Evaluation Question #2:</u> For substances classified as synthetic: Is the substance used in production, and does it contain an active synthetic ingredient in the following categories (7 U.S.C. 6517(c)(1)(B)(i)); copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines 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?

<u>Evaluation Question #3:</u> Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling (7 U.S.C. 6518(m)(1)).

The response to this request for development of technical information must describe any known chemical interactions between the petitioned substance and other substances allowed for use in organic production or handling as applicable. Describe any common combinations of materials used with the petitioned substance. Describe any substances resulting from these interactions.

<u>Evaluation Question #4:</u> Discuss (A) the toxicity and mode of action of the substance; (B) the toxicity and mode of action of its breakdown products or any contaminants; and (C) their persistence and areas of concentration in the environment (7 U.S.C. 6518(m)(2)).

(A) Describe whether the petitioned substance has been reported to have toxic effects and if its mode of action can cause adverse health and/or environmental effects.

(B) Describe whether the petitioned substance contaminants, or any of its breakdown products have been reported to have toxic effects and are capable of causing adverse health and/or environmental effects either present in the substance or arising from the degradation of the substance over time.

(C) Describe whether and how the petitioned substance and/or the breakdown products are persistent or cumulative when used in organic crop or livestock production as petitioned.

<u>Evaluation Question #5:</u> Discuss the probability of environmental contamination during manufacture, use, misuse or disposal of the substance (7 U.S.C. 6518(m)(3)).
The response must describe the occurrence and severity of environmental contamination during the manufacture, use, misuse, or disposal of the petitioned substance. Data or reports from U.S. or International universities, agencies, independent groups, or other news reports should be included in this response when available. This data may also be available through review of assessments performed per EPA, FDA, and/or NIEHS review.

<u>Evaluation Question #6:</u> Discuss the effects of the substance on biological and chemical interactions in the agroecosystem. Include the physiological effects of the substance on soil, crops, livestock or other organisms (such as aquatic) that could be affected by the substance when used as petitioned. (7 U.S.C. 6518(m)(5))
The response must describe the substances (the petitioned substance and/or its byproducts in combination with naturally occurring substances over time) that are capable of affecting the agro-ecosystem.

The response should describe whether and how the petitioned substance affects the survival and/or function of soil organisms, such as, but not limited to earthworms, mites, grubs, bacteria, nematodes, algae, and protozoa by changing soil temperature, water availability, pH levels, nutrient availability, salt concentration, solubility or other parameters. For crops, the response should also describe whether and how the substance affects plant physiology by creating changes in plant pH, nutrient or water utilization, or other parameters when used as petitioned. For livestock production, the response should also describe whether and how the substance affects animal physiology by creating changes in behavior, fertility, metabolism or other parameters.

In addition, the response should describe the potential or actual impacts of the substances upon endangered species, population, viability or reproduction of non-target organisms and the potential for measurable reductions in genetic, species or eco-system biodiversity, if possible.

<u>Evaluation Question #7:</u> Discuss and summarize findings on whether the use of the petitioned substance may be harmful to the environment (7 U.S.C. 6517(c)(1)(A)(i) and 7 U.S.C. 6517(c)(2)(A)(i)).
Considering the information described in questions #1-6 and any other relevant information, discuss if the petitioned substance and/ or its breakdown products can cause harmful effects on the environment. Describe the biological, chemical and physical factors that may be affected by the use of the substance and/ or its breakdown products.

<u>Harm to Human Health</u>

<u>Evaluation Question #8:</u> Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. 6517(c)(1)(A) (i), 7 U.S.C. 6517(c)(2)(A)(i)) and 7 U.S.C. 6518(m)(4)).
Drawing upon responses to above questions #1-7 and any other relevant information, describe the reported health effects that may be attributed to the petitioned substance and/or its breakdown products.

<u>Necessity and Alternatives</u>

<u>Evaluation Question #9:</u> Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. 6517(c)(1)(A)(ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. 6518(m)(6)).
The response must describe the availability of non-synthetic or natural substance(s), including organic agricultural products, which could be substituted for petitioned substance. The examination should address:

- a comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic or natural product with the petitioned substance;
- literature, including product or practice description, on performance and test data;
- name and address of the manufacturer(s), if applicable; and

- For livestock (and pet food) feed substances, information on technical barriers to production of organic agricultural products that may serve as alternatives.

<u>Evaluation Question #10:</u> Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. 6518(m)(6)).
The response to this request for development of technical information must describe the availability of specific alternative practices, such as cultural, biological, and mechanical controls, to the use of the petitioned substance.

When assessing alternative practices, the report should address:
- Literature, including specific practice description, on performance and test data;
- A comparison of the function and effectiveness of the proposed alternative practice with the petitioned substance; and,
- Frequency or prevalence of use of alternatives, if known.

Report Authorship

The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:
- Name, Title, Organization
- Name, Title, Organization
- Name, Title, Organization

All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

References

All citations listed in the report must be included in references section using MLA format.
A minimum of 20 current scientific references must be cited in the report to provide adequate scientific credibility and thorough review. Citation using MLA format must be included appropriately within the text to avoid plagiarism.

National Organic Standards Board
Handling Subcommittee Proposal
Ion Exchange Filtration Process – Resins
February 7, 2023

Background:
In an August 27, 2019 memo, the National Organic Program (NOP) requested the National Organic Standards Board (NOSB) provide recommendations related to the process of ion exchange filtration in the handling of organic products. During the NOSB's review, has become clear that there is inconsistency between certifiers in how they approve or disapprove this type of process. Some certifiers require only the solutions that are used to recharge the ion exchange membranes be on the National List in 7 CFR 205.605. Other certifiers require that all materials, including ion exchange membranes and resins be listed in § 205.605.

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

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

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

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

> *Ion exchange is based on the principle that a solid mass with immobilized charges can attract the mobile ions of the opposite charge in a fluid media. In practice, this involves a column that is like a large pipe packed with an exchanger, which may be in the form of beads, crystals, gels, or granules. The fluid can pass through, but the ions in solution will be pulled out and held to the exchanger. The process chemically changes the resulting fluid.*
>
> *Techniques used to produce various sweeteners offer a good example of how the process works. Minerals, salts, proteins and color bodies occur naturally in grape juice, cane juice, beet juice, and corn syrup. The refinement process seeks to remove these "impurities". They are also naturally present or—in case of color bodies—are formed between naturally present components during heating. These can be removed by a*

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

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

The Handling Subcommittee presented a discussion document at the Spring 2020 meeting and presented and voted on a proposal at the Fall 2020 meeting, which recommended that the recharge materials be listed, and the resins not be listed. This vote failed (9 yes, 6 no), and the NOSB requested to keep this as a work agenda item.

The Handling Subcommittee then presented a proposal at the Spring 2021 meeting that outlined the complexity of this material but didn't take a stance on whether recharge materials and/or resins should be listed. The Spring 2021 proposal passed with the inclusion of a request on the cover letter for the NOP to engage with FDA on this topic about how FDA categorizes resins – as secondary food additives or food contact substances.

The NOP sent a memorandum to the Board in August 2021 with a summary of the discussions. The findings from this meeting were inconclusive as the FDA expressed that ion exchange resins can be both secondary food additives and food contact substances (determined on a case-by-case basis). A clear result of the meeting between NOP and FDA is that it is dangerous territory for the NOSB to rely on the FDA definitions of secondary food additives and food contact substances to determine whether substances should be listed on the National List, as this would result in substances not on the National List needing to be petitioned and substances that are listed that would not need to be listed.

At the Fall 2022 meeting, the NOSB unanimously passed a proposal, recommending that recharge materials used in ion exchange filtration must be listed on the National List. The NOSB also discussed the discussion document on ion exchange resins that presented three options for stakeholders to comment on. For the upcoming April 2023 meeting, the Handling Subcommittee now presents this ion exchange resin proposal.

Subcommittee Review and Discussion:
The 2020 technical report (TR) provides a thorough review of ion exchange filtration and should be referred to for details on this process. It is clear that there is widespread use of ion exchange filtration in organic processing whether it be for removal of off-tastes, heavy metals, or clarification of the final product, among others. The TR indicates [880-882], there are no organic agricultural products that serve as an adequate alternative to ion exchange filtration…"

Also noted in the 2020 TR, ion exchange filtration differs from a physical filtration process. Ion exchange filtration induces a chemical change in the ensuing product due to the recharge materials used.

Leakage/Degradation:
The 2020 TR states that there are studies that demonstrate that the resins do degrade over time, however that degradation is generally in terms of their loss of resin activity or efficiency or capacity (2020 TR, lines 784-797). In other words, the resins are simply not as good at holding ions to be exchanged and thus need to be recharged sooner than they would when they were new. In some cases, this loss of efficacy may be because of a loss of functional groups that were originally present, however the citations referenced in the TR note that this loss seems to occur primarily during the recharge process. Thus, the loss of those functional groups would not be into an organic product, but rather into the recharge material. The 2020 TR further states that the TR writers found no published studies on the human health effects of the degradation of the resins (2020 TR, lines 796-797).

During the Fall 2022 meeting, the NOSB received several public comments that support the TR findings. Including the following:

- When ion exchange resin systems are in good working order, they are analogous to a plastic container, mechanical filter or a conveyer belt, a set of materials that are held to the requirements at §205.272.
- When degradation occurs over time, the result is loss of ion exchange activity, either due to strong adsorption of compounds from purified food products or additional crosslinking between existing functional groups on the polymer or with adsorbed materials, not that the resin materials are leaching into foods or materials being filtered.
- The term “leaking” is used when the resins are not capturing the ions they are intending to capture because the resin is full.

Organic Foods Production Act (OFPA)/National List:
Based on past NOP guidance, substances categorized as food contact substances may be used unless explicitly prohibited; whereas if categorized as secondary food additives, then they must appear on the National List. This position comes from a policy statement issued on December 12, 2002. This memo was archived when the NOP Program Handbook was created, however it has never been formally rescinded and remains in use by some certifiers.

To aid in our evaluation, the NOSB requested that the NOP meet with FDA to inform how resins should be categorized: as secondary food additives or food contact substances. Because food additives are listed on the National List and due to the precedent set by the December 2002 policy memo, we believed this distinction would help us to determine if the resins should be listed or not. This meeting took place on June 7, 2021. Unfortunately, the conclusion was that ion exchange resins can be classified both as food contact substances and secondary food additives and are evaluated on a case-by-case basis, and therefore did not provide information to guide the NOSB in either direction.

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

Given the above information, the below options were presented and discussed at the Fall 2022 meeting.

Option 1: Resins do not need to be listed
In previous public comment periods, stakeholders expressed concern that a de facto statement, that resins do not need to be on the National List, leaves a wide-open playing field for any resin to be used. While resins currently being used might be acceptable, the lack of a required review for resins could cause issues in the future with resins that would be less acceptable for use in organic production

systems. Allowing resin use without review could provide an unintentional loophole to the requirements of OFPA.

However, since resins are currently being used in organic production Option 1 is the least impactful option.

During the Fall 2022 meeting, several stakeholders were in support of Option 1, noting that OFPA requires the listing of ingredients (and processing aids – clarified through the Harvey lawsuit) on the National List. Ion exchange resins do not meet the definition of ingredient or processing aid and therefore should not be listed per OFPA. There was an acknowledgement that the National List does currently list other substances that may also not meet the definition of ingredient or processing aid.

Stakeholders in support of Option 1 also noted that it is part of the certifier's review process to:

- Review a description of ion exchange in an operation's Organic System Plan (OSP)
- Verify that the recharge substance is on National List
- Verify that resin was reviewed and approved by FDA as a Food Contact Substance

Stakeholders in support of this Option 1 stated that the above points should be provided by the NOP in an instruction to certifiers.

Option 2: Require listing of Resins – Categorically

An alternative to allowing all resins without review would be to create a listing on the National List that includes all resins used in ion exchange filtration (similar to other broad categories on the National List). Petitions to the NOSB could be used to annotate this broad listing to exclude problematic resins. This process, however, puts the onus on stakeholders to recognize which resins are being used and to act to exclude particular resins. A petition to remove a resin by annotation takes considerable time and forces the petitioner to provide documentation as to how the resin does not comply with OFPA. While this process is in action the resin would continue to be used. This is opposite the more normal procedures of the NOSB whereby the burden is put on the petitioner to document why something should be added to the List and that substance is not allowed to be used until it is added. In the past, removal of substances already being used from the National List becomes difficult due to economic impacts of that removal.

The NOSB received one comment in support of Option 2, with a slight modification. The commenter proposed that instead of annotating to prohibit problematic resins, the annotation could include certain characteristics or use parameters considered to be consistent with organic principles. The end result is the same as Option 1, as this would also be a blanket listing and the use parameters are already being reviewed by certifiers during the OSP review and inspection process.

Some stakeholders were concerned with the precedent Option 2 may set in listing other Food Contact Substances on the National List that do not meet the definition of ingredient or processing aid.

Option 3: Require listing of Resins – Individually

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

Requiring the listing of these resins could cause significant economic impact and disruption of current organic supply chains.

The NOSB received some comments from stakeholders in support of Option 3, noting the NOSB's prior vote on the proposal that recommended resins not be listed failed, which in their view eliminated Option 1. They also saw concerns with a categorical listing (Option 2). Additionally, while they also may not categorize resins as ingredients or processing aids, they concluded that they are also functionally different than some other food contact substances like a table. Due to this difference, stakeholders support the additional scrutiny through review by the NOSB for individually listing resins on the National List. Based on all these reasons they are in support Option 3. However, they did recognize the disruption to the market that would be caused if resins were to be prohibited during the petition and review process and so were in support of continuing to allow until the petition and review process is complete.

The Handling Subcommittee evaluated whether resins used in ion exchange must be included on the National List through analysis of comments received on the above three options presented in the Fall 2022 discussion document, the 2020 technical report, and the earlier record including discussion documents, proposals and written and oral comments.

Based on this evaluation the Handling Subcommittee is recommending **Option 1 – Resins do not need to be listed on the National List.** The Handling Subcommittee supports Option 1 as it most aligns with the requirements outlined in OFPA, as they will not add any non-organic substances to organic products.

Additionally, the Handling Subcommittee fully supports the review of the ion exchange process and oversight that is currently being conducted by certifiers. To further ensure proper and consistent review by certifiers the Handling Subcommittee requests that the NOP issue instruction to certifiers that includes the following requirements:

1) Verification of the ion exchange system through review of an operation's OSP including the requirements at § 205.201 (management practices, procedures, frequency, media, sanitation, contamination & commingling prevention, records, etc.), along with evaluation of adherence to the OSP at the on-site inspection.
2) Verification that the recharge materials are on the National List.
3) Verification that the exchange resins have been reviewed and approved by the FDA as food contact substances through inclusion on either the Inventory of Effective Food Contact Substance Notification Database or Inventory of Food Contact Substances Listed in 21 CFR.

Based on the public comments provided during the Fall 2022 meeting related to leaking and degradation, the Handling Subcommittee is comfortable with the review and oversight by certifiers and during the inspection process as the means of evaluating compliance with 7 CFR 205.272. However, the Handling Subcommittee acknowledges the concern expressed by some stakeholders around the concept of leaking or leaching. Therefore, the Handling Subcommittee requests information on current monitoring strategies or testing being used to ensure there is not leaching and that ion exchange systems are functioning properly.

Questions to Stakeholders

1. Are there tests or other ways to monitor final products for contamination?
2. What are the industry recognized practices to ensure your ion exchange system is in "good working order"?

Subcommittee Vote

Motion to approve the recommendation that the ion exchange resins used in the ion exchange filtration process are not required to be on the National List and that NOP provide instruction to certifiers as outlined in this recommendation.

Motion by: Kyla Smith
Seconded by: Wood Turner
Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 2

Sunset 2025
Meeting 1 - Request for Public Comment
Handling Substances § 205.605 & § 205.606
April 2023

Introduction

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

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2022 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2023 public meeting. Written public comments will be accepted through April 5, 2023 via www.regulations.gov.

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

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

For Comments that Support the Continued Use of § 205.605(a), § 205.605(b), and/or § 205.606 Substances in Organic Production:
If you provide comments supporting the allowance of a substance at § 205.605(a), § 205.605(b), and/or § 205.606, you should provide information demonstrating that the substance is:
1. not harmful to human health or the environment;
2. necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
3. consistent with organic handling.

For Comments that Do Not Support the Continued Use of § 205.605(a), § 205.605(b), and/or § 205.606 Substances in Organic Production:
If you provide comments that do not support a substance on §205.605(a), §205.605(b), and/or §205.606, you should provide reasons why the use of the substance should no longer be allowed in organic production. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:
1. harmful to human health or the environment;
2. unnecessary because of the availability of alternatives; and
3. inconsistent with organic handling.

For Comments Addressing the Availability of Alternatives:
Comments may include information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:
1. Alternative management practices that would eliminate the need for the specific substance;
2. Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
3. Other organic or nonorganic agricultural substances.

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

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

Written public comments will be accepted through April 5, 2023 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

§205.605 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)).'':

§205.605(a): Nonsynthetic substances allowed in organic handling:

- Calcium carbonate
- Flavors
- Gellan gum (high-acyl form only)
- Oxygen
- Potassium chloride

§205.605(b): Synthetic substances allowed in organic handling:

- Alginates
- Calcium hydroxide
- Ethylene
- Glycerides (mono and di)
- Magnesium stearate
- Phosphoric acid
- Potassium carbonate
- Sulfur dioxide
- Xanthan gum

§205.606 Sunsets: Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

§205.606: Nonorganic agricultural substances allowed in organic handling:

- Fructooligosaccharides
- Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean)
- Lecithin - de-oiled
- Tamarind seed gum
- Tragacanth gum

Calcium carbonate

Reference: 205.605(a) Nonsynthetics allowed. (6) Calcium carbonate.
Technical Report: 1995 TAP; 2018 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 12); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Calcium carbonate is widely used as a dietary supplement, antacid, dough conditioner, acidity regulator in wines, food stabilizer, anticaking agent, gelling agent, glazing and release agent, thickener, bulking agent, and nutritional fortification additive. The U.S. Food & Drug Administration (FDA) allows the use of calcium carbonate as a binding agent in meat and poultry pieces and a color additive mixture for coloring foods at 21 CFR 73.70. Calcium carbonate is also a precursor to the substance calcium citrate, which is identified on the National List in 7 CFR 205.605(b).

Manufacture
Calcium carbonate is a fine, white microcrystalline mined powder which is stable in air. Calcium carbonate is a mined mineral of at least 98% purity that is ground and screened.

International Acceptance

Canadian General Standards Board Permitted Substances List; CAN/CGSB-32.311-2015:
Allowed, prohibited for use as a coloring agent.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Appears in Annex VII, Section A - Food additives including carriers, shall not be used for colouring or calcium enrichment of products.

Appears in Annex VII, Section B – Processing aids and other products, which may be used for processing other ingredients of agricultural origin from organic production.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Appears on Table 3, Additives permitted for use under specified conditions in certain organic food categories or individual food items.

Appears on Table 4, Processing aids which may be used for the preparation of products of agricultural origin referred to in Section 3.

International Federation of Organic Agriculture Movements (IFOAM)
Appears in Appendix 4 – Table 1: List of approved additives and processing/post-harvest handing aids.

Japan Agricultural Standard (JAS) for Organic Production
Appears in Table 1, Food additives, Limited to be used for confectionary, sugar, processed bean foods, noodles and bread, or for dairy products as neutralizing substance.

Environmental Issues
The mining and processing of calcium carbonate can have negative environmental impacts, which may include impacts on both above and below ground water systems. Mining may have impacts on biological diversity, as the mining may draw down the water table and impact surface water features that play host to a variety of species. Inhalation of calcium carbonate dust may cause upper respiratory irritation, and exposure may cause eye irritation. Personal protective equipment will protect against these issues. There are limited studies on the impact of calcium carbonate on humans. In the reported studies, increased intake of calcium can result in hypercalcemia and the formation of kidney stones when total daily calcium intake reaches levels at or above 2000 mg. The Handling Subcommittee feels that calcium carbonate continues to be essential to organic production.

Ancillary Substances
None

Discussion
During the Fall 2018 Board meeting, public commenters widely supported the relisting of this material, noting its essentiality to organic production in the absence of viable alternatives. Commenters detailed uses including in soy cheese, yogurts, and beverages as a source of calcium; as much as 15% of the RDA. Comments also pointed to its use as a stabilizer.

Calcium carbonate is not listed in the Organic Foods Production Act of 1990.

Questions to our Stakeholders
1. What are the predominate uses for calcium carbonate?
2. Can alternative substances be used without reducing product quality? If so, what are these alternative substances?

Flavors

Reference: 205.605(a) Nonsynthetics allowed. (12) Flavors - nonsynthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.
Technical Report: 2005 TR; 2022 Limited Scope TR pending
Petition(s): 2015 Petition (to amend)
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 6); 04/2006 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290);

Sunset renewal notice published 03/15/2017 (82 FR 14420); Annotation change published 12/27/2018 (83 FR 66559); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Natural flavors are typically used in very small amounts in products (approximately 0.05 to 0.40 percent of ingredients) that contain less than optimal amount of flavor necessary to give the finished products the desired flavor profile. Natural flavors are widely used in baked goods, dairy products, jams and jellies, snack foods, and juice products, as well as in many other foods. Natural flavors are often proprietary formulations developed specifically for their intended purpose and functionality of the finished product. The significant function of natural flavors must be flavor rather than nutrition.

Manufacture
Flavors can be derived via several different methods. Distillates are a clear, flavorful liquids derived from fruits, herbs, roots, etc., produced and condensed by distillation. Extracts are products that use solvents (typically alcohol or alcohol-water mixture) to pull out certain volatile and non-volatile fractions from raw materials such as spices and herbs, cocoa and vanilla, or flowers. Extracts found on the grocer's shelf, such as orange, almond, lemon, etc., are essential oils dissolved in an alcohol-water mixture. Essential oils are volatile oils that give a botanical its aroma and can be the aromatic essence of a spice, flower, root, leaf, or peel. They are made by steam distillation or cold pressing. Essential oil isolates are a chemical or fraction obtained from a natural substance. For example, citral can be isolated from lemon oil or lemongrass. Oleoresins are solvent extracts of spices where the solvent has been completely removed. An oleoresin will contain the essential oil plus other important non-volatile components that characterize the flavor, color, and other aspects of the starting raw material. For example, the oleoresin of pepper will contain its aroma as well as its taste sensations of heat and spice. A single flavor chemical is a single molecule that provides flavor. These can be naturally or artificially derived, but they are specified to have a greater than 95% purity. Mixtures of these substances can also be considered natural flavors. A compounded flavor is a mixture of ingredients such as extracts, essential oils, and natural isolates. Processed flavors, also known as reaction flavors, are ones that are generated as a result of some form of processing upon a mixture of ingredients. A process flavor is a unique mixture of starting materials, like carbohydrates, proteins, and fat, which must then be heated for a length of time to yield the desired profile.

International Acceptance
Canadian General Standards Board Permitted Substances List.

- Permitted for use - derived from biological sources and substances. May contain permitted carriers.

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

- Flavoring substances in organic products must be natural or organic under European regulations. (EC 2018/848)

- The European Union's flavor regulations have a more limited number of processes that are acceptable for the production of natural flavors (Müller, 2007; Sabisch & Smith, 2020). Certain processes in Europe lead a substance to be classified as "artificial" that are considered "natural" in the U.S. (Müller, 2007).

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

- Permitted for use

International Federation of Organic Agriculture Movements (IFOAM) Norms

- The IFOAM Standards Appendix 4, Table 1, *List of Approved Additives and Processing/Post-harvest Handling Aids* includes "Flavoring Agents" with the following annotation (IFOAM, 2014):

  Operators may use:

  - organic flavoring extracts (including volatile oils), and, if not available,
  - natural flavoring preparations approved by the control body. Such approval shall include assessment that natural flavors shall meet the following criteria:
    - the sources are plant, animal, or mineral;
    - The process of production is in accordance with a recognized organic standard;
    - They are produced by means of solvents such as vegetal oils, water, ethanol, carbon dioxide and mechanical or physical processes."

Japan Agricultural Standard (JAS) for Organic Production

- The Japanese Agricultural Standard for Organic Processed Foods allows "Flavoring" with the annotation: "Limited only to those that are not chemically synthesized" (Japanese Agricultural Standard for Organic Processed Foods, 2020).

Environmental Issues
None

Ancillary Substances
Ancillary substances are present in flavors and are reviewed for compliance against the criteria in the annotation: "must not be produced using synthetic solvents and carrier systems or any artificial preservative." Flavoring constituents are considered proprietary by flavoring companies and are not normally disclosed.

Discussion
The TR was received close to the Subcommittee submission deadline and therefore the information from the TR was not fully incorporated into this review. The TR will be available as soon as the Handling Subcommittee determines it to be sufficient. Its contents will be incorporated into the Board discussion at the Spring meeting as well as the Fall 2023 proposal.

During the 2018 sunset review, the National Organic Program (NOP) had not completed rulemaking on the petitioned annotation change requiring the use of organic flavors when commercially available. This was the main focus of comments at the time urging NOP to complete rulemaking. The annotation change was finalized in 2019 and is reflected in the currently listed on the National List.

The Handling Subcommittee's discussion focused on trying to get a better idea of sources and manufacturing processes for flavors in an effort to determine the current and future availability of organic flavors in the market.

Questions to our Stakeholders

1. Do you produce or certify organic flavors that include ingredients listed on § 205.605? If so, what ingredients?
2. How would removal of flavors from § 205.605 impact the commercial availability of organic flavors?
3. Are there flavors currently used in organic products that cannot be produced organically (including any of the examples listed in the TR such as castoreum derived from beavers, Tonquin musk oil from musk deer, wood chips from nonorganic forest products, distilled liquid smoke, fish flavors)?

Gellan gum (high-acyl form only)

Reference: 205.605(a) Nonsynthetics allowed. (13) Gellan gum (CAS # 71010-52-1) - high-acyl form only.
Technical Report: 2006 TR; 2018 TR (gums)
Petition(s): 2005
Past NOSB Actions: 03/2007 NOSB recommendation (§205.605(b), not recommended for addition); 11/2007 NOSB recommendation (§205.605(a)); 10/2014 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to the National List 12/14/2010 (75 FR 77521); Sunset renewal notice published 06/19/2015 (80 FR 35177); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use

Gums are used in organic handling for different reasons, including: (1) thickening and gelling, (2) stabilizing foams, emulsions, and dispersion, (3) inhibiting ice and sugar crystal formation, (4) aiding formulation, and (5) controlling the release of flavors.

Despite having similar characteristics, the gums are not interchangeable. Due to their structure, some gums behave differently in different temperatures, pH ranges, physical agitation, etc. (2018 TR 194-200). This variability requires formulations specific to the type of food product, intended shelf-life, and product use. Often the gums are used in combination to impart specific properties of the finished goods (2018 TR).

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Source: Technical Report, 2018.

The 2018 TR specifies the functional uses of gellan gum as a thickener, gelling agent, and stabilizer. Gellan gum can be used at low levels in many products that require gelling, texturizing, stabilizing, suspending, film-forming, and structuring. Gellan gum is water soluble, heat stable, low pH stable, and is able to form thicker gels when positive ions (cations) are added to a solution. Gellan gum is considered a hydrocolloid and is very useful as a thickening and gelling agent in food products, including bakery fillings, confections, dairy products, dessert gels, frostings, icings, glazes, jams, and personal care items (2018 TR, 2006 TR). Typical use of gellan gum is at <0.5% of a finished product formula (Petition). The firmness of the gel can be enhanced by the additions of cationic materials such as potassium, calcium, etc. and this gives it numerous applications in different areas of food products.

Manufacture

Gellan gum is a high molecular weight polysaccharide gum produced through fermentation by the bacterium *Sphingomonas elodea*. This aerobic, gram-negative bacterium produces the material through fermentation and then separation of the gellan gum by isopropyl alcohol or ethanol (2006 TR, 2018 TR). The 2018 Technical report notes that no known genetically modified strain of this bacteria exists (2018 TR). Isopropyl alcohol cannot be at greater than 0.075% in the finished materials as dictated by FDA (2006 TR). The firmness of the gellan gum can be adjusted by the removal of acetyl groups through addition of cations (e.g., potassium, calcium, magnesium); these deacylated forms are not approved on 205.605(a) (2006 TR). As a result, the generation of gellan gum approved for 205.605(a) is through a naturally-occurring biological process (2006 TR).

International Acceptance

Canadian General Standards Board Permitted Substances List.

Gellan gum is permitted, and requires the use of allowable extraction solutions and precipitation aids. Isopropyl alcohols can be used for extraction as well.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
There is no explicit mention of gellan gum in the EC regulation.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Gellan gum is not explicitly mentioned.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Gellan gum is not explicitly mentioned.

Japan Agricultural Standard (JAS) for Organic Production
Gellan gum is not explicitly mentioned.

Environmental Issues
The two available technical reports (2018 and 2006 TRs) did not list any notable human health or environmental concerns regarding the use of gellan gum. A 2018 study, in response to an NOSB request for an updated study of the safety of gellan gum as a food additive, found no adverse health impacts of gellan gum and did not recommend establishing an acceptable daily intake level.[i]

Ancillary Substances
According to the 2018 TR, no information was found indicating that any additional materials are generally added to commercially available forms of the gums.

Discussion
During the Spring 2018 public comment period, a number of manufacturers wrote in support of the material, with multiple manufacturers stating that they are using gellan gum as a carrageenan replacement due to customer concerns. Examples of specific products that use gellan gum include plant-based creamers and beverages, dairy beverages, and yogurt.
The Handling Subcommittee's discussion centered around essentiality, the existence of an organic version, and questions about any environmental or human health concerns since the last review.

Questions to our Stakeholders

1. Is an organic version of gellan gum commercially available?
2. Is this product essential?
3. Are there any ancillary substances used with this product?
4. Have any environmental or health concerns emerged since the last sunset review?

[1] Younes, M., Aggett, P., Aguilar, F., Crebelli, R., Filipic, M., Frutos, M.J., Galtier, P., Gott, D., Gundert-Remy, U. and Kuhnle, G.G., 2018. Re-evaluation of gellan gum (E 418) as food additive. *EFSA Journal*, *16*(6), p.e05296.

Oxygen

Reference: 205.605(a) Nonsynthetics allowed. (21) Oxygen - oil-free grades.
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 329); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Oxygen is used in modified atmosphere packaging, the processing of olives, and by wineries, breweries, and manufacturers of carbonated beverages.

Oxygen is an odorless and tasteless gas and is commonly used to help maintain color and prevent pallor in food (although in some volumes, it can have the opposite effect). It can also aid in inhibiting the growth of bacteria. Oxygen can be helpful in a modified atmosphere packaging environment because it can help prevent spoilage in products that are high in sugar or water.

Manufacture
Oxygen is separated from air cryogenically, or the super-cold temperature liquefaction of air and fractional distillation.

International Acceptance

Canadian General Standards Board Permitted Substances List
Permitted for use.

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

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
Permitted for use.

Japan Agricultural Standard (JAS) for Organic Production
Permitted for use.

Environmental Issues
There does not appear to be significant environmental issues associated with the use of oxygen in modified atmosphere packaging. In fact, it can have the effect of extending shelf life or viability and reducing food waste/shrinkage.
No negative impacts on health or the environment have been previously expressed or brought to the attention of the Handling Subcommittee.

Environmental Issues
There does not appear to be significant environmental issues associated with the use of oxygen in modified atmosphere packaging. In fact, it can have the effect of extending shelf life or viability and reducing food waste/shrinkage.
No negative impacts on health or the environment have been previously expressed or brought to the attention of the Handling Subcommittee.

Ancillary Substances
None.

Discussion
The NOSB unanimously voted to relist oxygen in 2018.

Public comment prior to the Spring 2018 NOSB meeting was mostly in favor of relisting. One organization commented that oxygen should be removed from the National List if its necessity in organic production wasn't documented. According to public comment, it is used by wineries, breweries, and manufacturers of carbonated beverages. One certifier reported that it is listed on 14 Organic System Plans (OSPs). One winery commented they use it for micro-oxygenation, a process where oxygen is added to red wine at a controlled rate and flow to stabilize color, improve astringency, and aromatic components of the final wine. Micro-oxygenation also allows wines to be released to consumers at a younger age which in turn reduces the amount of sulfur dioxide that needs to be added during the wine making process.

The Handling Subcommittee has discussed the substance during its sunset review and currently supports relisting.

Questions to our Stakeholders
None.

Potassium chloride

Reference: 205.605(a) Nonsynthetics allowed. (23) Potassium chloride.
Technical Report: 1995 TAP; 2015 TR (nutrient vitamins and minerals); 2023 TR (crops, handling) pending
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 335); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290);

Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
According to the Food & Drug Administration FDA), potassium chloride is generally recognized as safe (GRAS). Affirmed uses of potassium chloride in foods are as a flavor enhancer, flavoring agent, nutrient supplement, pH control agent, and stabilizer or thickener. Like salt, potassium chloride provides a salty flavor and can also often play other functional roles (such as microbial management, protein modification, flavor enhancement) that affect the taste, texture, and shelf life of food products. Potassium chloride is generally used for two main purposes in food products: to provide potassium enrichment to foods, and as a salt replacement to reduce the sodium content in foods.

Manufacture
Potassium chloride is a mineral that occurs naturally and is a product of potash mining where water is forced into ground to dissolve potassium chloride deposits. Brine is brought back to the surface where the water is evaporated off. It can similarly be produced from seawater extraction via solar evaporation.

International Acceptance
Canadian General Standards Board Permitted Substances List
Permitted for use from mined sources such as sylvite, carnalite, and potash.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Not specified as permitted for use.

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
Permitted for use.

Japan Agricultural Standard (JAS) for Organic Production
Permitted as “fertilizers and soil improvement substances.”

Environmental Issues
Potassium chloride derives from mining activities, and there are impacts associated with its extraction. There has not been widespread concern about significant impacts.

The substance is considered to be of limited health concerns for people with normal kidney function; however, it is thought to create issues for people with conditions that make potassium excretion difficult.

At recommended daily rates of consumption, potassium chloride is thought to reduce health impacts typically associated with sodium chloride, such as high blood pressure and kidney stones.

Ancillary Substances
None.

Discussion
The National Organic Standards Board (NOSB) unanimously voted to relist potassium chloride in 2018 for its handling purposes.

At the time, public comment was unanimously in support of re-listing potassium chloride. Several commenters focused on potassium chloride as a key ingredient in low-sodium products. Another commenter stated that potassium chloride is essential in the fortification of infant baby formula.

A draft TR was submitted on December 2, 2022 and was deemed sufficient, although the Crops Subcommittee (which is also reviewing this material for different crop-related applications) requested additional information on effective organic alternatives to potassium chloride. Support for relisting among Handling Subcommittee members appears consistent with prior reviews. The draft TR primarily addressed crops-related applications of the substance.

Questions to our Stakeholders
1. Is potassium chloride widely used by handlers of organic products?

Alginates

Reference: 205.605(b) Synthetics allowed. (3) Alginates.
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 331); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Alginates are used in food production and handling as an emulsifier or emulsifier salt, firming agent, flavor enhancer or flavor adjuvant, formulation aid, processing aid, stabilizer or thickener, surface-active agent, and texturizer.
The use of alginates is not limited to foods. Industrial applications use alginates to improve the performance of products such as paper coating, textiles, adhesives, air freshener gels and ceramics Alginates are also utilized in a variety of ways in the medical field. Examples include wound dressings, surgical implants, pharmaceutical preparations, and as a source of dietary fiber (2015 TR 279 – 283].

Manufacture
Alginates are produced from algin and are usually extracted from the cell walls of brown algae. Commercial alginates are isolated mainly from the following algal species: *Laminaria hyperborea, L. digitata, L. japonica, Ascophyllum nodosum, Macrocystis pyrifera, Eclonia maxima, Lessonia nigrescens, Durivillea antarctica,* and *Sargassum spp* (Draget, Smidsrød and Skjåk-Bræk 2005; Hay, Rehman and Ghafoor, et al. 2010). Alginic acid in brown seaweeds is mainly present as calcium, magnesium, and sodium salts. The first step in the manufacture of alginate is to convert the insoluble calcium and magnesium alginate into soluble sodium alginate by ion exchange under alkaline conditions (World Health Organization 1997). Extraction involves ion exchange in an alkaline medium followed by precipitation, purification and conversion to the appropriate salt (Saltmarsh, Barlow and eds. 2013). "Commercial manufacturing of alginate almost always involves a purification step where an acid treatment precipitates the alginate as alginic acid" (Drageta, Skjak-Bræk and Stokke 2006). The extraction process renders alginates synthetic [2015 TR 444-454].

International Acceptance
Canadian General Standards Board Permitted Substances List
The following alginates are permitted: a) alginic acid; b) potassium alginate; and c) sodium alginate

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Permitted: E401 Sodium Alginate and E402 potassium alginate in milk-based products

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Sodium alginate (INS 401) and Potassium alginate (INS 402) are listed as approved additives.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Sodium alginate (INS 401) and Potassium alginate (INS 402) are listed as approved additives.

Environmental Issues
Seaweed cultivation is largely considered to be an environmentally friendly form of aquaculture due to the lack of added inputs for fertility, minimal changes in physical landscape and potential for bioremediation of polluted or nutrient rich waters (Eklof and Kautsky 2006) [2015 TR 704-706].
We are not aware of any evidence that the harvesting practices for brown seaweed are damaging to local ecosystems. Secondary environmental impacts of seaweed farming include depletion of nutrients in the coastal waters where the seaweed grows, which can affect primary food sources such as phytoplankton (Philips 1990). The use of plastic ties to secure seaweed fronds, Styrofoam floats and plastic bottle buoys has led to increased garbage and foreign debris on beaches, reefs, and mangroves. Given the insurmountable challenges of managing non-native seaweed populations, some researchers claim that it is preferable to focus on sustainable wild harvest techniques with regard to mitigating environmental impact (Titlyanov and Titlyanova 2010) [2015 TR 725-728].

Ancillary Substances
Publicly available specification sheets and ingredient lists did not report any ancillary substances (e.g., stabilizers, preservatives, or anti-caking agents). Sodium alginate and PGA are commercially prepared as 100% freeze-dried material (FMC BioPolymer 2012) [2015 TR 351-354].

Discussion
Alginates were added to the National List in 2022 and have been renewed at each sunset review.

Public comments from the previous sunset review demonstrated a continued need for this material. One stakeholder commented that alginic acid, like seaweed and fish oil, should be reviewed within the broader context of Marine Materials. Additionally, the Board was asked to consider the addition of an annotation related to harvest restrictions and risk-based testing for toxic materials, using a decision tree to identify harvesting areas where testing would need to be performed.

The Subcommittee discussion centered on the current forms of alginate that are being used in organic production.

Questions to our Stakeholders

1. What forms of alginates are currently being used in organic production (e.g., ammonium, calcium, potassium, sodium, propylene glycol)?

Calcium hydroxide

Reference: 205.605(b) Synthetics allowed. (8) Calcium hydroxide.
Technical Report: 1995 TAP; 2023 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 337); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Calcium hydroxide is used in food processing as a buffer, neutralizing agent, and firming agent. It is used in making calcium acid phosphate (a component of aluminum-free baking powder) and in nutrient supplements. Calcium hydroxide is an available source of calcium, an essential nutrient. In this regard, limestone (calcium carbonate) and thus calcium hydroxide, an essential intermediate in the industrial utilization of limestone, have no alternatives.

Manufacture
Calcium hydroxide is produced through four steps: 1) mining or quarrying raw limestone; 2) preparation of the limestone for the kilns; 3) calcining the limestone to produce quick lime (calcium oxide); and 4) hydrating (mixed with water) the quick lime. To produce calcium hydroxide, the temperature for calcining far exceeds temperatures achieved in the home kitchen, which the National Organic Standards Board (NOSB) has previously considered decisive in judging if a substance is synthetic.

According to the 2023 TR, new techniques for the manufacture of calcium hydroxide continue to develop. Nanoparticles of calcium hydroxide were reported to be synthesized as early as 2001 (Salvadori & Dei, 2001). One article described calcium hydroxide as "one of the most magnificent materials in nanotechnology by virtue of its unique physical and chemical properties" (Harish et al., 2022). Most literature cited refers to medical or dental applications of calcium hydroxide nanoparticles. However, with growing interest in food applications of nanotechnology, food-grade calcium hydroxide nanoparticles may become commercially feasible. Nanotechnology is not permitted in organic production (National Organic Program (NOP) Policy Memo 15-2: Nanotechnology).

International Acceptance

Canadian General Standards Board Permitted Substances List

Listed in Organic Production Systems as Permitted Substances List as `Lime' in a table 7.4 'Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory'.

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

There is no specific listing for calcium hydroxide in handling nor any information found.

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

There is no specific listing for calcium hydroxide in handling nor any information found.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Calcium hydroxide (hydrated lime) is listed as for the application on aerial plant parts only.

Japan Agricultural Standard (JAS) for Organic Production

Calcium hydroxide (Slaked lime) listed as `those derived from natural sources, or natural sources without the use of chemical treatment.'

Environmental Issues

According to the 2023 TR, literature on the environmental impacts of limestone quarrying and its processing into quick lime and hydrated lime is extensive. Limestone deposits occur in a wide range of geological formations that are connected to a variety of ecosystems. Almost all limestone is mined in open quarries or pit mines (Oates, 2008). Site preparation for open pit or quarry mining involves the clearing of trees, vegetation, and topsoil, resulting in the immediate loss of habitat (Ganapathi & Phukan, 2020). Some ecosystems are more sensitive to the intrusions of mining than others. The karst topography associated with limestone deposits creates a wide range of potential environmental impacts, including habitat and biota loss; air, noise, and water pollution; and cascading environmental impacts to natural systems far from the mining location (Langer, 2001). Limestone mining creates dust and other air pollution (U.S. EPA, 1998). Karst forms caves that are ideal bat habitat. The dust and noise from limestone mining can result in loss of that habitat and cause remaining bats to suffer increased mortality and deafness (Langer, 2001). Discharges from limestone quarries can also result in surface water contamination with sediment, heavy metals, and asbestos. This in turn can result in adverse impacts on aquatic biota, including fish mortality (U.S. EPA, 1982).

Ancillary Substances

None

Discussion

During the previous sunset review, public comments submitted by organic manufacturers, trade associations, material suppliers and certifiers detailed calcium hydroxide use and necessity in the processing. The majority of public comments supported relisting of calcium hydroxide. One commenter suggested that the NOSB clarify which uses of calcium hydroxide are permitted, specifically if calcium hydroxide can be used as a firming agent. Additional commenters stated that they use calcium hydroxide in infant formula.

Questions to our Stakeholders

2. Is calcium hydroxide essential for organic food production?
3. Since the last review, have additional commercially available alternatives emerged?

Ethylene

Reference: 205.605(b) Synthetics allowed. (14) Ethylene - allowed for postharvest ripening of tropical fruit and degreening of citrus.
Technical Report: 1995 TAP; 1999 TAP; 1999 TAP (pg. 14-54); 2022 TR (crops, handling) pending
Petition(s): 2008 (pears)
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 14); 10/1999 NOSB minutes and vote (tropical fruit and citrus) (pg. 443); 10/2001 NOSB recommendation (reaffirmed 1999 recommendation) (pg. 2); 11/2005 NOSB sunset recommendation; 11/2008 NOSB recommendation (pears, not recommended for addition) (pg. 14459-14491); 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Annotation change published 10/31/2003 (68 FR 61987); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use

Ethylene is used in the post-harvest ripening of tropical fruit and the de-greening of citrus. Ethylene produced naturally by fruits has not been commercialized, and the mount produced for agriculture are small compared to emissions from car exhaust, petrochemical plants, or fires.

Manufacture

The principal source of commercial ethylene is from thermal or catalytic cracking of hydrocarbon feedstocks such as natural gas or crude oil. During this process chemical bonds within the hydrocarbon molecules are broken, and a different chemical substance is produced.

Catalytic cracking uses a catalyst, typically a zeolite, which absorbs the long-chain hydrocarbon feedstocks by removing hydrogen atoms and causes the long chains to split into shorter chain molecules with double bonds (Lazonby, 2014). Small catalytic generators dehydrate ethanol by a similar process (Kays & Beaudry, 1987) 2022 TR 364-367].

All of these methods involve reactions that produce a chemically changed substance (ethylene) from either petroleum feedstocks, or from dehydration of ethanol mediated by catalysts. Thus, all these forms should be considered synthetic (NOP, 2016a) and from nonagricultural sources (NOP, 2016b). [2022 TR 369-371]

Ethylene is the petrochemical produced in the largest quantities worldwide (IARC, 1994). In 2014, world ethylene production was 134 million (metric) tonnes (Lazonby, 2017). As of 1994, over 95% of worldwide annual production is based on thermal "cracking" of petroleum hydrocarbons with steam (IARC, 1994). These fractions are obtained from drilling (or hydrofracturing) of oil or natural gas. Thermal cracking (sometimes referred to as pyrolysis) is a chemical process by which long chain hydrocarbons with higher molecular masses are converted to short chain hydrocarbons of lower molecular mass [2022 TR 304-309].

Various feedstocks, including ethane, propane, butanes, naphthas, and gas oils are used to produce ethylene, depending on availability, price, and products desired (Lazonby, 2017). Naphthas are the principal raw material used in western Europe and Japan, accounting for over 80% of the ethylene produced. Ethane is the primary feedstock in the U.S., followed by propane, naphthas, gas oils, and butane (Zimmerman & Waltz, 2011) [2022 TR 311-315].

In thermal cracking, the feedstock gases (ethane, propane or butane) or the liquids (naphtha or gas-oil) are preheated and vaporized, and are mixed with steam and heated to 1050-1150 K (777-877 °C) in a tubular reactor. The high temperature and pressure cause the long chain hydrocarbon to be converted to low relative molecular mass alkenes plus by-products (Lazonby, 2014). [2022 TR 317-320]

Catalytic cracking

Catalytic cracking uses a catalyst, typically a zeolite, which adsorbs the long-chain hydrocarbon feedstocks and removes hydrogen atoms. [1] This causes the long chains to split into shorter chain molecules with double bonds, which are useful to the petrochemical industry. The feedstock is gas oil, which is vaporized, passed through a fine zeolite powder, and heated to 700-800 K (427 - 527 °C) in a reactor. The products behave like a fluid and continuously flow out of the furnace with the cracking products. The temperature, residence time, and the catalyst determine the product proportions (Lazonby, 2014) [2022 TR 332-338].

Dehydration of ethanol

Dehydration of ethanol is another commercial route to ethylene (IARC, 1994; Zimmerman & Waltz, 2011; Fan 2013). In the catalytic dehydration of ethanol to form ethylene, an acid catalyst first protonates the hydroxyl group, which leaves as a water molecule. The conjugate base of the catalyst then deprotonates the methyl group, and the hydrocarbon rearranges into ethylene (Fan, 2013). This method is not commonly used to produce large volumes of ethylene, as it is endothermic with a high optimal reaction temperature (180-500 °C), which makes the ethylene expensive to produce. Dehydration of bioethanol is occurring in Brazil and India and holds promise for producing ethylene from non-fossil fuel sources (bioethanol from sugar cane or cellulose). At present, the output is relatively limited and used for further production of polyethylene (Fan, 2013; Lazonby, 2017; Schill, 2010) [2022 TR 340-349].

Catalytic generators

Small catalytic generators are used in sealed ripening rooms to dehydrate ethanol into ethylene, and can deliver controlled levels of ethylene gas to ripen fruit, e.g., 100-150 ppm for bananas. (NWHort 2008, Catalytic Generators 2022). This process uses dehydration of ethanol by passing it over a bed of solid catalyst held at high temperatures. The catalysts are typically activated alumina and phosphoric acid or zinc oxide with alumina (Kays & Beaudry, 1987) [TR 351-356].

International Acceptance

Canadian General Standards Board Permitted Substances List

- For post-harvest ripening of tropical fruit and de-greening of citrus and to control sprouting of potatoes post-harvest in holding bins.

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

- De-greening bananas, kiwis, and kakis; De-greening of citrus fruit only as part of a strategy for the prevention of fruit fly damage in citrus; Flower induction of pineapple; sprouting inhibition in potatoes and onions.

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

CODEX indicates:

"For degreening of citrus for fruit fly prevention and as a flowering agent for pineapples. As sprouting inhibitor for potatoes and onions: Need recognized by the certification body or authority for sprout inhibition of stored potatoes and onions where varieties that have long dormancy characteristics are not available, or these varieties are not suited to local growing conditions. Must be used in a manner that minimizes exposure to operators and workers."

International Federation of Organic Agriculture Movements (IFOAM) Norms

- De-greening and ripening of citrus

Japan Agricultural Standard (JAS) for Organic Production

- Limited to those used for ripening bananas, kiwifruits, and avocados after harvest.

Environmental Issues

According to the 2022 TR, the manufacturing process through cracking is highly energy intensive. Extraction and transport contribute significantly to increasing greenhouse gas emissions, acidification and eco-toxicity (air and water). [TR 479-482] A study conducted by Zhao et al. in 2018 found that China reduced C02 emissions by 29.4% per ton of ethylene produced from 2000-2016 due to improvements in technology, and evaluated various methods for future increased reductions. [TR 493-495]

Petroleum refineries are a major source of hazardous and toxic air pollutants. [TR 497]

As for ethylene's impact on the environment during postharvest handling, the 2022 TR states that since the ethylene is a gas at environmental temperatures, this is the primary route of exposure to the environment. Health Canada considered environmental modelling studies and found that ethylene released to the air will remain in the air, and that only negligible amounts will partition to soil, water and sediment. [TR 507-511]

According to the U.S. EPA Toxic Release Inventory (EPA, 2021), in 2021 the total release of ethylene as airborne emissions in the U.S. was 18.2 million pounds. Of that, 17.2 million pounds was emitted by the chemical manufacturing industry, and 0.7 million pounds was from the petroleum industry. It is not known how much ethylene is released in the atmosphere due to ripening and degreening uses. It is no doubt much smaller than the amount estimated to be applied to pineapple crops in the field. The Food and Agriculture Organization of the United Nations estimates that in 2021, there were 1,046,712 hectares of pineapples grown worldwide (FAO, 2022). If every hectare in the world was treated with 800 grams of ethylene (unlikely, as the harvest takes 12-18 months from flower induction), that would result in application of 837,369 kg (1,846,082 pounds) totally. [2022 TR 513-521]

The 2022 TR states that no data was found showing an impact on invertebrates or birds, which are most likely exposed to ethylene. Ethylene is not expected to be released in the water; therefore, no unwanted exposure is expected. The TR stated the greatest eco-toxicity impact to be on terrestrial plants as they are highly sensitive to ethylene in the air. A 2016 Health Canada study concluded that there is little risk of harm to the environment or to organisms since the substance is not present in quantities or concentrations that could cause long term harmful effects on the environment or biodiversity. [2022 TR 531-536]

As for the impact on human health, the main concern is worker safety due to the explosive nature of the gas. The use of this material is highly regulated through labeling and registration requirements. Beyond the risk of harm due to an explosive accident, overexposure causes headache, drowsiness, and muscular weakness and high concentrations can cause dizziness or light-headedness. [2022 TR 551-554]

Ancillary Substances
None

Discussion
During the last review, commenters stated that no commercially viable alternatives exist. Without ethylene, commenters said, it would be impossible to achieve the uniform ripening necessary for timing the harvest for fruit shipment. Others commented that the material does not fit any OPFA criteria, and it is not essential to produce the crop but rather is employed for economic reasons.

The Handling Subcommittee discussed the effects on the environment and human health, along with the apparent essentiality for the tropical fruit industry. Obviously, there is an alternative, which is to let fruit ripen naturally. However, as stated in the TR this is most ideal for local markets where fruit is picked closer to ripeness and time to market is short. According to the TR there are also alternative practices for degreening, such as being stored at low-moderate temperatures as the fruit is maturing on the tree. However, when comparing degreening via reduced temperatures vs. ethylene, ethylene was significantly faster at fully degreening fruit. There were also additional nonsynthetic substance alternatives such as smoke utilized in the Sri Lankan pit method. However, this resulted in blackening and over softening leading to decreased marketability. Smoke was also used in the past for citrus degreening, although there were problems with fire hazards, heat, and decay.

Questions to our Stakeholders
1. What types of organic tropical fruits are currently being ripened using ethylene?

Glycerides (mono and di)

Reference: 205.605(b) Synthetics allowed. (16) Glycerides (mono and di) - for use only in drum drying of food.
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 334); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation

Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Mono- and diglycerides have many applications as food processing aids. They are principally used as emulsifiers. This function also translates into stabilization, preventing food separation, stabilizing air pockets and extending shelf life [TR 2015 82-83]. However, the only use for which mono- and diglycerides are permitted in organic food processing is in the drum drying of food. In this application, mono- and diglycerides can have various functions, but most significantly they act as an emulsifier and release agent. When mixed with food, mono- and diglycerides help prevent sticking during processing, and in drum drying they help to strip the food from the cylinder walls once dried. In drum drying, a puree or slurry of food is added to one or two heated cylinders at varying feed rates depending on the particular food's viscosity. As the cylinders or drums rotate, the slurry dries. The process creates powder or very fine flakes that can serve as the basis for snacks, soups, baked chips, some bakery items and cereals [TR 2015 91-92]. The use of mono- and diglycerides in dehydrated potatoes also aids in rehydration [TR 2015 105-106]; at the spring 1995 National Organic Standards Board (NOSB) meeting, it was noted that the food industry was trying to move away from use of mono- and diglycerides, but that they were still needed for potato flake products [TR 2015 168-172].

Manufacture
Mono- and diglycerides occur naturally in food as minor constituents of fats, in combination with the major constituent of food fats: triglycerides. They are also metabolic intermediates of triglycerides. When manufactured, they are prepared by the glycerolysis of fats or oils, or from fatty acids derived from edible sources [TR 2015 56-59]. These edible sources are commonly animal fats or vegetable oils such as soybean, canola, sunflower, cottonseed, coconut, or palm oil [TR 2015 59-60], and the main fatty acids used to manufacture mono- and diglycerides include lauric, linoleic, myristic, oleic, palmitic, and stearic acid (FDA 2014). The glycerol component of mono- and diglycerides is also derived from these edible fats and oils[TR 2015 56-62].

International Acceptance
Canadian General Standards Board Permitted Substances List
Mono- and diglycerides are permitted under Canada's organic standards, with annotations: From organic sources if commercially available. For use in drum drying of products.

They do not appear in the following organic standards: CODEX, EU, IFOAM or Japan.

Environmental Issues
The 2015 TR does not identify any significant environmental impacts linked to mono- or diglycerides [TR 2015 433-459]. Glycerides are derived from natural fats or oils that are produced conventionally; production of these agricultural source materials with synthetic pesticide and fertilizers may result in harm to the environment and biodiversity.

Ancillary Substances
None

Discussion
According to the 2015 TR, alternative ways to dry foods include spray drying, freeze drying, fluidized bed dryers, air lift dryers, scraped wall heat exchangers, etc. Drum drying is said to be preferred for potato flakes. Freeze drying has been suggested as an acceptable alternative to drum drying.

Evaluation question #13 in the 2015 TR suggested a few potential agricultural alternatives. One is a commercial product, made of organic rice bran extract, which is marketed as an emulsifier and drum release agent. Trials by the manufacturer concluded that rice bran extract had the highest capacity for oil-in-water binding. However, the hydrophilic–lipophilic balance of rice bran extract is narrower than that of mono- and diglycerides, which may make it less versatile as an emulsifier depending on the composition of the mix to which it is added.

Organic soy lecithin and gum Arabic (both currently on the National List) were also raised as possible alternative substances to glycerides, although the use of gum Arabic in drum dried food is not widely reported. The TR also considered the use of lecithin as an alternative but stated that as compared to mono- and diglycerides it provides much less emulsion stability, much less starch interaction, and more fat modification.

The TR concluded that in general, each emulsifier (and its form) is selected based on specification of the food and the processing application [TR 2015 522-547].

The use of mono- and diglycerides appear to be limited, but compatible with OFPA because the health and environmental risks are minimal. It would be helpful to understand current uses.

Questions to our Stakeholders
1. What products are mono- and diglycerides currently used in?
2. Have any alternatives emerged?

Magnesium stearate

Reference: 205.605(b) Synthetics allowed. (19) Magnesium stearate - for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic".
Technical Report: 1995 TAP; 2018 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 16); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use

Magnesium stearate (CAS # 557-04-0) is not commonly used in organic products (TR 2018 102). In conventional production, it is routinely used as an anti-caking agent in salt, spices, powdered foods and drinks, leavening agents, and candy (TR 2018 103-105). It is a flow agent, food processing machine lubricant, and may be an incidental additive. The most common use of magnesium stearate is as a binding agent in dietary supplements. Magnesium stearate is permitted for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))" and is prohibited in agricultural products labeled "organic."

Manufacture

Typically manufactured as a synthetic from hydrogenation of animal fats or vegetable oils, magnesium stearate is produced by adding an aqueous solution of magnesium chloride to sodium stearate. Stearic acid is made by saponification of edible fat (lye plus tallow) that is treated with an acid to form stearic acid.

International Acceptance

Canadian General Standards Board Permitted Substances List
Canada allows magnesium stearate for use as an anticaking or releasing agent in products whose contents are ≥70% and <95% organic ingredients.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
The 2018 TR stated that the Codex Alimentarius Commission's "Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods" lists magnesium stearate (INS No. 470(iii)) as a food additive that may be used in foods as an anticaking agent, emulsifier, or thickener under the conditions of good manufacturing practices (GL 32-1999). However, it does not appear to be listed currently.

Magnesium stearate does not appear in the following organic standards: EU, IFOAM, Japan.

Environmental Issues

Magnesium stearate is derived from natural fats or oils that are produced conventionally; production of these agricultural source materials with synthetic pesticide and fertilizers may result in harm to the environment and biodiversity. In addition, while some of the substances involved in manufacturing of magnesium stearate could have water and soil health impacts at high concentrations, the amounts relevant here are not likely to pose significant environmental or biodiversity impacts.

Ancillary Substances

None

Discussion

The use of magnesium stearate appears to be limited, but compatible with OFPA because the health and environmental risks are minimal. The Handling Subcommittee is interested in answers to the following questions regarding current use:

Questions to our Stakeholders

1. How is magnesium stearate currently used by organic processors?
2. Have any viable alternatives to magnesium stearate emerged?

Phosphoric acid

Reference: 205.605(b) Synthetics allowed. (23) Phosphoric acid - cleaning of food-contact surfaces and equipment only.
Technical Report: 1999 TAP (pg. 9-20); 2003 TAP (pg. 1-7); 2021 TR
Petition(s): 2019 (to amend); 2020 (addendum #1); 2020 (addendum #2); 2022 (addendum #3)
Past NOSB Actions: 10/1999 NOSB minutes and vote (pg. 443); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Phosphoric acid is used in organic handling and processing as a cleaning agent for "food contact surfaces and equipment," as described in 7 CFR 205.605(b). Phosphoric acid has been approved for pH adjustment of some soil amendments (liquid fish products and squid byproducts) and as an equipment cleaner in both organic crop and livestock production. (7 CFR 205.601 and §205.603).

In addition to its appearance in 7 CFR 205.605, phosphoric acid has been used as an ingredient in plant extractions (USDA 2002, USDA 2019, USDA 2020a, USDA 2020b). When used in this manner, phosphoric acid acts as an acidifying agent and stabilizer to facilitate more efficient extraction of target compounds (Yoon et al. 2020).

In addition to organic applications, phosphoric acid is a widely used substance in conventional agriculture, with approximately 90% of wet process phosphoric acid used in the production of fertilizers (Shriver and Atkins 2008). Phosphoric acid has uses in food and beverage processing as a pH adjuster, flavor ingredient, and processing agent in dairy products (Wolke 2002, Gilmour 2019). Phosphoric acid is also a precursor to synthetic phosphates, which have a variety of uses including as fertilizers, surfactants, and detergents (Shriver and Atkins 2008) [TR 163-179].

Manufacture
Phosphoric acid is produced through two methods: the wet process and the thermal process (EPA 1995, Gilmour 2019; Haghani and Daneshpazhuh 2020). Historically, the end-point use for phosphoric acid was determined by its production method. High purity, technical and food grade phosphoric acid was produced by the thermal process (EPA 1995; Gilmour 2019). Lower purity phosphoric acid, primarily used in animal feed and fertilizer applications, was produced by the wet process (EPA 1995; Shriver and Atkins 2008; Gilmour 2019). Due to the expensive nature of the thermal process, there has been continued development of purification methods for wet process phosphoric acid, which now serve as

the predominant method for the production of technical and food grade phosphoric acid (Gilmour 2019).

Thermal process

The thermal process is broken down into three major steps: combustion, hydration, and demisting (collection) (EPA 1995; Gilmour 2019). In the combustion step, elemental yellow phosphorus (P_4) is reacted with oxygen gas, which oxidizes the phosphorous from its 0 to V oxidation state, as shown below in Equation 6 (EPA 1995; Gilmour 2019). The heat of combustion for phosphorus is highly endothermic and the reaction must be carried out at high temperatures (1650 – 2760 °C) (EPA 1995; Gilmour 2019).

$$P_4 + 5\ O_2 \rightarrow 2\ P_2O_5$$

Equation 6

Once the elemental phosphorus is oxidized to P_2O_5, it undergoes the hydration process to form orthophosphoric acid, as shown below in Equation 7 (EPA 1995’ Gilmour 2019). In this process P_2O_5 is generally reacted with water, although in some cases dilute solutions of Phosphoric acid are used instead of water alone (EPA 1995). Once phosphoric acid has been produced, it is isolated in the demisting process. In this step, phosphoric acid is collected as a mist with high-pressure drop demisters. The thermal process produces phosphoric acid with P_2O_5 concentrations between 54 and 62%, which are sufficiently pure for use in technical and food grade applications (EPA 1995; Gilmour 2019).

$$2\ P_2O_5 + 6\ H_2O \rightarrow 4\ H_3PO_4$$

Equation 7

Wet Process

The wet process produces phosphoric acid from naturally occurring phosphate mineral sources (fluorapatite [$Ca_{10}(PO_4)_6F_2$] and hydroxyapatite [$Ca_{10}(PO_4)_6(OH)_2$]) (EPA 1995; Shriver and Atkins 2008; Gilmour 2019; Haghani and Daneshpazhuh 2020). Once mined, these minerals are converted to phosphoric acid in four main steps, as outlined in Figure 5 below (Gilmour 2019). The phosphate rock is prepped in the initial step by being milled and ground to increase its surface area (EPA 1995; Haghani and Daneshpazhuh 2020).

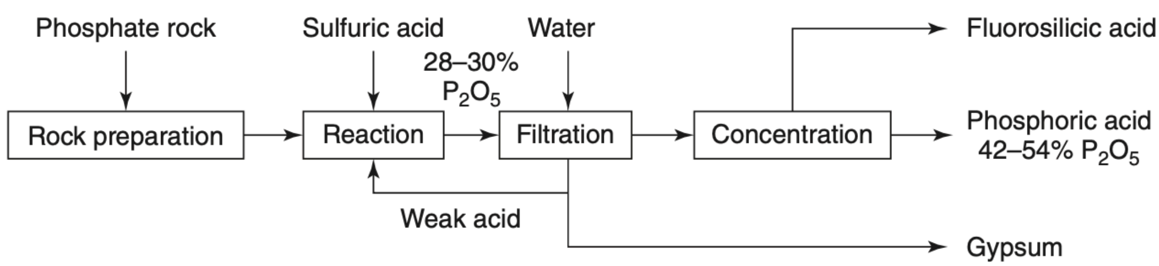

Figure 5

Once milled, the mineral phosphates are reacted with a strong mineral acid and converted to phosphoric acid, as shown in Equation 8 below (EPA 1995; Shriver and Atkins 2008; Gilmour 2019; Haghani and Daneshpazhuh 2020). While sulfuric acid is shown in both Figure 5 and Equation 8, other strong mineral acids (e.g., nitric acid [HNO_3] and hydrochloric acid [HCl]) may also be used (Jin et al. 2014; Haghani and Daneshpazhuh 2020). However, most commercial processes use sulfuric acid because it provides higher phosphoric acid yields, lower costs, and a solid form of calcium (Al-Fariss et al. 1992; EPA 1995; Shriver and Atkins 2008,; Gilmour 2019). The specific reaction conditions dictate the type of calcium sulfate hydrate ($CaSO_4 \bullet n\ H_2O$) formed, with lower temperatures favoring the formation of gypsum ($CaSO_4 \bullet 2\ H_2O$), as shown in Equation 8 (EPA 1995). The prevalence of fluorapatite among mineral phosphates also produces hydrofluoric acid (HF), as shown below in Equation 8.

$$Ca_{10}(PO_4)_4F_{2\,(s)} + H_2SO_{4\,(aq)} + 20\ H_2O_{\,(l)} \rightarrow 6\ H_3PO_{4\,(aq)} + 10\ [CaSO_4 \bullet 2\ H_2O]_{\,(s)} + 2\ HF_{\,(aq)}$$

Equation 8

The gypsum formed during the reaction with the mineral acid is removed via filtration. Once removed, the gypsum solids undergo several aqueous wash cycles to remove residual phosphoric acid from the solid surface, producing phosphoric acids yields of 99.9% (EPA 1995; Gilmour 2019). As shown previously in Figure 5, the aqueous gypsum washes are sent back to the reaction vessel to aid in the conversion of mineral phosphates (EPA 1995; Gilmour 2019). The presence of mineral silicon in the initial composition reacts with hydrofluoric acid to produce less reactive forms of silicon tetrafluoride (SiF_4) and SiF_6^{2-} ions, some of which are removed as solids with the gypsum (Gilmour 2019).

The phosphoric acid isolated following the filtration process is dilute, with P_2O_5 concentrations between 26 – 30% (EPA 1995; Gilmour 2019). Vacuum evaporation is used to remove water and concentrate the Phosphoric acid to 42 – 54% P_2O_5 (Gilmour 2019). Activated silica or clay is added during the concentration process to react with residual hydrofluoric acid. Silicon tetrafluoride isolated from the concentration step is hydrolyzed to fluorosilicic acid (H_2SiF_6), as shown in Figure 5 (Gilmour 2019).

Mineral impurities, including heavy metal contaminants, remain in phosphoric acid produced via the wet process, which have historically limited its use to agricultural fertilizer applications (EPA 1995; Shriver and Atkins 2008; Gilmour 2019; Haghani and Daneshpazhuh 2020). Wet process phosphoric acid results in concentrations of between 42 and 54% P_2O_5, which is largely unsuitable for technical applications (Gilmour 2019). The elemental phosphorous used in the thermal process can be purified via sublimation, resulting in no carry-over of heavy metal contaminants so that thermal phosphoric acid can be used in technical and food applications (Shriver and Atkins 2008). However, the thermal process is much more expensive and energy intensive than the wet process (~2000 °C vs ~80 °C) (EPA 1995, Gilmour 2019).

Wet process purification methods

Wet process phosphoric acid is commonly purified by crystallization or solvent extraction (Gilmour 2019). Crystallization is a common purification technique, which is based on the differing solubilities of pure and impure mixtures, with pure substances selectively crystallizing at reduced temperatures (Pavia et al. 1995). When phosphoric acid is concentrated to 61% P_2O_5 or higher, it selectively forms hemihydrate crystals ($H_3PO_4 \bullet \frac{1}{2}\ H_2O$) when cooled to 8 – 12 °C (Gilmour 2019). The crystals are removed from the mixture and can be melted to undergo additional recrystallization cycles to improve purity, with each cycle yielding a 10 to 100 times increase in purity (Gilmour 2019).

Solvent extraction is another traditional purification method based on solubility. In solvent extraction, the target compound migrates between immiscible phases (usually aqueous [polar] and organic [nonpolar]) based on solubility (Pavia et al. 1995). The selectivity of phosphoric acid does not differ greatly compared to its impurities, requiring additional purification steps. Prior to solvent extraction, concentrated phosphoric acid undergoes precipitation with calcium or barium salts to remove sulfate (SO_4^{2-}), sodium salts to remove fluorosilicates, and sulfides to remove arsenic (Shlewitt and Alibrahim 2008; Gilmour 2019; Haghani and Daneshpazhuh 2020). Phosphoric acid extractions are performed in one or more extraction columns with many possible organic solvents, including alcohols, ethers, ketones, amines, and kerosene blends (Shlewitt and Alibrahim 2008; Jin et al. 2014; Gilmour 2019).

Following extraction with an organic solvent, phosphoric acid is recovered with water. Residual organic solvents are removed via evaporation during the concentration of the recovered phosphoric acid from the aqueous solution (Shlewitt and Alibrahim 2008, Gilmour 2019). Solvent extraction of wet process phosphoric acid improves the purity of the substance from 42-54% P_2O_5 in the raw form to up to 97% P_2O_5 (Gilmour 2019). [TR 376-482]

International Acceptance

Canadian General Standards Board Permitted Substances List
Phosphoric acid is listed in the Organic Production Systems Permitted Substances List as an approved substance for pH adjustment of "fish meal, fish powder, fish wastes, hydrolysate, emulsions and solubles" that are used for "soil amendments and crop nutrition." Phosphoric acid is also listed as a "cleaner, disinfectant and sanitizer permitted on organic product contact surfaces for which a removal event is mandatory [for use] on dairy equipment." [TR 345-351]

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Phosphoric acid is not listed in EC No. 834/2007 or EC No. 889/2008. [TR 357-358]

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Phosphoric acid is not listed in the CODEX. [TR 353-355]

International Federation of Organic Agriculture Movements (IFOAM) Norms
Phosphoric acid is listed in the IFOAM NORMS for organic production and processing as an "equipment cleanser and equipment disinfectant only for dairy equipment," and as a "substance for pest and disease control and disinfection in livestock housing and equipment [for] dairy equipment." [TR 364-367]

Japan Agricultural Standard (JAS) for Organic Production
Phosphoric acid is not listed in the JAS. [TR 360-361]

Environmental Issues
The TR indicates that phosphoric acid is relatively benign regarding its impact on the environment. However, its production does have the potential to be harmful to the environment. The thermal process for producing it is energy intensive and requires high temperatures. The high energy requirements of the thermal process may contribute to atmospheric CO_2 levels if the energy is produced from fossil fuels. The thermal process also requires the treatment of combustion gases by scrubbers, cyclonic separators, mist eliminators, and electrostatic precipitators to prevent the release of phosphoric acid to the environment (EPA 1995; Gilmour 2019). The small size ($< 3\ \mu$m diameter) makes these phosphoric acid and phosphorus oxide (P_2O_5) particles difficult to capture, and contributes their release to the atmosphere at levels of "< 25 mg P_2O_5 per dry standard cubic meter of stack gas" (Gilmour 2019). Wet process phosphoric acid is produced from chemical changes to mined mineral phosphates. There may be initial harm to the environment and biodiversity in the mining process. Once the minerals are isolated, hydrofluoric acid presents the most likely source of environmental harm (Shriver and Atkins 2008). Hydrofluoric acid is removed as a solid or as fluorosilicic acid by reaction with silica sources. These include natural silicates present within the initial mineral, as well as activated silica and clay added during the manufacturing process (Shriver and Atkins 2008; Gilmour 2019). Additionally, scrubbers are used to remove gaseous fluorine compounds from concentration steps to prevent their release to the environment (EPA 1995).

In addition to the hazards from fluorine compounds, the gypsum produced may pose a hazard to the environment. Isolated gypsum may be used for other commercial applications if it is sufficiently pure (Gilmour 2019). In other cases, gypsum is left in gypsum stacks, or pumped out to sea (Gilmour 2019). However, the gypsum may also contain silicon fluorides, acids, and other impurities from the initial mineral source, which has resulted in its designation as a hazardous substance by the EPA in 40 CFR 261.4. [TR 566-594]

Ancillary Substances
None

Discussion
During the 2018 sunset review the NOSB unanimously voted to relist phosphoric acid. The discussion largely focused on the broader topic of sanitizers on the National List. It was stated at the time that while there is a general desire for a safer alternative to phosphoric acid, there didn't seem to be viable options at that time.

In 2020, the Board received a petition to expand the annotation of phosphoric acid "as an acidifier to adjust pH of an extraction solvent to extract antioxidants or other target molecules from *lamiaceae* plants, provided the amount of acid used shall not exceed the minimum needed to lower pH to 2.5" (USDA 2020b).

During the Fall 2022 Board meeting, the NOSB unanimously voted against the petitioned annotation expansion.

While there was a TR contracted in 2021 due to this petition, the TR focused on the petitioned use (not the current listing as an equipment sanitizer). Therefore, it did not specifically cover alternatives to phosphoric acid as an equipment sanitizer.

The Handling Subcommittee broadly discussed sanitizers and various options for how to address the broader topic. At this time the Subcommittee supports the continued listing of phosphoric acid.

Questions to our Stakeholders
1. Is phosphoric acid essential as an equipment sanitizer to be incorporated into your sanitizer rotation?
2. Is phosphoric acid used as an equipment sanitizer in a particular sector of the organic industry?

Potassium carbonate

Reference: 205.605(b) Synthetics allowed. (24) Potassium carbonate.
Technical Report: 1995 TAP; 2022 TR pending
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 338-339); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290);

Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Potassium carbonate is both a carbonate salt and a potassium salt with many uses. For processing and handling applications, the main uses are as follows:

Potassium carbonate is utilized in the production of yellow alkaline wheat noodles found in both Chinese and Japanese cuisines. It is used in cocoa production during the "Dutching" process to restore the desired dark pigmentation. In raisin production, potassium carbonate can be used as a drying agent to decrease drying time and reduce spoilage from open air drying. Potassium carbonate is applied as a pre-harvest spray onto fruit, or as a pre-drying dip at an optimal 0.6% concentration, along with either olive oil or ethyl oleate (Doymaz & Pala, 2002; Peacock et al., 2006). Potassium carbonate is utilized to raise the pH in the deacidification of wine. It is also an allowed substance in the production of modified hop extract, as listed at 21 CFR 172.560. Potassium carbonate is approved for use as a boiler additive in the preparation of steam that will come in direct contract with food. Meat processors are exploring the use of potassium carbonate as a replacement for phosphates in processed meat products, along with a number of other alternatives (Thangavelu et al., 2019). One study found that potassium carbonate, when applied at 0.3% or 0.5%, maintained the color of fresh pork, preserved tenderness, and reduced cooking loss when compared with an industry standard, sodium tripolyphosphate (LeMaster et al., 2019). It is also used in soap production, soft drinks, and confections.

The original technical advisory panel (TAP) notes that it be used only when sodium carbonate is not appropriate. However, it can be used to replace sodium carbonate when a lower sodium content is desired.

Manufacture
Potassium carbonate is one of several potassium-containing compounds that may be referred to as potash. Traditionally, potash was created by leaching wood ashes with water, which extracted a crude form of potassium carbonate (Schultz et al., 2000). This type of potassium carbonate, and its more refined by-product, pearl ash, have been utilized for millennia, with applications in baking and glassmaking. Following the discovery of naturally occurring potassium salts (e.g., potassium chloride or potassium sulfate) in the 1860s, wood ash-derived potassium carbonate was replaced by mineral potassium salts obtained through shaft mining, dissolution mining, and evaporation methods (Ciceri et al., 2015). Potash mining is active worldwide, and commercial production of potassium carbonate depends primarily on potassium chloride brines, which are derived from potassium chloride salts that are found in mineral potash (Schultz et al., 2000).

Modern, commercial production of potassium carbonate occurs through the reaction of potassium hydroxide with carbon dioxide, or CO2-containing off-gases from other industrial processes (Schultz et al., 2000).

International Acceptance

Canadian General Standards Board Permitted Substances List

Potassium carbonate is listed in the Canadian General Standards Board Organic Production Systems Permitted Substances List (CAN/CGSB-32.311 - 2020) in the following locations:

- In Table 6.3, as a food additive, with no origin or usage annotations.
- In Table 6.5 as an allowed processing aid, with no origin or usage annotations.
- In Table 7.4 for allowed "cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory" with the annotation that "documentation shall demonstrate that effluent discharge was neutralized to minimize negative environmental impact."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Potassium carbonate is listed in (EC) No 889/2008 under "Section A — Food Additives, Including Carriers" as an allowed substance for the "preparation of foodstuffs of plant origin." It is also listed under "Section B — Processing Aids and Other Products, Which May Be Used for Processing of Ingredients of Agricultural Origin from Organic Production" as allowed for the "preparation of foodstuffs of plant origin," and specifically for drying of grapes.

EU organic standards have been updated since 2008. (EU) 2018/848 is the current regulation. Its Article 24(2)(a) authorizes certain products and substances for use in the production of processed organic food as noted in restrictive lists. These lists are currently codified in (EU) 2021/1165. Part A of Annex V lists food additives and processing aids. Potassium carbonates, E 501, appear in "Section A1 - Food Additives, Including Carriers" for addition to products of plant origin. Potassium carbonate also appears in "Section A2 — Processing Aids and Other Products, Which May Be Used for Processing of Ingredients of Agricultural Origin from Organic Production," authorized only for the processing of organic grapes as a drying agent.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Potassium carbonate is listed in the CODEX (GL 32-1999) guidelines in Table 3.1 as a "food additive, including carriers" for specific use in "cereals/cakes & biscuits/confectionary." It is also listed in Table 4 as "processing aids which may be used for the preparation of products of agricultural origin referred to in section 3 of these guidelines" and specific use for the "drying of grape raisins."

International Federation of Organic Agriculture Movements (IFOAM) Norms
Potassium carbonate is listed in the IFOAM Norms under the Standard for Organic Production and Processing in Appendix 4 – Table 1: List of Approved Additives and Processing/Post-Harvest Handling Aids for use as both an additive and a processing/post-harvest handling aid, without any limitation note.

Japan Agricultural Standard (JAS) for Organic Production
Potassium carbonate is listed in the Japanese Agricultural Standard for Organic Processed Foods under the "Appended Table 1 Additives," where it is stated to be "limited to the use in the drying of processed fruit products or in processed grain products, sugar, products containing legumes, noodles, bread, or confections."

Environmental Issues
Emissions associated with manufacture include heat and CO_2 into air, as well as K^+ and OH^- in water (Maul et al., 2014).

As a food additive, potassium carbonate is utilized in small quantities compared to its applications as a livestock feed supplement or in other industrial processes (Chu et al., 1996; Fraley et al., 2015; Jaster & Moore, 1992). Negative effects on biodiversity or the general environment have not been reported in relation to the use of potassium carbonate as a food additive.

Ancillary Substances
None

Discussion
Potassium carbonate has a vast amount of uses in organic production. Public comments from the previous sunset review demonstrated a continued need for this material. One manufacturer noted its use as a sodium reduction agent and that removal from the list would result in a rise in sodium levels in their product by 18%. Other commenters noted use in a protein bar and as a nutritional supplement.

Questions to our Stakeholders
1. Since last reviewed, have there been any changes (either in substitute products or manufacturing process) that would warrant removal of potassium carbonate from the National List?

Sulfur dioxide

Reference: 205.605(b) Synthetics allowed. (35) Sulfur dioxide - for use only in wine labeled "made with organic grapes," Provided, That, total sulfite concentration does not exceed 100 ppm.
Technical Report: 1995 TAP; 2011 TR
Petition(s): 2010 (to amend)
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 333-334); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 12/2011 NOSB recommendation (annotation change not recommended); 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Sulfur dioxide has been used as an antimicrobial and antioxidant in food, including wine, since Greek and Roman times. Sulfur dioxide is primarily used to inhibit microbial growth and prevent spoilage and oxidation in wine. It has also been used to preserve conventionally produced meats and avoid browning in fresh and dried produce and other products. The current National List annotation limits the use of

sulfur dioxide to wine labeled "made with organic grapes" and further limits the sulfite concentration to not exceed 100 ppm.

Sulfur dioxide may play a number of roles in wine production, at multiple stages in processing. Cultivated yeasts added to enhance fermentation of wines have been selected to be more tolerant of sulfur dioxide than wild yeasts. Enough sulfur dioxide is added to deter growth of the wild yeasts or bacteria present in the grape juice, while not exceeding a level that will deter the growth of the desired added yeasts to the juice. This process helps to prevent the formation of "off" flavors. While sulfites occur naturally in wines, the level is too low to have a pragmatic effect.

Sulfites may be added to wine in various forms. Sulfur dioxide comes in pellet, liquid (sulfurous acid), or gaseous form. Potassium metabisulfite is commonly powdered; the 2022 Organic Materials Review Institute (OMRI) generic materials list states that potassium metabisulfite is prohibited.

Wine can be made successfully without added sulfites, but alternative interventions are often necessary to avoid microbial contamination, manage fermentation, and control oxidation. Sulfite reduction strategies include refrigerated fermentation in climate-controlled facilities, pasteurization via ultraviolet irradiation, and use of stable gases to fill the head space in packaging. Wines without added sulfur dioxide may also have a shortened shelf life.

Manufacture
Sulfur dioxide can be produced commercially from several sources including elemental sulfur, ores of sulfide containing minerals, gypsum and anhydrite, and waste materials or flue gasses that contain sulfur. Most commonly, sulfur dioxide is generated by simply burning sulfur in devices that control air flow and that can capture the sulfur dioxide as it is generated.

International Acceptance
Several major U.S. trade partners allow sulfur dioxide in "organic" wines and other alcoholic products produced from various fruits. Maximum sulfite levels vary depending on the product. Demeter Biodynamic standards also allow sulfur dioxide, potassium bisulfite, and potassium metabisulfite, up to 100 ppm sulfites at bottling.

Canadian General Standards Board Permitted Substances List
Sulphur dioxide, sulphurous acid, and potassium metabisulphite are allowed as preservatives in organic alcoholic beverages under Canadian organic standards, with the following limitations/specifics:

- Sulphur dioxide includes sulphites from SO2-bottled gas; as liquid SO2; or liberated from ignition of asbestos-free sulphur wicks
- Minimal use of SO2 is recommended
- Maximum allowable levels of SO2 in parts per million (ppm) are:
  a) in alcoholic beverages containing less than 5% residual sugar, 100 ppm and 30 ppm for total and free sulphites, respectively;
  b) in alcoholic beverages containing 5%-10% residual sugar, 150 ppm and 35 ppm for total and free sulphites, respectively; and
  c) in alcoholic beverages containing more than 10%

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Sulphur dioxide, potassium bisulphite, and potassium metabisulphite allowed in products of the wine sector, with maximum sulphur dioxide limits set for certain product categories (EU 203/2012):

- Sulphur dioxide content not to exceed 100 milligrams per litre for certain red wines with a residual sugar level lower than 2 grams per litre;
- Sulphur dioxide content not to exceed 150 milligrams per litre for certain white and rosé wines
- with a residual sugar level lower than 2 grams per litre;
- For all other wines, the standard sulphur dioxide content allowed by EU regulations shall be reduced by 30 milligrams per litre

Sulphur dioxide and potassium metabisulphite allowed (EC 889/2008):

- In fruit wines (wine made from fruits other than grapes) without added sugar (including cider and perry) or in mead: 50 mg (maximum levels available from all sources, expressed as SO2 in mg/l)
- For cider and perry prepared with addition of sugars or juice concentrate after fermentation: 100 mg/l (maximum levels available from all sources, expressed as SO2 in mg/l)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Sulphur dioxide is listed in the Codex organic guidelines for use in cider and perry, grape wines, wines (other than grapes), and mead (GL-32-1999, Annex 2, Table 3).

International Federation of Organic Agriculture Movements (IFOAM) Norms
The IFOAM norms list sulfur dioxide and potassium metabisulphite for use in wine (IFOAM Norms 2014, Appendix 4 – Table 1).

Japan Agricultural Standard (JAS) for Organic Production
INS #220 – Additives (Organic alcohol beverages) used in organic processed foods

Environmental Issues
There are no expected adverse environmental effects from the use of sulfur dioxide as currently listed in on the National List.

Health Issues
About 1% of the population reacts adversely to sulfites,[1] and reactions range from allergic reactions in individuals born without the enzyme needed to break down sulfur dioxide (sulfite oxidase), asthma attacks (which vary depending on individual sensitivity), hives and swelling, to anaphylaxis. Sulfite sensitivity may develop at any time, and reactions may not occur until middle age.[2]

U.S. law is highly protective of sensitive individuals. In the 1980s, widespread use of sulfites in restaurants, on products like salad bars and processed potatoes, led to several highly publicized deaths.[3] This prompted FDA to restrict the use of sulfites on some foods and implement labeling requirements.[4] Today, sulfur dioxide is not generally recognized as safe (GRAS) for use in meats, in food recognized as a source of vitamin B1 (because sulfites interfere with absorption), or fresh fruits and vegetables (e.g.,

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[1] Paul Grotheer et al., Sulfites: Separating Fact from Fiction (2011), *available at* http://edis.ifas.ufl.edu/fy731.
[2] Grotheer et al.
[3] Ruth Papazian, *Sulfites: Safe for Most, Dangerous for Some*, 30 FDA Consumer Magazine 10 (1996), *available at* http://permanent.access.gpo.gov/lps1609/www.fda.gov/fdac/features/096_sulf.html; Irvin Molotsky, *House Panel Hears Plea for Food Sulfite Ban*, N.Y. Times, Mar. 28, 1985, *available at* http://www.nytimes.com/1985/03/28/us/house-panel-hears-plea-for-food-sulfite-ban.html.
[4] Food Labeling: Declaration of Sulfiting Agents: Final Rule, 51 Fed. Reg. 25,012 (1986).

salad bars, fresh produce in supermarkets).[5] Products with over 10 ppm sulfites must declare the presence of sulfites on the label.[6] The Bureau of Alcohol, Tobacco, Firearms created similar labeling requirements for alcoholic beverages.[7] Federal regulations allow up to 350 ppm sulfur dioxide in wine[8] and require a sulfite declaration for wines with 10 ppm or more total sulfur dioxide in the finished product.[9] Accordingly, sulfite sensitive consumers have strong access to the information they need to protect themselves from exposure.

Ancillary Substances
None

Discussion
Sulfur dioxide is considered safe at the levels allowed under the current annotation, which are more restrictive than those for nonorganic wines. Strict sulfite labeling requirements also allow sulfite-sensitive consumers to avoid products with added sulfites.

Wine can be made successfully without added sulfites, but many winemakers do not find alternative methods and materials satisfactory to prevent spoilage and oxidation in wine.

The current annotation allows the use of sulfur dioxide only in wines labeled "made with organic grapes," which continues to contribute to confusion in the marketplace. Internationally, the U.S. is an outlier in limiting use of sulfur dioxide to wines labeled "made with organic"; our major trade partners allow it in wines labeled "organic" as well as other fermented fruit products like cider and perry.

The labeling limitations for wine produced from organic grapes using sulfur dioxide have an important relationship with the potential growth of organic grape acreage. For example, in 2020, California had 625,000 acres of wine grapes, but only about 25,000 acres of harvested organic wine grapes.[10] Wine grapes are routinely treated with a wide range of pesticides, including glyphosate which has been found in wine.[11]

The Subcommittee discussed the health risks of exposure to sulfur dioxide, as well as the protective measures that are in place for sensitive individuals and concluded that the continued listing of sulfur dioxide is compatible with the Organic Foods Production Act (OFPA). The Board may also wish to continue to discuss the current annotation and the best ways to balance the individual health risks associated with sulfites and the broader health and environmental threats of conventional wine

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[5] 21 C.F.R. § 182.3862 (1997); Grotheer et al.

[6] 21 C.F.R. § 130.9 (1997); Grotheer et al.

[7] Labeling of Sulfites in Alcoholic Beverages, 51 Fed. Reg. 34,706 (Sept. 30, 1986).

[8] 27 C.F.R. § 4.22(b)(1) (2004).

[9] 27 C.F.R. § 4.32(e) (2004).

[10] California Department of Food and Agriculture (CDFA), California Grape Acreage Report, 2021 Summary, https://www.nass.usda.gov/Statistics_by_State/California/Publications/Specialty_and_Other_Releases/Grapes/Acreage/2022/grpacSUMMARY2021Crop.pdf; CDFA, California Agricultural Organics Report, 2020-2021, https://www.cdfa.ca.gov/Statistics/PDFs/2021_Organics_Publication.pdf.

[11] California Department of Pesticide Regulation, Summary of Pesticide Use Report Data 2018, https://www.cdpr.ca.gov/docs/pur/pur18rep/pur_data_summary_2018.pdf (sulfur, allowed on organic and nonorganic acreage, contributes to the); Moms Across America, Widespread Contamination of Glyphosate Weedkiller in California Wine, 2016, https://d3n8a8pro7vhmx.cloudfront.net/yesmaam/pages/680/attachments/original/1458848651/3-24-16_GlyphosateContaminationinWineReport_(1).pdf?1458848651.

production. It would be helpful to understand the current state of the organic wine industry, label claims in use, and how sulfites are currently used in production of wine from organic grapes.

Questions to our Stakeholders

1. Do you or your members/clients produce wine from organic grapes? What label claims do you use and why?
2. What form of sulfur dioxide do you use? Is there another form you would prefer, and if so, what, and why?
3. At what stage is the sulfite content of wine measured/verified (e.g., at bottling)?

Xanthan gum

Reference: 205.605(b) Synthetics allowed. (37) Xanthan gum.
Technical Report: 1995 TAP; 2016 TR; 2018 TR (gums)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 332); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 11/2016 NOSB recommendation (none, reclassification not recommended); 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use

Xanthan gums are one of the many gums used in organic handling for reasons including: (1) thickening and gelling, (2) stabilizing foams, emulsions, and dispersion, (3) inhibiting ice and sugar crystal formation, (4) aiding formulation, and (5) to control the release of flavors. Xanthan gum is an important ingredient for gluten-free products; it also is used in salad dressings, sauces, dairy products, along with other products.

Despite having similar characteristics and performing similar functions, gums are not interchangeable. Depending on their structure, each gum has a unique response to temperature, pH range, physical agitation, and so on (2018 TR). This variability requires gums to be matched to the type of food, intended shelf-life, and product use. Often several gums are used in combination to impart the correct properties in the finished goods (2018 TR). The table below is from the 2018 Technical Report, which distinguishes the different characteristics of common gums.

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Xanthan gum was approved as a food additive by the Food and Drug Administration (FDA) in 1969 without restrictions on quantity in finished applications (2018 TR). The FDA specifies that the food additive xanthan gum may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a polysaccharide gum derived from *Xanthomonas campestris* by a pure-culture fermentation process and purified by recovery with isopropyl alcohol. It contains D-glucose, D-mannose, and D-glucuronic acid as the dominant hexose units and is manufactured as the sodium, potassium, or calcium salt.

(b) The strain of *Xanthomonas campestris* is nonpathogenic and nontoxic in man or other animals.

(c) The additive is produced by a process that renders it free of viable cells of *Xanthomonas campestris.*

(d) The additive meets the following specifications:

(1) Residual isopropyl alcohol not to exceed 750 parts per million.

(2) An aqueous solution containing 1 percent of the additive and 1 percent of potassium chloride stirred for 2 hours has a minimum viscosity of 600 centipoises at 75 deg.F, as determined by Brookfield Viscometer, Model LVF (or equivalent), using a No. 3 spindle at 60 r.p.m., and the ratio of viscosities at 75 deg.F and 150 deg.F is in the range of 1.02 to 1.45.

Xanthan gum must pass the locust bean gum test and the pyruvic acid test. See 21CFR172.695 for more specificity.[12]

Manufacture

Xanthan gum is a high-molecular weight polysaccharide produced though natural fermentation by *Xanthomonas campestris* and precipitation through addition of an alcohol; it subsequently is dewatered, possibly washed in a salt solution, dried, and milled (2018 TR). The gum is water soluble, stable at numerous pH, salt, and temperature ranges (including frozen temperatures) (2018 TR). The side chains

[12] Code of Federal Regulations. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=172.695

carry negative charges and will associate with positive cations to increase the firmness of the solution (TR 2018). Overall, the structure of xanthan gum is such that it is a cellulose chain with trisaccharide side chains. In solution, the side chains wrap around the cellulose backbone and aid in the ability for xanthan gum to be stable in low pH and high salinity solutions (2018 TR). In addition to its wide applicability under differing food mediums, it also has pseudo-plastic characteristics which under shear force make the solution less viscous and thus easier to move during processing. When the shear force is removed, the solution will again exhibit its characteristic thickness. Xanthan gum is not a gelling agent, and as a result it is often used in combination with other materials including locust bean gum, guar gum, starches, carrageenan and konjac glucomannan to increase viscosity (2018 TR).

International Acceptance
Canadian General Standards Board Permitted Substances List
Permitted but must be derived using substances listed in Table 6.3 (page 32 on document linked above). Extraction solvents and precipitation aids. By exception, isopropyl alcohol may also be used to derive gums.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Allowed for use in products of plant and animal origin. Information sourced here (and not the link above).

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

Allowable in plant foods: for fats and oils, and fat emulsions; fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds; bakery wares; and salads (e.g., macaroni salad, potato salad). Not allowed in food of animal origin.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Allowed as an approved additive, processing, and handling aid, with no limitations noted.

Japan Agricultural Standard (JAS) for Organic Production
When used in processed products of livestock origin, limited to the use in dairy products or confections. Information found in this document.

Environmental Issues
There was no mention in the TR of specific environmental issues regarding the production of xanthan gum.

Ancillary Substances
According to the 2016 TR (258-263), ancillary substances are not commonly added to commercially available forms of xanthan gum for use in foods. The 2018 sunset review indicates that through a search of publicly available specification sheets, a few exceptions were identified: glucose in a xanthan and guar gum blend and polysorbate 60 in GRINSTED®. For 2023 sunset, a review of the GRINSTED® product literature reveals it is synergistic with guar and locust bean gum.

Discussion
Xanthan gum has been used for decades globally in the food system and subsequently has undergone numerous clinical trials and studies to look for impacts on human health in adults, children, infants, and animals (TR 2018). Some studies have shown that xanthan gum is beneficial to human health; soluble fiber that may help improve colon health and reduce cholesterol (2018 TR).
A review of the safety of xanthan gum was conducted by the European Food Safety Authority Panel on Food Additives and Nutrient Sources found that xanthan gum can be classified as non-toxic. Xanthan gum would not be, they found, absorbed intact and would be partially fermented as it traveled through the large intestine. In studies on different animal species (dogs, rats, neonatal piglets) no adverse effects were observed. The panel recommended collecting data on usage and levels of xanthan gum to conduct a more realistic exposure level through diet.[13]

Recent research examines the impact of xanthan gum on the gut microbiome; the rationale for examining the impact is that xanthan gum is not similar to any existing dietary fiber.[14] Xanthan gum is an important ingredient for gluten-free products, and used in higher amounts for these products. Because of its 'low level but constant consumption,' a research team sought to try to understand its impact on gut microbiome health. The key finding is 'Our work demonstrates the existence of a potential xanthan gum food chain involving at least two members of different phyla of gut bacteria and provides an initial framework for understanding how widespread consumption of a recently introduced food additive influences human microbiomes.' The research team, in a different publication, indicate that in just 50 years, the introduction of xanthan gum to our diet has created a new chain (as described above).[15] Thus, the NOSB should keep abreast of this evolving line of research.

The Handling Subcommittee's discussion centered around essentiality, the existence of an organic version, and questions about any environmental or human health concerns since last reviewed.

Questions to our Stakeholders

1. Is xanthan gum essential?
2. Are there any ancillary substances used with this product?
3. Have any environmental or health concerns emerged since the last sunset review?

[13] EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), Mortensen, A., Aguilar, F., Crebelli, R., Di Domenico, A., Frutos, M.J., Galtier, P., Gott, D., Gundert-Remy, U., Lambré, C. and Leblanc, J.C., 2017. Re-evaluation of xanthan gum (E 415) as a food additive. *EFSA Journal*, *15*(7), p.e04909.
[14] Ostrowski, M.P., La Rosa, S.L., Kunath, B.J., Robertson, A., Pereira, G., Hagen, L.H., Varghese, N.J., Qiu, L., Yao, T., Flint, G. and Li, J., 2022. Mechanistic insights into consumption of the food additive xanthan gum by the human gut microbiota. *Nature Microbiology*, *7*(4), pp.556-569.
[15] Ostrowski, M.P., La Rosa, S.L., Kunath, B.J., Robertson, A., Pereira, G., Hagen, L.H., Varghese, N.J., Qiu, L., Yao, T., Flint, G. and Li, J., 2021. The food additive xanthan gum drives adaptation of the human gut microbiota. *bioRxiv*.

Fructooligosaccharides

Reference: 205.606 Nonorganic agricultural substances allowed: (g) Fructooligosaccharides (CAS # 308066-66-2).
Technical Report: 2006 TR (FOS); 2015 TR
Petition(s): 2006
Past NOSB Actions: 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 06/21/2007 (72 FR 35137); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Fructooligosaccharides (FOS) is on the National List at § 205.606 as a non-organically produced agricultural product allowed as an ingredient in or on products labeled as "organic". As a non-digestible carbohydrate, this substance is used as a soluble prebiotic fiber ingredient in food products. While FOS is included in food products as a source of energy for probiotic bacteria residing in the gut of humans, it is not used as a nutrient source directly for humans. FOS is incorporated into milk products, cakes, biscuits, cookies, crackers, yogurt, ice cream, soup, and hard candy, among other foods.

Manufacture
There are two common commercial methods of producing FOS:

1) **Inulin derived**. Inulin is a dietary fiber found in chicory (Belgian endive), Jerusalem artichoke, agave, and other plants. Chicory inulin is extracted from the source material via water extraction; the resulting inulin undergoes partial hydrolysis using the enzyme inulinase, which is extracted from an enzyme complex (carbohydrase) found in the fungus *Aspergillus niger.* The hydrolysis breaks long chain inulin into shorter chain FOS
2) **Sucrose derived**. Sugar cane or sugar beet extracted sugar is fermented with *Aspergillus japonicas.* The *A. japonicas* cells must be immobilized for the production of high-purity FOS, which can be accomplished by creating beads of the *A. japonicas* culture suspended in calcium alginate, a mobilizer. The *A. japonicas* cells hydrolyze (break) the sucrose molecules into glucose and fructose and then transfer molecules to an existing glucose-fructose chain to create one of the FOS complex sugars. Fermentation of sucrose by *A. japonicas* is generally inefficient. Higher purity FOS solutions can be achieved by several methods: filtration, enzyme extraction, or mixed culture fermentation with the yeast *P. heimii* to increase the purity of the FOS solution. Each of these methods introduces additional chemical or physical agents to the production process.

Both processes also use heat and pH control to speed up the enzyme reactions. Specifically, the adjustment of pH is accomplished using hydrochloric acid, which is a strong acid, or sodium hydroxide, a strong base. Potassium phosphate is also used for pH control. The FOS produced can then be further purified through filtration or further fermentation.

International Acceptance

Canadian General Standards Board Permitted Substances List
FOS is not officially recognized as a dietary fiber source by Health Canada. This is because the fiber policy has not been updated since 1997 (Health Canada, 2012).

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

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
FOS is not specifically listed.

Japan Agricultural Standard (JAS) for Organic Production
FOS is listed in the Approved FOSHU products list and classified as "foods to modify gastrointestinal conditions".

Environmental Issues
There is no information available from EPA or FDA to suggest that environmental contamination results from the manufacture, use, misuse, or disposal of short-chain FOS. Regarding human health concerns, there are no known harmful effects on human health after exposure to short-chain FOS.

Ancillary Substances
"There are no ancillary substances intentionally included in the FOS formulations as described in the petition, and no ancillary substances are intentionally added to the FOS products in the selected high-purity FOS fermentation." (2015 Technical Report)

Discussion
During the last Sunset review, FOS remained at § 205.606 by a vote of 14 to 1. Most stakeholder comments were in support of the continued listing of FOS. Further, there appear to be no new sources of organic FOS coming out of the last review session. Given that the strongest opposition to keeping FOS on the National List centers around the availability of organic supply, the Handling Subcommittee will focus on this aspect.

Questions to our Stakeholders
1. What is the current availability of suitable organic supply for the manufacture of FOS?

Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean)

Reference: 205.606 Nonorganic agricultural substances allowed: (j) Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean).
Technical Report: 1995 TAP (acacia, arabic, locust bean, guar, carob bean); 2018 TR (gums)
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 12-13); 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use
Gum arabic, locust bean gum, carob bean gum, and guar gum are high molecular-weight-polysaccharides extracted via water processing and then drying and milling (2018 TR). The gums are extracted from the endosperm of plants of the *Leguminosae*. The specific plants are guar, carob, and locust bean. Gum Arabic is obtained from the exudate from the bark of the acacia tree and is one of the oldest known natural gums (1995 TAP; 2018 TR). These gums are used in various food applications due to their ability to modify the viscosity of products (hydrocolloid function) through the binding of water and generation of gelling effects (2018 TR). These properties are the primary function of gums and lend them to be common and popular thickeners and stabilizers in food products. Guar gum, gum Arabic, and locust bean/carob bean gum are also thickening agents, which makes them useful since not all hydrocolloids function as thickening agents (2018 TR).
Despite having similar characteristics and performing similar functions, gums are not interchangeable. Depending on their structure, each gum has a unique response to temperature, pH range, physical agitation, and so on (2018 TR). This variability requires gums to be matched to the type of food, intended shelf-life, and product use. Often several gums are used in combination to impart the correct properties in the finished goods (2018 TR). The table below is from the 2018 technical report, which distinguishes the different characteristics of common gums.

Gum Arabic is used in soft drinks, icing, fillings, chewing gum, confectionary treats, and for color stability (this is general use in food).

Guar gum is used in yogurt, ice cream, cheese, salad dressings, and sauces.

Locust bean/carob bean gum is used in ice cream, yogurt, sauces, prepared foods, and soups. In some cases, it is used with xanthan gum.

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Source: Technical Report, 2018.

Manufacture

Gum arabic is obtained from the exudate from dried sap collected from the stems and branches of the Acacia tree, both wild grown and cultivated. The gum is cleaned by mechanical sieves and graded, then milled to a powder (2018 TR).

Locust/carob bean gum is derived from the seeds of the carob tree, which are processed through a series of crushing, sifting, and grinding steps (2018 TR).

Guar gum is formed from the seeds of the guar bean plant. The endosperm is dehusked, milled and screened, and the gum is then clarified (2018 TR).

International Acceptance

Canadian General Standards Board Permitted Substances List

Is permitted but must be derived using substances listed in Table 6.3 (page 32 on document linked above). Extraction solvents and precipitation aids. By exception, isopropyl alcohol may also be used to derive gums.

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

Allowed for products of plant and animal origin.

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

Allowed, although the restrictions of the General Standard for the Labeling of Prepackaged Foods apply.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Allowed as an additive.

Japan Agricultural Standard (JAS) for Organic Production

- Carob bean/locust bean: Allowed, but when used in processed products of livestock origin, limited to the use in dairy products or processed meat products.
- Guar gum: Allowed, but when used in processed products of livestock origin, limited to use in dairy products, canned meats, or egg products. Gum Arabic: Allowed, but limited to the use in dairy products, edible oils or fats, or confections.

Environmental Issues No environmental or health concerns were noted in the manufacture or use of these gums in the general population. The EFSA (European Food Safety Authority) Panel on Food Additives and Nutrient Sources evaluated five gums in 2017 including arabic, guar, and locust. The panel found no need for a numerical acceptable daily intake (ADI) and no safety concerns for the general population. The panel also concluded there wasn't adequate data available to assess the effects of locust bean and guar gum on infants and young children and recommended that additional data be generated.

Ancillary Substances
According to the 2018 TR, no information was found indicating that any additional materials are generally added to commercially available forms of the gums.

Discussion
Public comment received during the last review noted that while organic versions of these gums existed, the supply chain is inconsistent and therefore commenters supported continued listing at § 205.606. There was also a request that the gums be listed individually so that organic supply of each specific gum could be considered on an individual basis.
The Handling Subcommittee's discussion centered around essentiality, the existence of an organic version and questions as to whether there are any environmental or human health concerns since last reviewed.

Questions to our Stakeholders

1. Are organic versions of gum arabic, locust/carob bean gum, and guar gum commercially available?
2. Is this product essential?
3. Are there any ancillary substances used with this product?
4. Have any environmental or health concerns emerged since the last sunset review?

Lecithin - de-oiled

Reference: 205.606 Nonorganic agricultural substances allowed: (l) Lecithin - de-oiled.
Technical Report: 1995 TAP (bleached, unbleached); 2009 TR (bleached); 2022 Limited Scope TR (pending)
Petition(s): 2004 (to remove unbleached from §205.606); 2008 (to remove bleached from §205.605(b)); 2008 (to remove unbleached from §205.606)
Past NOSB Actions: 04/1995 NOSB minutes and vote (unbleached) (pg. 333); 05/2009 NOSB recommendation (unbleached/de-oiled) (to amend §205.606); 05/2009 NOSB recommendation

(bleached to amend § 205.605(b); 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation

Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Annotation change effective 03/15/2012 (77 FR 8089); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)

Sunset Date: 6/22/2025

Subcommittee Review

Use

The major uses for lecithin include as an emulsifier in margarine, chocolates, instantizing powders, release sprays, and baked goods. It is used as a natural surfactant between oil and water systems, as with margarine products. Lecithin also helps modify chocolates for better enrobing and reduces the crystallization of cocoa fat. With baked goods and dough, lecithin improves water absorption, increasing volume and shelf life, as well as improving uniformity. In addition, lecithin is used in pharmaceuticals for a wide range of purposes, including as a dietary supplement and an emulsifying agent for intravenous injections.

Manufacture

Lecithin is extracted from soybeans and other plants. For example, soybeans are dried and flaked, and crude soybean oil is extracted almost exclusively with the use of hexane. Some expeller-pressed oil is processed further. The crude oil is filtered, hydrated, centrifuged, dried, and cooked. Standardized lecithin is the fraction that is centrifuged. Some commercial lecithins are bleached with hydrogen peroxide or benzoyl peroxide to improve color.

International Acceptance

Canadian General Standards Board Permitted Substances List

Lecithin-bleached is allowed only when the unbleached form is not available from organic sources. Lecithin is listed in the table of “Food Additives” of the “Non-organic Ingredients” section under the permitted substances list for processing and sanitation.

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

The use of lecithin as 1) a fungicide, listed in the section, “Substances of crop or animal origin”, for plant protection; and 2) a food additive, listed in the subsection “Food additives, including carriers” of the section “Ingredients of Non-Agricultural Origin”, for preparation of foodstuffs composed of essentially one or more ingredients of plant and/or animal origin.

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

Lecithin used for pest and disease control must be recognized by the certification body or authority, e.g., volume, frequency of application, specific purpose, etc. In addition, lecithin (obtained without bleaches and organic solvents) as a food additive is permitted for use in foods of plant origin and certain foods of animal origin.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Lecithin (INS1: 322) functional uses as an antioxidant and emulsifier agent. Acceptable daily intake is not limited.

Japan Agricultural Standard (JAS) for Organic Production
There is no current mention of lecithin in JAS.

Environmental Issues
Hexane is used to extract crude oil in soy flakes, as it gives the highest yield. Then, hexane is then separated from the soybean oil in evaporators. The evaporated hexane is recovered and returned to the extraction process. Hydrogen peroxide or benzoyl peroxide is used in the bleaching process. Increased environmental concerns in using these chemicals have resulted in legislation which could restrict oil processing operations that use hexane. In 1979, a report contracted by the FDA concluded that there is no evidence in the available information on lecithin and lecithin bleached with hydrogen peroxide that demonstrates or suggests reasonable grounds to suspect a hazard to the public when used at levels that are now current or that might reasonably be expected in the future.

Regarding human health, there were no acute exposure studies found for soybean-derived lecithin in humans. Lecithin, including bleached lecithin, is affirmed as generally recognized as safe (GRAS) with no limitations other than current good manufacturing practice by FDA in 21 CFR 184.1400.

Ancillary Substances
Under current uses as an emulsifier, there are no ancillary substances required for use of lecithin.

Discussion
During the last Sunset review, the NOSB voted 12 to 3 to keep lecithin-de-oiled on the National List. Stakeholder comments tended to center around the availability of suitable and sufficient supply of organic raw material (mostly soybeans or corn). Five years ago, it was felt that there was not sufficient organic supply.

The question of suitable and sufficient supply of organic raw material was addressed by the 2022 limited scope TR which was received in early February 2023. While there appears to be some products that are both organic and readily available, it was noted that these alternatives do not result in the same quality of finished product.

Question to our Stakeholders
1. Are other organic oil seed commodities (e.g., canola) used to produce de-oiled lecithin?

Tamarind seed gum

Reference: 205.606 Nonorganic agricultural substances allowed: (r) Tamarind seed gum.
Technical Report: 2018 TR
Petition(s): 2017; 2017 (addendum #1)
Past NOSB Actions: 10/2018 NOSB recommendation
Regulatory Background: Added to National List 12/07/2020 (85 FR 70431)
Sunset Date: 12/07/2025

Subcommittee Review

Tamarind seed gum is being reviewed early to sync its cycle with the other gums.

Use

Tamarind seed gum is a relatively new gum, that is used as a thickener, stabilizer, emulsifier, or gelling agent in processed foods. The peer reviewed literature lists the following uses for tamarind seed gum: emulsifier, stabilizer, gelling agent, palatability improver, antimicrobial agent, insulator, odor improver, glazing agent, stickiness preventer, and bodying agent. Converts organic waste into biofertilizers. Allows proliferation of gram-negative bacteria.[1] The product is a replacement for, or used with other gums such as carob bean gum, guar gum, tragacanth gum, and xanthan gum. There are pharmaceutical uses for this product. Tamarind seed gum is limited to non-acid hydrolyzed forms.

The primary use of tamarind seed gum is as a stabilizer and thickener. The product can be used to replace pectin when making jams and preserves.

Tamarind seed gum is agricultural and non-synthetic and might be an acceptable alternative to synthetic gums if organic tamarind kernels can be sourced in the future. The nonorganic form of the ingredient will only be permitted when organic tamarind seed gum is not commercially available.

Table 2. Comparison of properties between tamarind seed gum and other gums on §205.605-606.

Property	Tamarind seed gum	Gum arabic	Tragacanth gum	Guar gum	Locust (Carob) bean gum	Gellan gum	Xanthan gum
Low Viscosity (only becomes viscous at concentrations greater than 50%)	Moderate viscosity	X					
High Viscosity at 1 % concentration			X				
High Viscosity at low concentrations (but above 1%)						X	X
Viscosity remains unchanged over time at low shear rates	X		X				
Viscosity decreases over time at low shear rates				X			
Forms thermo-reversible gels						X	
Thermally reversible						X	X
Thermally irreversible			X		X		
Insoluble in ethanol	X	X	X	X	X	X	X
Stable under acid conditions	X		X	X	X		X
Controls syneresis (weeping)	X			X	X		X

Source: Technical Report, 2018.

Manufacture

Tamarind seed gum comes from an evergreen tree, *Tamarindus indica*, a species of *Caesalpiniaceae,* subfamily native to Africa and southern Asia. The tree can grow in many types of

soil, including poor soils; it fixes nitrogen; and is drought tolerant (Hemshekhar, M., K. Kemparaju, K.S Girish. 2011).
The fruit is a pod with 3-10 seeds. To manufacture the gum, the seed is roasted to remove the seed coat. Next, the tamarind kernel is pulverized to a powder. Then, a water soluble galactoxyloglucan polysaccharide is extracted from the powder. The polysaccharide is dried, pulverized, sieved, and mixed with food-grade bulking agents such as sugars (sucrose, glucose, lactose, galactose and maltose), dextrin or maltodextrin to standardize the quality of the product for desired viscosity (FAO, 2017, Chemical) The powder is light brown in color.

Galactoxyloglucan is composed of a linear chain of (1→4)-β-d-glucan that is partially substituted with side chains of (1→6)-α-d-xylopyranose and β-d-galactopyranosyl linked with (1→2)-a-d-xylopyranose linked (1→6) to glucose residues. The ratio by weight of the three sugar constituents (glucose, xylose, and galactose) in tamarind gum is roughly 3:2:1 (Health Canada, 2017)

International Acceptance

There is growing interest in tamarind seed polysaccharide. Tamarind seed polysaccharide has been used as a food additive in Japan for more than 50 years.[2] FAO (Food and Agriculture Organization of the United Nations) performed a technical review of tamarind seed in 2017. The Food and Drug Administration (FDA) classified tamarind seed gum as Generally Recognized As Safe (GRAS) in 2014. The GRAS notice covers the use of tamarind seed polysaccharide as a thickener, stabilizer, emulsifier, and gelling agent in 12 food categories: ice cream, sauces and condiments, dressings and mayonnaise, fruit preserves, desserts, beverages, pickles, tsukudani, spreads and fillings, flour products, soup and all other food categories at levels ranging from 0.2–1.5 percent of product composition. Use levels are identified for each food category.

Canadian General Standards Board Permitted Substances List
First permitted for general use in Canada (i.e., not organic specifically) in 2017. Not mentioned in the list of approved gums.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Not mentioned

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
Not mentioned.

Japan Agricultural Standard (JAS) for Organic Production
Not mentioned.

Environmental Issues
There is little to no negative environmental impact from the use of tamarind seed gum. Because it has a structure similar to cellulose, soil bacteria existing in the natural environment have enzymes that can break down tamarind seed gum. There are no documented adverse human health impacts.

Ancillary Substances
None identified
Discussion
During the last review the NOSB determined that tamarind seed gum posed no harm to the environment or human health and recommended to list it due to its compatibility with organic production and handling systems.

The Handling Subcommittee's discussion centered around essentiality, the existence of an organic version, and questions about any environmental or human health concerns since it was last reviewed.

Questions to our Stakeholders

1. Is an organic version of tamarind kernels/seeds commercially available?
2. Is this product essential?
3. Are there any ancillary substances used with this product?
4. Have any environmental or health concerns emerged since the product was added to the National List?

Hemshekhar, M., K. Kemparaju, K.S Girish. 2011. Chapter 131 - Tamarind (Tamarindus indica) Seeds: An Overview on Remedial Qualities, Editor(s): V.R. Preedy, R.R. Watson, V. B. Patel, Nuts and Seeds in Health and Disease Prevention, Academic Press, pp. 1107-1114, https://doi.org/10.1016/B978-0-12-375688-6.10131-8.
FAO. 2017. Chemical and technical assessment: Tamarind Seed Polysaccharide.
Health Canada, 2017. Health Canada's Proposal to Allow the Use of Tamarind Gum as and Emulsifying, Gelling, Stabilizing and Thickening Agent in Unstandardized Foods and Certain Standardized Foods.

Tragacanth gum

Reference: 205.606 Nonorganic agricultural substances allowed: (s) Tragacanth gum (CAS #-9000-65-1).
Technical Report: 2018 TR (gums)
Petition(s): 2007
Past NOSB Actions: 05/2008 NOSB recommendation; 10/2014 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to the National List 12/14/2010 (75 FR 77521); Sunset renewal notice published 06/19/2015 (80 FR 35177); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 06/22/2025

Use
Tragacanth gum is a polysaccharide that forms a gel that can be used as a thickener and emulsifier. Tragacanth gum forms a gelatinous mass in water and is used as suspending agent, excipient, or emulsifier in food. This material is effective at low pH and at many temperatures. Its stability at low pH is noted as one of its distinguishing characteristics, and it is commonly used in high-acid products like salad dressings (2018 TR). This gum is widely used in low-fat or non-fat products (Nejatian, M., Abbasi, S. and Azarikia, F., 2020.) The percentage of tragacanth gum in final formulations is usually low, below 1% of a total formula (2018 TR).

Despite having similar characteristics and performing similar functions, gums are not interchangeable. Depending on their structure, each gum has a unique response to temperature, pH range, physical agitation, and so on (2018 TR). This variability requires gums to be matched to the type of food, intended shelf-life and product use. Often several gums are used in combination to impart the correct properties in the finished goods (2018 TR). The table below is from the 2018 Technical Report, which distinguishes the different characteristics of common gums.

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Source: Technical Report, 2018.

Manufacture

Tragacanth gum is prepared from the sap of various species of legumes in the *Astragalus* species (small woody shrubs, which grow in Southwest Asia, Iran, Syria, Turkey, and Greece) during July to September. A mass of gum grows in the roots of the plant, which is collected from the taproot and mechanically ground to a fine powder (EFSA Panel on Food Additives and Nutrient Sources). It may undergo a mitigation step to reduce the microbial load of the powder (2018 TR).

International Acceptance

Tragacanth gum (TG) was decreed "generally accepted as safe" by the FDA in 1972, 21CFR184.1351.

Canadian General Standards Board Permitted Substances List

Tragacanth gum is permitted but must be derived using substances listed in Table 6.3 (page 32 on document linked above). Extraction solvents and precipitation aids. By exception, isopropyl alcohol may also be used to derive gums.

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

Tragacanth gum is allowed as a food additive in compliance with the General Standard for Food Additives Annex II and III of the Regulation (EC) No. 1333/2008 on food additives (2018 TR 506-515).

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

Permitted, although exclusions of the general standards for food additives (GSFA) apply

International Federation of Organic Agriculture Movements (IFOAM) Norms
Allowed as an additive.

Japan Agricultural Standard (JAS) for Organic Production
Allowed, with no listed restrictions.

Environmental Issues
No environmental or health concerns were noted in the manufacture or use of tragacanth gum.

Ancillary Substances
According to the 2018 TR, no information was found indicating that any additional materials are added to commercially available forms of the gums.

Discussion
A review of the safety of tragacanth gum was conducted by the European Food Safety Authority Panel on Food Additives and Nutrient Sources, which found that humans tolerated a high dose for 21 days, with undesirable effects. There were no known carcinogenic effects for mice. The Panel recommended that the European Commission considers lowering the current limits for the toxic elements (lead, cadmium, mercury, and arsenic) in the EU specification to ensure that the food additive will not be a significant source of exposure to those toxic elements in food. The 2018 Technical Report (TR) for gums summarized the results from the 2017 European Food Safety Authority Panel on Food Additives and Nutrient Sources Added to Food, and for tragacanth gum the panel found no need for a numerical acceptable daily intake (ADI) and no safety concerns for the general population.

The Handling Subcommittee's discussion centered around essentiality, the existence of an organic version, and questions about any environmental or human health concerns since the last review.

Questions to our Stakeholders

1. Is organic tragacanth now commercially available?
2. Is this product essential?
3. Are there any ancillary substances used with this product?
4. Have any environmental or health concerns emerged since the last sunset review?