National Organic Standards Board Meeting
Dates: April 22 & 24, 2025 (Public Comment Webinars)
April 29 – May 1, 2025 (NOSB Meeting)

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National Organic Standards Board
Certification, Accreditation, Compliance Subcommittee (CACS)
Risk-based Certification Proposal
February 4, 2025

Introduction:

Risk-based oversight as a model for decision-making and compliance prevention strategy is an approach used by certified operations and certifiers in organic certification. These concepts are not new. An increase in fraudulent organic activities over the past decade by a few unscrupulous operations (relative to the number of compliant organic operations) has the organic community taking another look at the concept of risk-based certification. Due to an increase in organic fraud, we saw the implementation of the Strengthening Organic Enforcement (SOE) final rule, which codified the evaluation of an organic operation's risk of organic fraud as well as many other provisions aimed to make it harder for an operation to engage in fraudulent activities (e.g. requiring more operations to become certified, increasing labeling requirements, codifying audit requirements, etc.). While these more robust provisions were well-intentioned, the result is that low-risk operations (not the intended target) were caught in the crosshairs. As such, we have the opportunity to reflect on what we've learned over the past year and reexamine the idea of risk-based certification; i.e., where and how can we focus on high-risk operations and reevaluate the certification process for low-risk operations?

Background:

While the SOE final rule was intended to prevent fraud, it had unintended consequences such as increased costs or operational complexity for all operators, including those that are legitimate and/or low-risk. It also created potential additional barriers to entry for legitimate operators, even if they don't engage in fraudulent practices. So, while being well-intentioned, the result may have felt like an "over-correction."

Enter risk-based certification. The National Organic Standards Board (NOSB) requested this as a work agenda item in 2024 on the heels of the SOE final rule implementation. It became apparent, through comments to NOSB and reports from the National Organic Program (NOP), that while this rule was not intended to have major impacts to low risk (e.g. small producers) operations, unfortunately that was what was happening in practice. This was largely due to revisions to certifiers' organic system plan (OSP) templates that impacted all organic operations.

At the Fall 2024 NOSB meeting, NOP Deputy Administrator Dr. Jennifer Tucker introduced the idea of reconceptualizing "Sound and Sensible" to "Continuous Improvement." The NOP has further communicated this idea to certifiers, indicating that this will be an ongoing and collaborative effort to innovate our systems. The Certification, Accreditation, and Compliance Subcommittee (CACS) hopes this proposal will aid in this collaboration to rethink the structure of the certification process in order to preserve its sustainability for the long term, while also ensuring organic integrity throughout the marketplace.

Relevant areas in the organic regulations and OFPA:

Since the inception of organic certification as a federal program, risk-based certification has existed. OPFA and the organic regulations at 7 CFR Part 205 allow certified operations and certifiers to use

systems that are relevant to one's structure, production model/type, site specificity, etc. while developing their OSP and certification policies and procedures. As discussed in the Fall 2024 NOSB discussion document, the concept of risk-based certification is not new. However, due to several final rules published in the past few years, this topic is of the utmost importance in order to maintain and grow the organic industry while continuing to uphold organic integrity.

The SOE final rule included specific provisions for certified operations and certifiers to evaluate risk. Section 205.504(b)(7) now requires that certifiers develop policies and procedures in order to perform supply chain traceability audits (SCTA) on operations identified as high risk. Supply chain traceability audits may be smaller in scale (e.g. cross check of a smaller number of transactions between two entities); this is often referred to by certifiers as a routine SCTA. SCTAs may also be conducted as part of an investigation. The scope and scale of this type of SCTA may be expanded to cover more transactions or to go further up or down along the supply chain. The preamble to the SOE Final Rule included the following criteria as potential risk criteria (to be used to evaluate a certified operation's risk):

- Products for which there is a relatively high demand, low supply, and high organic premium;
- Products which may be subject to treatment with prohibited substances after production;
- Unpackaged products which are not enclosed in final retail containers;
- Products with multiple handlers in the supply chain;
- Products from a supplier that lacks a record of compliance;
- A sudden increase in the available supply of an organic product or commodity;
- Operations which change certifying agents frequently; and
- Operations which are certified by more than one certifying agent.

In addition, per §205.201(a)(3), a certified operation must include in their organic system plan a description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented. This must include a description of the monitoring practices and procedures to verify suppliers in the supply chain and organic status of agricultural products received, and to prevent organic fraud as appropriate to the certified operation's activities, scope, and complexity. In order for an operation to successfully create an organic fraud prevention plan, they need to evaluate the risks and vulnerabilities their operation is subject to.

Discussion:
This proposal aims to provide additional support to certifiers and inspectors on how to cultivate critical thinking as a core competency and effectively manage time as a resource in order to make sound and sensible decisions that best protect the marketplace and prevent fraud.

This proposal focuses on the fundamental building blocks certifiers and inspectors use in evaluating an operation's risk (fraud and/or compliance related) and picking the best verification tool possible. Specifically, the proposal suggests a common set of definitions, baseline risk assessment criteria, the development of a process and matrix certifiers can use to determine the best certification approach to use per operation, and additional training and resource development. See the Summary of Proposal section for more details.

Public Comment:

During the Fall 2024 NOSB meeting, the CACS received several comments on this topic. Most were in

favor of the concept of risk-based certification, acknowledging that the certification process can be burdensome and overly complex for low-risk operations as well as certifiers. That said, commenters thought it of the utmost importance to proceed cautiously as to mitigate against unintended consequences and not to lean so far into this concept that organic integrity is rendered meaningless.

CACS asked a series of questions and received thoughtful answers from our stakeholder community. These are summarized below:

1. How does your organization define risk?
    a. Would it be valuable for the definitions listed above (Risk-based oversight, Risk management, Risk, Vulnerability) to be included at §205.2 Terms Defined?
    b. Are there other definitions that would be beneficial to include at §205.2 Terms Defined besides those listed above? Is it important that all certifiers use the same risk criteria to evaluate certified operations? Why or why not?

Response summary: Most, if not all, commenters agreed having shared definitions was important. Some commenters thought these should be in the regulations, while others thought this could be elsewhere such as in Accredited Certifiers Association (ACA) best practice documents and/or the NOP Organic Integrity Learning Center (OILC). Commenters also thought that when evaluating an operation's risk, certifiers should use the same general risk criteria while being able to remain adaptable and flexible.

2. What other resources (e.g. trainings, models, certifications/credentialing program) are currently available that would help an organization become more proficient at risk-based oversight and/or risk evaluation?

Response summary: There were several resources identified including OILC courses, ACA best practice documents, OTA's Organic Fraud Prevention Guide, Dr. John Spink's website "Food Fraud Think Tank," the Cressey Fraud triangle, and ORG-Tracker.

Additionally, the idea of an interactive training or a certification/credentialing program focused specifically on risk-based decision-making was also mentioned by a few commenters. One commenter stated, "a comprehensive, mandatory program could ensure uniform adoption across the certifying community."

Lastly commenters suggested the following models could be consulted:

- HACCP and the food safety industry
- EU's approach to risk assessment
- ISO 31000 Risk Management Framework, which provides comprehensive guidelines for managing risk effectively across various sectors

3. What are the unintended consequences that could arise from using a risk-based oversight approach?

Response summary: Commenters stated the following as possible unintended consequences:

- smaller, low-risk operations feeling overlooked or undervalued in the certification process and/or losing connection with their certifier
- risks being missed, especially if new risks emerge

- too little attention paid to low-risk operations, resulting in impacts to organic integrity or losing the deterrent benefit of comprehensive oversight
- operations trying to game the system purposefully to position themselves as low-risk to get the benefits that may come along with that designation
- operations getting complacent in certain compliance verification points (e.g. record keeping)

However, commenters also noted that the risk of not using a risk-based approach is continuing to overburden our smaller, low risk operations, resulting in increasing attrition or operations not entering into organic certification. Additionally continuing to tax an already fragile certifier and inspector community by expecting more and more leads to burnout.

4. What other ways are there to reduce burdens on low-risk operations?

Response summary: Commenters suggested the following ideas to reduce burdens on low-risk operations:

- Inspection related items:
    - Inspection focused only on a specific element of organic compliance, rather than a full-scale inspection every year (with full inspections every other year or every third year)
    - Reduce the frequency of on-site inspections
    - Remote/virtual inspections for certain types of low-risk operations (e.g. no physical handling of organic product)
    - Simplified/reduced audits (e.g. mass balance and/or traceback) at inspection
- Reducing/simplifying the paperwork (e.g. OSPs, recordkeeping)
- Streamlined review processes related to certain types of materials or ingredient supplier changes

5. How can the community provide information to NOP and/or certifiers on acute risks?

Response summary: Some ideas from comments include reporting directly to NOP or the certifier through the current complaint system, email or a hotline. There was also mention of establishing a forum, which could be through the NOSB. Commenters also stated that NOP should communicate to certifiers, at the annual certifier training, identified areas of high-risk taken from the various data sources they have available to them.

6. Certifiers:
    a. Have you adopted or based your risk assessment criteria on the ACA Best Practices (ACA BP) documents?
    b. When operations are identified as low-risk, what actions are you taking to streamline and make these operations' certification less burdensome?

Response summary: Most certifiers indicated that they used the criteria from the ACA BP and that their criteria were based from that BP so there was a lot of alignment. There was one certifier that stated they did not use the ACA BP, but their criteria had some overlap with the ACA BP.

Certifiers stated they incorporated the following in order to reduce a low-risk operations' certification burden:

- Allowing for simplified recordkeeping systems (e.g. herd lists for closed herd operations). Records must still be auditable.

- Streamlined review processes (products and ingredient suppliers, certain types of materials, fast tracked initial review for operations with no changes from year to year)
- Hourly inspection rates
- Relative to high-risk operations, low-risk operations will not be subject to SCTAs and less likely to have a routine unannounced inspection or residue sampling

Summary of proposal: *Brief summary of what the subcommittee is proposing.*

1. **Definitions:** CACS proposes that all stakeholders use a common set of definitions. Some of these currently live in the OILC course NOP-230: Risk-based Oversight. CACS proposes the following definitions be revised in the OILC course. Additionally, CACS proposes that other stakeholders utilize these definitions in their resources (e.g. ACA best practice documents, individual certifier policies and procedures, industry white papers, other training resources, etc.). CACS is not recommending these be added to §205.2 Terms Defined at this time. Inclusion into the regulatory text may be reevaluated as a necessity at a later time. Strikethrough text is proposed to be deleted. Underlined, red text is proposed to be added.
    a. **Risk-based oversight** is a systemic, cyclical approach to considering risk. This approach involves the process of identifying and prioritizing risks (via a vulnerability assessment and risk assessment including all potential risks such as fraud risks and compliance risks), and planning and scheduling mitigation measures, with a goal of reducing and managing risks. Risk assessment and past performance inform the planning process. ~~Risk management is the execution of the planned and scheduled tasks that contribute to the overall goal.~~
    b. **Risk management** is the actionable step of the risk-based oversight approach. Risk management is the execution of the planned and scheduled tasks and processes that contribute to the overall goal of the prevention, reduction or minimization of risks, including mitigation strategies, preventive measures, and implementation. ~~consists of coordinated tasks and processes.~~ Risk management is only one component of the overall risk-based oversight approach.
    c. **Risk** is the potential exposure to deceptive, dishonest or noncompliant actions, resulting in financial losses, reputational damage, certification status changes and/or legal consequences. Risks on organic operations can be categorized as risk of noncompliances (in broader terms), or more specially, as risk of fraud ~~effect of uncertainty on objectives (ISO 22380), such as quality objectives or compliance objectives.~~
    d. **Vulnerability Assessment** is the step aimed at reviewing and assessing various factors that create vulnerabilities in a supply chain (i.e. weak points where fraud and/or noncompliances have the greatest chances to occur) ~~a deficiency or weakness that creates opportunities for exploitation or susceptibility to a given hazard.~~
    e. **Risk Assessment** is a systematic process of evaluating the potential risks (likelihood vs. severity) that may be involved in an activity or relationship. This may include the assessment of fraud and/or more board compliance related risks of an operation.
    f. **Risk Evaluation** is the process of making a judgement or determination about the amount or degree of risk identified (e.g. low, medium or high) in a risk assessment.
2. **Risk Criteria:** CACS proposes that certifiers use a baseline of common risk criteria while allowing certifiers flexibility to adjust based on their specific operation portfolio. CACS recognizes that many certifiers use the criteria in the "ACA SCTA Risk Score Card Template" and propose that this serve as the baseline criteria. Additionally, CACS proposes that certifiers, in collaboration with NOP, ACA and any additional stakeholders deemed necessary. identify a common objective/goal of performing risk assessments on organic operations for the purposes of

complying with the requirements at §205.504(b)(7). Lastly, CACS proposes that NOP communicate acute risks to certifiers at the annual certifier training. The predictable, annual communication is utilized by other schemes and will allow certifiers to better plan and maximize their resources. Currently, NOP utilizes issuing directives to certifiers. These are unpredictable and do not allow for certifiers to proactively and effectively allocate resources. This is not to say that directives will be entirely eliminated. They may still be required based on information that arises later in the year. However, communicating known risks on an annual basis will hopefully result in the reduction of directives being issued, again which will allow certifiers to more effectively manage resources, as well as comply with the requirements regarding performance of SCTAs in a more consistent manner across certifiers.

3. **Oversight Activities Process and Matrix:** CACS proposes that NOP, in coordination with ACA, develop a process by which certifiers can evaluate the regulatory text and use critical thinking to determine the opportunities to approach the certification of operations with different risk level differently. Furthermore, it is proposed that using this process that ACA develops a matrix of activities to add to a high-risk operation's certification and options to reduce a low-risk operation's certification burden. CACS acknowledges that certifiers need different tools to evaluate different types of operations. This process and matrix will help certifiers more consistently pick the right tool depending on an operation's risk evaluation. This process and matrix are, by no means, intended to convey that low-risk operations are being held to a lower standard. Once complete, CACS proposes that ACA inform NOP in order for NOP to conduct training of accreditation and audit team personnel. This will ensure that NOP staff and certifier staff are operating under the same expectations regarding risk-based certification and continuous improvement. The following are examples provided by commenters in response to the Fall 2024 Discussion Document on this topic:
    a. Examples of increased oversight activities that may be utilized for high-risk operations: unannounced inspections, residue testing, supply chain traceability audit, additional audits during annual inspection.
    b. Examples of reduced oversight activities:
        i. Inspection related suggestions: focused inspections in some years with full inspection every other or every third year; remote/virtual inspection for certain types of operations; fewer traceback and mass balance audits (compared to high-risk operations)
        ii. Minimize/reduce recordkeeping/paperwork requirements; common OSP
        iii. Cost structure to incentivize low-risk operations
4. **Training and Resources:** CACS proposes that NOP and ACA develop and revise resources and training materials to support certifiers in conducting risk-based certification (i.e. finding the right set of tools/activities for the specific operation based on their profile - organic activities and risk evaluation).
    a. Revise and/or create ACA Best Practice Documents to:
        i. Incorporate the definitions in this proposal
        ii. Explain the process to be used by certifiers to evaluate the regulatory text and use critical thinking to determine the opportunities to approach the certification of operations with different risk level differently
        iii. Communicate the oversight activities matrix to certifiers
    b. Revise NOP-230 in the OILC to:
        i. Incorporate the definitions in this proposal
        ii. Provide more interactive modules/activities pertaining to both risk of fraud and risk of noncompliance

c. Continue to include risk-based certification as a topic at annual NOP Certifier Training/ACA Professional Conference

Subcommittee Vote
Motion to accept the proposal on risk-based certification
Motion by: Kyla Smith
Second by: Amy Bruch
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 1

National Organic Standards Board
Certification, Accreditation, and Compliance Subcommittee
Residue Testing for a Global Supply Chain Proposal

Note: The National Organic Standards Board's (NOSB or Board) Certification, Accreditation, and Compliance Subcommittee (CACS) is working on many fronts regarding residue testing. This document discusses several topics, including proposed updates to Guidance Documents NOP 2610, NOP 2611, NOP 2611-1, NOP 2613, and NOP 5012. Additionally, CACS has put forth a discussion document exploring regulatory updates pertaining to residue testing.

Executive Summary of Changes to Existing Guidance Documents:
This table outlines the changes proposed to each of the current guidance documents in the National Organic Program (NOP) Program Handbook, which are discussed in more detail throughout this proposal. Also summarized are recommendations for additional guidance documents.

NOP 2610 – Sample Procedures for Residue Sampling	• Sampling Equipment • Inspector Training and Competencies • Duplicate Sampling and Sample Retention • Chain of Custody Integrity • Sample Collection Diversity & Sample Amounts • Time is of the essence • Additional Resources • Specific Redline Corrections
NOP 2611 – Laboratory Selection Criteria	• Expand Testing Guidance • Specific Redline Corrections
NOP 2611-1 – Prohibited Pesticides for NOP Residue Testing	• Expand What to Test • Retitle the Document (expanded focus) • Information Layout • Regional and Crop Specific Information • Test for Metabolites • Companion Testing • Fertilizer Authenticity Testing • Access to Most Current Information
NOP 2613 – Responding to Results	• Detection without Tolerance Level • Dehydrated, Extracted, or Concentrated • Other Prohibited Substances or Excluded Methods • Notifying Down Stream Buyers When Levels are above EPA Tolerance / FDA Action Level • Gaps in Decision Making • Specific Redline Corrections
NOP 5012 - Approval of Liquid Fertilizer for Use in Organic Production	• Specific Redline Corrections
Additional Guidance Documents	• Residue Sampling Decision Tree

	• Residue Sampling of Non-Crop and Non-Harvested Crop Products • Validation and Verification Guidance for 205.273(d) • Additional Instruction Considerations

Introduction:
The Certification, Accreditation, & Compliance Subcommittee (CACS) presented discussion documents at the Fall 2023, Spring 2024 NOSB, and Fall 2024 NOSB meetings on Residue Testing for a Global Supply Chain (RTGSC). Many commenters supported continuous improvement in testing to ensure integrity, considering the size of the organic marketplace and the program's global reach.

Residue testing is an essential tool for ensuring compliance with organic regulations. Residue testing does not substitute for the certification process and verification of compliance through an organic system plan review and annual inspection. However, it can support this process with objective results related to the presence of prohibited substances or the use of excluded methods.

The RTGSC series aims to work with the community to provide a recommendation that ensures testing remains a relevant and effective tool for compliance verification in the organic global supply. At the Fall 2023 NOSB meeting, a commenter wrote, “An updated and more rigorous testing program will augment the ability for both certifiers and certified operations to verify compliance, deter fraud, and prevent contaminated/fraudulent products from entering organic supply chains.”

Foundational Focus and Timing:
Foundational work is needed first. Therefore, the CACS aims to update the foundational elements in the respective related guidance and instruction documents with this proposal to, as one commenter stated, “...ensure there can be clarity and consistency in the testing and response practices.”

During the Spring and Fall 2024 NOSB meetings, the CACS asked the community for feedback on modernizing the guidance documents corresponding to residue testing. The common theme was that the guidance scope needed to encompass prohibited substances beyond residues of pesticides (e.g., synthetic solvents, heavy metals, and other prohibited substances) in addition to expanding guidance to address samples beyond the harvested crop/raw ag commodity (e.g., soil, water, plant tissue, livestock products, processed products, etc.). Also, there was a consensus that pesticide residue tests must be expanded based on known domestic and international risks (e.g., herbicides and fumigants) and common farming practices for the region based on agronomics. A public commenter from the certifying community noted, “Broadening the list to include solvents, fumigants (particularly those used at the borders), conventional fertilizers, herbicides, and other prohibited substances used in conventional food production would give us more useful tools without increasing the burden of testing.”

The “Pesticide Rule” that became effective January 1, 2013, clarified that certifiers “must” conduct periodic residue sampling of products to be sold, labeled, or represented as organic, expanded the amount of testing by clarifying that sampling and testing needed to be done regularly, and specified that certifiers must sample and test 5% of operations they certified annually. The focus of this residue testing rule wasn’t necessarily to identify fraud. Instead, it was used more as a tool to verify that an operation’s organic system plan was sufficient to prevent commingling and contamination. Certifiers built their residue sampling and testing programs with that premise in a way that complied with the requirements while attempting to be as cost-effective as possible since certifiers were required to bear the testing costs. Over ten years later, the organic industry has grown, and supply chains have become longer and

more complex. There are fraudulent actors that have and continue to benefit from our thriving industry. As a result, we must update our processes regarding residue sampling to align with current reality. This means taking a more risk-based approach to operation and sample selection and updating what we are testing for to keep pace with science and input development.

Additionally, the Board recognizes that other residue sampling and testing resources are not utilized as readily as the NOP Program Handbook documents. These include the Periodic Residue Testing of Organic Products (Notice to Certifiers) and the Organic Integrity Learning Center (OILC) NOP-190: Sampling and Testing course. Linking these resources together will assist certifiers in executing their sampling programs.

Updates to the guidance documents on these topics are necessary to support the work of inspectors, who collect samples, and certifiers, who analyze results. The guidance documents must provide certifiers and inspectors with the resources and information to collect samples confidently, ensure the appropriate type of test is ordered, and consistently respond when samples test positive for prohibited substances.

The goal of this proposal is to aid the NOP in updating guidance documents so residue sampling can remain a critical verification tool in the certification process. We also encourage the organic community, certifiers, scientists, farmers, inspectors, and NOP to share experiences of potential threats and determine best practices through testing to verify the integrity and authenticity of organic products. Below is a summary of public comments and NOSB proposals related to the various guidance documents on residue sampling.

Proposed Updates to NOP Guidance

Sampling Procedures for Residue Sampling (NOP 2610)
NOP 2610's primary focus is to outline sampling procedures. Stakeholders have identified the issue of this guidance being incomplete. NOSB acknowledges that the OILC course, NOP-190: Sampling and Testing, includes much of the information below. To resolve this issue, NOSB requests that either the information contained below be incorporated into NOP 2610 or that NOP-190 be referenced as additional information in the specific areas outlined below. Additional resources that are helpful for best practices in sample pulling, sample integrity, and sample training exist within the EPA, FDA, and other recognized and established sampling practices. Alignment helps reduce variation in approach and increase deterrents to fraud.

1. **Sampling Equipment**
    a. Sampling equipment can pose a risk of contamination of sampled products. To create a consistent sampling regime across all certifiers globally, NOP should update this guidance with a list of minimum equipment required for sampling including shipping cooler, ice packs, gloves, bags, sample collection reports, grain probe (for sampling grain bins), other specialized sampling tools, and proper cleaning methodology, as specific tests have different requirements.

2. **Inspector Training and Competencies**
    a. This guidance should specify the minimum qualifications and training inspectors need to take samples of organic operations consistently. Training should also be developed for more complicated sampling demands on higher-risk operations (e.g., imports, investigations, etc.).

3. Duplicate Sampling and Sample Retention

a. Many quality assurance programs retain a duplicate sample to retest when results are positive for residues. However, it is not currently best practice for inspectors to take a duplicate sample per §205.670. NOP 2610 should be updated to outline when this action is relevant, what steps inspectors should take to ensure the validity of results from duplicate samples, and how and where these duplicates should be retained.

4 Chain of Custody Integrity/Documentation

a. A residue sample chain of custody is essential in obtaining actionable sample results. If there is any breakdown in this chain of custody, the validity of the results can be questioned, and certifiers may not be able to take action if a positive outcome is found. The current guidance outlines the best practices for sealing bags, tamper-evident tape, and ensuring that shipping labels demonstrate a chain of custody. However, the updated guidance could include instructions for adequately identifying samples, ensuring integrity, and documenting the chain of custody including additional information such as the sample collector's name, client sample ID, name of certified operation representative present during the sampling, description of the sampling site, the reason for sampling, and testing requested (e.g., NOP pesticide screen, glyphosate, etc.). A clear set of procedures would assist certifiers with their staff training and potentially develop agreements with 3rd parties other than inspectors to conduct residue sampling activities.

b. Additionally, it is recommended that the inspector submit a report to the certifier that includes a copy of the sample collection information submitted along with the sample sent to the lab, whether a control sample was collected, a site or field map identifying where the sample was collected (e.g., GPS data), shipping documentation, a completed chain of custody form, and photos.

5. Sample Collection Procedure, Diversity, Sample Amounts

a. As mentioned in the lead-in, it is vital to provide references for best practices on sample collection within the OILC, FDA, EPA, laboratories, or other respected industries. We do not have to recreate the wheel to provide more detail on collecting a sample.

i. Include additional information regarding:

1. Proper sampling techniques and testing methodology

a. Outline that the auditor or certifier representative must collect the sample.

b. Indicate appropriate purge or best practices for avoiding sample site contamination and the collection scenario based on lot, origin, and commingling of multiple lots or sources.

i. NOTE: Sweeping up a sample from a bin, collecting off the top of a bulk tub, collecting from carryover crop storage of a crop already sold, or failure to adequately clean equipment before sampling may result in inaccurate results or results without compliance value to the program or to the operation, cost time and resources, and fail to support effective compliance decisions and defensible results.

c. Additional information on when to obtain composite or single samples

ii. NOP 2610 clearly describes the sample size necessary for obtaining valid pesticide residue results based on the commodity type. It provides some narrative guidance

on what part of the plant should be sampled if sampling occurs in the field or how to document a composite sample if several samples from different bulk containers are used to create a single composite sample. However, the instructions must clarify how samples are collected in various situations and include pre-collection preparatory information such as purging or best practices for avoiding sample site contamination. For example, collecting a grain sample in the field would dramatically differ from collecting a grain sample in a bulk ship. As we look to expand the handbook documents beyond prohibited pesticides, the guidance should include specific processes and amounts for collecting samples in inspectors' various situations. Hence, inspectors and certifiers have the confidence to take samples in many situations. At a minimum, NOSB would like to see specific sampling procedures for the following commodities and situations:

1. Produce in the field.
2. Produce in packed boxes.
3. Grain and oilseed in the field
4. Grain and oilseed in storage (bins, tanks, covered piles)
5. Grain and oilseed in transit (rail cars, containers, bulk ships)
6. Liquid processed products
    a. Oils
    b. Juice and other extracts
    c. Milk
7. Herbs and spices
8. Non-crop and non-harvested crop samples (soil, water, tissue, inputs, seeds)
9. All other crops appropriate to their condition

Note: A note of caution about sampling size can also differ depending on the lab's specific requirements.

b. Additionally, NOSB recommends that section 4.2 Sample Selection be revised to outline factors that certifiers may consider as part of their risk-based sampling program, which may include, but are not limited to, the factors below. The OILC course “NOP-190: Sampling and Testing” lists risk factors that certifiers should apply when developing their annual sampling plan:
    i. suspected risk of contamination from adjoining land use, commingling, or cross-contamination during handling.
    ii. repeat noncompliances that reflect potential systemic failure.
    iii. significant supply chain traceability concerns (i.e., unsuccessful mass balance or traceability exercises) that indicate the system is not auditable.
    iv. parallel production or handling of organic and non-organic commodities, especially visually indistinguishable varieties of a commodity or parallel processing with manufacturing systems that present difficulties for clean-out.
    v. regions presenting increased or unprecedented phytosanitary challenges.
    vi. production or handling of commodities that are experiencing sudden or unprecedented market growth, demand, and/or fluctuations in price.
    vii. located in or sourcing from areas of known risk (history of fraud or contamination).

c. Lastly, NOSB proposes the incorporation of determining what and where to sample depending on the type of contamination they are trying to find. As stated in NOP-190: Sampling and Testing, the certifier or inspector can ask, “Can I reasonably think that I can

determine the source of the contamination and the responsible parties if this sample is positive?" If the answer to this question is "No," then the certifier should instruct the inspector, or the inspector should take a sample farther back into the supply chain to ensure that positive results are actionable.

6. **Time is of the Essence**
    a. Sample collection and preparation must be thorough and expedient to minimize sample decay, pesticide losses, and contamination of products entering the chain of commerce. Best practices for sample holding and submission timeframes should be included.

7. **Additional Resources:** In addition to OILC, laboratories, and Extension offices, many sampling plans and best practices are available and can be selected by matrix.
    a. U.S. Department of Defense Military Standard Sampling Procedures and Tables for Inspection by Attributes MIL-STD-105E: (https://archive.org/details/MIL-STD-105E_1)
    b. U.S. Department of Defense Preferred Methods for Acceptance of Product MIL-STD-1916: (https://www.sqconline.com/sites/sqconline.com/files/MIL-HDBK-1916.pdf)
    c. USDA Grain Inspection Handbook: (https://www.ams.usda.gov/sites/default/files/media/Book1.pdf)
    d. UC Davis Analytical Lab Sampling and Preparation: (https://anlab.ucdavis.edu/Home/SamplingAndPreparation)
    e. AOAC International Resources: (https://www.aoac.org/resources/)

8. **Specific Redline Corrections:**
    a. Update section 4.4: Certifiers are called upon to record the variety of a crop and the brand name. However, circumstances may arise in which the individual collecting the sample cannot access this information. We recommend changing to "recording information when available."
    b. Evaluate that reference material is current, and that reference links are functional.
        i. Codex Alimentarius Commission links are broken in the reference section.
        ii. Reference links should be expanded to reflect best practices in sampling.
        iii. Add a reference to NOP-190: Sampling and Testing.

During the Fall 2024 meeting, the NOSB asked a series of questions about NOP 2610. The responses are summarized below and assisted in the formation of the proposed solutions above:

- Additional Comments: Overall, most stakeholders were focused on expanding the information found in NOP 2610 to encompass the breadth of the organic supply chain, not just commodities produced in crop production. In addition, providing information for alignment to aid in consistent enforcement decisions beyond the consumed or harvested commodity (i.e., foliarly) is critical. Referencing the OILC course will ensure that up-to-date information can be accessed even if the frequency of updates on the actual instruction is limited.
- Collaboration: A few stakeholders indicated that NOP staff should work with Pesticide Data Program (PDP) staff in developing sampling procedures that can fulfill the missions of both programs. We also encourage certifiers to use analytical labs for residue testing that utilize the PDP's testing protocols, setting the stage for certifier test results to be readily comparable to results from annual PDP testing.
- Internalizing Testing: Generally, the certifier and other organic stakeholders did not favor sub-contracting out sampling to a third party other than the inspector. There was an alternative opinion from one advocacy group and one consultant that did support involving third-party

experts, indicating that they could provide deeper insight technically into sample collection, and then training could be reduced for certifiers and inspectors in this area, and bandwidth for certifiers could be increased.

Laboratory Selection Criteria (NOP 2611)

NOP 2611 primarily focuses on ensuring the laboratories used for residue analysis are accredited to conduct multi-residue pesticide screens. As NOP expands guidance related to testing for other types of pesticides and prohibited substances, the laboratories conducting these analyses must be competent and consistent. Stakeholders have identified that NOP 2611 has not been updated to keep pace with these advancements and expand into testing for other prohibited substances. Therefore, to resolve this issue, NOSB requests that additional specific laboratory selection requirements accompany any additional tests described in handbook updates. Again, NOSB acknowledges that some of the information listed below currently exists in the OILC course NOP-190: Sampling and Testing. NOSB supports updating the guidance document or updating NOP-190 and linking to that resource in the guidance document.

1. **Issue: Only Contains Information on Pesticide Testing**
    a. **Solution:** Expand Testing Guidance, Best Practices, and Rename Document
        i. Identify labs that can test for specific risks across all organic scopes: crops, livestock, wild crops, and handling.
            1. Crops Scope—Guidance is needed for laboratory selection to include prohibited materials in inputs, synthetic herbicides, fertilizers, and other substances prohibited in organic production.
            2. Additional items to test outside pesticide residue must be included.
                a. For example, testing oilseed meal for prohibited synthetic solvents requires laboratory competencies in oil chemistry, and certifiers will need to determine if the laboratories they currently use for multi-residue pesticide screens have the necessary competency and accreditation to conduct these additional tests.
        ii. Identify current best practices for a broader set of needed test methods, matrices, and sample methodologies (remove specific focus on QuEChERS).
            1. Testing within the agricultural and food industry is routine and well-researched.
                a. Benchmarks with ISO, GAFTA, FOSFA International, Regulation EC No 619/201, and other respected institutions may be consulted as resources to help inform what type of lab accreditation and testing methods are needed across the NOP scopes.
                b. Benchmark with the USDA/AMS laboratories that conduct PDP testing for quality control and verification of procedures.
    b. **Solution:** Specific Redline Corrections
        i. Expand Scope and Rename Document: The Title of 2611 focuses solely on pesticide residue testing, and the instruction concentrates mainly on the QuEChERS (**Q**uick, **E**asy, **C**heap, **E**ffective, **R**ugged, **S**afe) method. With the recommended scope expansion changes suggested above, the title of this document will need to change to reflect the updated content.
            1. Note: The QuEChERS method is an analytical approach that vastly simplifies the analysis of multiple pesticide residues in fruits, vegetables, cereals, and processed products.

ii. Update Section 4.1: Revise the language from “should” to “must” in the last paragraph, which states, “If certifying agents suspect a prohibited substance was used that is not included on the NOP “target” list, they should initiate sampling/testing and investigation.”
    1. If testing is not conducted, an explanation as to why a test was not conducted should occur.
    2. NOTE: NOSB recommends that 2611-1 be updated and the limited/out-of-date "target list" retired; therefore, this language would need additional revising.
iii. Update Sections 4.1 and 4.2.3: Revise the scope of testing beyond QuEChERS and update to reflect the revised title and format of 2611-1.
iv. Update Section 4.2.1: Revise the Laboratory Selection Criteria to require “a current copy of the lab’s accreditation certificate on file” versus the need to have “lab accreditation certificates attached to each lab test.”

Note: Industry and regulatory collaboration must exist to ensure the current methodology is approved promptly. Clarifying requirements is also important to ensure consistency globally.

During the Fall 2024 meeting, the NOSB asked a series of questions about NOP 2611. The responses are summarized below and assisted in the formation of the proposed solutions above:

- Scope Expansion Critical: Public comments supported expanding the instruction to include testing beyond pesticide residues and renaming the document. Several stakeholders recommended establishing a working group of experts to develop recommendations for expanding this instruction beyond pesticide residue laboratory selection, including prohibited materials in inputs, synthetic herbicides, fertilizers, and other substances prohibited in organic production. Tests, in addition to the QuEChERS methodology, which are AOAC-approved lab methods, need to be recognized.
- Laboratories: Laboratories that maintain ISO 17025 compliance are approved for the recognized (AOAC or international equivalents) methods, and are in good standing with their accreditations, blind check samples vs. proficiency samples, and performed values of test methods vs. the written methodology. Industry and regulatory collaboration remain vital to ensuring methodologies are approved promptly.
- Redline Corrections: Several comments supported the redline correction in 4.1 that pointed to revising the language from “should” to “must” in the last paragraph, which states, “If certifying agents suspect a prohibited substance was used that is not included on the NOP “target” list, they should initiate sampling/testing and investigation.”
- Redline Corrections: One certifier commenter did not agree with the redline change proposed to 4.2.2. They stated that certifiers should not need to maintain the lab’s current proficiency test results and resolve corrective action. This is not within a certifier’s jurisdictional oversight and creates an undue and unnecessary burden for certifiers. Lab compliance should be determined and managed by the lab's accreditation body. The NOSB removed this recommended redline change from the proposal.

Prohibited Pesticides for NOP Residue Testing (NOP 2611-1)

NOP 2611-1 provides certifiers with a list of prohibited pesticides commonly included in multi-residue pesticide screens. The list offers a baseline multi-residue screen so that certifiers implementing pesticide residue sampling as a compliance tool request the most comprehensive list of substances possible from the laboratory. NOSB received substantial comments from stakeholders with suggestions for additional

substances that could be tested for and types of tests that could be performed. One commenter mentioned, “We believe that the list of prohibited substances provided is incomplete and including it as guidance could lead to the mistaken impression that it is comprehensive. Analyses should be based on the most likely pesticides found on the crop in the region where it is grown.” NOSB proposes the below edits to resolve the issue of the list being limited and out of date. Alternatively, all of the below information could be added to NOP 2611, and NOP 2611-1 could be archived.

1. **Issue: “Target list” is limited to only certain pesticides and is out of date**
    a. **Solution: Expand What to Test -** The list of what to test should not be prescriptive with substances that go out of date but rather be informed to reflect the breadth that the 2012 periodic residue testing memo has pointed to including, but not limited to, the items listed below. This list has been updated (i.e., strikethrough text) to reflect current substance status (e.g., removal of the acceptance for antibiotics in apple and pear production) as well as to align with the proposals being recommended in this document (e.g., deleting reference to “target list”).
        i. Prohibited pesticides ~~- possible target list at NOP 2611-1~~
        ii. Arsenic or other contaminant metals
        iii. Genetic engineering – review policy in Policy Memo 11-13
        iv. Synthetic hormones
        v. Antibiotics~~, except in organic apple and pear production per USDA organic regulations~~

    NOSB proposes, in addition to the substances and methods listed above, that the following also be added:
        vi. Solvents
        vii. Prohibited inputs, including synthetic nitrogen and other fertilizers
        viii. Etc.

    b. **Solution: Retitle the Document to Reflect its Expanded Scope.** For example: “Testing Methodology Selection Criteria for Residue Testing.”

    c. **Solution: Information Layout—**NOSB proposes that NOP update the structure to include specific testing methodologies for particular substances and the rationale for electing a specific test to accomplish this need. The following tips will help revise this guidance document to be more beneficial for certifiers engaged in broader residue sampling activities.

    For more information, please refer to the EPA index for pesticide types and families, which provides more information on the active ingredient/type/family/common name. Also, be aware that substances could be banned in the USA but are still available to be used overseas.

    Format for ease of use so that certifiers and inspectors can better identify the most appropriate type of test to select for the particular sampling scenario.

Test Type	**Specific Analyte Tested**	**Rationale for Selecting Test**

Multi-residue pesticide screen (ex. QuEChERS)	1-Naphthol, 3-Hydroxycarbofuran, 5-Hydroxythiabendazole, Acephate, Acetamiprid, etc.	Choose this screen when testing the efficacy of buffers on specialty crops grown near conventional production. When ordering and designing multi-residue screens, consider the product's origin. Tests should focus on the pesticides typically used in the country of origin.
Single analyte herbicide Screen	Glyphosate (with AMPA and Glyphosine), 2,4-D, Dicamba	Choose this screen when inspectors observe herbicides or when sampling a crop (e.g., wheat) where herbicides are routinely used, but other pesticides are not. Note: this is not a panel screen.
Residual Solvent Panel	Hexane, Acetone, Methanol, Dichloroethane, etc.	Choose this screen when sampling oilseed meals in transit or at handling facilities. Consider adding the fat content percentage to provide insight into whether the seed meal was expeller-pressed or solvent-extracted.
Heavy Metals	Cadmium, Arsenic, Lead, etc.	Choose this screen when determining the presence of heavy metals and the effectiveness of the OSP.

d. **Solution: Include Regional and Crop-Specific Information -** Understanding the region and what pesticides or processing aids are commonly used on conventional farms can provide insight into what to test for to identify the presence of residues. Some pesticides are illegal in the U.S. but still permitted in certain countries. One stakeholder mentioned, “We recommend using pesticide-use data to develop a list of prohibited substances that are most likely to be used for a specific crop in a production region.”
    i. A multi-residue single-panel screen is suitable for use in some scenarios; however, the target list is limited, and pesticides often do not appear on the crop's harvested portion.
        1. Foliar and soil tests are valuable; for example, if a producer sprays corn with fungicide before the ear has set, the grain may not contain the fungicide.
    ii. The NOP is expanding guidance on the types of tests that certifiers can perform to address broader contamination and fraud concerns.

iii. For example, solvents are ubiquitous in conventional production. Consider testing organic soybean meal for solvents. Guidance for testing livestock products (milk, eggs, fiber), livestock tissue, processed products, agricultural inputs, etc., must be considered.

iv. A commenter stated, "The prescriptive nature of this list creates an overtly focused emphasis on screening for pesticides instead of testing for any or all likely present prohibited substances. Testing needs to be targeted to the likely risk to a specific type of operation or the potential contamination observed on site."

e. **Solution: Testing for Metabolites -** Testing for metabolites can also have value. One commenter stated, "The metabolites aminomethylphosphonic acid (AMPA) and glyphosine should also be included. These degradants are more likely to persist in the soil and would be strong evidence that glyphosate had been applied recently on a given field."

f. **Solution: Companion Tests -** As the table states above, when examining a solvent test to identify the illegal use of a processing aid for soybean processing into soybean meal, a fat % test could provide an additional indication of fraud.

g. **Solution: Fertilizer Authenticity Testing**—This is an example of testing innovation that could potentially be a powerful tool for compliance verification within the organic community. A professional group has engaged AOAC to discuss opportunities for developing new approved testing methods to determine organic authenticity.

h. **Solution: Access to Most Current Information—**Certifiers should consult with laboratories and local extension offices regarding currently approved testing methods and substances to use in case-by-case scenarios (e.g., what is the best substance to test for in a particular region for a particular crop).

During the Fall 2024 meeting, the NOSB asked a series of questions about NOP 2611-1. The responses are summarized below and assisted in the formation of the proposed solutions above:

- General: The stakeholder community consensus is that this "target list" is outdated, limited to only a few pesticides, and the community wants more frequent updates. The instruction documents, unfortunately, are not the vehicle to receive frequent updates; therefore, the NOSB outlined solutions above to convert 2611-1 into a critical thinking and sample methodology document and encourages outreach to industry experts and labs to provide the current "threats" to sample.
- Note: Several commenters mentioned the power of a multi-screen residue test and its limitations. One commenter stated, "The QuEChERS method and variations on it have several advantages in conjunction with multi-residue analytical methods; it is not necessarily the best approach in every case nor the sole approach that should be utilized."
- Pesticide Data Program: The PDP is a resource that the organic industry should leverage, specifically to identify at-risk crops and their associated pesticide(s). Targeting high-risk pesticides and vulnerable crops could help the industry and certifiers develop appropriate risk assessments.
- Risk: Certifiers should have established programs to evaluate risk based on region, crop types, current input, and production practices for organic and non-organic production systems. Specific details about the time, place, and crop sampled & production practices, common pests,

common diseases, and everyday materials used for controls – wind direction, adjacent land use, and land history need to be considered.

Responding to Results (NOP 2613)

NOP 2613 provides guidance to certifiers when responding to results from multi-residue pesticide screens on raw agricultural commodities. However, this guidance document is not without its gaps. This proposal aims at solving the following issues and, therefore, resolving current gaps:

1. **Detection without Tolerance Level:** Positive results for pesticides not registered for the crop on which they are found (i.e., No EPA tolerance/FDA action level) are assessed at .01 ppm, which doesn't consider drift or UREC. It may also not be available for minor crops and non-food crops and may feel too strict.
2. **Dehydrated, Extracted, or Concentrated Organic Products:** Residues found in dehydrated, extracted, or concentrated plant material can be misleading and result in a loss of organic status for that product.
3. **Other Prohibited Substances or Excluded Methods**: Several other prohibited substances are not pesticides (e.g., solvents, heavy metals), and they are not currently addressed by NOP 2613.
4. **Notification of downstream buyers when levels are above EPA Tolerance/FDA Action Level.**
5. **Gaps in Decision-Making/Specific Redline Corrections:** Decisions pertaining to land status are not included. Additionally, some specific redline corrections are recommended.

We expand on the issues identified above and propose solutions below.

1. **Issue: Detection without Tolerance Level -** When detected pesticides are not registered for the crop on which they are found at any level above 0.01 ppm, the current guidance indicates that certifiers should exclude the crop from the organic marketplace and alert the appropriate authorities, including the EPA and FDA. This approach assumes that any detection of a prohibited pesticide when there is no established tolerance indicates that the product no longer qualifies for organic status and that there is a human health and safety concern. This approach is problematic in the following circumstances:
    a. **Minor Crops and Non-Food Crops:** The EPA is working on an ongoing project to update crop groups. That said, some minor crops may still not have tolerances established for many pesticides. NOP should develop alternative corrective action approaches when residues of pesticides not registered for the crop are detected on "minor crops" (EPA defines minor crops as crops grown on fewer than 300,000 acres nationwide). Criteria should also be developed to determine tolerance levels for non-food crops, such as cotton seed meal, other plant parts (e.g., leaves, stems, etc.), and soil.
        i. **Solution:** NOSB proposes that NOP develop criteria for certifiers to determine organic compliance for minor crops using established EPA tolerances for broader crop groups, and for non-food crops using established EPA tolerances for the edible portion of the crop. The criteria and procedure for using them would then be incorporated into NOP 2613.

        Additionally, NOP should clearly describe in NOP 2613 and the OILC course NOP-190: Sampling and Testing how to use the existing structure of Crop Groups [(§108.41) > Crop (specified in the Specific Tolerances tables in Subpart C) > Crop Definition (§180.1(g))] to assess positive detections on various commodities. Incorporating examples and interactive learning mechanisms will help certifiers better understand how to navigate the EPA regulations and appropriately evaluate positive detections.

b. **Drift or Inadvertent contamination:** The current guidance does not allow certifiers to factor drift or inadvertent contamination events versus fraudulent activities into their assessment if there is a positive detection but no EPA tolerance or FDA action level. The current guidance also does not provide clarification to certifiers for evaluating whether the presence of a residue is due to unavoidable residual environmental contamination (UREC). Certifiers are assumed to equate this to less than 5% of EPA tolerances. This approach is problematic when there is no EPA tolerance.

   For example, §180.129 o-Phenylphenol lists the tolerance for cucumbers at 10 ppm. This means that tests could show residues of up to 0.5 ppm (5% *10 ppm = 0.5 ppm) for cucumbers, and they'd still be allowed to be sold as organic. However, broccoli is not listed in this table, so if a test came back positive for broccoli for o-Phenylphenol, it could not exceed .01 ppm. This is seemingly unfair to an organic operation in an inadvertent drift scenario in that produce that might be in very close proximity (no difference in the operation's buffers, etc.) could have very different outcomes by having to rely solely on the inclusion of crops in the EPA tables.

   NOSB further explores UREC in our "Residue Testing for a Global Supply Chain: Regulation Review Discussion Document," which includes revising the current definition.

   i. **Solution:** NOSB proposes that NOP explore the following policy solution options:
      1. Utilize 40 CFR Subpart 180 paragraph (d) "Indirect or inadvertent residues":
         a. Recognize the values in 40 CFR Subpart 180 paragraph (d) "Indirect or inadvertent residues" as equivalent to 5% of EPA Tolerance for the purpose of responding to residue tests to determine organic compliance (i.e., 5% of the tolerance listed in (d) should not be taken given that these are already at inadvertent levels; evaluate compliance directly against values as they appear in (d)); and,
         b. Provide guidance to stakeholders for the process of requesting EPA to establish tolerances in paragraph (d) in cases where there isn't a current tolerance listed in paragraph (d) for that substance.
      2. Utilize crop group structure:
         a. NOSB requests that NOP provide guidance to certifiers on how to utilize the crop group structure for the purpose of determining organic compliance including but not limited to:
            i. Adding additional crops (that are missing) to crop groups with like characteristics.
            ii. State that if a crop is listed for a particular substance, all the crops in the corresponding crop group would have the same tolerance (e.g., for o-phenylphenol, cucumbers have a tolerance of 10 ppm). Since cucumbers are part of crop group 9 - cucurbit vegetables, all crops listed in crop group 9 would have the same tolerance as cucumbers).

3. Explore if other reliable data sets could be used to set action and inaction thresholds as an alternative to .01 ppm. These may include, but are not limited to, the USDA Pesticide Data Program or the Dietary Risk Index.

2. **Issue: Dehydrated, Extracted, or Concentrated Organic Products -** When sampling dehydrated, extracted, or concentrated organic products, positive results can be amplified and misconstrue the raw agricultural commodity's contamination level. For example, a fresh hop sample may indicate no pesticide residue detection. However, that same hop sample that is dehydrated and concentrated may reveal positive results. Another common example is grapes vs. raisins. EPA tolerances are established for various agricultural commodities, typically specific to the form (e.g., fresh, dried, etc.). However, this system only sometimes supports taking action on a positive sample result. It should be noted that, sometimes, the lab has specific testing methodologies for fresh vs. dried crops. However, this would not be helpful if the EPA tables only list one vs. the other.

    a. **Solution:** NOSB proposes that NOP develop a specific section in NOP 2613 related to responding to positive results for dehydrated, extracted, or concentrated products.
        i. NOSB proposes the following as potential paths and recommends NOP look into both as viable opinions:
            1. United States Pharmacopeia (USP) 561 as a guideline for establishing thresholds for dried/extracted products (e.g., dried herbs and spices; botanical extracts used in dietary supplements) that account for differences in water content between dried and fresh products. This would provide a value from which certifiers can apply the 5% threshold instead of defaulting to .01 ppm for extracted or dried products.
            2. The European Union model and the factor used to convert fresh to concentrated.

    These proposed approaches are built on models already in use—one by the FDA for over-the-counter drugs and one by the EU, which allows for international harmonization. NOSB acknowledges that these approaches introduce a complex intersection between FDA, EPA, and USDA regarding oversight of residues in NOP-certified food and supplements.

    NOP 2613 section 5.3.5(b) “Using EPA Tolerances” would also need to be revised depending on the chosen solution. It states, “Unless a specific tolerance exists for the processed product, certifying agents should use the tolerance for the raw commodity.” This would no longer be accurate if one of the above solutions were utilized.

3. **Issue: Other Prohibited Substances or Excluded Methods -** Periodic Residue Testing of Organic Products (Notice to Certifiers) and OILC Course NOP-190: Sampling and Testing acknowledge that certifiers can and should test for prohibited substances beyond pesticides. However, NOP 2613 only outlines how to respond to positive results of pesticide residues. It does not provide direction on responding to positive results of other prohibited substances. Additionally, the current regulations only exclude organic sales when residues are detected above the FDA action level or above 5% of the EPA tolerance. CACS is also exploring regulatory revisions in the tandem “Residue Testing for a Global Supply Chain: Regulation Review Discussion Document.”

a. **Solution:** Add a section to NOP 2613 that clarifies how certifiers should respond to positive results outside of pesticides (e.g., other prohibited substances and excluded methods). NOP-190 states that in situations where there is the presence of a prohibited substance, certifiers should "consider whether the presence of these prohibited substances:
    i. Was a result of unintended contamination, and future corrective actions by the operator could reduce or eliminate the contamination,
    ii. Was the result of a willful violation."

Based on the answer to the above questions and perhaps others, certifiers would follow the compliance process outlined at §205.662 and in accordance with NOP 4002: Enforcement of USDA Organic Regulations: Penalty Matrix.

4. **Issue: Notifying downstream buyers when levels are above EPA Tolerance/FDA Action Level -** The current guidance indicates that certifiers should notify the operation that the product is not eligible to be sold as organic and alert the appropriate authority (e.g., EPA or FDA). The guidance does not require that operations notify their downstream buyers. This additional communication could lead to increased oversight and testing downstream. Additionally, fraud has resulted in significant quantities of contaminated or illegitimate products being placed into the stream of commerce. NOP and certifiers currently do not have the ability to initiate stop-sale action on fraudulent products.
    a. **Solution:** NOSB proposes that 2613 be updated to require that operations inform downstream buyers of crops or products with exclusion level contamination.
    b. **Solution:** NOSB proposes that NOP explore the allowance to initiate sequencing for a stop sale action by certifiers or the NOP.

5. **Issue: Gaps in Decision-Making and Specific Redline Corrections**
Again, NOP 2613 does a good job guiding certifiers in their decision-making regarding the product eligibility for the specific sample tested, except as identified above. The guidance document does not provide certifiers with guidance on determining the land status due to positive residue samples.

For example, suppose a crop from a field is tested and returned positive for enough prohibited residue to remove the crop from certification. In that case, it wouldn't necessarily also require farmers to retransition their land, unless there was evidence of an application of a prohibited substance (e.g., it was determined the presence was due to drift). However, if a farmer self-reports a drift event, it must be re-transitioned by some certifiers. Clarification around decision-making in these scenarios would help certifiers make consistent decisions.

Additionally, now that the Strengthening Organic Enforcement final rule requires operations to include an organic fraud prevention plan (OFPP) in their organic system plan, it is unclear how the operation's adherence to their plan impacts the issuance of noncompliances when residues are found. NOP 2613 could be updated to specifically reference that noncompliance for not adhering to one's OFPP may be issued, as applicable. Alternatively, if certifiers found that an operation was adhering to their OFPP and/or the requirements listed currently in NOP 2613, then noncompliances related to those items would not be issued.

    a. **Solution:** NOSB proposes that NOP clarify how certifiers determine the status of land vs. the eligibility of the crop in the case of drift.

b. **Solution:** NOSB proposes that NOP 2613 be updated throughout regarding the issuance of noncompliances for not following other parts of the organic regulations, as applicable, such as 205.201(a)(3) - not adhering to their OFPP.
c. **Solution: Specific Redline Corrections**
    i. Update 5.3.2.b to clarify if it should also include detections "at or above" the FDA action level.
    ii. Update 5.3.3.a to clarify if it should also include detections "at or above" 0.01 parts per million.
    iii. Update 5.3.3 to clarify how to respond to positive results for materials that are not pesticides.

During the Fall 2024 meeting, the NOSB asked a series of questions about NOP 2613. The responses are summarized below and assisted in the formation of the proposed solutions:

1. How should a certifier select a reference EPA tolerance when the commodity or group is not listed with an established tolerance?

   The Board received several answers to this question, ranging from stating that certifiers should not use a reference crop or commodity that wasn't tested, to the opposite stance of using a like crop. One commenter highlighted why this issue requires a solution with an example: "The benchmark detection level of 0.01 ppm is minuscule and often cannot be associated with fraud or failure of an Organic System Plan (OSP). Unless there is direct evidence that material was willfully applied or a failure of an OSP, it seems unfair to prohibit organic sales at such low detection levels. Unintentional environmental contaminants cannot always be managed by an OSP, even the most robust. It would be sound and sensible if a reasonable threshold (e.g., 10 ppm) were used for materials that lacked an EPA tolerance or FDA action level for a particular commodity."

   Another proposed option was to average the tolerances for the listed crops, locate a similar substance (i.e., a substance in the same class of pesticide), and then average the tolerances of those crops for the like substance.

   Lastly, one commenter indicated that we should shift away from EPA tolerances and use cRfD values instead.

2. How should a certifier review metabolite detection?

   We received limited answers to this question. One commenter indicated that NOSB should confirm that metabolites are not included in the QuEChERS screen or a single analyte pesticide screen, as they were under the impression that they were included. Some commenters stated that metabolites should be reviewed against the tolerance for the parent pesticide. Most, however, indicated that more research was needed as some pesticides break down into naturally occurring substances. Therefore, it is unclear which metabolites are from the pesticide breakdown, and which are not.

3. What should a certifier do when results come from third-party operations with unknown sampling methodology?

Most commenters indicated that certifiers should use these results as the basis for investigation, which may include conducting additional inspections (announced or unannounced) and/or collecting additional samples for residue sampling. Most indicated that in cases where the methodology was unknown, or the chain of custody could not be verified, the results should not be used to initiate adverse action.

4. How should a certifier interpret samples of a multi-ingredient product or a tested lot composed of several lots from suppliers?

   Most commenters indicated that pulling multi-ingredient or multi-lot samples should be avoided as determining compliance is complicated. However, several indicated that when this situation occurs, certifiers should further investigate by determining which ingredient is the likely culprit, conducting a full supply chain audit on that ingredient, or testing that single ingredient or all ingredients in the product.

5. What should a certifier do with multiple tests for a single lot, but the test results conflict?

   There were varied answers from those received. Some commenters pointed out that this is where duplicative samples could come into play. Some commenters indicated that the lab should be contacted to determine next steps. Most stated that a case-by-case approach would be required and that certifiers would need to investigate more into the specifics of the scenario.

6. How should a certifier interpret and respond to results from foliage versus commodity tests?

   Some commenters indicated that certifiers needed to work within the bounds of the EPA tolerances in these situations. Some commenters indicated that certifiers could follow the compliance path (e.g., issue noncompliance or adverse action) but that the immediate exclusion from sale only applied to the edible portion of the crop. Due to that, some commenters indicated that it is the best practice to only sample the edible portion. In contrast, another showed that if a sample of the non-edible portion was taken, a subsequent sample of the edible portion could be taken.

7. How should a certifier address tests conducted outside the U.S. for materials not on the “NOP panel” multi-residue screen panel?

   Some commenters acknowledged that 2611-1 is not an exhaustive list. Most commenters indicated that the presence of any prohibited substance warrants an investigation.

8. How can instruction be improved to supply guidelines for prohibited material applications before harvest (intentional and unintentional) since EPA and FDA tolerances are established based on the consumption of the harvested commodity and what existing tools and resources are needed or available to inform the scenarios below:

   a. Identify what might have been applied when concerns exist so that appropriate testing can be conducted.

      Commenters indicated that guidance could include a list of chemicals, and their effects, commonly used in conventional agriculture—for example, chemically induced tobacco

suckering, fruit ripening, or oil extraction—so that certifiers could target testing based on the specific crop or commodity.

b. Evaluate the concentration of the material on commodities that aren't at the harvest stage so investigations can determine whether an application intentionally or unintentionally occurred.

   Commenters agreed that, ideally, certifiers would have guidance on determining what levels indicate an intentional vs. unintentional application. They also recognized the challenge of proving intent.

c. Determine whether crop or field status should or should not be impacted.

   Commenters were aligned in the sentiment that drift scenarios and their impact on land status must be addressed.

   One commenter stated, "Guidance documents or the regulations should address drift contamination and applications of prohibited materials, accidental or otherwise, and how certifiers should address these incidents. For example:

   - Direct and intentional application of a prohibited substance would normally constitute organic fraud, resulting in exclusion from sale and revocation of the operation's certification (Direct and intentional application of an input material that contains small amounts of the prohibited substance, such as a synthetic wetting agent in an otherwise natural potting mix, should not result in revocation or exclusion from sale. Plenty of gray areas exist between spraying a field with glyphosate and using a potting mix with a wetting agent.).
   - Direct but unintentional application of a prohibited substance should normally result in exclusion from sale, but not in adverse action unless the operation has repeatedly failed to address identified contamination risks.
   - Indirect application, such as by drift or flooding, should result in exclusion from sale if the residue is over 5% of the EPA tolerance, but would not result in adverse action unless the operation has repeatedly failed to address identified contamination risks.

Approval of Liquid Fertilizer for Use in Organic Production (NOP 5012)

This guidance clarifies the approval and use of liquid fertilizers in organic production. With innovation in testing methodology and early discussions regarding the possibility of developing an AOAC method for Organic Authenticity Testing, it is important that we also include an update to this document during the suite of testing guidance document updates planned by the NOP.

1. **Issue: Missing Reference to fertilizer authenticity test**
   a. **Solution: Specific Redline Suggestions**
      5.2 Approval - Add in 3A. Conduct a fertilizer authenticity test if an approved testing methodology exists for authenticity determination.

      5.3 Criteria for approval of fertilizer manufacturers—Add in 3A. Conduct a fertilizer authenticity test if an approved testing methodology exists for authenticity determination.

Suggestions for New Guidance Documents:
The discussion around residue testing as a compliance verification tool has identified gaps in the current guidance. In the sections above, we provided suggestions for improving the existing guidance. Below, we give some ideas and context for new guidance documents that could assist certifiers in deploying residue testing more effectively in the organic marketplace.

1. **Residue Sampling Decision Tree:** Overall, stakeholders commented that it would be tremendously helpful to certifiers if NOP developed a decision tree that could assist certifiers in determining when to sample, what to sample, where to sample, what types of tests to run, and how to respond to positive results from each situation. Guidance might not capture the nuance of every situation, but having a decision tree could support certifiers in understanding how to apply residue testing in a supply chain most effectively.
    a. Three samples from our stakeholder community are found in the appendix:
    b. Risk-Based Decision Tree
        i. Critical Aspect of Selecting the Product to Sample
            1. Testing targets are high-value large shipments, country of origin, market footprint, and split or parallel production.
        ii. Multi-ingredient processed products
    c. Residue Test Result Decision Tree based on Current Instruction
    d. Notice of Detection and Next Steps Decision Tree

2. **Validation and Verification Guidance for Importer Requirements 205.273(d):** The Strengthening Organic Enforcement rule now requires importers to have a prohibited substance prevention plan. For certifiers to validate and verify the efficacy of these plans, they must have some guidance related to how residue testing can support these validation and verification efforts. We welcome stakeholder comments on essential elements to guide validating and verifying importers' prohibited substance prevention plans.

In addition to guidance document updates, other comments from the public centered around:

- **Collecting and Aggregating Positive Test Result Information:** Testing results must be aggregated and disseminated to certifiers. Some commenters pointed to a unified reporting format and a centralized point for posting positive residue test information (e.g., ORG-Tracker). This would help transparency and inform the certifier's risk assessments and decisions on what to sample. Other commenters indicated that NOP should regularly communicate high-risk commodities to certifiers. NOSB proposes this in the Risk-based Certification Proposal (also on the Spring 2025 NOSB agenda). Lastly, one commenter referenced the provisions in the organic regulations that allow certifiers to share lab analysis results for residues of pesticides and prohibited substances. It was suggested that guidance be updated or that ACA incorporate into their best practices a process to share information at specified intervals to inform the creation of their sampling program for the following year.
- **Working Group:** Several members of the stakeholder community mentioned the value of a cross-functional working group consisting of inspectors, certifiers, laboratory personnel, and specialists in the field to identify and outline the industry's best practices and certifier policy for sampling and testing specific to the matrix sample and the test required. The ACA established a working group in Fall 2024. It is currently made up of certifier members. We understand that other ACA members may be invited to participate in the future.

- **Risk-Based Testing:** To maximize the impact of testing while managing costs and not overburden low-risk small producers, certifiers should focus on high-risk areas such as large shipments, products from regions with known contamination issues, or products/production sources/processing facilities with a history of fraud. A risk-based decision tree would be an effective tool to help certifiers decide when, where, and what to test.
- **Harmonization with International Standards:** The suggestion to align U.S. pesticide residue testing protocols with international standards will reduce discrepancies between domestic and international testing standards, promoting smoother trade relations and reducing barriers for U.S. organic products.

Conclusion:
Testing, as a tool, has played a crucial role in the organic program since the implementation of the 2013 Residue Testing rule, and was further enforced with the Strengthening Organic Enforcement (SOE) rule. SOE not only assists certifiers in validating compliance but also provides the ability to rapidly detect evidence of commingling/contamination in operations deemed to be high risk, thereby enhancing the program's proactive nature.

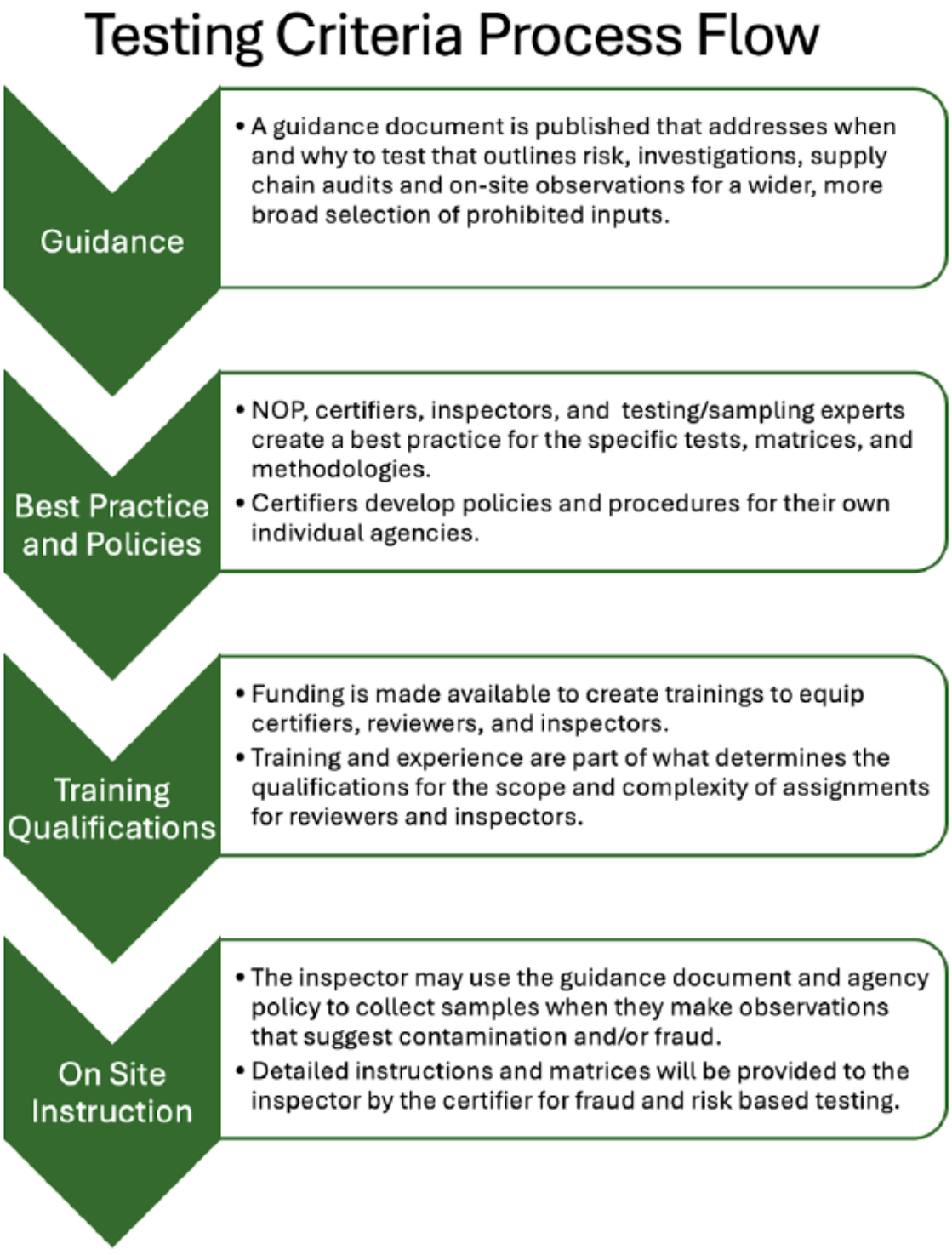
However, modern-day threats do not just come from pesticide residues. A one-size-fits-all test (e.g., “target list” specified in NOP 2611-1) is sometimes the correct tool for the job. Threats can also come from fumigants and conventional processing aids, such as solvents.

In the spirit of continuous improvement, CACS recommends a full revision of existing guidance regarding prohibited substance residue testing as specified in this proposal to protect organic integrity, unlock the power to assist in compliance verification, and help create consistent enforcement decisions.

Subcommittee Vote:
Motion to accept the proposal on Residue Testing for a Global Supply Chain: Guidance Documents
Motion by: Amy Bruch
Seconded by: Carolyn Dimitri
Yes: 4 No: 0 Abstain: 0 Recuse: 0 Absent: 2

Appendix - Decision Tree Framework Ideas from Stakeholders

Decision Tree Example #1: Risk-Based Decision Tree



Decision Tree Example #2: Residue Test Result Decision Tree Based on Current Instruction

A. Residue Detected
    a. No
        i. Notify the certified operation of the test results and indicate that the product may be sold as organic.
    b. Yes
        i. Residues Detected at less than 0.01 ppm
            1. Notify the certified operation of the test results and indicate that the product may be sold as organic. Asses Why the residue is present and follow up with the operation as appropriate
        ii. Residues Detected at or above 0.01 ppm
            1. EPA tolerance is established
                a. Yes
                    i. If residue is detected at or below 5% of the EPA tolerance
                        1. Notify the certified operation of the test results. Assess why the residue is present. If appropriate, consider a notice of noncompliance for the following violations: 205.202(b), 205.202(c), 205.272. If residues are not a result of the application of prohibited pesticides, the product may be sold as organic.
                    ii. If residue is detected above 5% of the EPA tolerance but not above the EPA tolerance level
                        1. Immediately Notify the certified operation of the test results and indicate that the product may not be sold as organic. Assess why the residue is present. Issue a notice of noncompliance for the violation of 7 CFR 205.671. Additional violations may include a notice of noncompliance for the following violations: 205.202(b), 205.202(c), 205.272.
                    iii. If residue is detected above the EPA tolerance level
                        1. Immediately notify the certified operation of the test results and indicate that the product may not be sold as organic. Immediately report the violation to the appropriate agency as described in section 5.3.4 of NOP 2613. Assess why the residue is present. Issue a notice of noncompliance for the violation of 7 CFR 205.671. Additional violations may include a notice of noncompliance for the following violations: 205.202(b), 205.202(c), 205.272.
                b. No
                    i. FDA Action Level Exists?
                        1. Yes
                            a. If residue is detected below the FDA action level

i. Notify the certified operation of the test results. Assess why the residue is present. If appropriate, consider a notice of noncompliance for the following violations: 205.202(b), 205.202(c), 205.272. If residues are not a result of the intentional or direct application of prohibited pesticides, the product may be sold as organic.

b. If residue is detected at the FDA action level
   i. (needs defined as requested above)
c. If residue is detected above the FDA action level
   i. Immediately notify the certified operation of the test results and that the product may not be sold as organic. The FDA or a foreign equivalent may provide guidance on addressing these products. Immediately report the violation to the appropriate agency as described in section 5.3.4 of NOP 2613. Assess why the residue is present. If appropriate, consider a notice of noncompliance for the following violations: 205.202(b), 205.202(c), 205.272

2. No
   a. If residue is detected at 0.01ppm
      i. (needs to be defined as requested above)
   b. If testing detects a residue of prohibited pesticides above 0.01ppm
      i. Immediately notify the certified operation of the test results and indicate that the product may not be sold as organic. Immediately report the violation to the appropriate agency as described in section 5.3.4 of NOP 2613. If appropriate, consider a notice of noncompliance for the following violations: 205.202(b), 205.202(c), 205.272.

Example #3 Decision Tree: Notice of Detection and Next Steps Decision Tree

1. Receive a notice of detection.
2. Verify lab results, methods, date of test, and authorized signature to determine how actionable the residue testing may be.
3. Review the material and brand name association products, comparing the affected crop type.
4. Confirm if the crop is allowed in organic production.
5. Confirm the EPA tolerance level and the amount of detected material.
6. Initiate a trace to determine the grower, ranch, lot, facility, and shipping locations.
7. Place the product on hold as applicable.
8. Review the grower application records to determine the source and whether the material is permitted in the affected crop.

National Organic Standards Board
Certification, Accreditation, and Compliance Subcommittee
Residue Testing for a Global Supply Chain: Regulation Review Discussion Document

Executive Summary

The Fall 2024 Discussion Document on Residue Testing for a Global Supply Chain highlighted several areas in the regulations that may need revision. These include:

1. **Exclusion from organic sale (§205.671):**
    a. Lack of clarity on whether the detection of direct prohibited material application (intentional, regardless of where or when) can or should be excluded from sale as organic per §205.671 Exclusion from sale
        i. Downstream notification of contamination when known
2. **Unavoidable residual environmental contamination (UREC) Definition (§205.2):**
    a. Revision to the definition of UREC
3. **Number and Cost of Sampling and Testing (§205.670):**
    a. Exploration regarding the cost and number of sample collection and testing (i.e., should certifiers continue to bear the expenses of residue sampling and testing in all scenarios, including follow-up tests)

Discussion

1. Exclusion from organic sale (§205.671)

The organic program has experienced exponential growth since the pesticide rule came into effect, and threats to integrity are ever-present. When the pesticide rule was being discussed, commenters stated that the regulation at §205.671 could be misinterpreted to allow products to be sold as organic when prohibited substances were applied if the tests showed levels of the prohibited substance less than 5% of EPA tolerance. Intentional or direct application of prohibited substances to a crop or product, regardless of whether the residue detected is below 5% of the EPA tolerance or FDA action level, should not be sold, labeled, or represented as organically produced. Clarity is needed to reconcile the regulatory text with the Organic Foods Production Act (OFPA).

Background/Regulatory References:

- Section 6511 of the Organic Foods Production Act (OFPA) states:

  (c)(2) *Removal of organic label.* If, as determined by the Secretary, the applicable governing State official, or the certifying agent, the investigation conducted under paragraph (1) indicates that the residue is—
  (A) the result of the intentional application of a prohibited substance or
  (B) present at levels greater than unavoidable residual environmental contamination as prescribed by the Secretary or the applicable governing State official in consultation with the appropriate environmental regulatory agencies; such agricultural product shall not be sold or labeled as organic under this title.

- 7 CFR Part 205 National Organic Program Regulations states:

§ 205.671 Exclusion from organic sale. When residue testing detects prohibited substances at levels greater than 5 percent of the Environmental Protection Agency's tolerance for the specific residue detected or unavoidable residual environmental contamination, the agricultural product must not be sold, labeled, or represented as organically produced. The Administrator, the applicable State organic program's governing State official, or the certifying agent may investigate the certified operation to determine the cause of the prohibited substance.

- 2013 Periodic Reside Testing Final Rule (77 FR 67239) - Preamble Response to comments state:

  (3) *Exclusion from Organic Sale*. Commenters expressed that section 205.671(a) could be easily misinterpreted. They said that section 205.671(a) did not make clear that residue testing may not be used to qualify crops to be sold as organic if a direct application of prohibited materials occurred. Commenters suggested that section 205.671(a) include: "Any crop or product, to which prohibited materials have been directly applied, shall not be sold, labeled, or represented as organically produced."

  NOP Response: We do not believe this additional language is necessary. Residue testing cannot be used to qualify any agricultural crop or product to which a prohibited material has been purposefully/directly applied. The presence of any prohibited substance on an agricultural product to be sold as organic warrants an investigation as to why the detected prohibited substance is present on the agricultural product. It does not matter if the product has come into contact with a prohibited substance through drift or intentional application. Suppose the outcome of the investigation reveals that the presence of the detected prohibited substance is the result of an intentional application. In that case, the certified operation will be subject to suspension or revocation of its organic certification and/or a civil penalty of not more than $10,000 if he/she knowingly sells the product as organic. The use of prohibited substances is not allowed in the Act or this final rule. Residue testing does not qualify a crop or product as organic if a prohibited substance has been intentionally/directly applied. It is a tool for monitoring compliance with the regulations outlined in the Act and this part.

- EU Regulations Articles 28 and 29 of EU 2018/848

  Article 29 (2) “The product concerned shall not be marketed as organic if the official investigation concludes that an operator has used non-authorized products or substances, has not taken the appropriate precautionary measures to avoid the risk of contamination, or has not taken measures in response to relevant previous requests from the competent authorities, control authorities or control bodies.

  SEE REFERENCE: A Vade Mecum on Official Investigation in Organic Products

  (2024) – Good Implementation Practices for Articles 28 and 29 of Regulation (EU) 2018/848. It can be downloaded for free here.

Compliance Process Overview:

- In regard to prohibited substances, there are two compliance pathways a certifier can take:
  1. Exclusion from organic sale (§205.671)
  2. Noncompliance procedure for certified operations (§205.662)

Exclusion from organic sale currently only applies to products that contain pesticide residues greater than FDA action levels or 5% of EPA tolerances. This means that certifiers can immediately exclude contaminated products from the organic marketplace. Additionally, certifiers may also follow the procedures outlined in §205.662, depending on the determination of why the residue is present.

Certifiers must follow the applicable compliance procedures for all other prohibited substances (not pesticides). The immediate exclusion from organic sale under §205.671 does not apply. The product ultimately may be excluded from sale if the operation's organic certification is suspended or revoked.

Section Summary:
NOSB is reviewing the possibility of amending §205.671 of the regulations to clarify that an intentional application of a prohibited substance or excluded method removes the organic label (a.k.a. exclusion from sale as organic), regardless of whether a tolerance level is established.

Also, the NOSB is reviewing whether the NOP should instruct certifiers to require operations to inform downstream buyers of crops or products with exclusion-level contamination, which could lead to increased oversight and testing via organic fraud prevention plans. With SOE, supply chain traceability is one of the major deliverables. Also, we only "know what we know," so additional feedback to inform certified operations fraud prevention plans is essential for continuous improvement.

Public Comment Summary:
During the Fall 2024 meeting, the NOSB asked a series of questions about §205.671. The responses are summarized below and assisted in the formation of the discussion above:

In general, commenters favored achieving alignment for exclusion of sale, especially when an intentional application earlier in the season yields a "passing" result on a test based on EPA Tolerances or FDA Action Level. In addition, it clarifies the intentional application of other prohibited substances (outside of pesticides) and excluded methods.

- More flexibility: Provide certifiers with more flexibility to exclude products from the organic marketplace when residues of prohibited substances are detected in non-crop samples such as soil, water, or tissue. The exclusion mechanism should not be limited to pesticide residues, but should apply to any substance that jeopardizes organic integrity. Note: EU regulation 2018/848 can be benchmarked.

- Eliminating noncompliant materials from the supply chain: A commenter mentioned holding orders. At the same time, a product analysis or investigation would motivate proactive prevention and increase supply chain preparation for sampling. The regulatory authority to exclude or recall products voluntarily or mandatorily would bolster consumer confidence in organic supply.

Differentiation between certain types of materials: One commenter stated that a regulatory mechanism is needed to distinguish between materials that have an agricultural or food processing use in nonorganic crops and products and materials that may occur naturally, such as nicotine in peppers and arsenic in rice. They said this regulatory mechanism should be based on a closed list of prohibited

materials that wouldn't exclude products from the organic marketplace if a material is detected because it occurs naturally.

Willful violations: A certifier stakeholder mentioned that certifiers have other means of investigation and enforcement, such as 7 CFR 205.662(d) and NOP 4002 (Penalty Matrix), that could prevent a contaminated product from entering the organic supply chain. However, addressing NOP 2613 to cover residue detections other than pesticides would make it easier for certifiers to enforce. If enough evidence is collected to show a willful violation was committed, a certifier can move forward with the proposed revocation of the entire operation.

2. Unavoidable residual environmental contamination (UREC) Definition (§205.2)

Under OFPA and the NOP regulations, organic certification is a process-based standard. However, consumers expect organic products to be free of any contamination with prohibited substances. This expectation is becoming increasingly challenging to meet as technology advances, allowing substances to be detected in trace amounts. Often, the contamination is outside the organic operation's control (e.g., contamination from adjoining land, atmospheric drift, etc.). Certifiers must use current EPA tolerances to determine if the organic product is eligible to be sold as organic. Due to this increased contamination reality, it is not uncommon for residues to be present at low levels, but there is no EPA tolerance established for that crop. Therefore, certifiers must use the .01 ppm level as the benchmark to determine the eligibility of organic products. In an ideal world, all substances would have a value for all crops or crop groups, so certifiers wouldn't need to default to .01 ppm. However, this is impossible.

In place of that ideal world, CACS is exploring how to bring these pieces more into alignment: the current reality of farming in today's landscape (which does, unfortunately, contain some level of contaminants) and certification being a process-based standard with consumer expectations of zero prohibited substances being in organic products even at trace amounts, for certifiers to respond to positive test results in a pragmatic yet compliant manner.

Section Summary:

Current definition at §205.2:

> *Unavoidable residual environmental contamination (UREC).* Background levels of naturally occurring or synthetic chemicals present in the soil or in organically produced agricultural products below established tolerances.
>
> Based on stakeholder comments, NOSB proposes the following revision to the definition of UREC:
>
> 1. *Unavoidable Residual Environmental Contamination (UREC).* Background levels of ~~naturally occurring or synthetic chemicals~~ prohibited substances and excluded methods that are ~~present in the soil or present in organically produced agricultural products that are below established tolerances~~ not caused by actions taken by organic farmers and ranchers and are, hence, typically beyond the control of certified organic operations.

NOTE: Additionally, NOP 2613 would require updates based on the ultimate approach decided for UREC. When regulations are updated, we understand that subsequent guidance document(s) updates occur.

Public Comment Summary:

In addition to updating the UREC definition, the NOSB received comments about UREC during the Fall 2024 meeting. The responses are summarized below and assisted in the formation of the discussion above:

Unfair punishment: A commenter indicated that we should be cautious about penalizing operations when there is no EPA tolerance, which defaults to 0.01 ppm even when the contamination is UREC. In that case, the product should be allowed to be sold as organic.

Rethinking the link to EPA tolerances concerning UREC: A commenter suggested that basing UREC levels of pesticides on a percentage of EPA-set tolerances is arbitrary and doesn't link to human health impact. They suggested an alternative approach, such as setting UREC levels concerning chronic Reference Doses (cRfDs) and defining inadvertent residues (e.g., 1/10th of a pesticide found in conventional samples).

Additional review is an investigative burden: An organic stakeholder mentioned that organic farmers often face the burden of investigations when pesticide residues are detected, even when they are trace amounts likely linked to environmental factors beyond their control - UREC. The extensive documentation and interviews required following such detections can detract from the farmers' primary operations. Streamlining investigative procedures, particularly in UREC cases, would help alleviate this issue. By adopting more efficient protocols, certifiers can ensure that farmers are not unduly burdened with investigations that are unlikely to yield substantial improvements in compliance.

3. Number and Cost of Sampling and Testing (§205.670)

205.670(c) states, "A certifying agent must conduct periodic residue testing of agricultural products to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." Samples may include collecting and testing soil, water, waste, seeds, plant tissue, plant, animal, and processed product samples. **Such tests must be conducted by the certifying agent at the certifying agent's own expense**" (bolded for emphasis).

205.670(d) states: **A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number.** A certifying agent that certifies fewer than thirty operations annually must sample and test from at least one operation annually. Tests conducted under paragraphs (b) and (c) of this section will apply to the minimum percentage of operations.

Section Summary:

Due to the regulatory references above, certifiers feel constrained from performing testing above the required 5%. However, if certifiers could pass the costs along to certified operations for increased oversight activities deemed necessary (e.g., complaint, investigation, high-risk operation), certifiers would likely increase the number of samples collected.

It is our understanding the certifiers are experiencing this inconsistently. Some pass along the cost to operations for complaints and investigations and do not count this towards their 5%, which appears compliant (haven't received noncompliance). In contrast, others have received noncompliances for passing the costs along in the same situations.

Public Comment Summary:

The NOSB received several comments regarding costs. Conducting 5% residue testing is a very high-dollar line item on a certifier's profit and loss statement (P&L). There is an incredible amount of variability in this cost value, especially when business decisions are made to manage to a budgetary number versus conducting the needed tests on a risk basis, which could require more travel, subsequent visits, more complex sample collection, etc. One certifier stakeholder mentioned that due to managing costs, they were not in favor of conducting multiple visits for sampling.

Risk: One commenter mentioned that a uniform 5% pesticide testing rate does not adequately address the varying levels of risk across different operations. It can disproportionately burden low-risk organic farms with unnecessary testing while under-scrutinizing operations at higher risk for contamination. This creates inefficiencies and places undue financial and operational strain on organic farmers, particularly small and medium-sized operations. Another commenter mentioned that fraud has been documented in imported and domestic corn, but evidence for other categories was limited. If changes in the residue testing program happen, it is critical that the response targets areas of the documented risk surveillance testing program, which would also be helpful to evaluate. A consultant for a processor mentioned that since the current mandate is that 5% of all operations have a single test performed under the regulation, it is entirely conceivable that not all pesticide residues would be caught, even at the producer level. Therefore, pesticide residue testing should be standardized and required of all producers, regardless of crop.

Re-allocating Costs: Several public commenters believed in the opportunity to explore spreading out the costs throughout the industry. One certifier mentioned that we could reasonably test 10% of operations annually without considering costs.

Other factors outside of costs: Crop timing can limit the collection of a limiting sample in addition to human capital resources.

Discussion Document Conclusion:
The regulations governing residue testing have remained largely unchanged since 2013, following notable revisions, while certain provisions, such as UREC, have been in place for even longer. However, the organic industry has evolved dramatically since then. It is both wise and essential—rooted in the very principles of organic production and certification—to consistently assess and enhance our practices to ensure we thrive in a dynamic marketplace. Now is the time to revisit and refine these regulations, celebrating the effective elements and courageously reimagining those that no longer serve our vibrant industry.

Questions:

1. **Exclusion from Sale:**
    a. Outside of EPA tolerances/FDA action levels, are certifier and inspector tools sufficient to determine willful violations of prohibited substances in categories other than pesticides, i.e., solvents, excluded methods, and fertilizer?
    b. Is it necessary to expand 205.671 to include intentional applications, or are other parts of the regulations allowing certifiers to exclude products from sale that were not produced under the regulations?
    c. Is there value in informing downstream supply chain recipients when known non-compliant products have been discovered and released into the "chain of commerce?"
        i. What are the unintended consequences?

d. There have been cases where questionable products have been received. Still, testing is avoided to confirm compliance due to the significant financial risk of knowing the product could be non-compliant (e.g., an imported product received that is already paid for). What are the solutions here?

2. UREC:

a. Do you agree with the proposed revision to the definition of UREC?
b. Do you have an alternative definition to propose?
c. Should guidance be revised to state that noncompliances should not be issued if the residue is determined to be UREC?
d. How can the testing process be streamlined and less burdensome for small producers faced with UREC or inadvertent drift challenges?

3. Number and Cost of Sampling and Testing:

a. Certifiers: If you could pass along the cost of residue sampling and testing in some circumstances (e.g., complaints, investigations, high-risk operations) and still have this count toward the required 5%, would this change how you approach your sampling program? How?
    i. Would this be valuable to your agency? Why?
    ii. Would this allow you to do more testing?
b. Are there other revisions to cost and the number of samples taken that the Board should consider to strengthen and enhance the effectiveness of sampling in identifying fraud?

Subcommittee Vote:
Motion to accept the discussion document on Residue Testing for a Global Supply Chain: Regulation Review
Motion by: Amy Bruch
Seconded by: Catherine McCluskey
Yes: 4 No: 0 Abstain: 0 Recuse: 0 Absent: 2

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Pear Ester

Summary of Petition and Background Information

In September 2023, the National Organic Program (NOP) received a petition from Trece Incorporated requesting the addition of Pear Ester (i.e., Ethyl-2E,4Z-Decadienoate), a semiochemical material, to the National List as a synthetic allowed for use in crop production [7CFR§205.601(j)]. Semiochemicals are bioactive molecules released by an organism to signal or provoke a behavioral or physiological response (Klassen et al., 2023). Signaling may be between members of the same species or between two or more distinct species. Pheromones, kairomones, and allomones are sub-categories of semiochemicals. Pear ester was previously allowed for use in organic crop production under the synthetic pheromone classification until its correct reclassification as a kairomone. Even though pheromones and kairomones are both semiochemicals, they differ in a couple of significant characteristics. Pheromones are volatile chemicals produced by a given species to communicate with other individuals of the same species to affect their behavior (EPA, 2011).

Pear ester is synthesized by a condensation reaction between two chemicals that are by-products of petroleum processing. The prevalent process for manufacturing pear ester is the condensation reaction between the eight-carbon allyl alcohol, oct-1-yn-3-ol (CAS No. 818-72-4), and triethylorthoacetate (CAS No 78-39-7). The condensation product is heated with propanoic acid as a catalyst, and the subsequent Johnson-Claisen rearrangement gives ethyl 2E, 4Z-decadienoate. It is a convenient one-step synthesis with good yields (Trécé, Inc., 2023; Tsubi et al., 1993).

Pear ester appears on the FDA list of Substances Added to Food (*formerly EAFUS*) for use as a flavoring agent or adjuvant food additive (US FDA, 2024). The EPA has registered pear ester formulations for pest management. This behavior-altering chemical (i.e., semiochemical) is particularly useful in the management of the codling moth, *Cydia pomonella* – an economically significant pest that principally affects apple, pear, and walnut crops (Trécé, Inc., 2023).

The proper classification of pear ester as a kairomone, instead of a pheromone rendered its continued use under the pheromone category, untenable in organic crop production (Trécé, Inc., 2023). The petition is aimed at providing organic crop producers with pest management tools that were available to them prior to the reclassification of pear ester as a kairomone instead of a pheromone.

The 2024 technical report on pear ester has detailed information on significant improvements in pest management outcomes from the incorporation of pear ester relative to results obtained with the use of pheromones alone. The report covers various uses of pear ester in codling moth management. This includes their use,

(a) As lures in traps to monitor populations of codling moth in orchards. These traps help to determine the “biofix point” which is date on which codling moths first appear in monitoring paths. Pear ester monitoring traps provides information for determining action thresholds and the timing of treatments.
(b) In mating disruption efforts. Research findings show mating disruption dispensers loaded with both codling moth sex pheromone and pear ester can be more than dispensers with pheromone alone.

Available data show that pear ester exerts significant economic impacts on pear and apple growers. The positive economic impact of pear ester is exerted through its documented direct impact on mass trapping, mating disruption and proper timing of treatments (including pesticide applications). These interventions result in significant reductions in fruit damage. The improved effectiveness of traps and monitoring tools when pear ester is combined with pheromones is well documented.

Subcommittee Review Fall 2024
Subcommittee discussions were based on a discussion document that was informed by the 2024 technical report (TR) on pear ester. Discussions covered pertinent elements of the petition (to add pear ester to the National List). Discussions also included the previous misclassification of kairomones as pheromones and the distinction between these behavior-altering chemicals. The essentiality of pear ester in apple and pear production was emphasized. There was a suggestion to explore the possibility of broadening the proposal to cover kairomones as a group instead of pear ester alone. All eight attendees voted to accept the discussion document on pear ester.

Fall 2024 Meeting Public Comments
Comments received at the Fall 2024 meeting were in favor of adding pear ester to the National List. A commenting organization stated that synthetic pear ester-based mating disruption products are Generally Recognized as Safe (GRAS) and are more effective in insect pest management in organic orchards relative to their alternatives. It was also pointed out that the chemical structure of synthetic pear ester is identical to the natural kairomone.

One commenter advised the Board to direct significant attention to determining whether the word "pheromones" was used in OFPA §6517.c.1.B.i to refer to only pheromones or if it could be interpreted to include other semiochemicals such as kairomones. The commenting organization was of the view that this determination will provide a basis (or otherwise) for continuation of the evaluation of pear ester, in addition to helping to clearly articulate the Board's intent for handling future petitions involving semiochemicals. A historical context of negotiations that resulted in the inclusion of pheromones in OFPA was provided. The Crops Subcommittee (CS) was advised to determine the correct interpretation of pheromones in OFPA §6517.c.1.B.i. to ascertain whether it covered only materials that satisfy the technical definition of pheromones or include other semiochemicals. It was argued that the absence of internet-based resources and poor access to technical expertise during the negotiations pertaining to the inclusion of pheromones in OFPA may have led to the wrong interpretation of the intent of OFPA drafters. The commenting organization was of the view that if the drafters of OFPA had access to the information available in the 2024 technical report on pear ester, OFPA §6517.c.1.B.i. would have highly likely contained the term "semiochemicals" instead of "pheromones."

One of the comments was for the Board to make a distinction between pear ester that is released from traps and those that are microencapsulated in polyamide materials that are then sprayed. The commenting organization considers the use of pear ester in traps to be consistent with OFPA, unlike its use in microencapsulated formulations. The commenter stated that polyamide particulates are microplastics and must be evaluated as such. According to the commenting organization, the Board needs to consider the following pieces of information in its deliberations on pear ester: (a) the essentiality of microplastics in microencapsulated pesticide formulations, and (b) the publication by Alijagic et al. (2024) about the need to investigate potential health risks to individuals exposed to polyamide microplastics. The Board was asked to consider the delivery mechanism in its deliberations on pear ester. An annotation to restrict the use of pear ester to traps was recommended.

Another commenting organization acknowledged the efficacy of semiochemicals in insect pest management but stressed the importance of guardrails that permit the use of synthetic materials that are identical to natural kairomones. In the perpetual quest for more effective pesticides, this guardrail would prevent the development of products that exert unintended/unexpected adverse impacts on non-target organisms in the farm ecosystem because they differ significantly from natural kairomones. The comment endorsed the use of pear ester in trapping and monitoring insect pests but opposed the broad application of microencapsulated formulations which release microplastics in the organic environment.

Fall 2024 NOSB Board Meeting Review:
There was widespread support for adding pear ester to the list. Board members sought information from public commenters on whether there were other kairomones (i.e., apart from pear ester) that were in use in insect pest management. This was to inform the NOSB's decision on whether to pursue the addition of pear ester alone or kairomones as a group to the National List. The Board did not receive any information that justified the addition of kairomones as a group.

Subcommittee Review Spring 2025

Category 1:Classification/categorization
There is a need for clarification and/or pursuit of supporting documentation on the intent or correct interpretation of the word "pheromone" in OFPA §6517.c.1.B.i. A section of the organic community is requesting information on the interpretation that informed the removal of pear ester from the National List. The current position/trajectory of the Crops Subcommittee (CS) is to proceed with a proposal to add pear ester to the National List until a determination that the drafters of OFPA intended to refer to semiochemicals instead of "pheromones" in particular. This approach is informed by the fact that even though kairomones and pheromones are both semiochemicals, they are technically different. The removal of pear ester from the National List represents a previous (correct or incorrect) determination that OFPA drafters did not intend to refer to semiochemicals in general. CS will proceed with the proposal while it pursues documentation and/or clarification of the intent of OFPA drafters on the use of pheromones and other semiochemicals.

Another item that will feature prominently in discussions on pear ester is its categorization based on the various delivery systems used in deploying them. This will inform the possible introduction of an annotation to distinguish between systems that may be consistent and inconsistent with OFPA.

Category 2: Adverse Impacts of Pear Ester

Human Health Impacts
Pear ester is a Generally Recognized as Safe (GRAS) food additive. In 2013, the EPA exempted it from the need to establish food tolerance for residues in or on food crops at 40 CFR 180.1323. The EPA concluded that "there is a reasonable certainty that no harm will result to the U.S. population from aggregate exposures to ethyl-2E-4Z-decadienoate (pear ester)" (78 FR 53051, August 28, 2013). Pear ester has low acute toxicity to mammals, and the oral LD_{50} for rats is 4,027 mg/kg. This number means pear ester is nearly non-toxic. Additionally, pear ester is an FDA-approved food additive, and average human consumption in the U.S. is about 3 µg per day (US EPA, 2013). According to the EPA, pear ester also has low chronic toxicity, and is not a likely developmental toxicant or mutagen. It is not on the EPA list of carcinogens, or on the IARC carcinogen list. The EPA reported in 2013 that pear ester had not been evaluated for endocrine disruption.

Even though the 2024 technical report on pear esters found no publications indicating harm to humans from pear ester or polyamide particulates, the product's safety data sheet states that it may cause allergy or asthma symptoms or breathing difficulties if inhaled. Contact with skin or eyes may cause irritation. It must be noted that the food tolerance exemption provided by the EPA does not include an evaluation for occupational exposure. The maximum label amount is about 400 µg pear ester/day, which is well below the acute toxicity of 4027 mg/kg. Pear ester vapors are not likely a health problem for orchard workers.

Exposure to Polyamide Particulates

Sprays of about 30 g/ha decadienoic acid (DA) ethyl ester (i.e. pear ester), commercially known as DA MEC™, are applied to tree canopies with an air blast sprayer (Cidetrak, 2020). Even though exceedingly tiny amounts of DA MEC™ are used, the sprays contain a large number of small polyamide particles. Each tree canopy receives about five hundred million microencapsulated pear ester particles. There might be a respiratory hazard from inhaling plastic microparticles when the spray is applied by air blast sprayer to individual trees. However, effects of exposure to the polyamide spherical capsules in the spray have not been evaluated by the EPA. Given the 4-hr re-entry restriction, the greatest acute risk is probably during spray applications with an air blast sprayer. But the DA MEC™ label does not require respiratory protection for workers (Cidetrak, 2020). It is important to note that maximum 8-hr worst case chronic exposure would be about 0.0357 mg/m^3 or 36 µg/m^3. This exposure is below the U.S. 24-hr particulate standard of 150 µg/m^3 for PM 10 (89 FR 16202, May 6, 2024).

Given the fact that sprayable microencapsulated pheromone particles can be washed out of tree canopies by wind, rain, and overhead irrigation sprays, pear esters are assumed/expected to meet the same fate.

Environmental and Ecological Health Impacts

The EPA did not require testing for bird, fish, and aquatic invertebrate toxicity because pear ester is expected to quickly disperse and degrade in the environment. However, the pear ester safety data sheet from Boudakian Research (Boudakian Research, 2023) states that pear ester is "very toxic to aquatic life with long lasting effects." The substance is, however, exempt from testing for toxicity to bird, fish, and aquatic invertebrates. According to the safety data sheet, pear ester is a marine toxicant and hazard (Boudakian Research, 2023). Environmental damage may be mitigated by the low application rate of 12 g DA MEC™/acre or 30 g/ha. That is about 0.27 mg DA MEC™/ft^2. That is a small amount, but each ml of the usual diluted field spray contains about 260,000 particles (Light & Beck, 2010). Once applied, microcapsules probably stay on the leaves until dislodged by wind and rain, which is the case for microencapsulated sprayable pheromones (A. L. Knight et al., 2004). When particles are dislodged by rain, they likely become part of runoff from an orchard (Trécé, Inc., 2023). Once the microencapsulated particles reach water, fish or other aquatic creatures might ingest them. No density information is given (Light & Beck, 2010), but it is likely the polyamide particles are less dense than water. The pear ester contained in the microparticles is an aquatic hazard (Boudakian Research, 2023). The 2024 technical report found no information on the environmental effects of pear ester polyamide microcapsules. There is no published information on the effects of these particles on earthworms. Birds can be exposed by feeding on earthworms that ingest polyamide microcapsules. However, again, the amounts of pear ester involved are exceedingly small. Because of its volatility, pear ester dissipates quickly in the environment. Manufacturers encapsulate volatile components of spray formulations to limit volatilization and produce products that have a lasting effect (US EPA, 2013).

The EPA did not require the product manufacturer to submit environmental toxicity tests of microencapsulated pear ester (US EPA, 2013).

Category 3: Alternatives/Compatibility

Performance of Alternatives
It is important to note that codling moth management performance of natural alternatives to synthetic pear ester tend to be enhanced when combined with the synthetic product. Products such as granulosis virus, Spinosad, BT products and the use of degree day methods are employed against the codling moth. The performance of these alternatives is, however, enhanced by pear ester in monitoring traps to determine the biofix point and, thus, the correct and most effective timing of pesticide applications.

Subcommittee Next Steps:
The NOSB has deemed the 2024 TR sufficient and has used the document as a basis for the Fall 2024 discussion document and the ongoing proposal for the Spring 2025 meeting. Comments received so far on pear ester have been positive.

The CS will seek additional information on the reasons behind the EPA not requiring testing for fish and aquatic invertebrate toxicity given the fact that the safety data sheet for pear ester states that it is a marine toxicant and hazard (Boudakian Research, 2023).

Questions for Stakeholders:
The CS has the following specific questions for stakeholders and welcomes any additional perspectives, solutions, and information related to pear ester.

1. Additional/new research-based information on the environmental and human health impacts of pear ester used in microencapsulated formulations and in traps.
2. Information on other kairomones that may be in use in the management of moths and other major insect pests.

Subcommittee Vote:

Motion to classify pear ester as synthetic.
Motion by: Franklin Quarcoo
Seconded by: Brian Caldwell
Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 0

Motion to add pear ester to the National List at §205.601(j).
Motion by: Franklin
Seconded by: Logan
Yes: 6 No: 0 Abstain: 1 Recuse: 0 Absent: 0

National Organic Standards Board
Crops Subcommittee
Spring 2025 Proposal: Compost, Feedstocks, and the National List

Summary
The National Organic Program (NOP) requested that the National Organic Standards Board (NOSB) address a petition from the Biodegradable Products Institute (BPI) to allow certain materials in organic-compliant compost. Several of BPI's requested changes to the regulations conflict with the process of classifying and evaluating synthetic materials and, therefore, cannot be adopted. The Crops Subcommittee (CS) recommends a formal clarification that compost feedstocks are subject to the same National List evaluation process as other materials proposed for use in organic agriculture.

Background
The Organic Foods Production Act of 1990 (OFPA) and NOP regulations include a process and criteria for the NOSB to use in evaluating synthetic substances proposed for use in organic crop production (7 U.S.C. 6504, 6508, 6517, 6518; 7 CFR 205.105; 205.600). In response to the Spring 2024 discussion document (DD) on this topic, many organic stakeholders, some composters, the CS, and the full Board acknowledged the well-established process for evaluating synthetic substances, and that adding a definition of compost feedstocks that presumptively includes compostable packaging to organic definitions, as requested in the BPI petition, would bypass the required evaluation of synthetic materials. Bypassing this established path would essentially amount to the allowance of synthetic substances in organic production without the approval from the NOSB.

In Fall 2024, the CS presented a proposal to amend the definition in 7 CFR 205.2 and the practice standard at § 205.203. The background section of that proposal indicates how the CS considered all points of the BPI Petition and reiterated that the process for evaluating compostable materials is the same as for all other substances proposed for use in organic agriculture. To avoid future confusion, the CS proposes a formal recommendation to confirm that synthetic compost feedstocks are subject to the same National List evaluation process as other synthetic substances.

The CS has also requested a Technical Report on compostable packaging materials in order to evaluate these synthetic substances according to established procedures around petitioned substances. The initial discussion of these substances is addressed in a separate discussion document that also aims to unpack the issues related to Unavoidable Residual Environmental Contamination(UREC) and contamination of compost from food waste and compostable packaging materials.

Classification
The BPI petition suggests that synthetic compost feedstocks are not subject to the National List petition process and requests that NOP allow "de minimus" amounts of synthetic substances in compost. The CS, however, has recommended and continues to support the National List review process for the evaluation of synthetic compost feedstocks. The CS will continue to address the implications of a 'de minimis' approach in future work, as applicable. The BPI petition seems to suggest that regardless of the synthetic or nonsynthetic classification of compost feedstocks going into the composting process, the resulting product of the composting process (i.e. compost) must be categorically allowed as a nonsynthetic substance. In support of this position, they reference the exception for naturally occurring biological processes included in the definition of "synthetic" in OFPA (7 U.S.C. 6502) and mirrored in the USDA organic regulations at 7 CFR 205.2 Terms defined:

Synthetic. A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

In contrast to the approach BPI is suggesting, the CS asserts that nonsynthetic materials subjected to only biological processes remain nonsynthetic, but a biological process cannot convert a synthetic material to a nonsynthetic material. Compost is an end product of a naturally occurring biological process, and compost products that consist entirely of nonsynthetic feedstocks are allowed for use in organic crop production. However, the same conclusion cannot be drawn for composts that include synthetic feedstocks. Objectively, compost feedstocks are not created by naturally occurring biological processes; therefore, composts containing intentionally added synthetic feedstocks are considered prohibited substances unless the synthetic feedstocks have been evaluated against National List criteria and are included on the National List (e.g., newspaper and other recycled papers).

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

(c) As compost feedstocks—Newspapers or other recycled paper, without glossy or colored inks.

In response to issues raised in the NOP Work Agenda request from the NOP to the NOSB, the CS is providing the following list in order to be transparent about how the Subcommittee and the full Board are reconciling the work agenda request and ongoing NOSB work on the compost work agenda:

- BPI Petition requested changes to 7 CFR 205.2 and 205.203; in response, the Board voted at the Fall 2024 meeting unanimously in support of alternative updates to the definition and practice standard..
- The current regulatory framework already identifies anaerobic digestate as distinct from composting, as per the Fall 2017 NOSB recommendation. Previous work by the NOSB indicated that anaerobic processes include pathogens of concern that vary from those appearing in aerobic composting conditions and should be distinctly evaluated.
- The Fall 2024 proposal did not alter guidance for vermicomposting, which also relies on aerobic conditions, thus maintaining consistency with current practices and the Fall 2024 proposal to update the definition and practice standard.
- The CS and the full Board have considered and declined a process path by which “compost feedstocks” would be added to § 205.2 in terms defined.
- The CS and the full Board have considered and declined to recommend a “de minimis” approach to synthetic substances intentionally included in compost.
- The CS and the full Board have unresolved questions related to whether ASTM standards for biodegradability provide adequate oversight of substances on the National List as required by OPFA. The CS has ordered a technical report in order to evaluate compostable substances petitioned by BPI.
- The CS is working on a discussion document and is in conversation with the Certification, Accreditation & Compliance Subcommittee (CACS) around issues of UREC and contamination as part of CACS’ ongoing work on residue testing.

Discussion

The NOP has requested that the Board update and refine organic compost standards to reflect current scientific research, regulatory alignment, and industry best practices for organic compost making. This

proposal ensures that compliant organic composting practices remain effective in maintaining soil fertility, nutrient management, and the overall integrity of the organic system. The Fall 2024 proposal to update the compost definition and composting requirements represent a crucial step in harmonizing the organic regulatory framework with other federal standards, while fulfilling the requirement listed at 7 CFR 205.203 that organic crop inputs "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." By simplifying and aligning the regulations, the Fall 2024 NOSB recommendation supports the continued advancement of organic agriculture while ensuring that the health and sustainability of the system remain central to all regulatory changes. This proposal is not intended to complete the process engaged by the CS or to complete the work agenda request of the NOP to the NOSB in the compost landscape. This proposal seeks to reinforce the Crops Subcommittee's process for the full Board's evaluation of synthetic compost feedstocks.

Subcommittee Vote:
Motion to accept the proposal stating synthetic substances intentionally included as feedstocks in organic compliant compost must be evaluated by the NOSB, recommended for addition to the National List by a two-thirds vote of the NOSB, and added to the National List through the Federal Register process of notice and comment rulemaking by the NOP.

Motion: Mindee Jeffery
Second: Logan Petrey
Yes: 8 No:0 Abstain: 0 Recuse: 0 Absent: 0

National Organic Standards Board
Crops Subcommittee
Synthetic Compost Feedstocks Discussion Document
Compostable Synthetic Food Packaging Plastics and Cellulosic Fiber-Based Materials

Summary of NOSB Activity:
On August 30, 2023, the Biodegradable Products Institute (BPI) submitted a petition for rulemaking to the USDA. The petition asks the National Organic Program (NOP) to engage in rulemaking to update the compost regulations in order to create a narrow allowance for certain "compostable" synthetic substances to be included as compost feedstocks without adding these substances to the National List of synthetic substances allowed in organic crop production. The petition proposes allowing substances that meet compostability specifications at ASTM D6400-21, D6868-21, or D8410-21 to be considered allowed "compost feedstocks" in compost used on organic farms.

The National Organic Standards Board (NOSB) unanimously passed a proposal at the Fall 2024 meeting recommending amendments to the organic regulations that would confirm that synthetic compost feedstocks should be reviewed and approved for inclusion on the National List at 7 CFR 205.601(c) and aligns time and temperature requirements to compost industry standards.

For the Spring 2025 meeting, NOSB will be considering a formal proposal that confirms the need for all allowed synthetic compost feedstocks to be added to the National List through a two-third majority vote of the Board, followed by notice and comment rulemaking by USDA. This proposal is designed to convey clarity to the NOP regarding NOSB's views on how synthetic compost feedstocks should be considered and allowed in compost used in organic crop production.

Summary of Review:
At NOSB's Spring and Fall 2024 meetings, public commenters expressed strong and varied opinions about the appropriateness of including compostable polymers on the National List and allowing them in compost used on organic farms. In general, those wary of including these substances provided comments focused on two major areas of concern: 1) The potential for the compostable polymers, themselves, to contaminate soil and water; and 2) The overuse of single-use plastics, in general, and whether the allowance for compostable plastics in organic production would violate the National List criteria that requires all substances on the National List to be consistent with organic farming. Additionally, those commenters in support of allowing compostable polymers into compost used on organic farms cited these substances' role in meeting waste reduction goals, their uniformity and consistency in degradation during the composting process, and the strength of the organic market to drive innovation and adoption of food waste reduction in order to meet greenhouse gas emission reduction goals.

In light of the BPI petition and NOSB's role in reviewing the suitability of compostable polymers for their inclusion in the National List as compost feedstocks, the Crops Subcommittee (CS) is moving forward with information gathering in order to inform the potential National List addition motion at a future meeting. The CS ordered a Technical Report (TR) of resins and formulated products that meet ASTM D6400-21, D6868-21, or D8410-21 standards in order to inform the evaluation of whether these substances' chemical properties align with the tenants of organic production.

NOSB is also engaging with organic stakeholders about composting as a driver of change towards sustainability, diverting food waste from the landfill and into composting operations, the role compostable polymers and other synthetic compost feedstocks play in meeting these waste reduction

goals, and reducing polyethylene plastic and other contamination in compost currently used on organic farms.

Lastly, the CS recognizes that compost poses unique challenges to organic production related to Unavoidable Residual Environmental Contamination (UREC), and that oversight of compost feedstocks is an essential element to preventing contamination of compost. Consistent with process-based compliance verification, the approval process for compost in organic production evaluates the entire composting system and does not ignore the presence of prohibited substances in compost feedstocks. In compost making, feedstocks could unintentionally carry prohibited substances into the compost making process. Compost operations make every effort to understand incoming feedstocks, while educating the public and adjacent industries on the importance of eliminating contaminants, and most commercial compost makers typically test their finished compost for pathogens, heavy metals, nutrients, and plastic contamination. Organic compliant compost operations demonstrate good faith efforts to make continuous improvement on preventing contamination of incoming compost feedstocks. Much like buffer zones in organic system plans, drift could occur on organic crops, but the difference between unavoidable residual environmental contamination and intentionally adding prohibited substances to organic crops is a bright line in organic compliance. In addition to the practice of avoiding and removing contaminants, the process of composting breaks down many contaminants on feedstocks into more benign constituents. At this stage, the CS views contamination as that which can be removed from compost feedstocks, and UREC as that which cannot be avoided. Utilizing preventive practices and strict oversight of compost feedstocks through the National List process aligns with organic principles, in contrast with the BPI petition's proposal to introduce a 'de minimis' allowance of new synthetic substances as compost feedstocks with no regular oversight into the organic regulations. The CS is supporting the process of continuous improvement in organic compost making by adding Research Priorities on the fate of prohibited substances in compost and the impacts and persistence of prohibited substances on microbial communities in finished compost.

Questions:

1. Does the current listing for newspapers or other recycled paper, without glossy or colored inks, as a synthetic compost feedstock adequately address the contamination concerns related with these types of products? Are there suggestions for improving this annotation to better reflect the role that paper has as a compost feedstock?
2. What are the risks and benefits to allowing all compostable polymers to be included as compost feedstocks in organic compost?
3. What are the risks and benefits to continuing the current prohibition on compostable polymers' inclusion in organic compost?
4. There have been suggestions to create an allowance for compostable food contact labels (e.g. fruit stickers) and compostable waste collection bags in order to reduce contamination in compost and get more food waste out of the landfill and into compost facilities, but to prohibit compostable plastics in organic compost when they're used in single-use service wear (e.g. cups, clamshells, utensils). What are the risks and benefits to this approach?
5. What are the unique contamination risks associated with composting food waste and the associated compostable polymers that typically come with food waste?
6. What other factors should NOSB consider when evaluating compostable polymers for inclusion on the National List?
7. Is the approach to evaluating UREC and contamination, as described in this document, consistent with organic principles?

Subcommittee Vote:

Motion to accept the discussion document on synthetic compostable polymers
Motion by: Nate Lewis
Seconded by: Brian Caldwell
Yes: 5 No: 0 Abstain: 1 Recuse: 0 Absent: 1

Sunset 2027
Meeting 1 - Request for Public Comment
Crops Substances § 205.601 & § 205.602
Spring 2025

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 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 2025 public meeting, the NOP requests that the public provide comments about these substances to the NOSB as part of the Spring 2025 public meeting. Written comments should be submitted via Regulations.gov at www.regulations.gov during the comment period as explained in the meeting notice published in the Federal Register.

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 §205.601 Substances in Organic Production:

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

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

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

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

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

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

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

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

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

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

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

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

Written public comments will be accepted via www.regulations.gov during the open comment period noted in the Federal Register. 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:

Potassium hypochlorite
Soap-based algicide/demossers
Ammonium carbonate
Soaps, insecticidal
Sucrose octanoate esters

Vitamin D3
Aquatic plant extracts
Lignin sulfonate
Fatty alcohols (C6, C8, C10, and/or C12)
Sodium silicate
EPA List 4 Inerts
Paper

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

Potassium hypochlorite

Reference: §205.601(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.
(2) Chlorine materials—For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.
(iv) Potassium hypochlorite—for use in water for irrigation purposes
Technical Report: 2011 TR (chlorine materials); 2025 Limited Scope TR
Petition: 2019 Request to add potassium chlorite; 2019 Addendum
Past NOSB Actions: 10/2019 recommendation to add
Recent Regulatory Background: Added to National List effective 03/23/2022 (87 FR 16371)
Sunset Date: 04/22/2027

Subcommittee Review

Use
Potassium hypochlorite is a chlorine material listed for pre-harvest use at 7 CFR 205.601(a)(2)(iv) as a synthetic substance for use in organic crop production. It is listed for use in the treatment of irrigation water with the requirement that residual chlorine levels of water in direct contact with crops or water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act. A limited scope technical report (TR) was done in 2024 to provide pertinent information specifically on potassium hypochlorite for the Board's review of the material. This is because prior to the 2024 TR, potassium hypochlorite was assessed based on information in a 2011 TR on chlorine/bleach materials. That TR only covered specific information on sodium hypochlorite, calcium hypochlorite, and chlorine dioxide.

Manufacture
Potassium hypochlorite is a powerful oxidizing agent produced by the reaction of chlorine with a solution of potassium hydroxide (2024 TR, lines 64-67):
$Cl_2 + 2\ KOH \rightarrow KCl + KClO + H_2O$

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
- Potassium hypochlorite is not explicitly mentioned in the regulations.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Potassium hypochlorite is not explicitly mentioned in the regulations.

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

- Potassium hypochlorite is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Potassium hypochlorite is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Potassium hypochlorite is not explicitly mentioned in the regulations.

Toxicity, Mode of Action of Substance and Persistence in Environment.

The antimicrobial mode of action of chlorine stems from both oxidation and chlorination (2024 TR, lines 234-235).

Mixing potassium hypochlorite with water generates highly reactive hypochlorous acid (HOCl), which is the active ingredient in hypochlorites. Hypochlorous acid exerts it effects by forming superoxide radicals that cause oxidative injury and cell death (2024 TR, lines 236-237). As pH increases, the proportion of HOCl can partially dissociate into hypochlorite ion (OCl^-) at physiological (neutral) pH levels. Hypochlorous acid and its conjugate base, OCl^-, are potent oxidizing agents under physiological conditions (2024 TR, lines 237-240).

According to the 2024 TR, hypochlorous acid (HOCl), which predominates at pH solutions below 7.5, is 20 to 30 times as effective a sanitizer as the hypochlorite ion (favored by pH above 7.5) (2024 TR, lines 235-240, 242-243). The strong oxidizing power of the neutral HOCl species enables it to penetrate pathogen cell walls and membranes; entry is followed by removal of electrons from those membranes (2024 TR, lines 243-245). Hypochlorous acid contributes to the unfolding of proteins through oxidation and the aggregation of essential proteins in bacteria. This protein unfolding is like heat-induced denaturation which causes proteins to irreversibly clump together in a mass that impairs their natural functioning (2024 TR, lines 245-248).

In developing the 2024 TR, even though no specific information on degradation of potassium hypochlorite was found (2024 TR, line 304), it was assumed to be comparable to that of sodium hypochlorite due to the similarity in their chemistry and uses. A major difference between the hypochlorites is the replacement of sodium with potassium in potassium hypochlorite, thereby reducing the salinization of soils associated with sodium hypochlorite. The half-life of aqueous chlorine (an equilibrium mixture of hypochlorite and its conjugate hypochlorous acid) is affected by solution concentration, pH, temperature, light exposure, wind, and presence of organic materials. As the concentration and temperature drop, the material becomes more stable (2024 TR, lines 306-309). Chlorine is converted between different chemical forms by natural processes in a global biogeochemical cycle. Chlorine is released from and returned to rock; added and removed from organic molecules; volatilized and degraded by sunlight; and oxidized and reduced both biotically and abiotically, with important implications for life on Earth at each step (2024 TR, lines 299-309).

Environmental Contamination

As stated previously, potassium hypochlorite is produced by the reaction of chlorine with a solution of potassium hydroxide (2024 TR, lines 64-67). Environmental contamination potential is heavily dependent on the source of chlorine used in the production of potassium hypochlorite. The three primary electrolytic

processes used in chlorine production are (a) the diaphragm cell process (b) the mercury cell process and (c) the membrane cell process (2024 TR, lines 368-370). The diaphragm cell process relies on the use of asbestos and was responsible for 75% of the US production in 2000 (2024 TR, lines 372-373). The mercury cell process results in mercury emissions and is thus being phased out by European manufactures (2024 TR, lines 375-377). The membrane cell process employs a modification of the diaphragm cell method. It is superior to the other two methods in its energy efficiency and lack of harmful chemicals and is used to produce more than 90% of chlorine in Japan (2024 TR, lines 384-388).

Application of potassium hypochlorite according to the NOP regulations is unlikely to result in levels that are harmful to human and environmental health. The regulations allow application rates that are consistent with drinking water standards for humans, which are 1-2 ppm and a maximum of free chlorine of 4 ppm (2024 TR, lines 537-539).

Even though the initial application rate can be much higher, the maximum residual disinfectant level under the Safe Drinking Water Act for chlorine materials is 4 mg chlorine/L water (NOP, 2024). At the maximum residual disinfectant level, potassium hypochlorite remaining in water that is discharged to fields or the environment is unlikely to have any detrimental interactions with other substances used in organic crop or livestock production or handling (2024 TR, lines 129-133). At higher concentrations, potassium hypochlorite may react explosively with finely divided carbon. Potassium hypochlorite solution produces highly toxic chlorine gas fumes upon heating or contact with acids. It may form highly explosive NCl_3 on contact with urea (2024 TR, lines 133-136).

Most natural water contains some amount of inorganic nitrogen in the form of ammonia (NH_3) emitted from decaying organic vegetation. In addition, some water treatment plants add ammonia to the water before chlorination is performed, a process called chlorine–ammonia disinfection or chloramination (2024 TR, lines 139-142).

When chlorine (including hypochlorite and other forms) is added to water, the chlorine reacts with the water to form hypochlorous acid. When the water in this reaction contains ammonia, the hypochlorous acid then combines with ammonia to form chloramines (nitrogen and chlorine compounds) (2024 TR, lines 144-147).

Inorganic chloramines are degraded by ammonia-oxidizing prokaryotes (archaea and bacteria) and nitrate oxidizing bacteria. While inorganic chloramines decay with time, organic chloramines both decay and continue to form, leading to a higher proportion of organic chloramines compared to inorganic chloramines in the total chlorine. Organic chloramines can form from the reaction of dissolved organic carbon or dissolved organic nitrogen with inorganic chloramines or free chlorine. Organic chloramines are less effective disinfectants than inorganic chloramines. The drop in effective chlorine disinfectant residuals creates a favorable environment for nitrifying microorganisms to metabolize ammonia and proliferate. This accelerates the nitrification process, which further depletes disinfectant residuals and causes biological and chemical deterioration of water quality (2024 TR, lines 185-194).

Even though no information was found on potassium hypochlorite specifically, the EPA in 2012 made the following conclusion in its registration review of hypochlorites of calcium and sodium. “All environmental fate and ecological effects data requirements for sodium and calcium hypochlorite have been satisfied since the Registration Standard was issued in 1986. Upon reevaluating these data, EPA has concluded that the currently registered uses of the hypochlorites will not result in unreasonable adverse effects to the environment” (2024 TR, lines 517-520).

Effect of Substance on Biological and Chemical Interactions in the Agroecosystem

The application rate of 1-2 ppm, not to exceed free chlorine of 4 ppm, is consistent with drinking water standards for human beings. Use at this level in irrigation water is unlikely to have adverse biological and chemical interactions in the agroecosystem (2024 TR, lines 538-539). The fact that high concentrations of sodium are toxic to plants, destroy soil structure, and create growth conditions that are detrimental to plants make potassium hypochlorite a better option relative to sodium hypochlorite (2024 TR, lines 526-529). When applied as a disinfectant, chlorine is unstable and it easily gets converted to chloride (Cl^-) ions. The Cl^- ion is stable in soil environments and can move within and between ecosystems (2024 TR, lines 347-348).

Tens of species across all phyla can convert chloride to organic compounds (2024 TR, line 349). Studies on the effects of low concentration of chlorine on soil-wheat microbiome systems found no significant lasting effects on soil microbial community diversity and composition in the root zone or in bulk soil. Even though metabolic functions of the microbial community in the rootzone were slightly affected by continuous chlorine treatment, researchers observed recovery to the original status (2024 TR, lines 451-454). Exposure of selected invertebrates to short-chain chlorinated paraffins (64% chlorine) revealed differences in sensitivity to chlorine. In the study involving species of earthworms, white worms, springtails, and nematodes, researchers found that springtails were the most sensitive (2024 TR, lines 463-465). A separate laboratory study involving selected fish species found differences in the toxicity of hypochlorite ion, hypochlorous acid, monochloroamine, and dichloroamine to emerald shiners, channel catfish, and rainbow trout. Hypochlorous acid was the most toxic, followed by dichloroamine. Monochloroamines and hypochlorite ions recorded between a third to a quarter of the toxicity of hypochlorous acid and dichloroamines. Emerald shiners were found to be most sensitive to the four forms of chlorine. The researchers concluded that fish species, total residual chlorine, and duration of exposure are principal factors that impact the effect of chlorine on fish (2024 TR, lines 470-485). In general, fish avoid elevated levels of chlorine when they detect the source point. Elevated temperature magnifies the toxic effects of chlorine on fish. Chlorine levels that are not high enough to elicit avoidance behavior in fish may cause high mortality at elevated temperatures (2024 TR, lines 489-492). Acute toxicity tests on other freshwater organisms (including insects, crustaceans, bivalves, and aquatic plants) revealed that mayfly nymphs and the water flea (crustacean) were the most sensitive; fish were the least sensitive. The researchers, however, described their acute toxicity data as conservative because of the use of flow-through systems that prolong exposure in ways that do not mimic field conditions (2024 TR, lines 499-510).

Effect on Human Health

The NOP regulations allow potassium hypochlorite application rates that are consistent with drinking water standards for humans, which is 1-2 ppm, and not to exceed free chlorine of 4 ppm. According to the EPA, these levels are unlikely to be harmful to human health or the environment (2024 TR, lines 537-539). The TR developers did not find any specific reports on the effect of potassium hypochlorite on human health (2024 TR, lines 549-550). It is a powerful oxidizing agent that produces highly toxic fumes of chlorine gas upon heating or contact with acids (2024 TR, lines 549-550). The TR authors did not find any reports on the effect of potassium hypochlorite on human health, specifically. Sodium hypochlorite was included in the search for human health effects because of its similarity to potassium hypochlorite in chemical characteristics and uses (2024 TR, lines 549-550). Chlorine, the active ingredient in hypochlorites (2024 TR, line 550) reacts with natural organic matter to produce a variety of toxic disinfection by-products. The removal of natural organic matter present in water via physical/chemical treatment processes helps to avoid such harmful reactions; treatment processes include enhanced coagulation and activated charcoal filtration (2024 TR, lines 556-558).

Hypochlorites pose human health and environmental concerns under some circumstances (2024 TR, line 560). Ingestion of hypochlorites may be dangerous to human health. Human exposure to high concentrations of hypochlorites may result in a wide range of reactions and damage, including, irritation or damage to the skin, eyes, and the respiratory tract, kidney damage, diarrhea, vomiting, inflammation, burns, perforation, stricture, and death (2024 TR, lines 568-578). A review of medical studies on the health effects of sodium hypochlorite led to the conclusion that health impacts resulting from long-term occupational or environmental exposure to low sodium hypochlorite concentrations were rare. Ingestion of large volumes of bleach can result in severe health problems including death (2024 TR, lines 587-588). Apart from the fact that ingestion is disallowed and inconsistent with label instructions, occupational and environmental exposure to the substance do not approach such levels.

Alternatives/Compatibility
Hypochlorites of sodium and calcium can be used for the same purposes as the potassium hypochlorite. The absence of sodium and the fact that potassium is a plant nutrient make potassium hypochlorite a better option relative to sodium hypochlorite. Overall, potassium hypochlorite is compatible with the principles and practice of sustainable agriculture.

Questions to our Stakeholders

1. Is the substance used in concentrations that do not exceed the maximum limits spelled out in the Safe Drinking Water Act?
2. Is there interest in introducing an annotation to ensure that only potassium hypochlorite produced using environmentally friendly chlorine production methods is allowed for use in organic production in the United States?
3. Are there effective alternatives?

Soap based algicide/demossers

Reference: 205.601(a)(7) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.
Technical Report(s): 1996 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: Actions: 09/1996 NOSB recommendation; 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

Subcommittee Review

Use
Synthetic soap salts are approved as algicides/demossers and are permitted to control algae and mosses in and around production areas including walkways, greenhouse surfaces, and irrigation systems.

Manufacture
Various preparatory methods depend on the desired soap salt composition for a particular herbicide/algicide formulation.

Potassium salts of fatty acids are produced through a process known as saponification, whereby aqueous potassium hydroxide is added to fatty acids found in animal fats and plant oils. Sources of potassium soap salts are prepared through hydrolysis of triglycerides using water under high pressure and temperature. A carbonate or hydroxide salt of an alkali metal (potassium or sodium) traps the free fatty acid into a soap salt. Commonly used fats (triglycerides) include coconut, sunflower, palm, tallow, and olive oil. Soaps are mixtures of fatty acid salts with various carbon chain lengths and generally do not consist exclusively of one soap salt compound (2015 TR, lines 254-265).

International acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Soap-based algicide (demossers) are permitted (Table 7.4 – Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Soap-based algicide/demossers are not explicitly mentioned in the regulations.

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

- Potassium soap (soft soap) is permitted (Table 2 - Substances for Plant Pest and Disease Control, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Soft soap is permitted (Appendix 3 - Crop Protectants and Growth Regulators, IFOAM NORMS 2014).
- Potassium soap is permitted when an intervening event or action must occur to eliminate risks of contamination (Table 2 - Indicative List of Equipment Cleansers and Equipment Disinfectants, IFOAM NORMS 2014).
- Sodium soap is permitted when an intervening event or action must occur to eliminate risks of contamination (Table 2 - Indicative List of Equipment Cleansers and Equipment Disinfectants, IFOAM NORMS 2014).
- Potassium and sodium soap is permitted (Appendix 5 - Substances for Pest and Disease Control and Disinfection in Livestock Housing and Equipment, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Potassium soap (soft soap) is permitted (Table B.1 - Chemical agents, JAS for Organic Feed).
- Soap is permitted (Table D.1 - Chemicals for cleaning or disinfecting livestock or poultry house, JAS for Organic Livestock Products).
- Invert soap is permitted (Table D.1 - Chemicals for cleaning or disinfecting livestock or poultry house, JAS for Organic Livestock Products).
- Ampholytic soap is permitted (Table D.1 - Chemicals for cleaning or disinfecting livestock or poultry house, JAS for Organic Livestock Products).
- Potassium soap (soft soap) is permitted, excluding cases in which it is used on plant products for the purpose of controlling pests and diseases (Table J.1 - Chemical agents, JAS for Organic Livestock Products).
- Potassium soap (soft soap) is permitted; not permitted for use in plant products for controlling pests and diseases (Table C.1 – Chemical Agents, JAS for Organic Processed Foods).

- Potassium soap (soft soap) is permitted, excluding cases in which it is used on plant products for the purpose of controlling pests and diseases (Table C.1 - Chemical agents, JAS for Organic Products of Plant Origin).

Environmental issues and human health

Environment:
When released into the environment, soap salts essentially behave as the carboxylate anions of fatty acids. In general, potassium and ammonium salts of fatty acids decompose rapidly and do not accumulate or persist in the environment. Biodegradation is expected to be an important fate process, and field tests show half-lives of less than one day for these salts (2015 TR, lines 479-482).

EPA/FDA:
U.S. EPA has waived all generic mammalian toxicity data requirements for potassium and ammonium soap salts due to the lack of effects at high doses in the available toxicity literature.

The FDA generally recognizes potassium salts of fatty acids as safe (GRAS) (2015 TR, lines 355-357). Studies have also shown that soap salts are practically non-toxic to honeybees (2015 TR, lines 367-368).

Discussion:
2015: The Crops Subcommittee voted to delist soap-based algicides/detergents in 2015 because they thought it was no longer used in organic crop production and keeping it on the National List was unnecessary. However, public comments indicated that some producers were still using these materials. Based on public comments, they were not removed.

2020: Public comments in 2020 supported continuing to list these products and indicated that they are still being used in organic farming. Public comments noted that there was a lack of viable alternatives.

Questions to our Stakeholders
None

Ammonium carbonate

Reference: 205.601(e) As insecticides (including acaricides or mite control). (1) ammonium carbonate —for use as bait in insect traps only, no direct contact with crop or soil.
Technical Report: 1995 TAP (Ammonium bicarbonate and ammonium carbonate); 2025 TR (Handling)
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

Subcommittee Review

Use
Ammonium carbonate is used in small quantities as an attractant in traps. In some cases, ammonium carbonate is used alone, and in others, as a mixture with yeast to enhance its chemical attraction to insects. It is used for the control of flies that are problematic in fruit and nut production. This material compliments other natural alternatives such as the release of natural predators and parasitoids and manure management.

Manufacture
Ammonium carbonate manufactured by the reaction of ammonia sourced from the synthetic Haber-Bosch process, with carbon dioxide sourced from industrial processes like power generation, cement manufacturing, or fossil fuel processing (2024 Handling TR, lines 100-102).

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Ammonium carbonate is permitted as an attractant in insect traps (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- Ammonium carbonate is permitted as a leavening agent (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- Ammonium carbonate is permitted as an attractant in insect traps (Table 8.2 – Facility pest management substances, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Ammonium carbonates are permitted in products of plant origin (Section A1 – Food Additives including carriers, EC No. 2021/1165).

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

- Ammonium carbonate is permitted for use as an acidity regulator and raising agent in food of plant origin with some GSFA exclusions but is not permitted in food of animal origin (Additives permitted for use under specified conditions in certain organic food categories or individual food items, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- **Ammonium carbonates** are permitted as additives only for cereal products, confectionery, cakes, and biscuits (Table 1 - List of Approved Additives and Processing/Post-Harvest Handling Aids, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Ammonium carbonate is permitted; limited to the use in processed products of plant origin (Table A.1 – Additives, JAS for Organic Processed Foods).
- Ammonium carbonate is permitted (Table B.1 – Additives, JAS for Organic Processed Foods).

Human Health and Environmental Issues
Ammonium carbonate is labeled as an irritant. The intended use in crop production is as a bait that would not come in contact with plants or soil. A small amount of ammonium carbonate is used alone or in a mixture with yeast. The ambient temperature during use would result in ammonium carbonate volatilizing, releasing ammonia and carbon dioxide as gases. Given the small amount of ammonium carbonate used, the

impact of its volatilization would be small. We were unable to find reports of non-target effects on other insect species; such information would aid in our review of this material.

Discussion
The main alternatives are manure management and enhancement of predators and parasitoids, but its use to trap adult flies complements the use of other methods that control egg-laying and immature stages. Previous boards supported the relisting of this material.

Questions to our Stakeholders
1. Is there new research determining the effects of ammonium carbonate bait on non-targeted insect species?

Soaps, insecticidal

Reference: 205.601(e)(8) - As insecticides (including acaricides or mite control).
Technical Report: 1994 TAP; 2020 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

Subcommittee Review

Use
Insecticidal soaps are used for control of soft bodied insects and hard bodied insects in the larval stage on organic crops.

Manufacture
A reaction of an alkali, such as sodium or potassium hydroxide, on natural fatty acids (from both animal and plant sources) is used to prepare insecticidal soaps. The fats, such as laurate, myristate, oleate, and ricinoleate, are further processed to create a blend of selected fatty-acid chain lengths. The cation for soap molecules is determined by the base used in its production. Potassium soaps are derived from treating fatty acids with potassium hydroxide, while ammonium soaps are produced by saponification with ammonium hydroxide (2020 TR, lines 58-65).

International acceptance
Summary:
1. European Economic Community (EEC) lists potassium soaps as an insecticide with applications “from traditional us in organic farming.”
2. Potassium soap (soft soap) is permitted, excluding cases in which it is used on plant products for the purpose of controlling pests and diseases (Table C.1 - Chemical agents, JAS for Organic Products of Plant Origin).
3. Canadian General Standards Board Permitted Substances List includes ammonium soaps as a permitted substance.
4. IFOAM lists potassium soaps as an equipment cleanser and equipment disinfectant.

Extended:
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Soaps (including insecticidal soaps) are permitted and shall consist of fatty acids derived from animal or vegetable oils (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Insecticidal soaps are not explicitly mentioned in the regulations.

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

- Potassium soap (soft soap) is permitted (Table 2 - Substances for Plant Pest and Disease Control, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Soft soap is permitted (Appendix 3 - Crop Protectants and Growth Regulators, IFOAM NORMS 2014).
- Potassium soap is permitted when an intervening event or action must occur to eliminate risks of contamination (Table 2 - Indicative List of Equipment Cleansers and Equipment Disinfectants, IFOAM NORMS 2014).
- Sodium soap is permitted when an intervening event or action must occur to eliminate risks of contamination (Table 2 - Indicative List of Equipment Cleansers and Equipment Disinfectants, IFOAM NORMS 2014).
- Potassium and sodium soap is permitted (Appendix 5 - Substances for Pest and Disease Control and Disinfection in Livestock Housing and Equipment, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Potassium soap (soft soap) is permitted (Table B.1 - Chemical agents, JAS for Organic Feed).
- Soap is permitted (Table D.1 - Chemicals for cleaning or disinfecting livestock or poultry house, JAS for Organic Livestock Products).
- Invert soap is permitted (Table D.1 - Chemicals for cleaning or disinfecting livestock or poultry house, JAS for Organic Livestock Products).
- Ampholytic soap is permitted (Table D.1 - Chemicals for cleaning or disinfecting livestock or poultry house, JAS for Organic Livestock Products).
- Potassium soap (soft soap) is permitted, excluding cases in which it is used on plant products for the purpose of controlling pests and diseases (Table J.1 - Chemical agents, JAS for Organic Livestock Products).
- Potassium soap (soft soap) is permitted; not permitted for use in plant products for controlling pests and diseases (Table C.1 – Chemical Agents, JAS for Organic Processed Foods).
- Potassium soap (soft soap) is permitted, excluding cases in which it is used on plant products for the purpose of controlling pests and diseases (Table C.1 - Chemical agents, JAS for Organic Products of Plant Origin).

Environmental issues and human health
The toxicological profile of the substances differ based on the environment in which they are located.

Impact:
Insecticidal soaps are widely regarded as having low toxicity to terrestrial organisms like mammals and avian animals (2020 TR, lines 341-343). Potassium salts are highly toxic to aquatic invertebrates and slightly

toxic to cold and warm water fish species. Due to this potential toxicity to aquatic environments, insecticidal soap product labels stipulate that the products are not intended for application to aquatic systems, including ponds and streams (2020 TR, lines 347-351). Recent studies (2018) have shown insecticidal soaps to be non-toxic to desirable insects such as ladybugs and the coccinellid beetle (2020 TR, lines 412-413).

Environmental:
Insecticidal soaps are rapidly biodegradable in the environment, and the half-life is estimated to be less than one day (2020 TR, lines 421-422). Microbial organisms rapidly degrade fatty acids in soils (2020 TR, lines 322-323). A recent technical review (2020) reports that "there is little to suggest that insecticidal soaps pose a threat to the environment when used as approved." The report goes on to state that because of the low toxicity, even if it is used improperly, environmental impact would be minimal (2020 TR, lines 430-434).

EPA/FDA:
EPA has given these insecticides the lowest Toxicity Category IV (indicating the lowest level of toxicity) (2020 TR, lines 343-344). Potassium salts of fatty acids used on food and feed crops have been exempted from the requirement of a tolerance (or maximum residue limit) for all raw agricultural commodities since 1982 (2020 TR, lines 267-271). They are also generally recognized as safe (GRAS) by the FDA.

Discussion
Alternatives include cultural pest control methods, oils, botanicals, or biological controls (depending on species). Various essential oils and pyrethrum have been used. However, horticultural oils and pyrethrum are easily degraded under common conditions like UV radiation. Moreover, differences in the mode of action and the targets (hard-bodied vs. soft-bodied) of essential oils and pyrethrum make them poor substitutes (2020 TR, lines 475-478).

2015: In the previous Sunset review in 2015, there was overwhelming support for the continued listing of this material. Public comments stated that this material remains a necessary tool in organic crop production and has increased in use due to the growth of organic production. Public comment stated that most organic certifying bodies allow these oils to be used worldwide.

2020: The 2020 public comments for this product, again, showed overwhelming support for the continued listing of insecticidal soaps and that they were also in wide use.

Questions to our Stakeholders
None

Sucrose octanoate esters

Reference: 205.601(e) - As insecticides (including acaricides or mite control) (10) Sucrose octanoate esters (CAS #s—42922-74-7; 58064-47-4)—in accordance with approved labeling.
Technical Report: 2005 TR; 2025 Limited Scope TR
Petition(s): 2004 Sucrose Octanoate Esters; Amendment #1; Amendment #2
Past NOSB Actions: 08/2005 NOSB recommendation for addition to NL; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 - recommendation to remove
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420); Sunset renewal notice published 02/28/2022 (87 FR 10930)
Sunset Date: 03/15/2027

Subcommittee Review
Sucrose octanoate esters (SOEs) belong to the organic chemical family, sucrose fatty acid esters (SFAEs) (2005 TR, lines 23-24). SOEs are manufactured from sucrose (table sugar) and an octanoic acid ester commonly found in plants and animals (2005 TR, lines 27-28). SOEs, marketed as biopesticides, are synthetic analogs of the naturally occurring sugar ester isolates of *Nicotiana* plant species (2024 TR, lines 57-58) that mimic the pest control properties of the natural forms of the compound in wild tobacco and other plants in the *Nicotiana* genus. *gossei* Domin (wild tobacco) and other *Nicotiana* species, including wild tomato and wild potato species and the petunia plant (2005 TR, lines 35-38).

Use
Sucrose octanoate esters are listed at §205.601(e) in organic crop production as insecticides (including acaricides or mite control) in accordance with approved labeling (2024 TR, lines 32-33). Producers use SOEs to control soft-bodied pest organisms including mites, aphids, and whiteflies (2024 TR, line 56). The EPA has registered SOEs as a biopesticide for foliar spray on greenhouse, nursery, and field crops, and for *Sciarid* fly control in mushroom-growing media.

Manufacture
Commercial synthesis of SOEs involves the use of materials such as alcohols, several catalysts, solvents, and sucrose octanoate acid (2024 TR, lines 60-62). Steps in the production include (1) Esterification of fatty acids, (2) Neutralization and separation of catalyst, (3) Second esterification with sugar, (4) Vacuum distillation and emulsification, (5) Separation of emulsified product, and (6) Purification and recovery of sugar ester product (2024 TR, lines 66, 140, 154, 178, 183, and 188). The raw materials are derived from various sources: octanoic acid from both synthetic and nonsynthetic sources, alcohol (methanol or alcohol) from synthetic and nonsynthetic sources, and sucrose that is usually obtained from nonsynthetic sources (2024 TR, lines 197-200). The petitioned substance is a soap derived from coconut oil fatty acids or palm kernel oil fatty acids.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
- Sucrose octanoate esters are not explicitly mentioned in the regulations.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
- Sucrose octanoate esters are not explicitly mentioned in the regulations.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
- Sucrose octanoate esters are not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)
- Sucrose octanoate esters are not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production
- Sucrose octanoate esters are not explicitly mentioned in the regulations.

Human Health and Environmental Issues

Effect on the Environment:

The chemical structure of SOEs, consisting of sucrose and octanoic acid, renders the material readily biodegradable (2024 TR, line 215). Naturally occurring microorganisms in soil and water can break down these compounds. The compound biodegrades within approximately five days at temperatures ranging from 68°F to 80°F in both aerobic and anaerobic conditions. Typical degradation products are carbon dioxide and water, both of which are harmless. In addition to the fact that these degradation products are harmless, some are incorporated as microbial biomass (2024 TR, lines 216-220).

Impact on Non-Target Organisms

The EPA's evaluation report on the potential impact of SOEs on non-target insects and other organisms, such as fish, stated that the use of the compound had minimal potential for exposure and toxicity to these organisms as well as soil and water (2024 TR, lines 223-225). According to the EPA, the fact that the mode of action of the compound is via physical effects as opposed to biochemical toxicity gives the compound a minimal toxicity profile. The petitioned substance primarily targets soft-bodied insects by physically disrupting the lipid layer of their cuticle, thereby causing dehydration and death. Insects with thicker and/or more robust exoskeletons are not affected by the petitioned substance (2024 TR, lines 231-233).

The physical mode of action enables the compound to target soft-bodied insects without producing general toxic metabolites, thereby decreasing the likelihood of adverse effects on mammals and birds (2024 TR, lines 225-229). Soft-bodied organisms targeted include mites and insects such as thrips, aphids, and whiteflies. The fact that SOEs do not exert their pesticidal effects via a biochemical pathway common to all insects renders it selective, resulting in minimal effects on non-target organisms such as pollinators (e.g., bees), predators (ladybugs), earthworms, and other soil organisms (2024 TR, lines 233-236). Some non-synthetic pesticides are known to have adverse effects on beneficial organisms such as predators and parasitoids. An assessment of the effect of SOEs on multiple beneficial insects from different insect orders in citrus ecosystems revealed a high survival rate of ladybeetles (Coccinellidae), lacewings (Chrysopidae), and parasitoids of red scale insects (Anthocoridae) even when exposed to 8,000 ppm (i.e., parts per million), which represents twice the recommended field application rate (2024 TR, lines 238-242). Soil organisms and non-target insects may be exposed to SOEs during and after applications until the compounds biodegrade in ~5 days. Direct and specific detrimental effects from SOEs on soil organisms have not been studied extensively. Available literature does not show detrimental physiological effects of SOEs on soil organisms, soil microbiome, or non-target insects (2024 TR, lines 257-260). Current literature states that SOEs have low toxicity and biodegrade rapidly. When SOEs are applied according to EPA-approved label directions, no direct exposure of birds or aquatic organisms to SOEs is expected (2005 TR, lines 201-202).

Effect on Human Health

SOEs have low toxicity to humans and are produced in a closed system. The 2005 technical report (TR) states that no sub-chronic, chronic, immune, or endocrine issues have been identified (2005 TR, lines 303-304). An ocular risk exists but it is unlikely if the product is used according to the label (2005 TR, lines 309-311).

Comparison with natural (Nonsynthetic alternatives

In the absence of research studies that compare SOEs to nonsynthetic alternatives, the 2024 TR covered the performance and characteristics of nonsynthetic pesticides including neem extract, Pyrethrins, *Bacillus thuringiensis* (Bt), Spinosad, miscellaneous botanicals such as essential oils derived from thyme and eucalyptus, garlic extracts, and biological control agents. Even though neem extracts were reported to be effective against listed insect pests, cases of neem oil poisoning in humans were reported (2024 TR, lines 299-300). Pyrethrins can harm beneficial insects such as bees and aquatic organisms if used improperly (2024 TR, lines 312-314). *Bacillus thuringiensis* affects a broader range of organisms than SOEs (2024 TR,

line 332). There are reports of non-targeted adverse effects on several groups of insects that are closely related or have an affinity to targeted insects (2024 TR, lines 337-339). At regular field application rates, Bt has been reported to impair the growth and developmental time of non-target true flies such as *Drosophila melanogaster* (common fruit fly) larvae (2024 TR, lines 341-344). There are also reports of insect pest resistance to Bt products (2024 TR, line 352). Spinosad breaks down quickly in the environment and is considered safe for humans and most beneficial insects. It can, however, be toxic to bees if applied directly to flowering plants. Spinosad application has also been demonstrated to have adverse effects on genes associated with energy production in honeybees (2024 TR, lines 367-368).

Rationale for Previous NOSB Recommendation
Despite the apparent low use of sucrose octanoate ester, the Crops Subcommittee voted in 2018 to relist it. Additional information obtained afterwards and prior to the 2018 Fall NOSB meeting, however, led the full NOSB to recommend removing this material from §205.601(e) of the National List. The current information at the time indicated that there were no EPA-registered pesticides containing sucrose octanoate esters. This meant that the material could not legally be used as an insecticide. Based on this information, sucrose octanoate esters were deemed to have failed the essentiality test for use in organic production. A majority of the Board voted to remove SOEs from the National List, but a minority were in favor of relisting it in anticipation of the availability of EPA-registered SOE-formulations in the future. The minority sought to avoid removing any tools from the organic producer's toolbox.

Subcommittee Discussion
During the February 4, 2025 Subcommittee call, a Board member said he was aware of one product that uses SOEs. He, however, described the product as expensive.

Questions to our Stakeholders
1. Are there EPA-registered products formulated using SOEs?
2. Is there current information on the need and use of SOE formulations in crop production?
3. Is there a need to keep SOEs in the crops toolbox to be rotated with other products?

Vitamin D3

Reference: 205.601(g) - as rodenticides.
Technical Report: 1995 TAP; 2011 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

Subcommittee Review

Use
Vitamin D3 (cholecalciferol) is used to fortify food and aids in the growth and maintenance of bones. It is typically found in milk and cereals (2011 TR, lines 45-47). Forms of vitamin D are also found in margarine and infant formula. In this listing, vitamin D3 is used as a synthetic rodenticide in gel and pellet baits.

Vitamin D3 kills gophers, mice, rats, and other rodents by causing an excessive, highly elevated level of calcium, which results in hypercalcemia and mineralization of major organs (including kidney failure), leading to death (2011 TR, lines 55-57).

Manufacture

The commercial manufacture of vitamin D3 utilizes cholesterol obtained by organic solvent extraction of animal skins (pig, sheep, or cow) and extensive purification. Typically, cholesterol is extracted from the lanolin of sheep wool and converted to 7-dehyrdocholesterol after a process of chemical synthesis that involves eighteen steps. The crystalline 7-dehyrdocholesterol is then dissolved in an organic solvent and irradiated with UV light. This process causes a photochemical transformation of 7-dehyrdocholesterol into cholecalciferol, which is similar to the natural process that occurs in the skin of humans. It is then purified and crystallized further before being formulated for use. Details of the manufacturing process are subject to several patents and are not publicly available (2011 TR, lines 179-187).

Since the formulations contain 0.075% cholecalciferol, with the remainder being "inerts," much of it will be attractive food to rodents.

International Acceptance

Summary:

1. The Canadian General Standards Board Permitted Substances List has this annotation on vitamin D3 (cholecalciferol) "if used outdoors and inside greenhouses for rodent control when methods described in 5.6.1 of CAN/CGSB-32.310 have failed. Prohibited inside on-farm food processing and food storage facilities."
2. CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (GL 32-1999), has an allowance for rodenticides with this caveat "Products for pest control in livestock buildings and installations. Need recognized by certification body or authority."
3. The European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 states rodenticides are only to be used in traps.
4. The Japan Agricultural Standard (JAS) for Organic Production. Not mentioned for Crop applications.
5. The International Federation of Organic Agriculture Movements (IFOAM) do not list this product, nor have any specific requirements for rodenticides.

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Cholecalciferol (vitamin D3) is permitted if used outdoors and inside greenhouses for rodent control when methods described in 5.6.1 of CAN/CGSB-32.310 have failed. Prohibited inside on-farm food processing and food storage facilities (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- Biological and mineral sources of all vitamins are permitted (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- Pre-mixes (concentrated mixture of minerals and vitamins) are permitted. From organic sources if commercially available. All ingredients in pre-mixes shall be essential for animal nutrition, and listed in Table 5.2. Non-GE fillers, for example rice hulls, may be non-organic (Table 5.2 – Feed, feed additives and feed supplements, CAN/CGSB-32.311-2020).
- Vitamins are permitted for enrichment or fortification. Vitamin formulants that comply with Canadian regulations are accepted. Vitamins not compliant to 5.1.2 of CAN/CGSB-32.311 are permitted (Table 5.2 – Feed, feed additives and feed supplements, CAN/CGSB-32.311-2020).

- Vitamin formulants that comply with Canadian regulations are accepted. Vitamins not compliant to 5.1.2 of this standard are permitted. Orally, topically or by injection (Table 5.3 – Health care products and production aids, CAN/CGSB-32.311-2020).
- Vitamins and mineral nutrients shall be used if legally required (e.g., fluid milk, white flour, infant formula, meal replacement, etc.) (Table 6.4 – Ingredients not classified as food additives, CAN/CGSB-32.311-2020).
- Cholecalciferol (vitamin D3) is prohibited inside organic food processing and food storage facilities (Table 8.2 – Facility pest management substances, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Feed of mineral origin, trace elements, vitamins, or provitamins of natural origin are permitted, except in cases where products or substances from such sources are not available in sufficient quantities or qualities or where alternatives are not available (Authorisation of products and substances for use in organic production, EC No. 2018/848).
- Minerals (trace elements included), vitamins, amino acids and micronutrients, provided that their use in food for normal consumption is "directly legally required," in the meaning of being directly required by provisions of Union law or provisions of national law compatible with Union law, with the consequence that the food cannot be placed at all on the market as food for normal consumption if those minerals, vitamins, amino acids or micronutrients are not added (Detailed requirements for the production of processed food, EC No. 2018/848).
- Vitamins and provitamins are permitted if derived from agricultural products. If not available from agricultural products, they may be derived synthetically. Only those identical to vitamins derived from agricultural products may be used for monogastric animals and aquaculture animals. Only vitamins A, D, and E identical to vitamins derived from agricultural products may be used for ruminants (Nutritional Additives, EC No. 2021/1165).

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

- Minerals (including trace elements), vitamins, essential fatty and amino acids, and other nitrogen compounds are permitted only if their use is legally required in the food products in which they are incorporated (Ingredients of Non-Agricultural Origin, CXG 32-1999).
- Feedstuffs of mineral origin, trace elements, vitamins, or provitamins can only be used if they are of natural origin. In case of shortage of these substances, or in exceptional circumstances, chemically well-defined analogic substances may be used (Specific criteria for feedstuffs and nutritional elements, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Organic animal management provides animals with vitamins, trace elements, and supplements only from natural sources unless they are not available in sufficient quantity and/or quality (Animal Production, IFOAM NORMS 2014).
- Organic processing only uses minerals (including trace elements), vitamins, essential fatty amino acids, and other isolated nutrients when their use is legally required or strongly recommended in the food products in which they are incorporated (Processing and Handling, IFOAM NORMS 2014).
- Animals may be fed vitamins, trace elements, and supplements from natural sources. Synthetic vitamins, minerals, and supplements may be used when natural sources are not available in sufficient quantity and quality (Animal Nutrition, IFOAM NORMS 2014).
- Fodder preservatives such as the following may be used: a) bacteria, fungi and enzymes; b) natural products of food industry; c) plant-based products; and d) vitamins and minerals subject to 5.5.6.

Synthetic chemical fodder preservatives such as acetic, formic, and propionic acid are permitted in severe weather conditions (Animal Nutrition, IFOAM NORMS 2014).

- Minerals (including trace elements), vitamins, and similar isolated ingredients shall not be used unless their use is legally required or where severe dietary or nutritional deficiency can be demonstrated in the market to which the particular batch of product is destined (Processing and Handling, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Feeding: Such natural substances or feeds derived from natural substances (that have not undergone chemical treatment), which are intended for vitamin or mineral supplementation (Criteria for Raising and Production methods, JAS for Organic Livestock Products).
- Health Management: Vitamins, minerals, veterinary biological drugs, or any veterinary medicinal products other than parasiticides, should be used only for the therapeutic treatment of livestock or poultry (Criteria for Raising and Production methods, JAS for Organic Livestock Products).

Environmental Issues

Aquatic Life/Animals: According to the TR, vitamin D3 is not expected to mobilize in soil, and its bioconcentration in aquatic life is expected to be very low (2011 TR, lines 238-239). Since the Environmental Protection Agency restricts its use to bait stations, the risk of accidental poisonings of non-target species has been addressed. Vitamin D3 is of low toxicity in birds, unlike the more widely used anti-coagulant rodent baits not approved for organic production (2011 TR, line 323). Most stakeholders report anecdotal findings that vitamin D3 has low toxicity to birds and to other non-target species, particularly as compared to other rodenticides.

Environment: Because of its insolubility in water, its use is unlikely to cause contamination to ground or surface waters (2011 TR, lines 260-261).

Subcommittee Review

Alternatives/Non-Target: Since birds of prey can greatly control rodents on the farm, vitamin D3 is preferred due to its very low risk to bird populations. Birds have a much lower body weight and consuming just one or two rodents that have consumed an anticoagulant bait could harm the bird's health or cause death. Using a rodenticide that does not harm the predator population is an ecosystem-friendly approach to controlling rodent populations.

While non-target mammals could consume ill rodents that consumed vitamin D3, it would take many of these rodents to cause harm to the food chain. Notably, one non-profit stakeholder organization has suggested, via public comment, that vitamin D3 can lead to a painful death in rodents and could be replaced with other substances.

There are system-based methods that can be used to control rodent populations, such as improving structures to prevent their entry and keeping food/water and harborage to a minimum. However, there are times when toxic bait is necessary to lessen the rodent population so that other system-based approaches can take over.

2020: At the April 2020 NOSB public meeting, a range of stakeholders provided public comment on vitamin D3 as a rodenticide. With almost no exception, the community expressed support for the material's continued listing for permitted use in organic production. Most of the comments addressed the issue of non-target species toxicity.

Use: Vitamin D3 continues to be widely used by many organic stakeholders as a rodenticide, particularly in situations where environmental factors and built structures create conditions conducive to rodent infestations. Some have criticized its efficacy, but nearly no grower or certifier expressed opposition to its continued listing as an essential substance for the organic toolkit.

Questions to our Stakeholders
None

Aquatic plant extracts

Reference: 205.601(j) As plant or soil amendments. (1) Aquatic plant extracts (other than hydrolyzed) – Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount is limited to that amount necessary for extraction.
Technical Report: 2006 TR; 2016 TR; 2025 Limited Scope TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

Subcommittee Review

Use
Plant extracts are composed of chemicals naturally found in aquatic plants (2006 TR, line 19), namely marine plants (also called seaweed). Aquatic plant extracts are used as foliar fertilizers or as soil conditioners. They also are used in combinations as a foliar/soil feed or transplant solution and seed treatment. The material is absorbed into the plant and acts as a growth promoter (2006 TR, lines 63-66). Aquatic plants contain proteins, lipids, sugars, amino acids, nutrients, vitamins, plant hormones, and other biochemicals (2006 TR, lines 26-27). Aquatic plants contain a wide range of naturally occurring plant nutrients and trace minerals essential to plant growth, health, and productivity (2006 TR, lines 41-42). Cytokinins, a class of plant hormones present in aquatic plant extracts, have been reported to have beneficial effects on crops, including increases in number or size of fruits or seed heads, synchronization of flowering within a field, and delayed decay of mature plants (2006 TR, lines 46-48).

Manufacture
Seaweeds are classified into three broad groups based on pigmentation: *Phaeophyceae* (brown), *Rhodophyceae* (red), and *Chlorophyceae* (green) (2016 TR, lines 103-104), and all three classes are used in aquatic plant extracts. Seaweeds are also called macro-algae, distinguishing them from micro-algae (*Cyanophyceae*) which are microscopic in size and often unicellular (2016 TR, lines 108-110). Seaweeds used in aquatic plant extracts are macro-algae.

Seaweed extract is produced from fresh, live plants that are processed into a soluble powder or liquid and may be stabilized with synthetic acids and fortified with other ingredients. An alkali extraction process is used to “digest” the plants and derive both micronutrients and naturally occurring plant hormones. This process also transforms the plants into a soluble, easily transported form. The majority of manufacturers use potassium hydroxide as the primary reagent in the alkali extraction process. Other alkali reagents used

by some manufacturers include sodium hydroxide, calcium hydroxide, and sodium carbonate (2006 TR, lines 181-189).

For this sunset review, the Crops Subcommittee (CS) requested a limited scope technical report (TR) to evaluate the use of synthetic alkali substances in the manufacture of aquatic plant extracts and whether additional restrictions on the use of these extraction substances is necessary. The TR revealed that the typical pH range among OMRI-listed products was 8-11 (2024 TR, lines 186-187). It also indicated that there is no set of industry specific considerations when determining what amount of alkali is necessary for extraction (2024 TR, lines 193-194) because extraction of aquatic plants is not necessarily focused on obtaining a singular substance from the algae, but rather a complex set of biologically active molecules (2024 TR, lines 198-203).

The current annotation for aquatic plant extracts is intended to prevent the practice of using extractants for their nutrient content. Currently, certifiers are requiring an attestation from the manufacturer explaining their rationale for including synthetic alkali extractants and how it meets the annotation restrictions. Another compliance verification method is a calculation method used for products extracted with potassium hydroxide. In this method, aquatic plant extracts are considered fortified by potassium hydroxide (and therefore prohibited) when the ratio of aquatic plant material to potassium hydroxide exceeds 3.20:1 (2024 TR, lines 257-288).

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- **Algae** is permitted (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- **Aquatic plants and aquatic plant products** are permitted, and may be extracted using these substances in the following order: a) substances in Table 4.2 Extractants; b) potassium hydroxide; and c) sodium hydroxide provided the amount of solvent used does not exceed the amount necessary for extraction (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- Growth regulators for plants are permitted. Plant hormones, such as gibberellic acid, indoleacetic acid and cytokinins, derived from terrestrial or **aquatic plants** or produced by microorganisms (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- Plant by-products and plants are permitted. Includes plant preparations of **aquatic** or terrestrial plants or parts of plants, such as cover crops, green manures, crop wastes, hay, leaves and straw. Parts of plants used as soil amendments and foliar feeds are permitted. Wastes from crops that have been treated or produced with prohibited substances are permitted as compost feedstocks (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- **Seaweed and seaweed products** are permitted (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- **Algae and algae products** are permitted when directly obtained by (i) physical processes including dehydration, freezing and grinding, (ii) **extraction with water or aqueous acid and/or alkaline solution**, and (iii) fermentation, only from organic or collected in a sustainable way in accordance with point 2.4 of Part III of Annex II to Regulation (EU) 2018/848 (Authorised fertilisers, soil conditioners, and nutrients, EC No. 2021/1165).

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

- Seaweed, seaweed meal, **seaweed extracts**, sea salts, and salty water are permitted, with the condition that their need is recognized by the certification body or authority, and they are not chemically treated (Table 2 - Substances for Plant Pest and Disease Control, CXG 32-1999).
- **Extract from Chlorella** is permitted (Table 2 - Substances for Plant Pest and Disease Control, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Organic aquatic plants are grown and harvested sustainably without adverse impacts on natural areas. Aquatic plant production shall comply with the relevant requirements of chapters 2 and 4. Harvest of aquatic plants shall not disrupt the ecosystem or degrade the collection area or the surrounding aquatic and terrestrial environment (Aquatic Plants, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Chlorella extract liquid** is permitted (Table B.1 - Agricultural chemicals, JAS for Organic Products of Plant Origin).
- Substances derived from plant, livestock, **marine** products which were used in food or textile industries are permitted: Natural substances or substances derived from natural sources which have not undergone any chemical treatment (excluding extraction of oils with organic solvents) (Table A.1 Fertilizers and soil improvement substances, JAS for Organic Products of Plant Origin).

Human Health and Environmental Issues

Aquatic plant extracts are biodegradable and are likely to have a low impact on crops (2006 TR, lines 242-243). They are not expected to cause toxicity to plants, soil organisms, or higher animals (2006 TR, lines 151-152). There are no known human health hazards (2006 TR, line 320). The potential for over-harvesting of kelp/seaweed fields for production of aquatic plant extracts was identified as a possible environmental concern in the 1995 TAP review, but it offered no additional information.

The 2016 TR and 2016, 2017, and subsequent public comments raised concerns about the potential for negative environmental impacts on marine ecosystems from seaweed harvesting. Some examples noted in the 2016 TR were specific to species used in organic crop fertility inputs and aquatic plant extracts. For example, in mechanical harvesting in Iceland, as with other areas where *Ascophyllum nodosum* and *Laminaria digitata* are harvested commercially, ecological concerns about changes in species diversity resulting from harvesting have been noted (2016 TR, lines 892-896). In Nova Scotia, commercial yields of rockweed are maintained. There still isn't sufficient information or analysis from industry or third-party research proving that their harvest rate is not detrimental to the habitat value that rockweed provides to associated plants and animals. Estimated recovery times based on percentages removed vary between publications (2016 TR, lines 597-600).

Additionally:
There is one species of red algae and two species of brown algae growing along the coasts of the United States that have gained attention as ecologically threatened in recent years. They are, respectively, Irish moss (*Chondrus crispus*), rockweed (*Ascophyllum nodosum*), and giant kelp (*Macrocystis pyrifera*). These plants are economically important and drive several seaweed industries including cosmetic products, nutraceuticals, fertilizers and hydrocolloids. Fertilizer applications are similar to farmyard manure, but may also include extracts and foliar applications (2016 TR, lines 522-527)

Kelp and rockweed are foundational species forming large expansive marine habitats supporting a diverse range of wildlife including other algal species, marine animals and many species of protozoans and bacteria. Without a good accounting of all of the species present, it is hard to predict the effects of harvesting

rockweed and kelp on each ecological niche. Thus, it has been important to recognize that sustainable seaweed production perceived as reproducible harvest capacity may not guarantee the sustained subsistence of each resident species. Although not part of any agricultural waste stream, extracts from wild-harvested kelp and rockweed are allowed for use in organic production as soil amendments (§205.601(j)(1)) (2016 TR, lines 528-535).

Even within the 2016 TR, differences of opinion about the environmental impacts of harvesting were noted within the scientific community. For example, one study addressing the major components of the resident fish community in the rocky intertidal zone after rockweed harvest found no evidence linking rockweed harvest to changes in the ichthyoplankton component or the juvenile and adult fish of that community. In a summarized review of selected work, a researcher at the University of Maine also concluded that the effect of 17% rockweed harvest on some species including seabirds was negligible (2016 TR, lines 326-331).

The TR goes on to explain that rockweed has an important role as habitat, as food, and as a nutrient source supporting a community of organisms that inhabit its "forests." Any cutting of rockweed can produce an effect on the supported eco-communities. Furthermore, many aspects of this ecosystem have not been elucidated, encouraging more precaution as the brown algae "forestry" industry grows into the future (2016 TR, lines 356-60).

Discussion
Previous Boards have exhaustively focused on the impacts of seaweed harvesting on marine ecosystems and proposed regulations to address these concerns. NOP has declined to implement these recommendations. We are now focusing on the current annotation restriction and whether there is any update needed for this group of substances. We hope to receive information from manufacturers regarding the oversight of their products and the risk of fortifying aquatic plant extracts with potassium derived from the extractant rather than the aquatic plants themselves.

Questions to our Stakeholders

1. Should NOSB consider an annotation change to aquatic plant extracts to ensure that extractants are not used for their nutrient content? If yes, please provide suggestions for annotation changes and rationale.

Lignin sulfonate

Reference: 205.601(j) As plant or soil amendments. (4) Lignin sulfonate —chelating agent, dust suppressant.
Technical Report: 1995 TAP; 2011 TR; 2020 TR (lignins)
Petition(s): 2014 Petition to remove as floating agent
Past NOSB Actions: 10/1995 NOSB Minutes and vote; 04/2006 Sunset Rec; 04/2011 NOSB Rec to amend, 04/2011 NOSB Sunset Rec; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

Subcommittee Review

Use
Lignin sulfonate acts as a dust suppressant due to its large size and high affinity for binding with polar and nonpolar compounds. Small dust particles of fertilizers adsorb to lignin sulfonate to form a larger, heavier complex which reduces dust (2011 TR, lines 143-145). Products with less dust are easier to handle and are applied more efficiently and accurately. Similarly, lignin sulfonate acts as a chelating agent by binding with smaller, charged micronutrient ions such as boron, manganese, and iron, and are slowly released into the soil in a bioavailable form (2020 TR, lines 146-148).

Prior to 2015, lignin sulfonate could be used as a floating agent in postharvest handling for pears. However, it was petitioned for removal at § 205.601(l)(1) in 2014 and voted off the list by the Board in Fall 2015. There were no comments supporting its listing, indicating a lack of essentiality of this synthetic material as a floating agent.

Manufacture
Lignin sulfonates are produced from the process of sulfite chemical pulping. Sulfite pulping involves cooking softwood chips under pressure in sulfur dioxide-containing cooking liquors. When the cooking process is complete, sulfonated lignin is collected as a liquid by-product in the spent liquor (2020 TR, lines 520-524), while the pulp is used for paper production. Lignin sulfonates may also be obtained from the Kraft pulping process, which is similar to sulfite pulping, but involves treating the wood at high temperatures and pressure in a water solution containing sodium sulfide and sodium hydroxide (2020 TR, Table 4).

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Lignin and lignin sulphonates (lignosulphonates) are permitted as chelating agent(s), as formulant ingredient(s) and as dust suppressant(s) (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Lignin sulfonate is not explicitly mentioned in the regulations.

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

- Lignin sulfonate is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Lignin sulfonate is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Granulating agents and anticaking agent for fertilizers are permitted: Natural substances or substances derived from natural sources which have not undergone any chemical treatment. However, if granulating substance and anticaking agent for fertilizers are impossible to be produced by only using the relevant substances, lignin sulfonates may be used (Table A.1 Fertilizers and soil improvement substances, JAS for Organic Products of Plant Origin).

Human Health and Environmental Issues
Sodium lignosulfonate is relatively low in toxicity based on results of tests in laboratory animals. However, high doses have been found to cause adverse health effects in laboratory animals. Rats that were given drinking water containing purified sodium lignosulfonate at a 10 g/100 ml concentration for 16 weeks had skin lesions, decreased weight gain, and increased white cell counts (2011 TR, lines 300-305).

Lignin sulfonates are soluble in water, so it is possible for dissolved lignosulfonates to enter waterways through direct contamination or soil runoff (2011 TR, lines 332-333). Also, as they break down in water, they consume dissolved oxygen in water due to their high BOD, which affect aquatic organisms through decreased available oxygen (2011 TR, lines 334-336). In a previous TAP Report (1995) the issue of potential dioxin contamination was addressed as a potential contaminant from the process of pulping paper. Dioxin is created during the bleaching process of paper production and the lignosulfonates are removed from the pulp before the bleaching process making it unlikely that they would be generated (2011 TR, lines 339-346).

The 2020 TR did not uncover any reports of environmental harm resulting from the use of lignins (2020 TR, lines 688-689). The lignin component typically comprises 10 percent or less of a fertilizer formulation and is applied at rates of approximately 50–200 pounds of lignin sulfonate per acre (2020 TR, lines 237-240).

Discussion
Dust suppressants are essential to reduce dust inhalation, air pollution, and surface water contamination from organic fertilizers and soil amendments during handling and application. Previous Boards have supported the relisting of this material, stating its essentiality to organic crop production. Opposing commenters stated that lignin sulfonate is not necessary since organic production methods increase organic matter in the soil and provide naturally occurring chelates and alternative dust suppressants are available.

Questions to our Stakeholders
1. Are lignin sulfonates still used as chelating agents or dust suppressants?

Fatty alcohols (C6, C8, C10, and/or C12)

Reference: §205.601(k) As plant growth regulators (2) Fatty alcohols (C6, C8, C10, and/or C12) - for sucker control in organic tobacco production.
Technical Report: 2016 TR (C8, C10)
Petition: 2015 to add at §205.601 for use as a pesticide (sucker control) (C8C10); 2017 petition addendum; 2018 to add at §205.601 for use as a pesticide (sucker control) (C6C8C10C12)
Past NOSB Actions: 11/2017 recommendation to not add; 10/2019 recommendation to add
Recent Regulatory Background: Added to National List effective 04/22/2022 (87 FR 16371)
Sunset Date: 04/22/2027

Subcommittee Review

Use
Currently, EPA's registration for this material is limited to use on tobacco. Fatty alcohols (octanol and decanol) are used to chemically remove flower buds and suckers from tobacco plants. Removal of the flower tops and the suckers encourages the growth of larger leaves. The use of fatty alcohols is an alternative to two laborious hand operations in tobacco production (2016 TR, lines 64-66). A course spray of 5% decanol or a combination of decanol and octanol applied before bud formation inhibits the formation of the bud. Fatty alcohol dripping down the stem of the plant inhibits sucker formation (2016 TR, lines 68-70). Topping and suckering are the most time-consuming tasks associated with growing organic tobacco and may be necessary every week for 10 weeks. It can take one person per acre per day to do the job (2016 TR, lines 498-499). Yields are also increased with the use of this treatment (2016 TR, line 70).

Manufacture
The present world capacity of plant derived- and petroleum derived-fatty alcohols is greater than two million metric tons/year. Much of this production goes in to making detergents or plastics. Petroleum derived fatty alcohols production is estimated to be just 23% of total global capacity, whereas plant derived fatty alcohols production is currently 77% of total global capacity. In the USA the bulk of fatty alcohols is of petrochemical origin, whereas in Europe more than 60% of the total volume is made from natural fats and oils (2016 TR, lines 219-224).

The Lurgi process has been in commercial use since 2004. In the Lurgi process fatty acids are first converted to wax esters and then hydrogenated over a fixed bed reactor. This differs from the Davy process since there is no conversion to methyl esters and fatty alcohols come directly from wax esters. The Davy Process is used primarily for detergent alcohols with greater than 12 carbons; however, it can also be used for the production of plasticizer alcohols containing between 6 and 12 carbons. The Davy process provides an improved process for production of fatty alcohols by hydrogenation of lower alkyl esters, particularly methyl esters of fatty acids derived from natural triglycerides under conditions that minimize formation of byproduct alkanes and ethers followed by refining of the resulting ester containing product. Many production plants throughout the world have been licensed to produce fatty alcohols using the Davy process (2016 TR, lines 194-203).

Fatty alcohols are also produced synthetically from petroleum. Alkylaluminum derivatives are produced by adding hydrogen and ethylene to an aluminum slurry. Alkylaluminum reacts with ethylene to increase carbon chain length. Higher trialkylaluminum species produced by reacting ethylene with alkylaluminums under pressure at about 120°C can be further reacted with ethylene at higher temperatures to give straight chain alcohols with up to 22 carbons (alfene process). Reaction of the higher trialkylaluminums with air and sulfuric acid yields higher n-alcohols: alfol process. The choice of catalyst and reaction conditions significantly affect the process. For fatty alcohol production, it is difficult to practice an esterification on a continuous basis, thus it is convenient to adopt batch processing (2016 TR, lines 204-212).

Because fatty alcohols have important industrial uses as medicines, cosmetics, skin care products, detergents, fuels and plasticizers in addition to their role in tobacco production, extensive research to develop fermentation systems producing fatty alcohols has been undertaken over the past few years with the intention of industrial production in the near future. Naturally found strains of bacteria including *Escherichia coli*, *Salmonella spp*., *Klebsiella spp*., and *Enterobacter spp*. are known to excrete 1-octanol, 1-decanol, and 1-dodecanol. Several *E. coli* strains being examined for commercial scale production of 1-octanol and 1-decanol respectively produced as much as 508 and 740 nanograms/milliliter of culture (2016 TR, lines 230-237).

Mutations introduced into *Escherichia coli* strains have resulted in a number of commercially viable fermentation approaches to produce n-alcohols (2016 TR, lines 239-240). Mutated *E. coli* strains that produce upwards of 6.33 grams of fatty alcohol per liter of culture support future alternative industrial fermentation methods for the production of fatty alcohols (2016 TR, lines 246-248).

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Alcohol, organic sources are permitted (Table 7.3 – Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Fatty alcohols are not explicitly mentioned in the regulations.

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

- Fatty alcohols are not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Fatty alcohols are not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Alcohol is permitted (Table D.1 - Chemicals for cleaning or disinfecting livestock or poultry house, JAS for Organic Livestock Products).

Human Health and Environmental Issues

Alcohols with chain lengths up to C18 including hexanol, octanol, decanol, dodecanol, tetradecanol, hexadecanol, and octadecanol are readily biodegradable within ten days (2016 TR, lines 251-252). The fatty alcohols are susceptible to atmospheric degradation by hydroxyl radicals, with half-lives ranging between approximately 10-30 hours. Longer chain lengths have shorter estimated half-lives within this range. Fatty alcohols are used in the manufacture of surfactants for detergents and personal care products. These products are mostly disposed of down the drain at a rate of about 185,000 metric tons per year. Most use is as laundry detergent totaling about 532,000 metric tons per year (2016 TR, lines 258-263). By comparison, the contribution of fatty alcohols to the environment from tobacco topping and suckering is very small (2016 TR, lines 264-265).

Fatty alcohols all have the same mode of ecotoxicological action. In addition, they are all rapidly biodegradable especially at environmentally relevant concentrations (2016 TR, lines 315-317). 1-hexanol and 1-octanol present a hazard for the environment (acute toxicity to fish, daphnids and algae in the range 1-100 mg/l). However, both of these substances are readily biodegradable. 1-decanol and 1-undecanol present a greater hazard for the environment (high acute toxicity to fish, daphnids and algae, in the range 0.1-1 mg/l, and/or high chronic toxicity). The substances in this subgroup biodegrade rapidly and environmental monitoring data from seven countries indicates exposures to the environment is anticipated to be low (2016 TR, lines 320-326).

Available toxicity data indicate that aliphatic alcohols are “practically non-toxic” to honeybees (acute contact LD50 > 25 µg/bee). However, given that aliphatic alcohols can be used as Lepidopteran sex inhibitors, there is a potential for sublethal (e.g., reproductive) effects on non-target Lepidopterans, such as butterflies. This potential effect cannot be quantified at this time (2016 TR, lines 327-329).

Toxicity data for the aliphatic alcohols consisting of acute toxicity, irritation, and sensitization studies, developmental rat (oral and inhalation) toxicity studies and a 90-day rat (dermal) study were evaluated for the Environmental Protection Agency (EPA) human health risk determination (2016 TR, lines 389-391).

Based on the results of the available studies, no endpoints of toxicological concern have been identified for human health risk assessment purposes. The EPA concluded that there are no human health risks of concern for aliphatic alcohols. Currently, there is no known mode of toxicological action for the aliphatic alcohols. Based on the low hazard concern via the oral, dermal, and inhalation routes of exposure, a quantitative risk assessment for the aliphatic alcohols was not found necessary (2016 TR, lines 397-402).

1-Decanol, which is a component of all the tobacco sucker control products in this case, is an acute Toxicity Category I eye irritant; therefore, products with agricultural uses must require a 48 hour REI and the

following personal protective equipment (PPE) for early entry: coveralls, chemical-resistant gloves made of any water proof material, shoes plus socks, and protective eyewear (2016 TR, lines 404-409).

Discussion
In the previous review, the Board received numerous comments noting the essentiality of this material to organic tobacco growers. Numerous tobacco growers noted that without this material, they would be unable to produce organic tobacco and would most likely drop their organic certification, including the certification for crops they use in rotation with tobacco.

The TR refers to hand application of soybean or mineral oil as an alternative practice to remove suckers in tobacco. The question arises as to whether approved organic "burn down" herbicides could also be used for this purpose.

The Crops Subcommittee is well aware of the negative impacts on human health of tobacco use. However, tobacco is a legal crop and a crop eligible for organic certification. Like any other material reviewed for use on organic crops, the Subcommittee is limiting our review to whether the material meets the criteria necessary for adding it to the National List as a crop production aid.

Since fatty alcohols occur naturally throughout the plant world, break down readily after use, help to prevent worker exposure to tobacco poisoning, and reduce insect problems, they are compatible with a system of sustainable agriculture.

Questions to our Stakeholders

1. Are approved organic herbicides, such as those made with organic acids, effective to de-sucker tobacco?

Sodium silicate

Reference: 205.601(l) As floating agents in postharvest handling. Sodium silicate—for tree fruit and fiber processing.
Technical Report: 1996 TAP; 2011 TR; 2025 Limited Scope TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

Subcommittee Review

Use
Sodium silicate, also known as "water glass," has had a range of uses that include fiber processing, fire prevention, adhesives, egg preservation, and as an anti-corrosion agent (2011 TR, lines 39-44). For organic production, it may be used to modify water density in the water tanks that remove fruit from picking bins at the start of the packing process. This is especially important for pear packing lines since pears are denser than water and will sink to the bottom of the water tank. Adding sodium silicate to the water increases the density of the water, thus causing the pears to float and making them easier to remove from the dump tank and onto the packing line (2011 TR, lines 416-417).

The 2011 technical report (TR) notes that there are a number of uses of sodium silicate for fiber processing, but it did not specifically identify organic uses in fiber processing. For fiber processing in general, sodium silicate may be used as a peroxide buffer for processing cotton and jute. It also has uses as a bleaching agent, detergent for fiber cleaning, degumming of jute fibers, and in combination with various other bleaching and processing compounds.

Additionally, the TR notes that sodium silicate is exempt from the requirement of a tolerance when it is used as an inert ingredient in pre- and post-harvest agricultural products (40 CFR 180.910).

Manufacture
Solid glass is usually produced in a rotary kiln or tank furnace by fusing quartz sand with potash or soda at temperatures ranging from 1,100 to 1,330 degrees C. Sodium silicate, which makes up the majority of soluble silicates produced, is converted from solid glass to a liquid solution at 100 degrees C. The concentrations of sodium silicate in water can be varied according to particular processing needs (2011 TR, lines 176-180).

The 2011 TR notes that the production processes for lump glass and sodium silicate require high temperatures and sometimes high pressures to change silicon dioxide and soda or potash to soluble silicates. These processes do not occur in nature and, thus, this material was deemed to be synthetic (2011 TR, lines 189-193).

Early in 2025, the Crops Subcommittee (CS) received an updated, limited scope TR for this substance. The TR notes that "[s]odium silicate is not extracted from naturally occurring plants, animals, or minerals. It is produced by reacting the minerals silicon dioxide with sodium carbonate or sodium sulfate…[a]lternatively, sodium silicate is produced by reacting silicon dioxide and the synthetic chemical sodium hydroxide" (2025 TR, lines 101-103).

The 2025 TR goes on to update information from the EPA in 2022 which indicates that "most sodium silicates in the United States are produced with the furnace method, using silicon dioxide and sodium carbonate as precursors. Authors of an older source state that when sodium carbonate is not available, sodium sulfate can be used as a precursor" (2025 TR, lines 113-115).

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Silicon, silica and silicates: Sodium and potassium silicates are permitted only for crop protection (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- Sodium silicate is permitted in detergents (Table 7.4 – Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Sodium silicate is not explicitly mentioned in the regulations.

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

- Mineral powders (stone meal, silicates) are permitted (Table 2 - Substances for Plant Pest and Disease Control, CXG 32-1999).
- Sodium silicate is permitted (Table 2 - Substances for Plant Pest and Disease Control, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Silicates (e.g. sodium silicates, quartz) are permitted (Appendix 3 - Crop Protectants and Growth Regulators, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Sodium silicate is permitted, excluding cases in which it is used on plant products for the purpose of controlling pests and diseases (Table B.1 - Chemical agents, JAS for Organic Feed).
- Sodium silicate is permitted, excluding cases in which it is used on plant products for the purpose of controlling pests and diseases (Table J.1 - Chemical agents, JAS for Organic Livestock Products).
- Sodium silicate is permitted, except for the use in plant products for controlling pests and diseases (Table C.1 – Chemical Agents, JAS for Organic Processed Foods).
- Sodium silicate is permitted, excluding cases in which it is used on plant products for the purpose of controlling pests and diseases (Table C.1 - Chemical agents, JAS for Organic Products of Plant Origin).

Human Health and Environmental Issues

As noted in the 2011 TR, sodium silicates are quickly diluted and depolymerize in the environment. These processes yield molecular forms that are indistinguishable from natural, dissolved silica in naturally occurring water (2011 TR, lines 220-221). Other testing has shown these silicates to be generally non-toxic, except for contact exposure to very high concentrations of the material which can cause dermatitis or, if ingested, vomiting and diarrhea. Additionally, the 2011 TR concluded that, based on its normal use patterns, sodium silicate is unlikely to contaminate soil or adversely affect soil organisms (2011 TR, lines 317-318). Sodium silicate has been characterized as Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration. The U.S. Environmental Protection Agency has determined it is exempt from the requirement of a tolerance when used as an inert ingredient in pre- and post-harvest products (2011 TR, lines 76-81).

While normal uses of sodium silicate are unlikely to cause environmental damage, large scale spills of sodium silicate could have some environmental effects, either by altering the pH of the spill area or affecting the balance of nitrogen and phosphorous in the spill area (2011 TR, lines 320-322 and 327-329).

The 2025 TR attempted to build on previous information in order to update potential human health concerns for this substance. Unfortunately, the TR notes that "[l]ittle information exists on the effects on human health from exposure to sodium silicate in fruit packhouses. Packhouse workers might be exposed to sodium silicate on their skin or eyes" (2025 TR, lines 273-274). The TR also noted that research was unable to "find information related to residues of sodium silicate solutions on fruits as a result of petitioned use" (2025 TR, lines 309-310).

Discussion

Previous reviews of this substance generated few public comments. Commenters indicated that the substance is primarily used by small pear packers to float pears out of a water dump tank and into packaging lines. Larger pear packers use mechanical means to accomplish this, but for smaller packers, the equipment is prohibitively expensive. One commenter in a previous review did not view this material as compatible with organic systems of agriculture.

Previous Boards relisted sodium silicate, citing the benefit to small producers in the organic industry, does not contribute to environmental degradation during normal usage, is Generally-Recognized as Safe (GRAS) by the U.S. Food and Drug Administration, and the U.S. Environmental Protection Agency has determined it is exempt from the requirement of tolerance when used as an inert ingredient in pre- and post-harvest products (2011 TR, lines 76-81).

The 2025 TR provides an update on alternatives to the use of sodium silicate as floatation agents. The TR proposes sodium carbonate, potassium carbonate, calcium chloride, or naturally occurring sodium sulfate as floating agents allowed for use in post-harvest handling of tree fruit. The TR is able to provide some information about alternative substances and practices.

A study on alternative substances "found that fruit treatment with calcium chloride, potassium carbonate, sodium carbonate, or sodium sulfate resulted in no damage to the fruits when the process was done at either temperature range. They also reported that injury was moderate to severe when using potassium phosphate or calcium chloride for 45- or 60-minute durations" (2025 TR, lines 390-393).

The 2025 TR notes that "advances in pear genetics and processing techniques have reduced the need for floating agents" which led to the "removal of lignin sulfonate as an approved organic floating agent in 2017" (2025 TR, lines 404-406). The TR indicates that sodium silicate and previously mentioned alternatives allowed for use as floating agents are only used in "immersion water dumps, fruit unloading systems that do not rely on this method would make using sodium silicate unnecessary. Switching to a soft-landing, dry-drop system could be an alternative" (2025 TR, lines 408-410). The TR goes on to suggest foam coated belts and padded picking containers might be viable alternatives to water immersion methods that require floating agents.

The Subcommittee discussed the post-harvest handling dynamics for apple and pear producers, indicating that pears sink, and floating agents could be necessary as processing will have a step that involves moisture. A member observed that Dry-Pack is progressing, but pears will get exposed to moisture at some point in post-harvest handling where a floating agent is necessary and helpful to send fruit in right directions based on size, color, etc. This type of infrastructure also allows apples and pears to be processed in the same facility A member questioned the relationship of floating agents to sanitizing materials like chlorine, reflecting that the 2025 TR indicates that sodium silicate prevents the rapid decomposition of chlorine materials.

Questions to our Stakeholders

1. Is sodium silicate still an essential tool as a floating agent for small tree fruit producers?
2. Are the alternative methods and substances indicated in the updated TR being used by organic producers?
3. The limited TR indicates that sodium silicate prevents the rapid decomposition of chlorine materials. Does its use as a flotation agent in pear processing have impacts on the efficacy and longevity of chlorine materials that may be used for food safety reasons in pear packing?

EPA List 4 Inerts

Reference: 205.601(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances. (1) EPA List 4 – Inerts of Minimal Concern.

Technical Report: 2015 Limited Scope TR: Nonylphenol ethoxylates (NPEs)
Petition(s): N/A
Past NOSB Actions: 02/1999 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 04/2010 recommendation; 10/2010 NOSB sunset recommendation; 10/ 2012 NOSB recommendation; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

Subcommittee Review
As explained below, the Crops Subcommittee (CS) expects this listing to be fully replaced before its next sunset review.

Use
Inert ingredients in pesticide formulations are added to enhance functionality and efficacy. Any of the pesticides approved for organic use may contain inert ingredients. For example, surfactants may improve the solubility and half-life of active pesticide ingredients. As described in Shistar (Shistar, T. "Inert" Ingredients Used in Organic Production. Beyond Pesticides, Washington, D.C., 2017), "The relatively few registered pesticides allowed in organic production contain product formulations with so-called "inert" ingredients that are not disclosed on the product label. The "inerts" make up the powder, liquid, granule, or spreader/sticking agents in pesticide formulations. The "inerts" are typically included in products with natural or synthetic active pesticide ingredients recommended by the National Organic Standards Board (NOSB) and listed by the National Organic Program (NOP) on the National List of Allowed and Prohibited Substances."

Manufacture
Since this listing covers many different materials, the manufacture of these substances cannot be specifically stated.

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Formulants used in crop production aids may only be used with substances listed in Column 2 of this table. Only formulants classified as **List 4A or 4B** by the Pest Management Regulatory Agency (PMRA) or derived from biological or mineral sources may be used with substances in Table 4.2 (Column 2). Formulants classified as List 3 by PMRA may be used with passive pheromone dispensers. Formulants classified as **List 4A, 4B** or 3 by PMRA are not subject to 1.4 or 1.5 of CAN/CGSB-32.310. Formulants classified as List 1 or 2 by PMRA are prohibited (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- Formulants may only be used with substances listed in Table 8.2. Only formulants classified as **List 4A or 4B** by the Pest Management Regulatory Agency (PMRA) or derived from biological or mineral sources may be used with substances in Table 8.2. Formulants classified as List 3 by PMRA may be used with passive pheromone dispensers. Formulants classified as **List 4A, 4B** or 3 by PMRA are not subject to 1.4 or 1.5 of CAN/CGSB-32.310. Formulants classified as List 1 or 2 by PMRA are prohibited (Table 8.2 – Facility pest management substances, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- The following products and substances referred to in Article 2(3) of Regulation (EC) No 1107/2009 shall be allowed for use in organic production, provided that they are authorised pursuant to that

Regulation: (a) safeners, synergists, and co-formulants as components of plant protection products; (b) adjuvants that are to be mixed with plant protection products (General production rules, EC No. 2018/848).

- In accordance with Article 9(3) of Regulation (EU) 2018/848, safeners, synergists, and co-formulants as components of plant protection products, and adjuvants that are to be mixed with plant protection products shall be allowed for use in organic production, provided that they are authorised pursuant to Regulation (EC) No 1107/2009. The substances in this Annex may only be used for the control of pests as defined in Article 3(24) of Regulation (EU) 2018/848 (Annex I: Active substances contained in plant protection products authorised for use in organic production, EC No. 2021/1165).

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

- Inerts are not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Organic crop production ensures that co-formulants (e.g. inerts and synergists) in formulated farm input products are not carcinogens, mutagens, teratogens or neurotoxins (Crop Production, IFOAM NORMS 2014).
- Recommendation: In case operators need to use commercial formulated inputs, preference should be given to formulations approved for use in organic agriculture by a specialized organic material review organization/program (Pest, Disease, and Weed Management, IFOAM NORMS 2014).
- Any formulated input shall have only active ingredients listed in Appendix 3. All other ingredients shall not be carcinogens, teratogens, mutagens, or neurotoxins (Pest, Disease, and Weed Management, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Inerts are not explicitly mentioned in the regulations.

Human Health and Environmental Issues

As noted below, some of the materials listed on EPA List 4 may have negative environmental and human health consequences, while others may be relatively benign. A complete review of materials listed as to environmental issues is not possible without technical reviews of each material.

Discussion

Inerts are not necessarily biologically or chemically inert. They may be relatively benign or may be documented as harmful to the environment or human health. Without a way to individually evaluate each substance listed on EPA List 4 or to evaluate substances as a group, it is difficult to discern the acceptability of each substance for use in organic agriculture.

Presently, § 205.601(m) of the National List references EPA List 4 – Inerts of Minimal Concern as acceptable in organically approved pesticide formulations. List 4, however, is outdated and no longer maintained by EPA. The list of inerts that is referenced for review of products for organic certification was last updated in August 2004 (https://www.epa.gov/pesticide-registration/epas-national-organic-program-guidance) and may include materials that some stakeholders believe are inappropriate for organic agriculture. For example, nonylphenol ethoxylates (NPEs) are included on List 4. These materials are endocrine disruptors, may adversely impact fauna and flora, and have been identified by the California Department of Toxic Substances Control's Safer Consumer Products Program as a likely high priority chemical that should be formally phased out

https://www.ams.usda.gov/sites/default/files/media/NPE%20Technical%20Evaluation%20Report%20%282015%29.pdf. If evaluated on an individual basis, NPEs would likely not meet OFPA criteria for acceptability.

The NOSB and NOP have struggled with how to evaluate EPA List 4 – Inerts of Minimal Concern during sunset review. OFPA has specific criteria for inerts which states: "*(ii) …contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern"* (§6517 C.1.B.ii). Due to EPA changes in its categorization of inerts and discontinued support for List 4, the NOSB (starting in 2010) has adopted a series of recommendations to revise this sunset listing.

Most recently, AMS published an Advance Notice of Proposed Rulemaking (ANPR) incorporating several of these recommendations on September 2, 2022, which received extensive stakeholder feedback on updated references for inert ingredients in organic production. Based on that feedback, the NOP requested that the NOSB evaluate four options for updating the inerts listing on the National List. The NOSB has recommended two options, plus a hybrid combination of those two options, at the Fall 2024 meeting. At the time of this review, the NOP is moving forward with the rule-making process based on this recommendation.

National List Motion, approved by NOSB in Fall 2024 (shown with changes from current language)**:**

Motion to add individual substances identified in Appendix A] at 205.601(m)

(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

~~(1) EPA List 4-Inerts of Minimal Concern~~
~~(2) EPA List 3-Inerts of unknown toxicity-for use only in passive pheromone dispensers~~
(1) 1,2,3-Octadecenoate (CAS 9007-48-1)
(2) 12-Hydroxystearic acid-polyethylene glycol copolymer (CAS 70142-34-6)
(3) …

Motion to add individual substances identified in Appendix A] at 205.603(e)

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

~~(1) EPA List 4-Inerts of Minimal Concern~~
~~(2) EPA List 3-Inerts of unknown toxicity-for use only in passive pheromone dispensers~~
(1) 1,2,3-Octadecenoate (CAS 9007-48-1)
(2) 12-Hydroxystearic acid-polyethylene glycol copolymer (CAS 70142-34-6)
(3) …

OR

Motion to amend 205.601(m)

(m) ~~As s~~Synthetic inert ingredients as classified by the Environmental Protection Agency (EPA) and exempted from the requirement of a tolerance, for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances, except for:

~~(1) EPA List 4-Inerts of Minimal Concern~~

~~(2) EPA List 3 Inerts of unknown toxicity for use only in passive pheromone dispensers~~
(1) Alkylphenol ethoxylate substances
(2) Per- and polyfluoroalkyl substances

Motion to amend 205.603(e)

(e) ~~As s~~Synthetic inert ingredients as classified by the Environmental Protection Agency (EPA) and exempted from the requirement of a tolerance, for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances, except for:
~~(1) EPA List 4 Inerts of Minimal Concern~~
~~(2) EPA List 3 Inerts of unknown toxicity for use only in passive pheromone dispensers~~
(1) Alkylphenol ethoxylate substances
(2) Per- and polyfluoroalkyl substances

The Crops Subcommittee expects an improved listing to be implemented by the NOP in the next two years, replacing the reference to List 4. In the meantime, in order to maintain continuity in pesticide formulations used by organic farmers, we recommend that List 4 Inerts be relisted in this review at 205.601(m) on the National list.

Questions to our Stakeholders

1. Do stakeholders agree that List 4 Inerts should be relisted until they are replaced with a new listing via the rulemaking process currently underway?

Paper

Reference: §205.601 205.601 (p) Production Aids: (2) Paper-based crop planting aids as defined in § 205.2. Virgin or recycled paper without glossy paper or colored inks.
Technical Report: 1995 TAP (Newspaper, recycled paper); 2006 TR (Newspaper, recycled paper); 2017 TR (Newspaper, recycled paper); 2019 TR (Paper-based crop planting aids)
Petition: 2018 petition to add for use as a production aid (paper-based crop planting aids); 2018 petition addendum
Past NOSB Actions: 04/2021 recommendation to add
Recent Regulatory Background: Added to National List effective 11/14/2022 (87 FR 68021)
Sunset Date: 12/14/2027

Subcommittee Review

Use
A paper-based crop production and planting aid is defined at § 205.2 as "a material that is comprised of at least 60% cellulose-based fiber by weight, including, but not limited to, pots, seed tape, and collars that are placed in or on the soil and later incorporated into the soil, excluding biodegradable mulch film. Up to 40% of the ingredients can be nonsynthetic, other permitted synthetic ingredients in § 205.601(j), or synthetic strengthening fibers, adhesives, or resins. Contains no less than 80% biobased content as verified by a qualified third-party assessment (e.g., laboratory test using ASTM D6866 or composition review by qualified personnel)."

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

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

Most of the paper used as a crop planting aid is functionally identical to newspaper and recycled paper, and so the inclusion of paper production and planting aids such as paper pots on the National List was evaluated in the context of information about newspaper and recycled paper. While the current listing of newspaper and recycled paper – like the addition of paper production and planting aids -- has been found to have no detrimental interactions with other materials in organic agriculture, there has been sustained concern about the full composition of these products and the potential impact they could have on soils and composts supporting organic cropping systems.

Manufacture

Paper can be made from various plant sources including wood, trees, straw, hemp, bamboo, reeds, kenaf, sisal, jute, sugarcane bagasse, sunflower stalks as well as recycled sources of pulp (2017 TR, lines 67-68 and 80). Cellulose sources are typically mechanically ground and then chemically "cooked" using an alkali or sulfite process (2017 TR, lines 380-382). Newspaper and recycled papers can also have a variety of inks, although colored ink and glossy paper are not allowed as compost feedstocks or mulch under the organic rule. The paper used as a planting aid could include the typical adhesives and ink residues found in newspaper and recycled paper.

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Biodegradable planting containers (for example, pots or cell packs) may be left to decompose in the field if all ingredients are listed in Table 4.2 (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Paper-based crop planting aids (paper) is not explicitly mentioned in the regulations.

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

- Paper-based crop planting aids (paper) is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Paper-based crop planting aids (paper) is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Physical control: To control pest and disease by using light, heat, sound, etc. by using mulch derived from wastepaper (limited to those to which no chemically synthesized substances are added in the

manufacturing process) or plastic mulch (limited to those, that are to be removed after use), or by manual or mechanical means (Terms and definitions, JAS for Organic Products of Plant Origin).

Human Health and Environmental Issues

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

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

There could be contaminants released into the environment during the manufacture of paper, and environmental degradation caused by harvest of cellulose, but no more than newspaper or recycled paper, which historically have been approved for use in organic agriculture. A difference between this paper and the previously approved newspaper is that we are not restricting it to the use of only recycled paper products. The annotation allows virgin stocks of cellulose to be used in the paper used as a planting aid in organic agriculture. There are negative environmental impacts from harvesting trees to make paper such as road building, soil erosion, degraded water quality, and loss of habitat, but there are forestry best management practices that can mitigate some of these negative effects. Furthermore, there are non-tree cellulose sources that could be utilized in the future. The synthetic fibers that could be used in paper are manufactured in a wide range of production systems. These were not specifically addressed in the 2019 TR.

Paper that does contain high percentages of synthetic fibers that do not biodegrade readily could leave residues that would be harmful to terrestrial, avian, and aquatic wildlife if consumed. This potential and difficult-to-trace synthetic content could also have an impact on the total biodegradability of paper production and planting aids and the soil that harbors them. This content is also notable for its potential persistence in compost that could be used on organic farms (reference: Fall 2024 Compost Proposal, Crops Subcommittee).

In paper pots, use of synthetic pesticides embedded in the pots could also have adverse impacts on biodiversity, but only organically allowable nutrients would be allowed in the paper used as a planting aid and there is a restriction on the types of materials allowed in the 40% non-cellulose-based portion of the planting aids. The percentage of adhesives in the paper pots is very small. There could be an issue with paper used as a planting aid containing large percentages of synthetic fibers that would not biodegrade readily.

Discussion

NOP guidance 5034-1 “Materials for Organic Crop Production” excludes virgin paper from the “newspaper or other recycled paper” allowance for mulch or compost feedstocks. The guidance states: *“Includes newspaper and other recycled paper such as cardboard, without glossy or colored inks. Does not include paper that is not recycled (i.e., virgin paper).”*

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

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

When discussing the possible allowance for paper used as a planting aid, the Subcommittee also considered the fact that currently there is an allowance for "newspaper or other recycled paper" as weed control or as compost feedstocks and there are very few differences between the currently allowed paper and the paper as a planting aid under review, with the exception of paper pots that have a very high percentage of non-cellulose synthetic fibers. Requiring 60% cellulose fiber prevents the planting aids from being completely made of biobased, non-degradable plastics, and yet allows current products on the market. It is the hope that this percentage can increase over time. Requiring 80% biobased content prevents the use of planting aids made primarily from petroleum sources and allows the products currently on the market. Again, it is hoped that this percentage can be increased over time and that future Boards will be able to modify this annotation to reflect manufacturing technological advances that incorporate more natural materials and additional cellulose and biobased content. These future reviews should also encompass the biodegradability of both fibers and adhesives. Such reviews have most recently occurred in the context of work by the Crops Subcommittee to clarify parameters for organic compost.

The latest iteration of the Crops Subcommittee has had robust discussions about the implications of the paper pots listing in its first sunset review. Members have asserted the need to understand more fully whether paper pots are having broader negative impacts than believed at the time of approval. One issue that was raised related to the fact that many small producers were strongly in support of the original paper pots listing, which elicited at least two questions: (1) whether larger producers have identified benefits to paper pots since listing and are using it in larger operations, thus creating more concern about possible contaminants from the non-cellulose components of paper pots; and (2) whether paper pots – in keeping with OFPA – are indeed a necessity in small cropping systems. On the latter point, members have noted that the issue of necessity is often posed to larger producers in the context of listed materials they rely on, and so if paper pots are essential to small producers, they should also provide regular justification within the sunset cycle.

Questions to our Stakeholders

1. Are our stakeholders aware of materials of concern (like phthalates or PFAS) that could be appearing in paper planting and production aids like paper pots?
2. Is there soil contamination concerns unique to paper pots because of the potential to use paper pots multiple times in concentrated areas over the course of a single growing season?
3. Are the restrictions on paper pot composition applicable to the paper feedstock issues that have been raised in the context of compost?

Arsenic

Reference: 205.602(b)
Technical Report: None
Petition(s): N/A

Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

Subcommittee Review

Use
Arsenic and its compounds, especially arsenic trioxide, are used in the production of pesticide-treated wood products, herbicides, and insecticides. These applications are declining due to the toxicity of arsenic and its compounds.

Arsenic is sometimes alloyed with lead to form a harder, more durable metal. Some areas of use include car batteries and bullets. Until recently, arsenic was commonly used in glassmaking. However, due to pressure from the EPA and environmentalists, most glass manufacturers have slowed down or stopped using arsenic.

Manufacture
Arsenic is a naturally occurring element in the environment that can enter the food supply through soil, water, or air. Arsenic levels in the environment are generally low, but can vary depending on the natural geological makeup of local areas.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Arsenic is not explicitly mentioned in the regulations.
- Health Canada continues to monitor the concentrations of various chemicals, including arsenic, in foods through its ongoing Total Diet Study surveys and also conducts targeted surveys of arsenic in specific foods (Canadian Total Diet Study, Trace Elements 1993-2018). Health Canada will also continue to evaluate the potential human health risks associated with dietary arsenic exposure. Additionally, the Canadian Food Inspection Agency carries out monitoring and surveillance work for arsenic in foods, including those commonly consumed by infants and children.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 **and** 2021/1165

- Arsenic is not explicitly mentioned in the regulations.

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

- Arsenic is not explicitly mentioned in the regulations.
- In 2017 CODEX adopted a code of practice for the prevention and reduction of arsenic contamination in rice. The Codex provides national or relevant food control authorities, producers, manufacturers and other relevant bodies with guidance to prevent and reduce arsenic contamination in rice as source directed measures and agricultural measures. The Codex also includes guidance on monitoring and risk communication (CXC 77-2017: Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Arsenic is not explicitly mentioned in the regulations.
- Natural non-renewable resources—such as mined minerals—require a description of the deposit or occurrence in nature. Non-renewable resources are generally restricted or limited in their use. They

may be used as a supplement to renewable biological resources, provided they are extracted by physical and mechanical means, and are not rendered synthetic by chemical reaction. Inputs with high levels of natural environmental contaminants, such as heavy metals, radioactive isotopes, and salinity, may be prohibited or further restricted (Crop and Livestock Criteria: Source and Manufacturing, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Arsenic is not explicitly mentioned in the regulations.

Environmental Issues and Human Health Concerns

Contamination from mining, fracking, coal-fired power plants, arsenic-treated lumber, and arsenic-containing pesticides contribute to increased levels of arsenic in certain locations. As a naturally occurring element, it is not possible to remove arsenic entirely from the environment or food supply. The FDA, therefore, seeks to limit consumer exposure to arsenic to the greatest extent feasible.

The FDA tests arsenic levels in foods as part of a comprehensive approach to monitoring toxic elements and nutrients. The agency prioritizes monitoring inorganic arsenic levels in foods more likely to be eaten by infants and toddlers. These foods are a greater potential source of dietary inorganic arsenic exposure for infants and young children than for adults, because:

- they are commonly consumed by infants and young children;
- infants and children's dietary patterns are often less varied than those of adults, and
- infants and children consume more food relative to their body weight than do adults.

The FDA tests for toxic elements through:

- the Total Diet Study;
- the FDA's Toxic Elements in Food and Foodware, and Radionuclides in Food compliance program; and
- sampling assignments. Sampling assignments may be conducted in response to reports of elevated arsenic levels in certain foods or to focus on a specific food, food additive, or specific food group (such as foods commonly eaten by infants and toddlers).

A December 7, 2022, document issued by the World Health Organization (WHO) titled: "Arsenic" has seven sub tiles: 1) Key Factors; 2) Overview; 3) Sources of Exposure; 4) Health Effects; 5) Magnitude of Problem; 6) Prevention and Control and 7) WHO Response.

The third bullet point under Key Facts reads: "Contaminated water used for drinking, food preparation and irrigation of food crops poses the greatest threat to public health from arsenic." The fourth bullet point reads: "Long term exposure to arsenic from drinking-water and food can cause cancer and skin lesions. It has also been associated with cardiovascular disease and diabetes. In utero and early childhood exposure has been linked to negative impacts on cognitive development and increased deaths in young adults."

The first sentence under Health Effects reads: "Inorganic arsenic is a confirmed carcinogen and is the most significant chemical contaminant in drinking-water globally."

Discussion

Arsenic was discussed at subcommittee on 03 December, 2024 and added additional information under Environmental Issues and Human Health Concerns from a December, 2022 World Health Organization (WHO) document titled: "Arsenic."

Questions to our Stakeholders
None

Strychnine

Reference: 205.602(i)
Technical Report: None
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699).
Sunset Date: 3/15/2027

Subcommittee Review

Use
Strychnine is a toxic alkaloid that is a transparent crystal or white, crystalline powder. It was widely used in poison (toxic) baits to kill rodents and other mammals. Exposure to strychnine can be fatal. It is colorless, odorless and has a bitter taste.

Strychnine can be absorbed into the body by inhalation or ingestion. It can also be injected into the body when mixed with a liquid. Strychnine is rapidly metabolized and detoxified by the liver. This substance is also well-absorbed and acts very rapidly, producing muscular hyperactivity, which can quickly lead to respiratory failure and death.

Strychnine has been placed in Toxicity Category I, indicating the greatest degree of acute toxicity with oral and ocular effects; inhalation toxicity is also presumed to be high.

According to the USDA, above-ground uses were canceled in 1988; however, it remains registered for below-ground use to control damage caused by pocket gophers.

Manufacture
The primary natural source of strychnine is the plant *Strychnos nux-vomica*. This plant is found in southern Asia (India, Sri Lanka, and East Indies) and Australia.

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Strychnine is not explicitly mentioned in the regulations.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Strychnine is not explicitly mentioned in the regulations.

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

- Strychnine is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Strychnine is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Strychnine is not explicitly mentioned in the regulations.

Environmental Issues

According to the EPA, acute toxicity to birds is assumed to be very high. Subacute dietary data indicate that strychnine ranges from slightly to highly toxic to avian species. Strychnine may pose a threat to birds who may be subject to repeated or continuous exposure from spills.

Mammalian studies indicate that strychnine is highly toxic to small mammals on both an acute oral basis and dietary basis. The signs of toxicity, including death, occur within one hour. Acute freshwater fish data reveal that strychnine ranges from moderately to highly toxic to freshwater fish. Aquatic invertebrate acute toxicity data indicates that strychnine is moderately toxic to aquatic invertebrates.

Discussion

There was very little discussion during subcommittee meetings. Previous boards have voted unanimously to keep this material listed as a prohibited substance.

Questions to our Stakeholders

None

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Ethylene
February 4, 2025

Summary of Petition [link]:
In August 2023, the manufacturer of equipment that generates ethylene gas from ethanol submitted a petition to expand the currently allowed uses of ethylene gas in organic handling to include preventing sprouting in stored potatoes and onions.

Summary of Review:
The NOSB Handling Subcommittee (HS) ordered a limited scope Technical Report (2024 TR) to address questions and concerns related specifically to the use of ethylene in the petitioned applications (preventing sprouting of onions and potatoes). HS also relied on the full Technical Report ordered in 2023 (2023 TR) for the sunset evaluation of ethylene used for the ripening of tropical fruits and degreening of citrus. NOSB requested comments on the use of ethylene as a sprout inhibitor at the Fall 2024 meeting as the HS was waiting for the limited scope TR, and received comments from organic potato and onion growers, as well as the Washington State potato commission, all of whom were generally supportive of being able to try a new substance for sprout inhibition.

Category 1: Classification

1. Substance is for: ____x___ **Handling ___ Livestock**

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

Ethylene is not a mineral, bacterial culture, microorganism, a substance derived from crops or livestock, and, therefore, it is not an agricultural substance.

    b. If the substance is **Non-agricultural**, is the substance **Non-synthetic** or __x__ **Synthetic?**

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

In this petition, the manufacturing process of ethylene via an onsite ethylene generator is through the catalytic conversion of ethanol. Ethylene is also manufactured as a pyrolysis product of petroleum hydrocarbon feedstocks and stored in cylinders for future use (2024 TR, lines 42-43). Both of these processes render the final product synthetic despite the fact that they are both chemically identical to naturally occurring ethylene.

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)]

Ethylene is typically used in its pure form or in combination with other allowed gases (nitrogen and carbon dioxide) (2023 TR, lines 197-201). It does not appear to have any detrimental chemical interactions with other materials used in organic farming.

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

There are no known negative effects of ethylene on invertebrates or birds which are the most likely to be exposed to ethylene, and there are no expected negative affects to aquatic organisms as ethylene gas does not end up in water. Additionally, concentrations of ethylene found to have adverse effects on rats are considerably higher than concentrations expected in the environment (2023 TR, lines 515-517). Terrestrial plants are highly sensitive to ethylene in air, yet Health Canada concluded through monitoring of industrial ethylene releases 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 (2023 TR, lines 522-527). Ethylene used in ripening, degreening, or sprout prevention ultimately remains in the atmosphere and only negligible amounts will partition to soil, water and sediment (2023 TR, lines 501-502). The amount of ethylene released due to these uses is not known, but it is assumed to be lower than the 1.8 million pounds annually used to regulate pineapple flowering in the field (2023 TR, lines 511-512).

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

The manufacture of ethylene does produce significant amounts of carbon dioxide, and by some estimates, is responsible for 16% of direct global CO_2 emissions (2023 TR, lines 479-483). Petroleum refineries are a major source of hazardous and toxic air pollutants. It is not known how much of the global production of ethylene is used for fruit ripening or degreening, but it is very little as compared to other industrial manufacturing uses of ethylene.

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

Ethylene used as a growth regulator to prevent sprouting in potatoes and onions requires concentrations of 10-15 ppm, and EPA concluded that ethylene in these concentrations would be considered nontoxic (2024 TR, lines 261-263). In the UK, a self-contained breathing apparatus is required for ethylene use only when concentrations are above 1000 ppm (2024 TR, lines 266-267). The EPA-approved label for the Restrain Generator (ethylene produced onsite) requires only long-sleeved shirt, long pants, shoes, and socks (2024 TR, lines 269-270).

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)]

Since ethylene used for preventing sprouting of potatoes and onions does not end up in the soil, its effects on soil organisms are negligible.

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

Health Canada concluded that the risk to biodiversity from the use of ethylene as a plant growth regulator was very low (2023 TR, lines 522-527).

Category 3: Alternatives/Compatibility

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

In potato and onion cultivation a number of management practices are used to produce crops that are better suited to storage conditions including cultivar choice, curing, irrigation practices, maturity at harvest, and nutrient management. In addition, storage conditions like light, temperature, and humidity are managed to prevent spoilage and sprouting (2024 TR, lines 304-316). Carbon dioxide can be used to control sprouting; however, CO_2 can also damage potato tissues if not managed carefully (2024 TR, line 407). Currently, handlers are also using nonsynthetic essential oils such as carvone, limonene, and eugenol with limited success in managing sprouting. Public commenters to NOSB in the Fall 2024 meeting indicated that use of eugenol (clove oil) can have negative effects on the skin and respiration of workers who must apply the substance regularly to achieve effectiveness.

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

Ethylene does not appear to have significant negative impacts on the environment and appears to be able to replace some less effective and more harmful substances currently in use to prevent sprouting of potatoes and onions.

Category 4: Additional criteria for synthetic substances used in Handling (does not apply to nonsynthetic or agricultural substances used in organic handling):

Describe how the petitioned substance meets or fails to meet each numbered criterion.

1. The substance cannot be produced from a natural source and there are no organic substitutes; (§205.600(b)(1)).

Ethylene does not appear to be readily available in a natural form.

2. The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling; (§205.600(b)(2)).

Ethylene's use as a post-harvest substance does not appear to directly cause negative environmental effects. It is a product of the fossil fuel industry, which has significant negative impacts on the environment. However, the use of ethylene as a post-harvest substance represents a negligible percentage of total ethylene usage worldwide.

3. The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations; (§205.600(b)(3)).

Ethylene is a volatile substance that does not remain in or on food (2024 TR, line 216). Potatoes and onions are at peak nutritional quality at harvest. In delaying the sprouting event, ethylene maintains nutritional quality as well as safety (2024 TR, lines 225-226).

4. The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law; (§205.600(b)(4)).

Ethylene is not considered to be a preservative (2024 TR, line 221).

5. The substance is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; (§205.600(b)(5)).

Ethylene is not considered GRAS since it is not regulated by FDA. It is considered a pesticide by EPA and exempt from any residue tolerance restriction at 40 CFR 180.1016 (2023 TR, lines 380-381).

6. The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6))

While prolonging storage times of annual temperate crops like potatoes and onions may not be essential to all organic stakeholders, having the ability to lengthen storage of these crops allows for longer marketing windows for producers and handlers, higher quality, less cullage, less reliance on shipping crops long distances for counter-seasonal supply, and, in the case of potatoes, an ability to produce higher quality seed tubers for the next year's production. Due to the limited efficacy of natural alternatives and management options, the use of ethylene for preventing sprouting in potatoes and onions is essential.

7. In balancing the responses to the criteria in Categories 2, 3 and 4, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, Compatibility with Organic Production and Handling, April 2004)

Yes. It appears that ethylene is compatible with a system of organic agriculture. Its chief benefits are preventing spoilage of stored potatoes and onions, lengthening marketing windows for these crops, reducing reliance on crops shipped long distances to fill demand gaps, increasing quality of organic seed tubers, and reducing worker exposure to irritants from the natural alternatives for sprout inhibition, namely eugenol (clove oil). Additionally, ethylene is currently approved for preventing sprouting in potatoes and onions in Canada and the EU.

Classification Motion:
Ethylene is already classified as synthetic.

National List Motion:
Motion to amend the listing of ethylene at § 205.605(b)(14) Ethylene—allowed for postharvest ripening of tropical fruit, ~~and~~ degreening of citrus, and postharvest sprouting inhibition of potatoes and onions.

Motion by: Nate Lewis
Seconded by: Kyla Smith
Yes: 9 No: 0 Abstain: 0 Recuse: 0 Absent: 0

National Organic Standards Board
Handling Subcommittee
Fish Oil CAS Technical Correction Proposal
January 7, 2025

Summary of Issue
A public commenter identified an apparent error in the fish oil listing at 7 CFR 205.606. The listing includes two fatty acid CAS numbers (10417–94–4 and 25167–62–8); however, fish oil itself does not have a CAS number. The Handling Subcommittee recommends deleting the CAS numbers, as a technical correction to the listing, to avoid confusion.

Background
In response to petition question 8 regarding CAS numbers, the 2007 petition to add fish oil to the National List stated, "The 18/12TG fish oil that is the subject of this petition is a mixture of fatty acids; therefore, no Chemical Abstracts Service (CAS) Registry Number exists for this substance. The CAS Registry Numbers for EPA and DHA, the primary components of this product, are 10417-94-4 and 25167-62-8, respectively."

The 2007 NOSB recommendation to add fish oil to the National List only recommended adding "fish oil" to 7 CFR 205.606. However, the 2007 interim final rule added the current listing, "Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8)—stabilized with organic ingredients or only with ingredients on the National List, §§ 205.605 and 205.606."

During the 2024 sunset review of fish oil, the NOSB received a public comment that noted the CAS numbers in the listing are incorrect.

Discussion
The Subcommittee appreciates the public comment that brought this issue to the NOSB's attention. Upon review, it appears that the CAS numbers included in the listing describe individual components of the fish oil, but not fish oil itself, and were included in the listing in error. Since the listing is for fish oil, and the NOSB's recommendation was to add fish oil, not its individual components, to the National List, the Subcommittee recommends removing the CAS numbers as a technical correction to the listing.

Subcommittee Motion:
Motion to eliminate the CAS numbers included in the fish oil listing at 7 CFR 205.606, as a technical correction, so it reads: "(f) Fish oil—stabilized with organic ingredients or only with ingredients on the National List, §§ 205.605 and 205.606"

Motion by: Allison Johnson
Second by: Dilip Nandwani
Yes: 8 No: 0 Abstain: 0 Recuse: 0 Absent: 1

National Organic Standards Board
Handling Subcommittee
L-Malic Acid Reclassification Discussion Document
February 4, 2025

Summary of Issue

Reclassification of L-malic acid has been on the National Organic Standards Board (NOSB) work agenda for a number of years, and it was put on hold in 2020. The Handling Subcommittee is attempting to resolve confusion and ensure consistency in use of this material by recommending the addition of synthetic L-malic acid to 7 CFR 205.605(b) with a commercial availability limitation, in addition to retaining the nonsynthetic listing currently included at 7 CFR 205.605(a). This change would align the regulations with current use practices, as well as codify a preference for the nonsynthetic version.

Background

L-malic acid can be obtained by enzymatic synthesis or fermentation (2019 Technical Report [TR], lines 53-54).

There are two main pathways for producing L-malic acid on a commercial scale (2019 TR, lines 282-292):

- **Two-step process**:
    1. Production of fumaric acid, either synthetically from petroleum or by fermentation of carbohydrates;
    2. Enzymatic conversion of fumaric acid to L-malic acid.
- **One-step process**: Fermentation using carbohydrates.

Under NOP Guidance 5033-1, natural substances that undergo strictly biological processes, including fermentation and enzymatic conversion, are determined to be nonsynthetic. Accordingly, the product of the one-step process is nonsynthetic L-malic acid. In addition, the fermentation and enzymatic conversion used in the two-step process are nonsynthetic processes. However, the synthetic/non-synthetic status of the product of the two-step process depends on how fumaric acid is produced. When fumaric acid is produced from fermentation of carbohydrates, the resulting L-malic acid is nonsynthetic (2019 TR, lines 361-386). The status of L-malic acid resulting from synthetically produced fumaric acid, however, depends on what is considered the "natural source" (2019 TR, lines 388-391). If synthetic fumaric acid is considered the "source," the resulting L-malic acid is synthetic; if the "source" is the solution resulting from the microbial fermentation (the "culture broth"), from which the L-malic acid is extracted, the L-malic acid could be considered nonsynthetic (2019 TR, lines 392-394, 412). The 2019 TR notes that the starting material or growth medium have not been consistently used to categorize the non/synthetic status of materials (2019 TR, lines 418-419) – that is, that guidance on materials produced through fermentation has not placed restrictions on the use of synthetic growth media in the production of a nonsynthetic input.

There are several other ways to produce L-malic acid that are not commercially relevant options. L-malic acid occurs naturally in many fruits and vegetables, including apples and cherries (2019 TR, lines 85-87); however, it is not economical to extract L-malic acid from natural foodstuffs (2019 TR, line 282). L-malic acid may also be separated from synthetically produced DL-malic acid; however, this process is expensive and not used to make commercial quantities (2019 TR, lines 294-328).

DL-malic acid, the material that was originally petitioned for inclusion on the National List, is a mixture of L-malic acid and D-malic acid. Production of DL-malic acid starts with petroleum products and involves chemical changes that are not the result of naturally occurring biological processes (2019 TR, lines 294-314); the process is similar to that used to produce the synthetic fumaric acid that can feed

into the two-step process for L-malic acid production (2019 TR, lines 314-316). In the original 2003 TAP review, all three reviewers concluded that DL-malic acid is synthetic and should not be added to the National List because a non-synthetic alternative (L-malic acid produced by double fermentation) was viable (2003 TAP, p. 1). The TAP noted that L-malic acid is produced by fermentation of fumaric acid and that fumaric acid can be produced by fermentation from glucose (2003 TAP, p. 5). The reviewers recommended rejecting DL-malic acid because L-malic acid produced from fermentation of carbohydrates seemed like a potential non-synthetic alternative; however, they also noted that they did not have full information about the commercial availability of L-malic acid from a natural source (2003 TAP, pp. 8, 10, 12). None of the reviewers directly addressed L-malic acid derived from synthetic fumaric acid, but the emphasis on fermentation of glucose implies that they would have viewed the synthetic fumaric acid version as synthetic and incompatible with organic production.

The Handling Subcommittee noted in the Spring 2019 sunset document for L-malic acid that the material should be placed on 7 CFR 205.605(b), in light of the new information about the manufacturing process and role of synthetic fumaric acid described in the 2019 TR. However, the Subcommittee noted that reclassification could not be completed via sunset review and proposed to address reclassification separately at a future meeting. The Subcommittee then considered an L-malic acid reclassification discussion document in Spring 2020 that asked stakeholders for input on the classification question, the potential precedential impacts, and the availability of L-malic acid derived from different processes and raw materials. Questions raised in comments about the impact of this classification decision on review of other materials appear to have generated enough confusion that the NOSB ultimately put this work agenda item on hold.

Discussion

There appears to be general consensus that the substance currently in use by many organic processors is classified as “synthetic” and that if its use should continue, it should be listed at 7 CFR 205.605(b). The NOSB did not receive any comments at the Spring 2024 meeting that quantified the amount of nonsynthetic L-malic acid currently in use, but commenters confirmed that most of what is currently in use would be classified as “synthetic.” There were numerous opinions regarding how “synthetic” L-malic acid should be considered or added to the National List. Some commenters preferred adding L-malic at 7 CFR 205.605(b) and keeping the nonsynthetic listing at 205.605(a). Some commenters preferred removing L-malic from 205.605(a) and requiring a petition to add it at 205.605(b).

The original review of this material resulted in addition of L-malic acid to only § 205.605(a), as an alternative to adding synthetic DL-malic acid to the National List. However, the NOSB’s recommendation appears to have been based on incomplete information about the commercial availability of L-malic acid produced from fumaric acid derived from fermentation, rather than fumaric acid derived from a synthetic process. Currently, there does not appear to be an adequate supply of nonsynthetic L-malic acid to meet demand for L-malic acid from organic processors.

Given that the original non-synthetic listing was based on a presumption of commercial availability that has not turned out to be accurate, and L-malic acid has repeatedly been determined necessary for organic production, the Subcommittee recommends adding synthetic L-malic acid to 7 CFR 205.605(b), with a commercial availability annotation. This change will accurately reflect the current practice of allowing L-malic acid produced from synthetic fumaric acid in organic food processing, while codifying a preference for the nonsynthetic version. The Subcommittee also recommends retaining the listing for nonsynthetic L-malic acid at 7 CFR 205.605(a), as there may currently be nonsynthetic forms of L-malic acid in use. If commercial quantities of non-synthetic L-malic acid become available, organic processors can shift to the nonsynthetic option, as long as the listing at 7 CFR 205.605(a) is retained. The ongoing sunset review of both versions will provide opportunities to continue to examine the availability of and

need for each form, as well as the environmental and health concerns associated with fumaric acid derived from petroleum.

The Subcommittee put forward a proposal at the Fall 2024 meeting, and the NOSB voted to return the proposal to the Subcommittee to clarify and address concerns raised in comments. The Subcommittee considered two key concerns:

1. **Precedent**: Because the need for reclassification turns on the lack of commercial availability of a nonsynthetic material (L-malic acid produced from fumaric acid derived from fermentation of glucose) that was originally listed based on a presumption of commercial availability, the implications of action taken will be specific and confined to L-malic acid. It would not establish a general precedent for adding synthetic materials to the National List. The NOSB will continue to identify and address areas where current practice does not align with the letter of the law and make recommendations to improve alignment and compliance with OFPA.

2. **Fermentation**: Commenters raised concerns about the implication of reclassification on other materials that are the product of fermentation. Reclassification of L-malic acid is consistent with NOP Guidance 5033-1, in that a synthetic material cannot become nonsynthetic even if it is subjected to additional nonsynthetic processes. The Subcommittee is not aware of any other materials currently included on the National List that are listed as nonsynthetic but derived from a synthetic primary source material. If there are other materials that may be in a similar situation, the Subcommittee welcomes that feedback and could address them accordingly. To the extent that there are broader questions about the synthetic/nonsynthetic mix of ingredients that may be included in growth media, those issues may be dealt with separately (and if necessary, applied to the L-malic acid listings at that time).

Questions for Stakeholders

1. Organic processors currently use L-malic acid derived from synthetic fumaric acid, and there does not appear to be sufficient supply of nonsynthetic L-malic acid to meet demand. The Subcommittee recommends updating the National List to align with current practice and attaching a commercial availability requirement to the use of synthetic L-malic acid, to drive use toward the nonsynthetic form if it becomes more widely available. Are there any alternative approaches to addressing this issue that the Subcommittee should consider?

Subcommittee Vote:
Motion to accept the discussion document on; 1) classifying L-malic acid produced from synthetic fumaric acid as synthetic, and 2) adding the following to 7 CFR 205.605(b): L-malic acid, when nonsynthetic L-malic acid is not commercially available.

Motion by: Allison Johnson
Second by: Dilip Nandwani
Yes: 9 No: 0 Abstain: 0 Recuse: 0 Absent: 0

Sunset 2027
Meeting 1 - Request for Public Comment
Handling Substances §§ 205.605(a) 205.605(b) & 205.606
Spring 2025

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 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 2025 public meeting, the NOP requests that the public provide comments about these substances to the NOSB as part of the Spring 2025 public meeting. Written comments should be submitted via Regulations.gov at www.regulations.gov during the comment period as explained in the meeting notice published in the Federal Register.

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:

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

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 via www.regulations.gov during the open comment period noted in the Federal Register. Comments received after that date may not be reviewed by the NOSB before the meeting.

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

Kaolin
Sodium bicarbonate
Waxes-nonsynthetic (wood resin)

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

Ammonium bicarbonate
Ammonium carbonate
Calcium phosphates (monobasic, dibasic, and tribasic)
Low-acyl gellan gum
Ozone
Sodium hydroxide

§205.606 Sunsets: Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic.":

Carnauba wax
Colors:
(1) Beet juice extract color
(2) Beta-carotene extract color
(3) Black/purple carrot juice color
(4) Chokeberry, aronia juice color
(5) Elderberry juice color
(6) Grape skin extract color
(7) Purple sweet potato juice color
(8) Red cabbage extract color
(9) Red radish extract color
(10) Saffron extract color
Cornstarch (native)
Glycerin
Inulin-oligofructose enriched
Orange shellac

Kaolin

Reference: 205.605(a)(15)
Technical Report: 1995 TAP (kaolin, bentonite)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Kaolin is a filtration component in the manufacture of juices organic juices. It is also an ingredient in personal care products, used as a filler, additive, and functional ingredient. While past reviews have suggested that kaolin at one time was used as anti-caking agent in processed food (1995 TAP), there is no evidence this use continues.

The 2025 TR for kaolin identified several other relevant uses for kaolin: post-harvest pest control of stored grains; clarification of fruit wine; and filtration of seed oils.

Manufacture

Kaolin is a soft white clay consisting principally of the mineral kaolinite. Kaolin clays are formed by weathering and/or hydrothermal alteration of granites and rhyolites. It is found worldwide and commonly mined in many locations.

International Acceptance

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Kaolin is permitted as a clarifying agent (Table 6.5 – Processing aids, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165Kaolinitic clays, free of asbestos, are permitted (Binders and anti-caking agents, EC No. 2021/1165).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Kaolin is permitted (Table 4 - Processing aids which may be used for the preparation of products of agricultural origin, CXG 32-1999).
Kaolin is permitted in the extraction of propolis (For livestock and bee products, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)
Kaolin is permitted as a processing/post-harvest handling aid (Table 1 - List of Approved Additives and Processing/Post-Harvest Handling Aids, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production
Kaolin is permitted: limited to the use in processed products of plant origin (Table A.1 – Additives, JAS for Organic Processed Foods).

Environmental Issues

Historically, kaolin has not been the focus of significant environmental concern beyond persistent questions related to global mining practices which can affect sensitive areas, habitats, and native soils, and both terrestrial and aquatic ecosystems. The mining process also results in significant waste byproducts (mostly sand and rock). The 2025 TR specifically mentions research that has been done in the Brazilian Amazon on the ecosystem impacts (forest canopy loss) from various industrial activities that include kaolin mining, as well as impacts in Chinese kaolin mining areas on soil bacterial and fungal communities. Larger organisms – including megafauna (mammals, birds, and fish) – appear to be more affected by the impacts of kaolin mining than smaller ones. This updated technical review also provided evidence of ecosystem resilience in various contexts where kaolin mining occurs.

The 2025 TR did indicate that heavy metals (particularly lead and cadmium) can be found in raw, whole kaolin materials, sometimes at levels of health concern. The TR included a limited survey that identified two kaolin materials that exceeded the specified tolerances for arsenic and lead.

Regulatory bodies overseeing various applications of kaolin relevant to this listing generally considered kaolin, when used responsibly, to be safe for use. Most concerns around health risk exposure from

consumption of kaolin relates to those who consume it specifically and intentionally, in which case it can be linked to iron-deficiency anemia; anemia during pregnancy; potassium deficiency; and bowel obstruction and perforation.

The TR also discusses the potential for nano-sized kaolin particles to appear in food-contact packaging, but also acknowledges that these considerations are outside the scope of this review.

Ancillary Substances

In the use of kaolin in clarification of fruit wines, the 2025 TR did indicate the following from the Alcohol and Tobacco Tax and Trade Bureau (TTB) regulations: "Inert fibers, pulps, earths, or similar materials, may be used as filtering aids in the cellar treatment and finishing of wine. Agar-agar, carrageenan, cellulose, and diatomaceous earth are commonly employed as inert filtering and clarifying aids. In general, there is no limitation on the use of inert materials and no records need to be maintained concerning their use."

Discussion

There were minimal comments about kaolin during the previous sunset review period in 2020. Multiple certifiers conveyed that kaolin appeared in a number of Organic System Plans. The Handling Subcommittee, and ultimately the full Board, continued to view this material as relatively benign with no significant environmental or health concerns.

Given the updated review of kaolin in the form of the 2025 TR, the Handling Subcommittee looks forward to fresh insights from the community.

Questions to Our Stakeholders

1. Does kaolin appear in more Organic System Plans that it has during previous reviews? In other words, is the substance in growing or declining use?
2. Does the community have additional information about the presence of heavy metals in some kaolin products?

Sodium bicarbonate

Reference: 205.605(a)(26)
Technical Report: 1995 TAP (Baking powder, aluminum-free); 1995 TAP (Sodium carbonates)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use

Sodium carbonates are used as raising (leavening) agents in food processing. Sodium bicarbonate (baking soda) is a common compound in baking powder; that helps to regulate acidity for things like tomato soup, or in pastes and beverages. It can be used as an anti-caking agent or as a stabilizer helping to maintain the appearance and consistency of foods. Sodium bicarbonate is often used in pancakes, biscuits, muffins,

crackers, and in cookies. It often is used in self-rising flour and confections. It may also be used as a neutralizer for use in butter, cream, and ice cream.

Manufacture
The main source of sodium bicarbonate is from natural deposits of trona ore. It can also come from natural brine found in Searles Lake, California. Trona ore (sodium sesquicarbonate) is heated and then mixed with water to dissolve the soda ash and separate out the impurities. Then it is allowed to evaporate to crystallization. Carbon dioxide is added to the kiln gas to a saturated pure sodium carbonate solution, after which the sodium bicarbonate then precipitates out.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Sodium bicarbonate (baking soda) is permitted (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- Sodium bicarbonate (baking soda) is permitted (Table 6.5 – Processing aids, CAN/CGSB-32.311-2020).
- Sodium bicarbonate (baking soda) is permitted (Table 7.3 – Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

- Sodium hydrogen carbonate is permitted in foods of both plant (confectionery, bakery wares) and animal (dairy products and analogues, excluding products of food category) origin (Table 3 - Ingredients of Non-Agricultural Origin, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

Japan Agricultural Standard (JAS) for Organic Production

- Sodium bicarbonate is permitted: limited to the use in confectionery, sugar, prepared legumes/beans, noodles, or bread; or as a neutralizer in dairy products (Table A.1 – Additives, JAS for Organic Processed Foods).
- Sodium bicarbonate is permitted: limited to the use in confectionery, sugar, prepared legumes/beans, noodles, bread, beverages, processed vegetable products, or processed fruit products; or as a neutralizer in dairy products (Table A.1 – Additives, JAS for Organic Processed Foods).
- Sodium bicarbonate is permitted (Table B.1 – Additives, JAS for Organic Processed Foods).
- Sodium bicarbonate is permitted (Table C.1 – Chemical Agents, JAS for Organic Processed Foods).
- Sodium bicarbonate is permitted (Table B.1 - Agricultural chemicals, JAS for Organic Products of Plant Origin).

Ancillary Substances
None

Environmental Issues
Since sodium bicarbonate is derived from sodium sesquicarbonate, a mined material, and the usual environmental issues of mining would be present. However, no major issues have been raised in past reviews.

Human Health issues
None

Discussion
The original Technical Advisory Panel Report (TAP) combined the two sodium carbonates (sodium carbonate and sodium bicarbonate) for their preliminary review. The original TAP, previous Subcommittee reviews, public comments, historical information, and current review indicate no environmental concerns. Likewise, there were no human health concerns raised during the original TAP review or during the following sunset reviews. Previous public commenters have noted that sodium bicarbonate is a primary component of baking powder and is still widely used in a variety of baked goods, and that it is an essential leavening agent.

The Handling Subcommittee was awaiting a new TR on sodium bicarbonate at the time of this review

Questions:
Is there any new information related to environmental concerns, human health, or use that would cause this substance to be considered for delisting?

Waxes (Wood rosin) (sic. resin)

Reference: 205.605(a)(29) Nonsynthetics allowed: Waxes—nonsynthetic (Carnauba wax; and Wood resin).
Technical Report: 1996 TAP; 2014 TR waxes; 2014 TR - Wood Rosin
Petition(s): N/A
Past NOSB Actions: NOSB minutes and vote 09/1996; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699); Technical correction: 11/14/2022 87 FR 68021
Sunset Date: 3/15/2027

Subcommittee Review

Use
According to the 2014 technical report (TR), wood rosin is used in organic processing and handling primarily as a component of fruit wax, most commonly applied to citrus fruit (2014 TR, line 86).

At the most basic level, wood rosin, when formulated as part of a fruit wax, reduces the gas exchange between the surface of the fruit and the atmosphere, which in turn reduces the respiration rate and resulting weight loss. The reduced gas exchange happens in two ways: the wax forms a physical barrier that the gas must permeate, and the coating also fills openings in the fruit peel. Hagenmeier and Baker (1993) found that some factors, such as thickness of coating and the waxiness vs. resinous qualities of the coating, also affect the action of fruit waxes. For example, coating thickness is as important as type of coating for resistance to water vapor. Wood rosin, when formulated with carnauba wax at differing percentages, only offers limited resistance to water vapor unless carnauba wax comprises approximately 90% of the formula (2014 TR, lines 120-128).

Manufacture

Wood chips are passed through a series of extractors, where each batch of new chips is extracted with several portions of solvent in succession. Each portion of solvent is used on several different batches of chips. This is a counter-current process where fresh solvent is used on the final extraction of the wood chips, and then it is successively used on the chips that receive one, two, or three more extractions. Thus, the oldest solvent is used on the freshest wood chips. After the wood chips have received the final solvent extraction wash, the solvent is drained and the chips are pressure-steamed to recover any residual solvent. The solvent from the terpene oil-rosin solutions leaving the extractors is recovered by vacuum-distillation separation and reused for subsequent extraction processes. The resulting terpene oils are separated by fractional distillation into refined terpentine, dipentene, and pine oil. The remaining residue is the non-volatile extract and is considered to be crude wood rosin (not food grade). The crude wood rosin is further refined and purified by a liquid fractionation process. It is placed into refining towers, where a proprietary polar solvent is used to extract the darker components. According to the EPA Toxic Release Inventory (2013), methanol is the likely solvent used in this process step. The solvent is evaporated off, recovered, and reused. The resulting lighter wood rosin is called Vinsol and the remaining, darker grade (Grade K) wood rosin is considered ”food grade” and permitted as an ingredient in citrus fruit waxes. The manufacturing process may differ by the solvents used, but this is the only known method for manufacturing wood rosin. No chemical changes occur during the extraction and refinement of wood rosin (2014 TR, lines 230-248).

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Wood rosin is not explicitly mentioned in the regulations.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Pine rosin extract is permitted for the processing of sugar only for antimicrobial purposes and must be from organic production, if available (Processing aids and other products, EC No. 2021/1165).
- Aleppo pine resin is permitted (Authorised products and substances for the production and conservation of organic grapevine products of the wine sector, EC No. 2021/1165).

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

- Wood rosin is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Wood rosin is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Wood rosin is not explicitly mentioned in the regulations.

Ancillary Substances

Raw wood rosin is sold directly to further formulators of fruit wax and other products without any additional ingredients such as stabilizers or preservatives (2014 TR, lines 141-142).

Human Health and Environmental Issues

Wood rosin is derived from two pine species including Longleaf pine, which is categorized as endangered by the IUCN Red List of Threatened Species (2013). While wood rosin is considered a by-product of the timber industry (derived from the remaining tree stumps), the conversion of farmland for timber use has

contributed to the decline of Longleaf pine which, due to its slow growth, cannot economically compete with other pine species for replanting (2014 TR, lines 380-389).

The solvent extraction of wood rosin from wood chips has the potential to negatively affect human health. Although the specific solvents used by Pinova, Inc. are proprietary, the EPA Toxic Release Inventory (2013) suggests that methyl isobutyl ketone (MIBK) is the likely solvent used for the initial extraction, and methanol for further refinement. According to the EPA (2003), human studies of acute inhalation exposures to MIBK indicated "transient sensory irritation, neurological effects, and/or strong odor sensation during exposure." Another study showed some nose and throat irritation at an exposure rate of 100-200 mg/m^3. A study by the National Institute for Occupational Safety and Health, on the other hand, did not find any changes in neurological or irritation systems after a 2-hour exposure to MIBK at 100ppm. For the second extraction step, methanol is considered to be environmentally preferable to other solvents of similar properties. However, workers repeatedly exposed to methanol have experienced headaches, sleep disorders, gastrointestinal problems, and optic nerve damage. Exposure to large amounts of methanol can result in death or severe abdominal, leg, and back pain. No information is available on the carcinogenic, reproductive, and developmental effects of methanol in humans, but birth defects have been observed in the offspring of rats and mice exposed to methanol by inhalation (2014 TR, lines 392-414).

Discussion
The three main pine species in the southeast are Loblolly, Slash, and Longleaf. Wood rosin is derived primarily from Slash and Longleaf. Slash and Loblolly pine grow much faster than Longleaf and are, therefore, the predominate species planted for timber production. Stump removal after timber is harvested is very expensive but necessary cleanup for the land to be replanted or converted for other uses. With recent hurricanes in the Southeast, thousands of acres of pine timber tracts were damaged. Hurricane winds typically cause these trees to twist or snap, making them unmarketable. However, this material could be used to produce wood rosin. Previous Boards voted overwhelmingly in favor of keeping this material on the National List.

Questions to our Stakeholders
1. Could damaged trees from hurricanes be used to produce wood rosin?

Ammonium bicarbonate

Reference: 205.605(b)(4) - for use only as a leavening agent
Technical Report: 1995 TAP (Ammonium bicarbonate, Ammonium carbonate); 2025 TR (Handling)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Ammonium bicarbonate and carbonate are salts composed of ammonium and carbonate ions. Ammonium bicarbonate is the monoammonium salt of carbonic acid with the formula NH_4HCO_3 and a molecular weight of 79.06 g/mol.

Ammonium carbonates are used as leavening agents. Ammonium bicarbonate has critical functionality as a raising (leavening) agent in certain cookies and crackers. Compared to baking soda, it produces more gas, thus not leaving behind a salty or soapy taste in the finished baked goods, as it completely decomposes into water and gaseous products that evaporate during the baking process. It is used in baking where yeast is not used. Ammonium bicarbonate cannot be used for moist baked goods. It also helps provide certain characteristic textures (such as in crackers), as well as aids in controlling cookie spread.

This is the only leavening agent (ammonium carbonates) that is completely eliminated through the baking process. There are no organic alternatives to replace ammonium bicarbonate.

Manufacture
The ammonium carbonates are made from ammonia and carbon dioxide. Ammonium bicarbonate is made when carbon dioxide is bubbled through an ammonia solution. Crystals of ammonium bicarbonate precipitate from this saturated solution.

International Acceptance
Ammonium carbonates are approved for use in the following organic standards: They are considered GRAS by the FDA

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Ammonium bicarbonate is permitted as a leavening agent (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Ammonium bicarbonate is not explicitly mentioned in the regulations.
CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Ammonium hydrogen carbonate is permitted for use as an acidity regulator and raising agent in food of plant origin with some GSFA exclusions but is not permitted in food of animal origin (Additives permitted for use under specified conditions in certain organic food categories or individual food items, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)
Ammonium bicarbonate is not explicitly mentioned in the regulations.
Japan Agricultural Standard (JAS) for Organic Production
Ammonium bicarbonate is permitted: limited to the use in processed products of plant origin (Table A.1 – Additives, JAS for Organic Processed Foods).

Ancillary Substances
None

Environmental Issues
The original 1995 TAP combined the two ammonium carbonates (ammonium carbonate and ammonium bicarbonate) for their preliminary review. Subsequently, they have been looked at together during their previous two sunset reviews. The original TAP, previous subcommittee review, public comments, historical information, and current review all found no environmental concerns, and no concerns have been brought to the subcommittee's attention during this current review.

Human Health Issues

Likewise, there were no human health concerns raised during the original TAP review or during the following two sunset reviews. The current sunset review and public comment periods (oral and written) have also not raised any environmental concerns, human health concerns, or any other reasons for why this material should not continue to be allowed for organic handling.

Discussion
During the previous public comment period, a stakeholder mentioned that this material was still critical for handlers, especially for baking crackers and similar baked goods. Other commenters supported its continued allowance on the National List. There were no comments against its relisting.

Questions
None

Ammonium carbonate

Reference: 205.605(b)(5) – for use only as a leavening agent
Technical Report: 1995 TAP (Ammonium bicarbonate, Ammonium carbonate); 2025 TR (Handling)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Past NOSB Review
The NOSB found no concerns regarding the continued listing of ammonium carbonate. This material still continues to satisfy all OFPA criteria, and public comments confirmed its current use and need.

Subcommittee Review
Use:
Ammonium bicarbonate and carbonate are salts composed of ammonium and carbonate ions. Ammonium carbonate is the diammonium salt of carbonic acid with the generalized formula $(NH_4)_2CO_3$ and a molecular weight of 96.09 g/mol.

Ammonium carbonates are used as leavening agents. Ammonium carbonate is used as a raising (leavening) agent for flat baked goods such as cookies and crackers. It is often referred to as “Bakers Ammonia” in cooking recipes and by chefs. Ammonium carbonate is also used to make breadsticks, cookies, and crackers because it helps to make them both lighter and crispier. It is also used in many traditional Greek cooking recipes. The ammonium carbonates are heat activated, so baked goods will not rise until whatever is being baked actually goes into the oven, thus helping with food preparation and time requirements. This is the only leavening agent (ammonium carbonates) that is completely eliminated through the baking process. There are no organic alternatives to replace the ammonium carbonates.

Manufacture
Ammonium carbonates are manufactured by the reaction of ammonia sourced from the synthetic Haber-Bosch process with carbon dioxide sourced from industrial processes like power generation, cement manufacturing, or fossil fuel processing. Ammonium carbonate is made when carbon dioxide is passed

through an ammonia solution and by then allowing the vapors to distill, thus the resulting solid is ammonium carbonate.

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Ammonium carbonate is permitted as a leavening agent (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- Ammonium carbonate is permitted as an attractant in insect traps (Table 8.2 – Facility pest management substances, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Ammonium carbonates are permitted in products of plant origin (Section A1 – Food Additives including carriers, EC No. 2021/1165).

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

- Ammonium carbonate is permitted for use as an acidity regulator and raising agent in food of plant origin with some GSFA exclusions but is not permitted in food of animal origin (Additives permitted for use under specified conditions in certain organic food categories or individual food items, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Ammonium carbonates are permitted as additives only for cereal products, confectionery, cakes, and biscuits (Table 1 - List of Approved Additives and Processing/Post-Harvest Handling Aids, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Ammonium carbonate is permitted (Table A.1 – Additives, JAS for Organic Processed Foods).
- Ammonium carbonate is permitted (Table B.1 – Additives, JAS for Organic Processed Foods).

Ancillary Substances

None

Discussion

The original 1995 TAP combined the two ammonium carbonates (ammonium carbonate and ammonium bicarbonate) for their preliminary review. Subsequently, they have been looked at together during their previous two sunset reviews. The original TAP, previous subcommittee review, public comments, historical information, and current review all found no environmental concerns. Likewise, there were no human health concerns raised during the original TAP review or during the following two reviews.

According to 2024 TR (pg. 18)-Aquatic animals are especially susceptible to the toxic effects of ammonia because they have thin permeable skin surfaces; even very low concentrations of ammonia can cause fish mortality.

Questions

None

Calcium phosphates (monobasic, dibasic, and tribasic)

Reference: 205.605(b)(9)
Technical Report: 1995 TAP; 2016 TR (Phosphates)
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Calcium phosphates are used as raising (leavening) agents and used as a critical component in baking powder (aluminum free). All three of the calcium phosphates are used as leavening agents: dough conditioner, yeast food, or as an expanding agent. Monobasic and dibasic calcium phosphate are often used for reduced sodium baking. Monobasic is also a buffer, firming agent, sequestering agent, and is popular in pancake mixes. It is the commonly used acid, along with sodium bicarbonate, used to make baking powder. It is also used in baked goods, such as cookies, cakes, and potato chips, and as a firming agent for canned fruits and vegetables. Dibasic is used in enriched flour, noodle products, and in both dry and cooked forms of breakfast cereals. It is often used as a dough conditioner. It also can be used as a thickening agent for various cheese products. Tribasic is an anti-caking agent and buffering agent. It also provides a very critical function as a free flow aid in finely powdered salt used in baking. Additionally, it is used as a food source for yeast in bread making, as an anti-caking agent in dry powders, such as in spices, and as a thickener, stabilizer, and sequestering agent for some dairy products. Calcium is derived from either mined limestone or from oyster shells.

Manufacture
Calcium and phosphorus are sourced from limestone and phosphate rock, respectively. The food grade phosphates are formed by reacting purified phosphoric acid with sodium, potassium, or calcium hydroxides (2016 TR, lines 43-44).

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Calcium phosphates (mono-, di-, and tribasic forms) are permitted (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Dicalcium phosphate is permitted (Feed Materials of Mineral Origin, EC No. 2021/1165).
- Monocalcium phosphate is permitted (Feed Materials of Mineral Origin, EC No. 2021/1165).
- Monocalcium phosphate is permitted in self-rising flour as a raising agent (Section A1 – Food Additives including carriers, EC No. 2021/1165).

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

- Monocalcium orthophosphate is permitted in food of plant origin (flours) but is not permitted in food of animal origin (Additives permitted for use under specified conditions in certain organic food categories or individual food items, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Monocalcium phosphate is permitted as an additive only for raising flour (Table 1 - List of Approved Additives and Processing/Post-Harvest Handling Aids, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Limestone etc. are permitted: Limestone, shelly fossils, seashells, dolomite, phosphate rocks, and diatomaceous earth (Terms and definitions, JAS for Organic Feed).
- Limestone etc. and calcium carbonate, magnesium carbonate, phosphate hydrogen calcium, phosphate calcium, and silicic acid are permitted: derived from limestone and are not chemically treated, and to which no chemically synthesized substances are added (Ingredients, JAS for Organic Feed).
- Calcium dihydrogen phosphate is permitted: limited to the use in flour as a leavening agent (Table A.1 – Additives, JAS for Organic Processed Foods).
- Calcium dihydrogen phosphate is permitted (Table B.1 – Additives, JAS for Organic Processed Foods).

Ancillary Substances
None

Human Health and Environmental Issues
During previous public comment, stakeholders raised concerns about the cumulative effects on human health associated with the use of phosphorous additives in foods. The NOSB review responded to the issue of human health concerns regarding cumulative phosphorous consumption by stating that no single phosphate additive or ingredient can be implicated as an isolated risk factor. Further information on each phosphate additive can be found in the TR (lines 438-687). The Board also determined that calcium phosphates have no viable organic substitute, particularly in baked products.

Discussion
During previous board discussions, it was determined that calcium phosphates have no viable organic substitute, particularly in baked products.

Calcium phosphates (monobasic, dibasic, and tribasic) are compliant with OFPA.

Questions to our Stakeholders

1. Should calcium phosphates be annotated in alignment with potassium phosphates to limit use to “made with” only?

Low acyl gellan gum

Reference: §205.605(b)(18)
Technical Report: 2018 TR (Gums)
Petition: 2019; 2020 Addendum
Past NOSB Actions: 10/2020 - recommendation to add

Recent Regulatory Background: Added to National List effective 11/14/2022 (87 FR 68021)
Sunset Date: 12/14/2027

Subcommittee Review

Use
Low acyl gellan gum is used in various food formulations, such as aspics; frostings; brownies and bakery fillings; gelatins and puddings; non-standardized jams and jellies; dairy drinks and soy milks; nutritional products; beverages (dairy alternative milks, dairy drinks, fruit drinks, drinking jellies, novelty drinks); beverage mixers; kefir; yogurt, sour cream and cheese where the standards of identity do not preclude its use; yogurt fruit and fruit sauces; marinades; pourable and spoonable dressings; and dairy desserts.

Gellan gum is approved in animal and pet food and is also used in personal care products such as body washes, sunscreen/lotions, skin hydration sprays, oral care, toothpaste, and mouthwash. The typical amount of gellan gum in food for human consumption doesn't exceed 0.5%.

The mode of action is as a suspending or gelling agent with film-forming and texturizing attributes, forming gels in the presence of ions when heated and cooled.

Manufacture
The 2018 TR on gums and the 2019 petition note gellan gum is a high-molecular weight polysaccharide, produced by the pure-culture aerobic fermentation of a carbohydrate with Sphingomonas elodea (ATCC 31461), formerly known as Pseudomonas elodea. The carbohydrate fermentation substrate is comprised of glucose syrup derived from maize or wheat, inorganic nitrogen, an organic nitrogen source (protein) and trace elements. Pasteurization kills the bacteria. The structure of high acyl gellan gum consists of a 4-sugar repeating unit with acetate and glycerate side chains. Removing the acetate and glycerate groups results in a linear molecule with unique properties.

The petitioner provides the following detail specific to their manufacturing.

- The first step of producing the gum is by inoculating a carefully formulated fermentation medium with this organism.
- The medium contains a bio-based glucose syrup carbon source, phosphate, organic and inorganic nitrogen sources, and appropriate trace elements.
- The fermentation is carried out under sterile conditions with strict control of aeration, agitation, temperature, and pH.
- Deacylation of the gum develops the required functionality. A strong base is used to deacylate gellan gum. This additional step does not change the polysaccharide backbone of the molecule. After deacylation, acid is used to neutralize the gellan gum solution.
    - High acyl gellan gum is treated with potassium hydroxide and heated. This produces low acyl gellan gum and potassium acetate and potassium glycerate. The potassium acetate and potassium glycerate are removed from the low acyl gellan gum during the precipitation and recovery of the low acyl gellan gum with isopropyl alcohol.
- The gum is recovered by precipitation with isopropyl alcohol.
- The precipitate is then dried and milled to a fine powder.
- The powdered form of the product is packaged.

Low-acyl gellan gums (e.g. (KELCOGEL® [E], KELCOGEL® CG-LA [E], KELCOGEL® F[E])) produced by CP Kelco (the original petitioner) are Non-GMO Project certified.

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Gums: The following gums are permitted: Arabic gum, carob bean gum (locust bean gum), gellan gum, guar gum, karaya gum, tragacanth gum, and xanthan gum. Shall be derived using substances listed in Table 6.3 Extraction solvents and precipitation aids. By exception, isopropyl alcohol may also be used to derive gums (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Only high-acyl gellan gum is permitted in products of plant and animal origin, and only from organic production (Section A1 – Food Additives including carriers, EC No. 2021/1165).

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

- Low-acyl gellan gum is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Additives and processing aids from biological sources, such as fermentation cultures, enzymes, flavors, and gums must be derived from naturally occurring organisms by the use of biological, mechanical, and physical methods. Nonorganic forms are allowed in organic products only if there are no organic sources (Processing and Handling Criteria, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Low-acyl gellan gum is not explicitly mentioned in the regulations.

Ancillary Substances

According to an internet search, it was noted that some ancillary substances could be present, such as calcium salts, residual sugars, pH adjusters, or carrier agents (like silicon dioxide). The 2018 TR for gums did not include this information as this was completed prior to the revision to the TR template, which now specifically asks about ancillaries.

Environmental and Human Health Issues

The two available technical reports (TRs) (2018 and 2006) 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.

Discussion

Low-acyl gellan gum was added to the National List in November 2022. This is its first sunset review. In 2010 gellan gum was annotated to limit its use to the high-acyl form only. It was indicated during that rulemaking process that since there were additional processing steps between high-acyl gellan gum and low-acyl gellan gum that only the high-acyl form could be classified as non-synthetic and that the low-acyl form would need to be petitioned separately as a synthetic substance.

The low acyl form of gellan gum is technically a synthetic substance as described above but is viewed from a regulatory and food safety perspective as identical to the high acyl form. The tenets of organic production tend to favor nonsynthetic options when available. However there do not appear to be significant differences between the nonsynthetic high acyl and synthetic low acyl forms of gellan gum.

There are several gums on the National list. Each has specific properties that may not be shared by other gums. Use of low-acyl gellan gum in hard and soft capsules gives a functionality that cannot be achieved with most materials currently on the National List. Carrageenan is the only material currently listed which offers producers of hard and soft capsules the necessary technical function/properties. Additionally, gellan gum is used at significantly lower levels (<20%) than other gums on the National List.

Low-acyl gellan gum is produced via a fermentation process. As with any substance that undergoes a fermentation step there are concerns pertaining to the use of excluded methods. All of the other gums on the National List were just reviewed in 2023. They were all unanimously relisted (13 yes, 2 absent).

Questions

1. What types of organic products is low-acyl gellan (synthetic) used in compared to high-acyl gellan gum (nonsynthetic)?
2. Are there additionally ancillaries present in low-acyl gellan gum that the board should be aware of?

Ozone

Reference: 205.605(b)(21)
Technical Report: 1995 TAP
Petition(s): N/A **Past NOSB Actions:** 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Ozone is a powerful oxidant with many industrial and consumer applications related to oxidation. The primary use of ozone globally is as a water treatment. In this capacity, ozone oxidizes organic and inorganic compounds, improving water quality when used as a broad-scope disinfectant. In food production, handlers also apply ozone directly to food as an antimicrobial treatment. Consequently, ozone is also a preservative (2024 TR, lines 119-122).

Manufacture
Ozone occurs naturally, mostly in the upper atmosphere. Naturally occurring ozone is often the product of ultraviolet radiation on atmospheric oxygen. Producers generate most ozone by applying a low-current electrical discharge (corona discharge) to atmospheric oxygen. Increasingly, producers generate ozone through the electrolysis of water. Ozone can also be manufactured photochemically by exposing oxygen in air or water to ultraviolet light (2024 TR, lines 54-61). Ozone is an unstable gas in the air and even more so in water, so it must be produced on site.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Teat dips and udder wash: Substances, such as alcohol, iodine, hydrogen peroxide, chlorine dioxide and **ozone**, can be used as disinfectants for a pre- or post-teat dip or udder wash if they are registered for this use by Canada's *Food and Drug Regulations* (Table 5.3 – Health care products and production aids, CAN/CGSB-32.311-2020).

- **Ozone** is permitted (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- **Ozone** is permitted (Table 6.5 – Processing aids, CAN/CGSB-32.311-2020).
- **Ozone** is permitted (Table 7.3 – Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- With regard to disease prevention, ultraviolet light and **ozone** may only be used in hatcheries and nurseries (Production rules for algae and aquaculture animals, EC No. 2018/848).

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

- **Ozone** is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- **Ozone** is permitted (Table 2 - Indicative List of Equipment Cleansers and Equipment Disinfectants, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Ozone** is permitted: limited to the use only for the purpose of disinfecting meat or cleaning eggs (Table K.1 - Substances for preparation or other purposes, JAS for Organic Livestock Products).
- **Ozone** is permitted: limited to the use for disinfecting processed meat products or cleaning of eggs (Table A.1 – Additives, JAS for Organic Processed Foods).
- **Ozone** is permitted (Table D.1 - Substances for preparation etc., JAS for Organic Products of Plant Origin).

Ancillary Substances
N/A

Environmental Issues and Human Health Impacts
The primary human health concern of ozone treatment for food and water is worker safety. Employees are exposed to higher levels than the general public. Ozone is an irritant to the eyes, nose, mouth, and upper respiratory system (2024 TR, lines 773-775). According to the U.S. Environmental Protection Agency (EPA), ozone exposure in the air we breathe can be harmful to human health and the environment. However, the application of ozone directly into water as a disinfectant minimizes this exposure. Once introduced into water, ozone decomposes into elemental oxygen in a brief amount of time. Exposure to atmospheric ozone generated from on-site production can be minimized through equipment maintenance. Ozone is Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration (FDA) without limitations other than current good manufacturing practice (2024 TR, lines 155-156). The impacts of ozone pollution on plant growth and health have received considerable attention from scientists world-wide with visible yellowing of the leaves and leaf death at higher levels (2024 TR, lines 704-708).

During the April 2020 meeting, the Board received comments voicing broad support for the continued listing of ozone. Comments from certifiers noted 51 operations listing this material in their organic system plans (OSPs). Numerous comments pointed to ozone's importance as a disinfectant and sanitizer for food contact surfaces. Many noted the material's essentiality in reducing microbial loads on finished produce and grains.

One group acknowledged ozone's strong oxidizing properties and usage that does not leave toxic residues.

However, they noted the potential risk to workers from leaks in irrigation water treatment when the material is not transferred to the water and is released as a gas. The group encouraged the Crop and Handling Subcommittees to review ozone in the context of all sanitizers.

Discussion
The Handling Subcommittee finds that the positive attributes of ozone and its role in food safety programs outweigh the manageable risks to worker safety and supports relisting at this time.

Questions to our Stakeholders
None

Sodium hydroxide

Reference: 205.605(b)(32) - prohibited for use in lye peeling of fruits and vegetables.
Technical Report: 1995 TAP; 2020 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Sodium hydroxide is a highly caustic substance used as a processing aid in cocoa manufacturing, as a caustic bath for pretzels that makes the pretzel surface smooth and helps it to develop brown color during baking, and for removing bitterness from olives. It is also used as an alkali to peel fruits and vegetables, but this use is specifically prohibited in organic foods by the annotation. Sodium hydroxide is used to manufacture soaps, oral care products and detergents, and can be used as an ingredient in food preservatives to prevent the growth of mold and bacteria. Soda ash ($NaCO_3$), magnesium oxide (MgO) or sodium hydroxide can be used in the production of sugar to increase the pH and alkalinity of the sugar cane juice. It is highly soluble in water.

Manufacture
Sodium hydroxide is derived from saltwater brine and manufactured by the electrolysis of this salt brine solution. During the electrolysis process, the water (H_20) is reduced to a hydrogen gas (H_2) and a hydroxide ion (OH^-). The hydroxide ion bonds with the sodium to form sodium hydroxide (NaOH). Chlorine is also produced during this process.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Sodium hydroxide (lye or caustic soda) is permitted (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- Sodium hydroxide (lye or caustic soda) is prohibited for use in lye peeling of fruits and vegetables (Table 6.5 – Processing aids, CAN/CGSB-32.311-2020).
- Sodium hydroxide (lye or caustic soda) is permitted (Table 7.3 – Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Sodium hydroxide is permitted in 'Laugengebäck' flavourings for use as a surface treatment and acidity regulator (Section A1 – Food Additives including carriers, EC No. 2021/1165).
- Sodium hydroxide is permitted in the processing of sugar(s), oil from plant origin excluding olive oil, and plant protein extracts (Processing aids and other products, EC No. 2021/1165).

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

- Sodium hydroxide is permitted in food of plant origin (cereals and cereal products, derived from cereal grains, from roots and tubers, pulses and legumes, excluding bakery wares of food category; yeast-leavened breads and specialty breads), but is not permitted in food of animal origin (Additives permitted for use under specified conditions in certain organic food categories or individual food items, CXG 32-1999).
- Sodium hydroxide is permitted for pH adjustment in sugar production (Table 4 - Processing aids which may be used for the preparation of products of agricultural origin, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Sodium hydroxide is permitted as an additive and processing/post-harvest handling aid for sugar processing and for the surface treatment of traditional bakery products (Table 1 - List of Approved Additives and Processing/Post-Harvest Handling Aids, IFOAM NORMS 2014).
- Sodium hydroxide (caustic soda) is permitted when an intervening event or action must occur to eliminate risks of contamination (Table 2 - Indicative List of Equipment Cleansers and Equipment Disinfectants, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Sodium hydroxide is permitted (Table D.1 - Chemicals for cleaning or disinfecting livestock or poultry house, JAS for Organic Livestock Products).
- Sodium hydroxide is permitted: limited to the use in the processing of sugar (as a pH control agent) or pH adjustment in processed algae products or use in the production of edible fats & oils or in the production of processed grain products (Table A.1 – Additives, JAS for Organic Processed Foods).

Ancillary Substances

It does not appear there are any ancillary substances associated with this material.

Environmental Issues

Sodium hydroxide must be handled by personnel according to manufacturer guidelines because of its caustic nature. The concentration of sodium hydroxide is routinely monitored in pretzel production to verify complete conversion to sodium bicarbonate during baking. The EPA allows sodium hydroxide for use in treating sewage systems to control tree roots, and as a fungicide and algicide on water well casings. Effluent containing sodium hydroxide is not to be discharged into lakes, streams and other public waters without a NPDES (National Pollutant Discharge Elimination System) permit. Well water casing treatment would result in minimal exposure of birds, mammals, and other organisms. The EPA states that current product labeling helps to protect wildlife from undue exposure to sodium hydroxide.

The 2020 Technical Report states there are no alternatives that provide the desired browning properties of pretzels. Baking soda can be used but is not sufficiently alkaline to result in distinctive crust and flavor. Certain varieties of olives rely on sodium hydroxide to remove bitterness, as salt or water curing does not

result in acceptable product. Potassium carbonate, potassium bicarbonate, sodium carbonate, sodium bicarbonate, ammonium carbonate, ammonium bicarbonate, ammonium hydroxide, magnesium carbonate, and magnesium oxide, as well as sodium hydroxide, can be used to alkalize cocoa. Each type of alkalizing agent results in different flavors and functional attributes. The label claim "processed with alkali" is used when these alkalis are used in cocoa production. It appears sodium hydroxide is the only alkali in use when an alkali is needed in sugar processing.

Questions to our Stakeholders
None

Carnauba Wax

Reference: 205.606 205.606 (a) Carnauba wax
Technical Report: 1996 TAP; 2014 TR
Petition(s): N/A
Past NOSB Actions: NOSB minutes and vote 09/1996; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Carnauba wax is used as a component in fresh fruit coatings, as a candy coating, and as component of an edible coating for nuts. Other uses include a base for chewing gum and in soft drinks. It can also be used as a processing aid, as a releasing agent, and in defoamers. Its Generally Regarded as Safe (GRAS) listing doesn't provide any limitations on its use as an ingredient in food (2014 TR, lines 65-72).

When formulated as part of a fruit coating, carnauba wax functions to reduce gas exchange between the surface of the fruit and the atmosphere, thereby reducing the respiration rate and weight loss of the fruit (2014 TR, lines 114-116). It also has antifungal properties beyond the creation of a gas barrier.

Manufacture
The production of carnauba wax begins with leaves cut from the carnauba palm tree during Brazil's dry season. They are dried in the sun and then beat or scraped until the wax falls off as a fine powder. The wax is collected and then melted by steam or a solvent (2014 TR, lines 253-259). The wax is then cooled and filtered via a filter press or through filter cloth, and then cooled and dried (2014 TR, lines 263-265). The wax may also be clarified by centrifugation or with hydrogen peroxide.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Waxes, produce: Organic beeswax and organic **carnauba wax** may be used to wax produce. See 9.2.1 d) of CAN/CGSB-32.310 if organic wax is commercially unavailable (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- **Carnauba wax** is permitted in confectionery and citrus fruit for use as a glazing agent, mitigating method for mandatory extreme cold treatment of fruit as a mandatory quarantine measure against harmful organisms in accordance with Commission Implementing Directive (EU) 2017/1279, and only from organic production (Section A1 – Food Additives including carriers, EC No. 2021/1165).
- **Carnauba wax** is permitted in products of plant origin for use as a releasing agent and only from organic production (Processing aids and other products, EC No. 2021/1165).

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

- **Carnauba wax** is permitted as releasing agent (Table 4 - Processing aids which may be used for the preparation of products of agricultural origin, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- **Carnauba wax** is permitted as a processing/post-harvest handling aid (Table 1 - List of Approved Additives and Processing/Post-Harvest Handling Aids, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- **Carnauba wax** is permitted: limited to the use as a separating medium in processed products of plant origin (Table A.1 – Additives, JAS for Organic Processed Foods).

Ancillary substances

According to the 2014 TR, raw carnauba is sold to formulators without any additional ingredients such as stabilizers or preservatives. While formulations containing carnauba as the only wax are available, it is more common to combine it with other waxes and coasting materials such as beeswax, candelilla wax, wood rosin, or shellac.

Human Health and Environmental Issues

It was stated in the 2014 TR that chronic toxicology or carcinogenicity studies have been done; however, the European Food Safety Authority does not consider carnauba wax a safety concern for human health.

Leaves harvested for the production of wax regrow every year, and the leaf remnants remaining after the wax extraction are used for making brooms and hats etc. There were no environmental concerns reported (2014 TR, lines 437-441).

Discussion

In previous sunset years, some commenters referenced the sufficient availability of organically produced carnauba wax and, therefore, supported delisting. Others suggested the organic form does not provide a satisfactory result when used as a processing aid. It was also mentioned through several comments that waxes, in general, are not always used, but they are important on those occasions when and where necessary; having alternative forms of waxes available allows for more export opportunities due to regulation differences at the respective destination. The previous Board voted to retain carnauba wax on the list, with 11 votes in favor of relisting, and 3 to remove.

Questions to our Stakeholders

1. What is the current organic availability of carnauba wax?

Colors

Reference: 205.606(d) Colors derived from agricultural products - Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(1) Beet juice extract color derived from Beta vulgaris L., except must not be produced from sugar beets.
(2) Beta carotene extract color – derived from carrots (Daucus carota L.) or algae (Dunaliella salina).
(3) Black/Purple carrot juice color derived from *Daucus carota* L.
(4) Chokeberry, Aronia juice color - derived from *Aronia arbutifolia* (L.) Pers. Or *Aronia melanocarpa* (Michx.) Elliott.
(5) Elderberry juice color - derived from *Sambucus nigra* L.
(6) Grape skin extract color - derived from *Vitis vinifera* L.
(7) Purple sweet potato juice - derived from *Ipomoea batatas* L. or *Solanum tuberosum* L.
(8) Red cabbage extract color - derived from *Brassica oleracea* L.
(9) Red radish extract color - derived from *Raphanus sativus* L.
(10) Saffron extract color - derived from *Crocus sativus* L.

Technical Report: 2015 TR - Colors (all); 2011 (Beta carotene); 2012 Supplemental TR
Petition(s): 2007 Petition
Past NOSB Actions: 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Added to NL effective 06/21/07 (72 FR 35137); Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Colors are added to food products to enhance the attractiveness of the food, to assure uniformity of color, to add back color lost during processing, to intensify existing colors, to protect light-susceptible vitamins, and to preserve flavor (2015 TR, lines 22-24). The natural colors market has grown dramatically since colors were added to the National List (2015 TR, lines 345-348).

The colors that remain on the National List fall into three categories (2015 TR, lines 17-22):

- Anthocyanin colors (chokeberry, black/purple carrot, red cabbage, elderberry, grape skin, purple sweet potato[1], red radish);
- Carotenoid colors (beta carotene, black/purple carrot, saffron); and
- Other colors (beet).

Anthocyanins are used in fruit products to add back reds, blues, purples, and oranges lost in processing (2015 TR, lines 33-35). They are composed of a pigment molecule, anthocyanidin, linked to a sugar molecule (2015 TR, lines 45-46). There are six main anthocyanidin pigments in colors covered by the 2015 TR, but there are about 25 known anthocyanidins in the world, which combine in various ways with sugars

[1] Note: The 2015 TR addresses “purple potato”, but it is presumed to mean purple sweet potato.

to make several hundred anthocyanins (2015 TR, lines 46-47, 139-141). They exist in varying concentrations and at varying pH, which affects their color and other properties (2015 TR, lines 46-61).

Carotenoids, the most widely distributed group of pigments, are used to give red, orange, or yellow colors to a wide range of products (2015 TR, lines 27-29, 145). They synthesized by microorganisms and plants, and about 600 carotenoid pigments have been identified (2015 TR, lines 149-153). Carrots contain significant amounts of beta-carotene (and black carrots also contain anthocyanins) (2015 TR, lines 64-68, 148-149). Saffron's major pigment is the water-soluble compound crocin (2015 TR, line 181). One other source of crocin, gardenia fruit, is not approved as a food colorant in the United States (2015 TR, 187-189).

Beet juice color is used in dairy, meat, baked, candy, and fruit products (2015 TR, lines 35-37). Beet juice contains red pigments called betalains or betacyanins, which are similar to anthocyanins (2015 TR, lines 112-113). While betalains occur in other plants, beets are the only allowed source of betalain colorant in the United States and European Union (2015 TR, lines 194-196). Beet color is more purple and brighter than anthocyanin pigments, and it has a more stable pH range; however, it has low heat stability (2015 TR, lines 198-200).

Manufacture

Colors can be produced via a number of production methodologies that vary by individual crop and pigment. While most sources have common agricultural crop names, those used for color extraction are often specific varieties that are grown in specific geographical regions using specific production techniques to produce the specific pigments for coloring purposes. Since these items are listed as agricultural – processing is restricted to physical or biological means. The most common types of extraction will be water extraction, milling, pressing, drying, distillation, enzyme treatment, ethanol extraction, or oil extraction. The annotation prohibits the use of synthetic solvents, carrier systems, and artificial preservatives.

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Colouring agents are permitted "from biological sources such as spices, annatto, juices made from plant sources, etc. derived using approved methods (see Table 11 B (1) & (2), Origin and mode of production of CAN/CGSB-32.310), and substances in Table 6.3 Extraction solvents and precipitation aids" and "May contain permitted carriers (see Table 6.3 & 6.4 Carriers)" (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- Specific colors are not explicitly mentioned.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Colours for stamping meat and eggshells pursuant to regulation (Processed food production rules, EC No. 2018/848).
- Natural colours and natural coating substances for the traditional decorative colouring of the shell of boiled eggs produced with the intention of placing them on the market at a given period of the year (Processed food production rules, EC No. 2018/848).
- Annatto for certain cheeses (Part A, Authorized food additives and processing aids, EC No. 2021/1165).
- Other specific colors are not explicitly mentioned.

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

- Specific colors are not explicitly mentioned.

International Federation of Organic Agriculture Movements (IFOAM)

- A substance shall not be used solely or primarily as a preservative, to create, recreate or improve characteristics such as flavors, **colors**, or textures, or to restore or improve nutritive value lost during processing, except where the replacement of nutrients is required by law (IFOAM NORMS 2014, B.5.3).
- Specific colors are not explicitly mentioned.

Japan Agricultural Standard (JAS) for Organic Production

- Specific colors are not explicitly mentioned.

Ancillary Substances

The 2015 TR notes that additional ingredients may be added to stabilize or preserve pigments, and it identifies those ingredients by pigment group (2015 TR, lines 292-298). It notes that sulfur dioxide may be used to decrease browning in anthocyanin colors, in the presence of citric acid; however, it also notes the limitations on sulfur dioxide use (2015 TR, Table 5). Protective coatings or antioxidants may be used to protect carotenoid colors from degrading, and ascorbic acid may be used to prevent fading; the 2015 TR also specifically notes that green tea polyphenols may be used to prevent discoloration, but that they are not on the National List (2015 TR, Table 5). Citric acid may be used to extract beet juice extract color, and ascorbic acid may be used to stabilize it (2015 TR, Table 5). Purple (sweet) potato juice color may have water, invert sugar, and citric acid added, and saffron extract color may have moisture added for stability (2015 TR, Table 5).

Human Health and Environmental Issues

Color additives generally require Food and Drug Administration (FDA) approval before use in food, but certain pigments derived from fruits and vegetables are exempt from that requirement, including all those on the National List (2015 TR, lines 263-278). Many pigments have antioxidant or anti-inflammatory properties and may be helpful to health, and ingestion is unlikely to be harmful to human health (2015 TR, lines 649-651, Table 8, 752-759).

Nonorganic natural colors are products of conventional agriculture, and the 2015 TR identifies potential for contamination of natural colorants with aflatoxins, solvents used in processing (not an issue for listed colors because of the prohibition on solvent extraction), and pesticide and heavy metal residues (2015 TR, lines 656-660). Some colors are derived from agricultural waste products leftover from processing, and there may be environmental benefits to reducing that waste (2015 TR, lines 742-747).

Discussion

In the 2015 sunset review of colors, the NOSB documented the emerging presence of certified organic colors and recommended that future Boards carefully review the supply of individual colors, rather than renewing colors in whole on § 205.606. In the Fall 2020 NOSB sunset review, the NOSB voted to relist the 10 colors that are currently up for review. The NOSB also voted to sunset 8 that were subsequently removed due to findings that those colors were available in organic form (black current juice color, blueberry juice color, carrot juice color, cherry juice color, grape juice color, paprika color, pumpkin juice color, and turmeric extract) (Fall 2020 NOSB Formal Recommendation re 2022 sunset reviews - handling). The following is a summary of the feedback the NOSB received for the 2020 review, for the colors that are currently listed:

(1) Beet juice extract color - derived from Beta vulgaris L., except must not be produced from sugar beets: Mixed information about whether organic forms were available in sufficient form or quantity

(2) Beta carotene extract color - derived from carrots (Daucus carota L.) or algae (Dunaliella salina): Strong concerns about supply

(3) Black/Purple carrot juice color - derived from *Daucus carota* L: Mixed information indicating organic supply may not be adequate or has too much color variation

(4) Chokeberry, Aronia juice color – derived from *Aronia arbutifolia* (L.) Pers. Or *Aronia melanocarpa* (Michx.) Elliott: Limited information indicating variable and inadequate organic supply

(5) Elderberry juice color – derived from *Sambucus nigra* L: Limited organic supply

(6) Grape skin extract color – derived from Vitis vinifera L: Supply tied to wine industry and impacted by limited organic wine production (grape skins and derivatives from wine labeled "made with organic grapes" would not qualify for an organic claim)

(7) Purple sweet potato juice – derived from Ipomoea batatas L. or Solanum tuberosum L: Inadequate supply

(8) Red cabbage extract color – derived from *Brassica oleracea* L: Inadequate supply

(9) Red radish extract color – derived from *Raphanus sativus* L: Mixed information on supply

(10) Saffron extract color – derived from *Crocus sativus* L.: Mixed information on supply

The 2015 TR (lines 834-844) identifies several potential alternatives to certain pigments, including:

- Organic palm fruit oil beta-carotene in place of beta-carotene from carrots
- Organic annatto for yellow to red carotenoids
- Organic marigold for the carotenoid lutein

The subcommittee discussed the value of colors in meeting consumer expectations, the colors that were removed in the last sunset cycle, and the impacts on market growth that 205.606 listings may have. As the most recent information available to the subcommittee is from the 2020 sunset review, the subcommittee seeks stakeholder input on the current commercial availability of the listed colors.

Questions to our Stakeholders

1. Which of these colors are now commercially available in organic form?
2. Where information about commercial availability is mixed (i.e. where some, but not all, commenters note that the organic color is available), should those colors be removed from the National List to ensure adequate market pressure to complete the transition to organic?
3. How essential are the colors that remain on the list? For example, could a different anthocyanin be substituted for red radish?
4. Are there any other specific barriers to organic transition for individual colors (e.g., grape skin extract supply is limited by constraints on organic winemaking)?

Cornstarch (native)

Reference: 205.606(e) Starches.

(1) Cornstarch (native).

Technical Report: 1995 TAP - Cornstarch; 2025 TR
Petition(s): N/A - Cornstarch; 2007 Petition - Sweet Potato Starch
Past NOSB Actions: 10/1995 NOSB minutes and vote; 10/2010 sunset recommendation on cornstarch; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Starches are used in many foods as thickeners, formulation aids, to make corn syrup, and as bulking agents and moisture adsorption agents. Cornstarch is made from special strains of corn that are high in amylose and amylopectin (1995 TAP).

Manufacture
Cornstarch is obtained from the endosperm of the kernel (1995 TAP). The corn is steeped for 30 to 48 hours, which ferments it slightly. The germ is separated from the endosperm and those two components are ground separately (still soaked). The starch is then removed by washing. The starch is separated from the corn steep liquor, the cereal germ, the fibers and the corn gluten mostly in hydrocyclones and centrifuges, and then dried. This process is called wet milling. Finally, the starch may be modified for specific uses.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Starch is permitted from rice and waxy maize—Shall be derived using substances listed in Table 6.3 Extraction solvents and precipitation aids, where applicable. Starch shall not be modified by chemicals. Starch may be modified using physical or enzymatic methods. Cornstarch—May contain substances that are plant derived or listed in Tables 6.3, 6.4, or 6.5 (Table 6.4 – Ingredients not classified as food additives, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Cornstarch is not explicitly mentioned in the regulations.

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

- Cornstarch is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Cornstarch is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Cornstarch is not explicitly mentioned in the regulations.

Ancillary Substances
None noted

Human Health and Environmental Issues
Cornstarch poses no acute health hazards from ingestion or dermal absorption. Dust produced during

production may pose inhalation risks, and potentially a fire hazard if levels in air reach critical combustion concentrations. Cornstarch that is not organic may be produced from conventional corn that was grown with synthetic fertilizers and pesticides that pose risks to human health and the environment.

Discussion
There are organic starches on the market, but they are not necessarily suitable for all uses. Based on previous comment - Special strains of corn are grown to achieve the right ratio of the two glucose polymers (amylopectin and amylose) and these special varieties are all identity-preserved to maintain their amylose ratio and so are never genetically engineered. During the 2017 review, public commenters indicated that some types of organic cornstarch are not available, but that non-GMO derived cornstarch was readily available. Others indicated that some organic forms were not functional to manufacture their products or there was not enough specialized organic material available to meet their needs.

A December 2024 search of the Organic Integrity Database identified 133 suppliers of "cornstarch" or "corn starch," located in the United States, China, and India. Cornstarch is listed under §205.606, so non-organic material should be used only when organic cornstarch is not available.

During the previous relisting, many certifiers, trade organizations, and food manufacturers supported relisting of cornstarch on §205.606. One commenter recommended an annotation limiting cornstarch on §205.606 to specialized forms that are not available organically, thus encouraging broader use of available organic cornstarch when it meets production requirements. In the previous review, the Subcommittee wanted to encourage policies that increase use of organically sourced cornstarch. There was debate about whether this could be accomplished by an annotation, as described above, or by removing cornstarch, as listed, from §205.606, and encouraging direct listing of any specialized forms that are not available organically. The Subcommittee ultimately voted to recommend removal of cornstarch from §205.606 because of an abundant supply of organic cornstarch.

Questions to our Stakeholders

1. In the past 5 years, the number of suppliers of organic cornstarch has nearly tripled. Does this mean that there is a sufficient supply of organic cornstarch?
2. Are there *any* barriers to using organic cornstarch instead of the non-GMO based conventional cornstarch? We are especially interested in understanding why there organic and conventionally produced cornstarch would not be completely interchangeable.
3. Is there sufficient supply of non-GMO based conventional cornstarch?

Glycerin

Reference: 205.606(i) Glycerin (CAS # 56-81-5)—produced from agricultural source materials and processed using biological or mechanical/physical methods as described under §205.270(a).
Technical Report: 1995 TAP; 2013 TR
Petition(s): 1995 N/A**,** Glycerin (2012 Petition to remove)
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Glycerin is used in food as a binder, humectant, solvent, and carrier. It is widely used in natural flavors. It is used in alcohol-free applications as an alternative to ethanol (as a carrier or solvent). It is also used in cosmetic and personal care products as an emollient, carrier, lubricant and filler. It has a neutral to sweet taste (2013 TR, lines 24-25).

Manufacture
Glycerin can be manufactured from a variety of sources using a variety of means. Glycerin exists in nature as part of triglycerides as a backbone glycerin molecule with three fatty acid chains. The product must undergo processing to break the fatty acids from the glycerin. The processing of glycerin will determine if it is agricultural or non-agricultural, and the organic certification status of the raw materials, processing plant, and compliance with the National List would determine if the product could be organic or not. It should be noted that it is possible to produce an organic glycerin that would be classified as non-agricultural.

Common practices are high-pressure hydrolysis (considered agricultural), saponification (considered synthetic but possible to be certified organic if origin materials are organic and the caustic material is on the National List), methyl esterification (product of biodiesel, considered synthetic), and fermentation of carbohydrates (considered agricultural, but uncommon). Common feedstocks to produce glycerin are palm oil, soy oil, tallow, canola oil, and rapeseed oil. Fermented glycerin is produced from carbohydrates with the common source being corn. When produced from a fat, the glycerin yield is generally 1:10 glycerin to fatty acid.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Glycerol (glycerine, glycerin) is permitted: Shall be from organic sources if commercially available. Shall be from vegetable oil or animal fat. Shall be produced using fermentation or by hydrolysis (Table 5.3 – Health care products and production aids, CAN/CGSB-32.311-2020).
- Glycerol (glycerine, glycerin) is permitted: Shall be from organic sources if commercially available. Shall be from vegetable oil or animal fat. Shall be produced using fermentation or by hydrolysis (Table 6.3 – Ingredients classified as food additives, CAN/CGSB-32.311-2020).
- Collagen casings are permitted: Collagen shall be derived from animal sources. If derived from cattle, collagen shall be guaranteed free of Specified Risk Material (SRM). Other ingredients (such as, but not limited to; cellulose, calcium coatings, glycerin, etc.) added to collagen casings during their manufacture that remain in the collagen casing when it is used shall respect the requirement provided in 1.4 a) of CAN/CGSB-32.310 (Table 6.4 – Ingredients not classified as food additives, CAN/CGSB-32.311-2020).
- Glycerol (glycerine, glycerin) is permitted: Shall be a) sourced from vegetable oil or animal fat; b) produced using fermentation or by hydrolysis (Table 7.3 – Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Glycerol is permitted in plant extracts and flavourings with the following conditions: only from plant origin, solvent and carrier in plant extracts and flavourings, humectant in gel capsules, surface coating of tablets, and only from organic production (Section A1 – Food Additives including carriers, EC No. 2021/1165).

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

- Glycerol is permitted when obtained from plant origin and allowed as a carrier for plant extracts and in untreated fresh fruit; surface-treated fresh fruit; processed fruit; surface-treated fresh vegetables; dried vegetables; vegetables; canned or bottled (pasteurized) or retort pouch vegetables; fermented vegetables; herbs, spices, seasonings, and condiments. **Glycerol** is not permitted in food of animal origin (Additives permitted for use under specified conditions in certain organic food categories or individual food items, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Glycerin is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Glycerin is not explicitly mentioned in the regulations.

Ancillary Substances
None mentioned in the TR.

Human Health and Environmental Issues
There are few, if any, potential human health concerns regarding glycerin exposure. The 2013 TR indicates that repeated oral exposure may cause GI irritation. Exposure to glycerin via inhaled aerosol shows local irritant effects at and above 662 mg/m^3, and no observable adverse limit is 167 mg/m^3. Evidence suggests that glycerin is not a skin sensitizer.

According to the 2013 TR, small amounts of glycerin may escape during the production process into either water or the atmosphere. Glycerin is biodegradable, and is not thought to bioaccumulate. Glycerin has low toxicity to fish and aquatic invertebrates. Overall, there is a low level of concern that glycerin is an environmental hazard. It is exempt from an EPA tolerance. Glycerin is manufactured from palm and coconut oils, so there is concern about its contribution to deforestation.

Discussion
In December 2018 the NOP finalized rulemaking on the NOSB recommendation, moving glycerin from § 205.605(b) to § 205.606 and changing the annotation to read "produced from agricultural source materials and processed using biological or mechanical/physical methods as described under § 205.270(a)."

During the previous sunset, the board and subcommittee discussed the issue of "commercial availability." There was general agreement that, given the wide use of glycerin as a binder, humectant, solvent, and carrier, there was currently no suitable commercially available alternative. During this same time period, the HS addressed the question about the make-up of the remaining 1% left over from the "99% pure" claim attributed to glycerin. In reviewing the 2013 TR and through review of several stakeholder written comments, it is generally held that glycerin is at least 99% pure with the balance of the remaining material being water and fatty acids that, perhaps, support processing.

Questions to our Stakeholders
None

Inulin oligofructose enriched

Reference: 205.606(k) Inulin-oligofructose enriched (CAS # 9005-80-5)

Technical Report: 2015 TR
Petition(s): 2007 Petition
Past NOSB Actions: 04/2007 recommendation; 2010 NOSB sunset recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 07/06/17 (82 FR 31241); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Inulin-oligofructose enriched (IOE) is on the National List as a nonorganically produced agricultural product allowed in or on processed products labeled as "organic." IOE is a non-digestible carbohydrate that is used to increase calcium bioavailability and absorption, as a soluble dietary fiber, as a noncaloric sweetener, and for functional effects on the texture/consistency of food (2015 TR, lines 130-132). It is used in many foods including yogurt, baked goods, candies, jams, baby formulas, and other dairy products.

Manufacture
IOE contains inulin and oligofructose, two carbohydrates found in many plant foods that function as dietary fiber. Oligofructose can be produced from sucrose or inulin, however, the most common commercial method to produce oligofructose for use in IOE production is from inulin. Inulin is a dietary fiber found in chicory (Belgian endive), Jerusalem artichoke (sunchokes), agave, and other plants. Chicory inulin is the most commercially available inulin, however in organic production, inulin is generally derived from agave (Mexico) and Jerusalem artichokes (China). Chicory inulin is produced by shredding chicory roots, which are treated with hot water, juiced, and filtered to remove the raw inulin. The raw inulin is purified by treatment with calcium hydroxide, carbonated, and filtered and spray-dried. The resulting inulin polymers range in chain length from 2–60 units. The shortest polymers range from 2–10 fructose units and are called oligofructose. The longer polymers range from 10–60 units (2015 TR, lines 294-296). If insufficient amounts of oligofructose are present, polymers ranging from 10–60 units are treated with inulinase enzyme from *Aspergillus niger* to create more oligofructose and is mixed back in with the original inulin.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
- Inulin-oligofructose enriched is not explicitly mentioned in the regulations.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
- Inulin-oligofructose enriched is not explicitly mentioned in the regulations.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
- Inulin-oligofructose enriched is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)
- Inulin-oligofructose enriched is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production
- Inulin-oligofructose enriched is not explicitly mentioned in the regulations.

Ancillary Substances
The 2015 TR indicated no ancillary substances but noted that IOE could contain up to 20% glucose, fructose, and sucrose left over from the chicory source material or enzymatic conversion (2015 TR, lines 208-209). Further, the TR noted processing aids are removed in favor of a pure IOE product. The amounts of these remaining substances may vary, but the general approach in producing IOE is to purify the IOE solution, thereby limiting the amount of processing aids that remain (2015 TR, lines 335-338). The TR for fructooligosaccharides (FOS) noted the following residuals: glucose, sucrose, calcium gluconate, glucose oxidase enzyme, catalase enzyme, or ethyl alcohol. There are no ancillary substances to list for IOE.

Human Health and Environmental Issues
The 2015 TR was a limited TR and did not cover human health and environmental concerns.

Discussion
Public comments from the previous sunset received from stakeholders were mixed, however, a majority supported relisting citing the widespread use of this material, examples of its unique functionality, and that the alternative (fructooligosaccharides) has a lack of functionality in terms of fiber and sweetness in some applications. Due to the widespread use, these commenters expressed concern about the commercial availability of the organic forms. Those against relisting cited adequate organic supply but with little or no documentation.

Questions to our Stakeholders
1. Is there adequate supply of inulin derived from organic sources?
2. Are there technical or other barriers to using inulin derived from organic sources in place of inulin derived from conventional sources?

Orange shellac

Reference: 205.606(n) Orange shellac-unbleached (CAS # 9000-59-3).
Technical Report: 1999 TAP (Waxes); 2002 TAP; 2014 TR
Petition(s): N/A
Past NOSB Actions: 10/1999 NOSB minutes and vote; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Orange shellac is used to coat fruits and vegetables to reduce water loss and retain firmness. It is an ingredient in lozenges, capsules and tablets, and is a part of confectionary glazes on candy, chocolate and coffee beans. Shellac dye is also used as a food color. It is a natural bio-adhesive polymer that is soluble in alkaline solutions such as ammonia and in solvents such as ethanol. Shellac is water insoluble. There are also numerous non-food uses: on wood, in cosmetics, in clothing, on seeds, and in adhesives, varnish, and polishes.

Manufacture

Orange shellac or “shellac” as it is commonly known is the purified product of the natural resin lac, which is the hardened secretion of the small, parasitic insect *Kerria lacca*, popularly known as the lac insect (2014 TR, lines 40-41). These insects suck the sap of certain host trees, and when digested by the insects the sap undergoes a chemical transformation and is eventually secreted through the pores of the insect. When this secretion comes into contact with the air, if forms a hard shell-like coating over the larger swarm of insects (2014 TR, lines 45-49). The main areas of the world where it is produced are India, Thailand, and Myanmar (2014 TR, lines 55-56).

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Orange shellac is not explicitly mentioned in the regulations.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Orange shellac is not explicitly mentioned in the regulations.

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

- Orange shellac is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Orange shellac is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Orange shellac is not explicitly mentioned in the regulations.

Ancillary Substances

From the 2014 Technical Report (TR), there are a number of substances that are used to process the orange shellac for use in fruit coatings. Some are allowed in organic production and some are not, they include: isopropyl alcohol, morpholine, oleic acid, candelilla wax, fatty acid soaps and fast drying solvents, wood rosins, paraffin wax, petroleum wax, carnauba wax, sugar cane wax, polyethylene emulsions, castor oil, triethanolamine, ammonia, sodium o-phenyl phenate, stearic acid, alkyl naphthalene sulfonates, sodium hydroxide, bentonite, borax, potassium hydroxide, glycerol, palmitic acid, luric acid, and stearic acid (2014 TR, lines 159-164). Fungicides, growth regulators, and preservatives could be added as well as plasticizers such as castor oil, vegetable oils (corn, soy, etc.), acetylated monoglycerides, fatty acids, etc. that are not soluble in water can be used in formulating shellac products. Plasticizers are additives that increase the plasticity or fluidity of material. Coloring agents such as dyes, titanium dioxide, iron oxide, natural colors and other materials such as talc, calcium carbonate and alumina may be used (2014 TR, lines 166-172). Only items allowed on the National List can be included in orange shellac used in or on organic products.

Environmental Issues

The TR states there are no major adverse environmental effects on the production and processing of orange shellac. However, wash-water originating from processing units contain water soluble dye, fragments from insect bodies, proteinaceous matter, vegetable glue, and some sugars. These effluents collect in a pit outside factories and putrefy, generating an offensive smell. This may be a potential environmental hazard for which further studies are required. During washing of sticklac to seedlac, the effluents of lac factories are allowed to flow and collect in reservoirs. This accumulated water is treated with acid, precipitating all solid matter called lac-mud. Lac-mud is also a source of lac dye and lac wax (2014 TR, lines 432-437).

Human Health Issues
The TR states there are no reported adverse effects on human health due to orange shellac. The TR stated that some individuals may show allergic symptoms, and some vegetarians may consider it as animal product not suitable for their consumption (2014 TR, lines 445-446). The TR also indicated the allegoric reaction during processing is likely to stem from the solvents used in manufacturing vs the orange shellac itself (2014 TR, lines 452-456).

Orange shellac has an acceptable present use (as a coating, glazing, and surface-finishing agent externally applied to food) that is "not of toxicological concern" established at the 39th Joint Experts Committee for 460 Food Additives (1992) (2014 TR, lines 458-460).

Discussion
At the previous sunset review, there was a split vote out of subcommittee. The main concerns of the subcommittee in 2020 were largely due to a lack of information about whether its use in organic products is widespread or necessary as well as the absence of comments on this substance (historically).

Limited public comments were received during the last round. However, stakeholders that did submit comments were overwhelming supportive of relisting this material. There were several comments that suggested adding an annotation to require labeling of fruits and vegetables that had orange shellac applied. This is, in part, due to some individuals showing allergic symptoms and that some vegetarians may consider this material an animal product not suitable for consumption. Disclosing fruit coatings on labels is nuanced. The subcommittee discussed this and determined that this is an FDA labeling issue and is outside of NOP's jurisdiction.

Other commenters pointed out that while alternatives do exist (e.g. wood rosin, carnauba wax, beeswax, and candelilla wax), variability in shine and permeability may mean that certain waxes work better in some applications while others perform better in other applications. Only wood rosin and carnauba wax are currently listed as non-synthetics allowed on the National List. If beeswax, and candelilla wax would be used, they would be required to be organic. Additionally corn zein was petitioned for inclusion on the National List as a food coating and processing aid. The board narrowed the scope by adding an annotation for nutraceutical and pharmaceutical industries only. Despite the narrowed scope the NOSB voted to not add zein to the National List.

The lack of information about whether orange shellac's use in organic products is widespread or necessary as well as the dearth of public comments on this material led the Board to consider delisting, however, there was not adequate evidence demonstrating that non-synthetic substances are adequate alternatives. As such the board unanimously relisted orange shellac during the last sunset review.

Questions
1. Is orange shellac necessary for use in organic production (i.e. should it remain on §205.606)? Why?

National Organic Standards Board
Livestock Subcommittee
Iodine Annotation Change Proposal

Summary of Review:
The National Organic Standards Board (NOSB) acknowledges that iodine remains necessary to livestock operations as a sanitizer for medical procedures and for topical use, particularly as a teat dip for dairy animals. NOSB has heard from numerous stakeholders that it is time to ensure that iodine products used on organic farms are free from nonylphenol ethoxylates (NPEs) since they role a role in endocrine disruption. A limited scope TR was requested to evaluate the availability of NPE-free iodine products and their suitability, the potential for NPEs contained in iodine products to contaminate organic products and the environment, and what detrimental effects may occur should NPEs enter the supply chain or be applied to soil.

At NOSB's Spring 2024 meeting, the Livestock Subcommittee (LS) requested comments from stakeholders related to a potential annotation on iodine to prohibit NPEs. Commenters generally expressed support for the phase out of iodine formulas that contain NPEs. Environmental groups applauded the idea that organic farmers would lead the way in the removal of these harmful substances from their organic system plans. Certifiers and material review organizations (MROs) indicated that there are numerous formulations available on the market approved for use in organic system plans that do not contain NPEs. Dairy producers indicated support for the additional restriction, as it would better support organic principles of minimizing the impact to the environment, while not overly burdening organic dairy farmers with too few options for iodine products. Commenters suggested that the annotation prohibit all alkylphenol ethoxylates, and not just NPEs.

At its Fall 2024 meeting the NOSB proposed annotating iodine to prohibit all alkylphenol ethoxylates. However, public comments indicated that industry has not developed the necessary skillset and best practices to identify and prohibit iodine products containing alkylphenol ethoxylates that are not NPEs. Public comments also indicated that the vast majority of iodine products containing alkylphenol ethoxylates use NPEs, not alternative substances. Additionally, while there are some patents that include octylphenol ethoxylates as alternative formulants, it is extremely uncommon for manufacturers to use these substances. Based on feedback from stakeholders at the Fall 2024 meeting, the LS has revised its proposed annotation change to restrict only NPEs from iodine products.

Subcommittee Vote

Motion to amend the listing for iodine at § 205.603(a)(16) and § 205.603(b)(4) as follows:
Iodine, must be produced without the use of nonylphenol ethoxylates
Motion by: Nate Lewis
Seconded by: Brian Caldwell
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Sunset 2027
Meeting 1 - Request for Public Comment
Livestock Substances § 205.603 & § 205.604
Spring 2025

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 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 2024 public meeting, the NOP requests that the public provide comments about these substances to the NOSB as part of the Spring 2025 public meeting. Written comments should be submitted via Regulations.gov at www.regulations.gov during the comment period as explained in the meeting notice published in the Federal Register.

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

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

For Comments that Do Not Support the Continued Use of §205.603 Substances in Organic Production:
If you provide comments that do not support a substance at §205.603, you should provide reasons why the use of the substance should no longer be allowed in organic production. Specifically, comments that

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

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

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

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

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

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

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

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

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

Written public comments will be accepted via www.regulations.gov during the open comment period noted in the Federal Register. 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:
Butorphanol
Flunixin
Magnesium hydroxide

Oxytocin
Poloxalene
Formic acid
Sucrose octanoate esters
EPA List 4 Inerts
Excipients

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

Butorphanol

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(5) Butorphanol (CAS #-42408-82-2) - federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:
(i) Use by or on the lawful written order of a licensed veterinarian; and
(ii) A meat withdrawal period of at least 42 days after administering to livestock intended for slaughter; and a milk discard period of at least 8 days after administering to dairy animals.
Technical Report: 2002 TAP
Petition(s): 2002 Petition
Past NOSB Action: 2002 Livestock Subcommittee recommendation; 09/2002 Meeting minutes and vote; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: National List Amended 12/12/2007 (72 FR 7049); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review
Use
Butorphanol is used in livestock production as a pre-operative treatment of pain before surgery. Butorphanol belongs to a general class of drugs known as opiate agonists. It is commonly used as an anesthetic used to treat patients prior to surgery. Other related drugs in this class include buprenorphine, fentanyl, merperidine, and morphine. Xylazine, acepromazine, and butorphanol serve similar functions, but each has its own specific advantages that make it the preferred treatment at the time: acepromazine has no analgesic activity, it is only a sedative; xylazine has both analgesic and sedative properties; and butorphanol is a pain killer with no real sedative activity (2002 TAP, page 24). Although there are non-synthetic opiates (refers to a group of drugs used for treating pain), butorphanol is preferred for several reasons: it is associated with fewer adverse effects for the animal and it has less abuse potential in humans, thereby reducing unwanted consequences if the drug is diverted to illicit use (2002 TAP, page 26).

Manufacture
Butorphanol is an opioid analgesic derived from morphine. Known for the ability to reduce the perception of pain without a loss of consciousness, the original opioids were derived from opium, which is a partially dried latex harvested from the opium poppy, *Papaver somniferum* (2002 TAP, page 3).

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Substances that appear in CAN/CGSB-32.311, *Organic production systems — Permitted substances lists,* are subject to the FDA when used in Canada as veterinary drugs destined to food producing animals and to the Feeds Act (FA) when used in Canada as livestock feed. Health Canada's Veterinary Drugs Directorate is the federal authority responsible for the regulation of veterinary drugs under the FDA Regulations (Introduction, CAN/CGSB-32.311-2020).
- Botanical compounds: Botanical preparations, such as atropine, butorphanol, and other medicines from herbaceous plants shall be used according to label specifications (Table 5.3 – Health care products and production aids, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Butorphanol is not explicitly mentioned in the regulations.
- Disease prevention shall be based on breed and strain selection, husbandry management practices, high-quality feed, exercise, appropriate stocking density and adequate and appropriate housing maintained in hygienic conditions. Immunological veterinary medicinal products may be used. Chemically synthesised allopathic veterinary medicinal products, including antibiotics and boluses of synthesised allopathic chemical molecules, shall not be used for preventive treatment (Disease prevention, EC No. 2018/848).
- Disease shall be treated immediately to avoid suffering of the animal. Chemically synthesised allopathic veterinary medicinal products, including antibiotics, may be used where necessary, under strict conditions and under the responsibility of a veterinarian, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular, restrictions with respect to courses of treatment and withdrawal periods shall be defined. The withdrawal period between the last administration to an animal of a chemically synthesised allopathic veterinary medicinal product, including of an antibiotic, under normal conditions of use, and the production of organically produced foodstuffs from that animal shall be twice the withdrawal period referred to in Article 11 of Directive 2001/82/EC, and shall be at least 48 hours (Veterinary treatment, EC No. 2018/848).

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

- Butorphanol is not explicitly mentioned in the regulations.
- The basis for organic livestock husbandry is the development of a harmonious relationship between land, plants and livestock, and respect for the physiological and behavioural needs of livestock. This is achieved by a combination of providing good quality organically grown feedstuffs, appropriate stocking rates, livestock husbandry systems appropriate to behavioural needs, and animal management practices that minimize stress and seek to promote animal health and welfare, prevent disease, and avoid the use of chemical allopathic veterinary drugs (including antibiotics) (Description and Definitions, CXG 32-1999).
- Organic livestock management should aim to utilize natural breeding methods, minimize stress, prevent disease, progressively eliminate the use of chemical allopathic veterinary drugs (including antibiotics), reduce the feeding of animals with products of animal origin (e.g. meat meal), and maintain animal health and welfare (Livestock and Livestock Products, CXG 32-1999).
- The use of veterinary medicinal products in organic farming shall comply with the following principles: a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted; b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that

their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended; c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours; d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited (Health care, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Butorphanol is not explicitly mentioned in the regulations.
- Organic animal management does not practice any prophylactic use of synthetic allopathic veterinary drugs. Organic animal management strictly limits use of antibiotic and other allopathic chemical veterinary drugs for animals to the treatment of illness and injuries under the supervision of qualified personnel, and subject to defined withdrawal periods. Common withdrawal period: at least twice the legislated withdrawal period or 48 hours, whichever is longer (Animal Production, IFOAM NORMS 2014).
- Organic animal management systems follow the principle of positive health, which consist of a graduated approach of prevention (including vaccinations and anti-parasite treatments only when essential), then natural medicines and treatment, and finally if unavoidable, treatment with allopathic chemical drugs (Livestock production, IFOAM NORMS 2014).
- Use of synthetic allopathic veterinary drugs or antibiotics will cause the animal to lose its organic status. Producers shall not withhold such medication where doing so will result in unnecessary suffering of the livestock. Regional or other exception: The animal may retain its organic status if: a) the operator can demonstrate compliance with 5.6.1, and; b) natural and alternative medicines and treatments are unlikely to be effective to cure sickness or injury, or are not available to the operator, and; c) the chemically synthetized allopathic veterinary medical products or antibiotics are used under the supervision of a veterinarian, and; d) withdrawal periods shall be not less than double of that required by legislation, or a minimum of 14 days, whichever is longer; e) this exception is granted for a maximum of three courses of remedial treatments with chemically synthesized allopathic veterinary medicinal products or antibiotics within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year (Veterinary Medicine, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Butorphanol is not explicitly mentioned in the regulations.
- Do not use veterinary medicinal products unless a specific disease or health problem has occurred or is likely to occur and no other appropriate treatment or control method is available, or unless required by laws and regulations (including orders and dispositions based on the provisions of laws; the same applies hereinafter). In the case where veterinary medicinal products are used, veterinary medicinal products other than medicines requiring medical examination or antibiotics are to be used. Vitamins, minerals, veterinary biological drugs, or any veterinary medicinal products other than parasiticides, should be used only for the therapeutic treatment of livestock or poultry (Health management, JAS for Organic Livestock Products).

Ancillary Substances

Butorphanol tartrate includes sodium chloride, sodium citrate, and citric acid.

Human Health and Environmental Issues

Impacts of manufacture of butorphanol are unknown (2002 TAP, page 25). Butorphanol is administered via

injection. Butorphanol and metabolites are not considered toxic if released. Although the fate of butorphanol in the environment is not known, the metabolites that are excreted via urine and bile are water-soluble which will not likely accumulate in the local environment. Butorphanol disposal in city water drainage/sewer systems is an accepted practice (2002 TAP, page 25).

Discussion
The NOSB has reviewed several substances related to pain relief in livestock over the past 2 years. The community consistently highlights the necessity of having adequate pain relief materials available to organic livestock producers. Butorphanol is effective at managing pain in mild to moderate pain scenarios.

Questions to our Stakeholders
1. In what circumstances is Butorphanol commonly used on organic livestock operations?
2. Is the pain relief material toolbox for managing pain in surgical applications sufficient?

Flunixin

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(12) Flunixin (CAS #-38677-85-9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA
Technical Report: 2007 TAP
Petition(s): N/A
Past NOSB Actions: 10/2002 NOSB recommendation; 10/2010 NOSB sunset recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: National List Amended 12/12/2007 (72 FR 7049); Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Flunixin, in its compounded state called flunixin meglumine, is a potent, non-narcotic, nonsteroidal analgesic agent with anti-inflammatory and antipyretic activity. Flunixin, in its drug form, Banamine®, exists for intravenous or intramuscular use in horses and for intravenous use in beef and non-lactating dairy cattle only to treat inflammation and pyrexia (2007 TAP, pages 1-2).

Banamine® has been used to rapidly reduce the fever and lung inflammation that typically accompany Bovine Respiratory Disease (BRD). As a result of usage, cattle feel better faster and have fewer lung lesions in comparison to treatment with other remedies. Additionally, Banamine® has been used to reduce inflammation associated with endotoxemia (2007 TAP, page 3).

If all precautions are followed and the drug is administered appropriately, there will be no harm done to humans who consume the meats from these animals - and the livestock are able to cope with the disorder and actually heal from it, quickly recovering, and granting the farmer economic satisfaction (2007 TAP, page 1).

Manufacture
Flunixin is a synthetic drug more commonly made into flunixin meglumine, which is the primary component

of Banamine® (the injectable flunixin meglumine solution). It has been FDA approved and used in horses for intravenous or intramuscular injections for beef and non-lactating dairy cattle for many years to help cope with inflammation, pyrexia, and colic. Administered intravenously and intramuscularly, flunixin is quickly broken down internally and cleared from the bloodstream in urine (2007 TAP, page 1).

Flunixin meglumine is a potent inhibitor of the enzyme cyclooxygenase (2007 TAP, page 19), is often classified as a non-steroidal anti-inflammatory drug (NSAID), and it functions by reducing the production of mediators of the inflammatory process. It acts as an anti-inflammatory by inhibiting the effect of prostaglandins by inhibiting cyclooxygenase (COX), the enzyme responsible for the direct synthesis of prostaglandins (2007 TAP, page 3).

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Flunixin is not explicitly mentioned in the regulations.
- Substances that appear in CAN/CGSB-32.311, *Organic production systems — Permitted substances lists,* are subject to the FDA when used in Canada as veterinary drugs destined to food producing animals and to the Feeds Act (FA) when used in Canada as livestock feed. Health Canada's Veterinary Drugs Directorate is the federal authority responsible for the regulation of veterinary drugs under the FDA Regulations (Introduction, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Flunixin is not explicitly mentioned in the regulations.
- Disease prevention shall be based on breed and strain selection, husbandry management practices, high-quality feed, exercise, appropriate stocking density and adequate and appropriate housing maintained in hygienic conditions. Immunological veterinary medicinal products may be used. Chemically synthesised allopathic veterinary medicinal products, including antibiotics and boluses of synthesised allopathic chemical molecules, shall not be used for preventive treatment (Disease prevention, EC No. 2018/848).
- Disease shall be treated immediately to avoid suffering of the animal. Chemically synthesised allopathic veterinary medicinal products, including antibiotics, may be used where necessary, under strict conditions and under the responsibility of a veterinarian, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular, restrictions with respect to courses of treatment and withdrawal periods shall be defined. The withdrawal period between the last administration to an animal of a chemically synthesised allopathic veterinary medicinal product, including of an antibiotic, under normal conditions of use, and the production of organically produced foodstuffs from that animal shall be twice the withdrawal period referred to in Article 11 of Directive 2001/82/EC, and shall be at least 48 hours (Veterinary treatment, EC No. 2018/848).

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

- Flunixin is not explicitly mentioned in the regulations.
- The basis for organic livestock husbandry is the development of a harmonious relationship between land, plants and livestock, and respect for the physiological and behavioural needs of livestock. This is achieved by a combination of providing good quality organically grown feedstuffs, appropriate stocking rates, livestock husbandry systems appropriate to behavioural needs, and animal management practices that minimize stress and seek to promote animal health and welfare, prevent disease, and avoid the use of chemical allopathic veterinary drugs (including antibiotics) (Description and Definitions, CXG 32-1999).

- Organic livestock management should aim to utilize natural breeding methods, minimize stress, prevent disease, progressively eliminate the use of chemical allopathic veterinary drugs (including antibiotics), reduce the feeding of animals with products of animal origin (e.g. meat meal), and maintain animal health and welfare (Livestock and Livestock Products, CXG 32-1999).
- The use of veterinary medicinal products in organic farming shall comply with the following principles: a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted; b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended; c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours; d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited (Health care, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Flunixin is not explicitly mentioned in the regulations.
- Organic animal management does not practice any prophylactic use of synthetic allopathic veterinary drugs. Organic animal management strictly limits use of antibiotic and other allopathic chemical veterinary drugs for animals to the treatment of illness and injuries under the supervision of qualified personnel, and subject to defined withdrawal periods. Common withdrawal period: at least twice the legislated withdrawal period or 48 hours, whichever is longer (Animal Production, IFOAM NORMS 2014).
- Organic animal management systems follow the principle of positive health, which consist of a graduated approach of prevention (including vaccinations and anti-parasite treatments only when essential), then natural medicines and treatment, and finally if unavoidable, treatment with allopathic chemical drugs (Livestock production, IFOAM NORMS 2014).
- Use of synthetic allopathic veterinary drugs or antibiotics will cause the animal to lose its organic status. Producers shall not withhold such medication where doing so will result in unnecessary suffering of the livestock. Regional or other exception: The animal may retain its organic status if: a) the operator can demonstrate compliance with 5.6.1, and; b) natural and alternative medicines and treatments are unlikely to be effective to cure sickness or injury, or are not available to the operator, and; c) the chemically synthetized allopathic veterinary medical products or antibiotics are used under the supervision of a veterinarian, and; d) withdrawal periods shall be not less than double of that required by legislation, or a minimum of 14 days, whichever is longer; e) this exception is granted for a maximum of three courses of remedial treatments with chemically synthesized allopathic veterinary medicinal products or antibiotics within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year (Veterinary Medicine, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Flunixin is not explicitly mentioned in the regulations.
- Do not use veterinary medicinal products unless a specific disease or health problem has occurred or is likely to occur and no other appropriate treatment or control method is available, or unless required by laws and regulations (including orders and dispositions based on the provisions of laws; the same applies hereinafter). In the case where veterinary medicinal products are used, veterinary medicinal products other than medicines requiring medical examination or antibiotics are to be

used. Vitamins, minerals, veterinary biological drugs, or any veterinary medicinal products other than parasiticides, should be used only for the therapeutic treatment of livestock or poultry (Health management, JAS for Organic Livestock Products).

Ancillary Substances
Flunixin is an ancillary substance in other pain relief drug formulations.

Human Health and Environmental Issues
Generally, flunixin has been declared safe and the probability of environmental contamination during use or disposal of flunixin is very low. EPA stated in a report on PPCP (Pharmaceuticals and Personal Care Products) that are found in the environment, particularly in the water, flunixin was not among the other NSAIDs (i.e. aspirin, ibuprofen, etc.) that had residues left in the waters.

Discussion
The Livestock Subcommittee has generally heard over the past 4 meetings that pain management in organic livestock is a top priority.

Questions to our Stakeholders
1. What are the common applications of this material?
2. Are the tools available for surgical pain relief sufficient to manage pain in organic animals?

Magnesium hydroxide

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(18) Magnesium hydroxide (CAS #-1309-42-8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires use by or on the lawful written order of a licensed veterinarian.
Technical Report: 2007 TAP
Petition(s): 2002 Petition
Past NOSB Actions: 2002 NOSB recommendation; 03/2005 NOSB sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Magnesium hydroxide, also referred to as milk of magnesia, is used as an antacid for temporary relief of an upset stomach and as a laxative for short-term relief of constipation. Magnesium hydroxide is used as a flame retardant and smoke depressant for temperatures exceeding 400 degrees Fahrenheit. It is also a general food additive used as a color-retention agent, drying agent, pH control agent, or processing aid.

Manufacture
The TAP states magnesium hydroxide (Brucite) is found naturally in serpentine, chlorite or dolomitic schists, or in crystalline limestones as an alteration product of periclase (magnesium oxide). It is prepared by mixing

sodium hydroxide with a water-soluble magnesium salt. It is also formed by the hydration of reactive magnesium oxide. Either case produces magnesium hydroxide as a white precipitate (2007 TAP, page 3).

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Magnesium hydroxide is not explicitly mentioned in the regulations.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Magnesium hydroxide is not explicitly mentioned in the regulations.

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

- Magnesium hydroxide is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Magnesium hydroxide is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Magnesium hydroxide is permitted when obtained by grinding natural ores (Table A.1 Fertilizers and soil improvement substances, JAS for Organic Products of Plant Origin).

Ancillary Substances

N/A

Human Health and Environmental Issues

According to the TAP, the EPA has deemed magnesium hydroxide environmentally safe. This assessment is based on toxicology reports provided by the Center for Disease Control. Magnesium hydroxide is not listed on the EPA's list of regulated chemicals (2007 TAP, page 8). In addition, magnesium hydroxide is allowed for extra-label use in livestock under the provisions of AMDUCA.

Discussion

The reference material for this substance is from 2007. While the substance appears to remain necessary for organic livestock production and there does not appear to be any new information to suggest it now fails any of the National List criteria, future boards may want to consider requesting an updated Technical Review for its use in livestock production.

Questions to our Stakeholders

None

Oxytocin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(17) Oxytocin—use in post parturition therapeutic applications
Technical Report: 1995 TAP; 2005 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation to remove
Recent Regulatory Background: Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 02/28/2022 (87 FR 10930)
Sunset Date: 03/15/2027

Subcommittee Review

Use
Oxytocin is a hormone produced primarily in two discrete locations in the brains of all male and female mammals (2005 TR, lines 18-19). In nonorganic production, it can be used regularly to help nonorganic dairy cows relax and "let down their milk" (1995 TAP, page 9). There are some concerns with overuse of oxytocin in nonorganic production systems. In the USDA organic regulations, it is used "in post parturition therapeutic applications," which is ambiguous.

Manufacture
Oxytocin is chemically manufactured as a both a veterinary and medical synthetic hormone. It is identical in structure ($C_{44}H_{68}N_{12}O_{12}S_2$) to the naturally occurring hormone. In brief, oxytocin's peptide synthesis goes through multiple steps and involves a series of condensation reactions using various solvents (e.g., triethylamine, ether) to form amide bonds. Biologically active oxytocin exists in a cyclic configuration formed by oxidation of two thiol groups to form a disulfide bond between the cysteine and asparagine amino acids. Other molecular configurations (e.g., non-cyclic) also may exist (2005 TR, lines 95-101).

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Oxytocin is permitted for post-parturition therapeutic use. Meat from treated animals will not lose its organic status. See 6.6.10 d) of CAN/CGSB-32.310, for criteria pertaining to the mandatory withdrawal period (Table 5.3 – Health care products and production aids, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Oxytocin is not explicitly mentioned in the regulations.
- Disease shall be treated immediately to avoid suffering of the animal. Chemically synthesised allopathic veterinary medicinal products, including antibiotics, may be used where necessary, under strict conditions and under the responsibility of a veterinarian, when the use of phytotherapeutic, homeopathic and other products is inappropriate.

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

- Oxytocin is not explicitly mentioned in the regulations.
- The use of veterinary medicinal products in organic farming shall comply with the following principles: a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted; b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended; c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours; d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited (Health care, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Oxytocin is not explicitly mentioned in the regulations.

- Organic animal management does not practice any prophylactic use of synthetic allopathic veterinary drugs. Organic animal management strictly limits use of antibiotic and other allopathic chemical veterinary drugs for animals to the treatment of illness and injuries under the supervision of qualified personnel, and subject to defined withdrawal periods.
- Use of synthetic allopathic veterinary drugs or antibiotics will cause the animal to lose its organic status. Producers shall not withhold such medication where doing so will result in unnecessary suffering of the livestock. Regional or other exception: The animal may retain its organic status if: a) the operator can demonstrate compliance with 5.6.1, and; b) natural and alternative medicines and treatments are unlikely to be effective to cure sickness or injury, or are not available to the operator, and; c) the chemically synthetized allopathic veterinary medical products or antibiotics are used under the supervision of a veterinarian, and; d) withdrawal periods shall be not less than double of that required by legislation, or a minimum of 14 days, whichever is longer; e) this exception is granted for a maximum of three courses of remedial treatments with chemically synthesized allopathic veterinary medicinal products or antibiotics within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year (Veterinary Medicine, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Oxytocin is not explicitly mentioned in the regulations.
- Do not use veterinary medicinal products unless a specific disease or health problem has occurred or is likely to occur and no other appropriate treatment or control method is available, or unless required by laws and regulations.

Ancillary Substances
None

Human Health and Environmental Issues
In general, the acute toxicity of oxytocin is considered low. The lethal dose (LD_{50}) of oxytocin has been determined by the oral route of administration in rats (> 20.5 mg/kg) and mice (> 514 mg/kg). Its LD_{50} in rats via intravenous administration is much lower and has been reported in the literature to range from > 2.275 mg/kg to 5.8 mg/kg. Veterinary oxytocin is not available in oral form because it is destroyed in the stomach and intestines of mammals. More specifically, the nonapeptide is degraded into biologically inactive smaller peptides and amino acids by enzymes of the gastrointestinal tract (2005 TR, lines 164-170).

Because oxytocin is used in small doses on a case-by-case basis and only by or under the direction of a veterinarian in organic livestock production, it is unlikely to reach significant concentrations in the environment (agro-ecosystem) through normal use (2005 TR, lines 133-135).

Oxytocin consumed by humans in contaminated milk or drinking water would likely be destroyed in their stomach and intestines (2005 TR, lines 248-249).

Discussion
Oxytocin has been on the National List of approved synthetics since the USDA organic regulations were implemented.
In comments received for the 2020 sunset review, the two largest organic milk buyers in the U.S., CROPP Cooperative/Organic Valley and White Wave/Horizon, did not support renewal of this material. Numerous comments stated the current annotation of “use in post parturition therapeutic applications” is unclear, leading to uses on organic milk animals that do not meet the intention of this annotation. Commenters asked for clarity detailing what time frame is considered “post parturition,” and which therapeutic

applications are allowed. Some certifiers would not allow its use for "milk let down," others would not allow its use for displaced abomasum, while other certifiers would. Two different certifiers, Pennsylvania Certified Organic (PCO) and California Certified Organic Farmers (CCOF), noted a total of 47 operations had used it, while others noted it was not commonly used. Those in favor of relisting stated this is an important material in the dairy health toolkit to assist animals after giving birth. Those not in favor stated there were preventative measures, as well as other activities that could be performed post birthing, that make oxytocin unnecessary in organic livestock production.

In 2020, the NOSB voted to remove oxytocin from the National List, but this recommendation was not implemented. The NOP stated, "By retaining oxytocin on the National List, organic livestock producers will continue to be permitted to use the drug to treat specific conditions within a limited timeframe following parturition without forfeiting the animal's organic status." And, "The current annotation allows producers to use oxytocin to treat conditions related to labor and to an animal's postpartum survival. Its use is not permitted on a routine basis (*i.e.,* as protocol). Instead, it is available for emergency situations and severe complications in the immediate postpartum (following birth of young) period. It may not be administered to increase an animal's milk production (volume) or for milk letdown. As previously noted in this document, Federal law restricts this drug to use by or on the order of a licensed veterinarian (21 CFR 522.1680(c)(3))."

In the current review, the LS discussed the 2020 recommendation as well as possible reasons for relisting. It was pointed out that some dairy processors do not allow their dairy farms to use oxytocin, and thus can make the labeling claim of "no synthetic hormones." For other livestock farmers, the use of oxytocin is part of their approach to birthing problems. The LS recommends that oxytocin be relisted, on the balance of these considerations.

Questions to our Stakeholders

1. Is oxytocin an essential material for safe and humane treatment of animals in organic production and why?
2. Are there nonsynthetic alternatives, or other methods that can be used to accomplish the same results as oxytocin?

Poloxalene

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(26) Poloxalene (CAS #-9003-11-6)—for use under 7 CFR part 205, the NOP requires that poloxalene only be used for the emergency treatment of bloat
Technical Report: 2001 TAP; 2025 Limited Scope TR
Petition(s): 2000 Petition
Past NOSB Actions: 03/2001 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Poloxalene (chemical formula: $C_5H_{10}O_2$) is a copolymer of polyethylene and polypropylene ether glycol that is a non-ionic polyol surface-active agent. Poloxalene is a fast-acting synthetic material approved under the

organic regulations only for emergency treatment of bloat in ruminants, such as cattle and sheep. Poloxalene destabilizes foam and allows gas to release from the rumen.

Manufacture

A limited scope TR was completed in 2024 to evaluate the manufacturing process of poloxalene. As stated in the TR, the process for synthesizing poloxalene always involves the polymerization of ethylene oxide (EO) and propylene oxide (PO) to form a block copolymer. However, the process manufacturers use to produce the monomers can vary. PO and EO manufacturing is further described in the TR, as well as the steps involved in the polymerization reaction used to synthesize poloxalene. Once both monomers (PO and EO) are available, they are copolymerized to form poloxalene. Manufactures typically do this in the presence of a catalyst – such as KOH – which facilitates the polymerization reaction. The process consists of three steps: initiation, propagation, and termination. Poloxalene is not created using excluded methods.

Prior to the updated TR, manufacturing information was derived from the 2001 NOSB TAP review of poloxalene, which stated "There are two principal processes used [to manufacture poloxalene], the traditional chlorohydrin process and indirect oxidation by the hydroperoxide process that uses a molybdenum catalyst. Both processes start with propylene (propene) derived from cracking of petroleum. The chlorohydrin process involves reaction of propylene ($CH_3CH=CH_2$) and chlorine in the presence of water to produce two isomers of propylene chlorohydrin. This is followed by dehydrochlorination using caustic soda or lime to produce propylene oxide and salt. The hydroperoxide process involves oxidation of propylene to PO by an organic hydroperoxide, producing an alcohol as a co-product. One of the possible alcohols (tert-butanol, TBE) produced as a by-product from this process is used as feedstock for MTBE, a gasoline additive (2001 TAP, page 1).

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Poloxalene is not explicitly mentioned in the regulations.
- Substances that appear in CAN/CGSB-32.311, *Organic production systems — Permitted substances lists,* are subject to the FDA when used in Canada as veterinary drugs destined to food producing animals and to the Feeds Act (FA) when used in Canada as livestock feed. Health Canada's Veterinary Drugs Directorate is the federal authority responsible for the regulation of veterinary drugs under the FDA Regulations (Introduction, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Poloxalene is not explicitly mentioned in the regulations.
- Disease prevention shall be based on breed and strain selection, husbandry management practices, high-quality feed, exercise, appropriate stocking density and adequate and appropriate housing maintained in hygienic conditions. Immunological veterinary medicinal products may be used. Chemically synthesised allopathic veterinary medicinal products, including antibiotics and boluses of synthesised allopathic chemical molecules, shall not be used for preventive treatment (Disease prevention, EC No. 2018/848).
- Disease shall be treated immediately to avoid suffering of the animal. Chemically synthesised allopathic veterinary medicinal products, including antibiotics, may be used where necessary, under strict conditions and under the responsibility of a veterinarian, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular, restrictions with respect to courses of treatment and withdrawal periods shall be defined. The withdrawal period between the last administration to an animal of a chemically synthesised allopathic veterinary medicinal product, including of an antibiotic, under normal conditions of use, and the production of organically produced foodstuffs from that animal shall be twice the withdrawal period referred to in Article 11 of Directive 2001/82/EC, and shall be at least 48 hours (Veterinary treatment, EC No. 2018/848).

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

- Poloxalene is not explicitly mentioned in the regulations.
- The basis for organic livestock husbandry is the development of a harmonious relationship between land, plants and livestock, and respect for the physiological and behavioural needs of livestock. This is achieved by a combination of providing good quality organically grown feedstuffs, appropriate stocking rates, livestock husbandry systems appropriate to behavioural needs, and animal management practices that minimize stress and seek to promote animal health and welfare, prevent disease, and avoid the use of chemical allopathic veterinary drugs (including antibiotics) (Description and Definitions, CXG 32-1999).
- Organic livestock management should aim to utilize natural breeding methods, minimize stress, prevent disease, progressively eliminate the use of chemical allopathic veterinary drugs (including antibiotics), reduce the feeding of animals with products of animal origin (e.g. meat meal), and maintain animal health and welfare (Livestock and Livestock Products, CXG 32-1999).
- The use of veterinary medicinal products in organic farming shall comply with the following principles: a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted; b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended; c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours; d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited (Health care, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)

- Poloxalene is not explicitly mentioned in the regulations.
- Organic animal management does not practice any prophylactic use of synthetic allopathic veterinary drugs. Organic animal management strictly limits use of antibiotic and other allopathic chemical veterinary drugs for animals to the treatment of illness and injuries under the supervision of qualified personnel, and subject to defined withdrawal periods. Common withdrawal period: at least twice the legislated withdrawal period or 48 hours, whichever is longer (Animal Production, IFOAM NORMS 2014).
- Organic animal management systems follow the principle of positive health, which consist of a graduated approach of prevention (including vaccinations and anti-parasite treatments only when essential), then natural medicines and treatment, and finally if unavoidable, treatment with allopathic chemical drugs (Livestock production, IFOAM NORMS 2014).
- Use of synthetic allopathic veterinary drugs or antibiotics will cause the animal to lose its organic status. Producers shall not withhold such medication where doing so will result in unnecessary suffering of the livestock. Regional or other exception: The animal may retain its organic status if: a) the operator can demonstrate compliance with 5.6.1, and; b) natural and alternative medicines and treatments are unlikely to be effective to cure sickness or injury, or are not available to the operator, and; c) the chemically synthetized allopathic veterinary medical products or antibiotics are used under the supervision of a veterinarian, and; d) withdrawal periods shall be not less than double of that required by legislation, or a minimum of 14 days, whichever is longer; e) this exception is granted for a maximum of three courses of remedial treatments with chemically

synthesized allopathic veterinary medicinal products or antibiotics within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year (Veterinary Medicine, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Poloxalene is not explicitly mentioned in the regulations.
- Do not use veterinary medicinal products unless a specific disease or health problem has occurred or is likely to occur and no other appropriate treatment or control method is available, or unless required by laws and regulations (including orders and dispositions based on the provisions of laws; the same applies hereinafter). In the case where veterinary medicinal products are used, veterinary medicinal products other than medicines requiring medical examination or antibiotics are to be used. Vitamins, minerals, veterinary biological drugs, or any veterinary medicinal products other than parasiticides, should be used only for the therapeutic treatment of livestock or poultry (Health management, JAS for Organic Livestock Products).

Ancillary substances
No clear information on ancillary substances was available.

Environmental/Health Issues
According to the 2001 TAP review, "The production of organic polymers from petroleum sources is a large volume chemical manufacturing process that has significant environmental impact." The 2001 TAP also states that the "FDA does not list any withdrawal times or residue tolerances for poloxalene (21CFR)" and also added the following in regard to human health: "Poloxalene is listed by USP for use as pharmaceutics aid. It is reported to have no known toxicity and is not listed in the National Toxicology Program Database" (2001 TAP, page 3).

Discussion
Many preventive measures can be taken to avoid pasture bloat. Organic farmers seeking to establish a pasture-based system for ruminants may occasionally experience unforeseen incidence of pasture bloat that requires an emergency remedy, and the use of this synthetic material could be justified to alleviate animal suffering on an emergency basis.

In previous NOSB meetings, many comments either supported continued listing of the substance as necessary in emergencies when natural approaches to treating bloat are not effective, or stated that the substance was used by organic farming operations for emergency situations. The consensus was that while poloxalene is rarely needed, in certain emergency situations it is essential.

Questions to our Stakeholders

1. Are there any non-synthetic, approved, and effective bloat remedies for ruminants that are commercially available to ranchers?

Formic acid

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(3) Formic acid (CAS # 64-18-6) - for use as a pesticide solely within honeybee hives
Technical Report: 2011 TR
Petition(s): 2010 Petition

Past NOSB Actions: 2010 NOSB recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Added to National List, effective August 3, 2012 (77 FR 45903); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Formic acid is a pesticide employed to control Varroa and tracheal mites in honeybee hives. Deployed in the form of a compressed pad inside the hive, the material volatilizes to kill mites throughout the hive including mites attacking broods, and those located externally on and internally in the adult bees.

The EPA first registered formic acid as a pesticide in 1999 as material control for Varroa and tracheal mites in honeybees (2011 TR, lines 89-95). Formic acid kills mites by asphyxiation while not causing harm to the bees (2011 TR, lines 121-125). Typically employed over a 21-day treatment period (per label instructions), the efficacy of formic acid in killing mites has been found to be as high as 95%. Label recommendations instruct producers who treat hives with formic acid to not harvest honey from the hive for two weeks after the introduction of the formic acid pads.

Natural sources of formic acid, which include coffee, nectars, some fruits, as well as the stings of ants and bees, have proven insufficient to extract commercially viable quantities (2011 TR, lines 223-224).

Manufacture
Primarily produced through the hydrolysis of methyl formate. Formic acid may be produced as a byproduct of other chemicals (e.g. acetic acid) though these have not proven to be commercially viable (2011 TR, lines 199-203).

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Hay or silage preservation products are permitted: Preference should be given to bacterial or enzymatic additives derived from bacteria, fungi and plants and food by-products (such as molasses and whey). The following acids may be used: lactic, propionic and formic (Table 5.2 – Feed, feed additives and feed supplements, CAN/CGSB-32.311-2020).
- Acids: Ascorbic, acetic, propionic, citric, formic and lactic acids and vinegar. Permitted for all uses such as treatment of water and bedding (Table 5.3 – Health care products and production aids, CAN/CGSB-32.311-2020).
- Formic acid is permitted for apicultural use, to control parasitic mites. This substance may be used after the last honey harvest of the season and shall be discontinued 30 days before the addition of honey supers (Table 5.3 – Health care products and production aids, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Formic acid, lactic acid, acetic acid and oxalic acid, as well as menthol, thymol, eucalyptol or camphor, may be used in cases of infestation with *Varroa destructor* (Health care, EC No. 2018/848).
- Soft ground rock phosphate is permitted. Product obtained by grinding soft mineral phosphates and containing tricalcium phosphate and calcium carbonate as essential ingredients. Minimum content of nutrients (percentage by weight): 25% P_2O_5. Phosphorus expressed as P_2O_5 soluble in

mineral acids, at least 55% of the declared content of P_2O_5 being soluble in 2% formic acid (Authorised fertilisers, soil conditioners and nutrients, EC No. 2021/1165).
- Formic acid is permitted as a preservative (Authorised feed additives and processing aids used in animal nutrition, EC No. 2021/1165).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
- Silage additives and processing aids may not be derived from genetically engineered/modified organisms or products thereof, and may be comprised of only: sea salt; coarse rock salt; yeasts; enzymes; whey; sugar or sugar products such as molasses; honey; lactic, acetic, formic and propionic bacteria, or their natural acid product when the weather conditions do not allow for adequate fermentation, and with approval of the competent authority (Livestock and Livestock Products, CXG 32-1999).
- For pest and disease control the following are allowed: lactic, oxalic, acetic acid; formic acid; sulphur; natural etheric oils (e.g. menthol, eucalyptol, camphor); *Bacillus thuringiensis*; steam and direct flame (Beekeeping and bee products, CXG 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)
- Fodder preservatives such as the following may be used: a) bacteria, fungi and enzymes; b) natural products of food industry; c) plant-based products; and d) vitamins and minerals subject to 5.5.6. Synthetic chemical fodder preservatives such as acetic, formic, and propionic acid are permitted in severe weather conditions (Animal Nutrition, IFOAM NORMS 2014).
- For pest and disease control the following are permitted: a) lactic acid, formic acid; b) oxalic acid, acetic acid; c) sulfur; d) natural essential oils (e.g. menthol, eucalyptol, camphor); e) *Bacillus thuringiensis;* f) steam, direct flame and caustic soda for hive disinfection (Bee Keeping, IFOAM NORMS 2014).
- Formic acid is permitted (Table 2 - Indicative List of Equipment Cleansers and Equipment Disinfectants, IFOAM NORMS 2014).
- Citric, peracetic acid, formic, lactic, oxalic and acetic acid are permitted (Appendix 5 - Substances for Pest and Disease Control and Disinfection in Livestock Housing and Equipment, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production
- Formic bacteria is permitted (Table A.1 Substances used in the preparation etc., JAS for Organic Feed).
- Natural acids are permitted: limited to those made from lactic bacteria, acetic acid bacteria, formic bacteria or propionic acid bacteria (Table A.1 Substances used in the preparation etc., JAS for Organic Feed).

Environmental Issues

Due to its localized use inside the beehives, no residue is found outside the hive environment. Formic acid is generally recognized as safe (GRAS) by the FDA (21 CFR 186.1316) (2011 TR, lines 99-100). Human health may be adversely affected if formic acid is inhaled or ingested, so respirators and skin covering personal protective equipment are recommended to protect against applicator contact.

Discussion

Formic acid is found in nature. Synthetic formic acid is a relatively benign substance when used to treat Varroa mites, an important pest of honeybees. Because of its low environmental impact and GRAS status, the Livestock Subcommittee recommends retaining it on the National List.

Questions to our Stakeholders

1. Are the options for controlling Varroa mites in beehives sufficient or redundant?
2. Are there natural ways to combat mites that could reduce the dependency on parasiticides?

Sucrose octanoate esters

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(10) Sucrose octanoate esters (CAS #s-42922-74-7; 58064-47-4)—in accordance with approved labeling
Technical Report: 2005 TR; 2025 Limited Scope TR
Petition(s): 2004 petition; 05/2004 petition amendment; 09/2004 petition amendment
Past NOSB Actions: 08/2005 NOSB recommendation; 10/2010 sunset recommendation; 10/2018 sunset recommendation to remove
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/17 (82 FR 14420); Sunset renewal notice published 02/28/2022 (87 FR 10930)
Sunset Date: 3/15/2027

Subcommittee Review
Sucrose octanoate esters (SOEs) belong to the organic chemical family sucrose fatty acid esters (SFAEs) (2005 TR, lines 23-24). SOEs are manufactured from sucrose (table sugar) and an octanoic acid ester commonly found in plants and animals (2005 TR, lines 27-28). SOEs, marketed as biopesticides, are synthetic analogs of the naturally occurring sugar ester isolates of *Nicotiana* plant species (2024 TR, lines 57-58) that mimic the pest control properties of the natural forms of the compound in wild tobacco and other plants in the *Nicotiana* genus. *gossei* Domin (wild tobacco) and other *Nicotiana* species, including wild tomato and wild potato species and the petunia plant (2005 TR, lines 35-38).

Use
Sucrose octanoate esters are listed at §205.603(b)(10) in organic livestock production as a topical treatment, external parasiticide or local anesthetic as applicable, in accordance with approved labeling (2024 TR, lines 34-35). The product is used in controlling Varroa mites in honeybees.

Manufacture
Commercial synthesis of SOEs involves the use of materials such as alcohols, several catalysts, solvents, and sucrose octanoate acid (2024 TR, lines 60-62. Steps in the production include (1) Esterification of fatty acids, (2) Neutralization and separation of catalyst, (3) Second esterification with sugar, (4) Vacuum distillation and emulsification, (5) Separation of emulsified product, and (6) Purification and recovery of sugar ester product (2024 TR, lines 66, 140, 154, 178, 183, and 188). The raw materials are derived from various sources: octanoic acid from both synthetic and nonsynthetic sources, alcohol (methanol or alcohol) from synthetic and nonsynthetic sources, and sucrose that is usually obtained from nonsynthetic sources (2024 TR, lines 197-200). The petitioned substance is a soap derived from coconut oil fatty acids or palm kernel oil fatty acids. Producers use SOEs to control soft-bodied pest organisms including mites, aphids, and whiteflies (2024 TR, line 56). The EPA has registered SOEs as a biopesticide for foliar spray on greenhouse, nursery, and field crops; for *Sciarid* fly control in mushroom-growing media; and for Varroa mite control on honeybees (2005 TR, lines 70-72).

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Strychnine is not explicitly mentioned in the regulations.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
- Strychnine is not explicitly mentioned in the regulations.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
- Strychnine is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)
- Strychnine is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production
- Strychnine is not explicitly mentioned in the regulations.

Ancillary Substances
None

Human Health and Environmental Issues

Effect on the Environment
The chemical structure of SOEs, consisting of sucrose and octanoic acid, renders the material readily biodegradable (2024 TR, line 215). Naturally occurring microorganisms in soil and water can break down these compounds. The compound biodegrades within approximately five days at temperatures ranging from 68°F to 80°F in both aerobic and anaerobic conditions. Typical degradation products are carbon dioxide and water, both of which are harmless. In addition to the fact that these degradation products are harmless, some are incorporated as microbial biomass (2024 TR, lines 216-220).

Impact on Non-Target Organisms
The EPA's evaluation report on the potential impact of SOEs on non-target insects and other organisms, such as fish, stated that the use of the compound had minimal potential for exposure and toxicity to these organisms as well as soil and water (2024 TR, lines 223-225). According to the EPA, the fact that the mode of action of the compound is via physical effects as opposed to biochemical toxicity gives the compound a minimal toxicity profile. The petitioned substance primarily targets soft-bodied insects by physically disrupting the lipid layer of their cuticle, thereby causing dehydration and death. Insects with thicker and/or more robust exoskeletons are not affected by the petitioned substance (2024 TR, lines 231-233).

The physical mode of action enables the compound to target soft-bodied insects without producing general toxic metabolites, thereby decreasing the likelihood of adverse effects on mammals and birds (2024 TR, lines 225-229). Soft-bodied organisms targeted include mites and insects such as thrips, aphids, and whiteflies. The fact that SOEs do not exert their pesticidal effects via a biochemical pathway common to all insects renders it selective, resulting in minimal effects on non-target organisms such as pollinators (e.g., bees), predators (ladybugs), earthworms, and other soil organisms (2024 TR, lines 233-236). Some non-synthetic pesticides are known to have adverse effects on beneficial organisms such as predators and parasitoids. An assessment of the effect of SOEs on multiple beneficial insects from different insect orders in citrus ecosystems revealed a high survival rate of ladybeetles (Coccinellidae), lacewings (Chrysopidae), and parasitoids of red scale insects (Anthocoridae) even when exposed to 8,000 ppm (i.e., parts per million) which represents twice the recommended field application rate (2024 TR, lines 238-242). Soil organisms and non-target insects may be exposed to SOEs during and after applications until the compounds

biodegrade in ~5 days. Direct and specific detrimental effects from SOEs on soil organisms have not been studied extensively. Available literature does not show detrimental physiological effects of SOEs on soil organisms, soil microbiome, or non-target insects (2024 TR, lines 257-260). Current literature states that SOEs have low toxicity and biodegrade rapidly. When SOEs are applied according to EPA-approved label directions, no direct exposure of birds or aquatic organisms to SOEs is expected (2005 TR, lines 201-202).

Effect on Human Health:
SOEs have low toxicity to humans and are produced in a closed system. The 2005 technical report (TR) states that no sub-chronic, chronic, immune, or endocrine issues have been identified (2005 TR, lines 303-304). An ocular risk exists but it is unlikely if the product is used according to label (2005 TR, lines 309-311).

Comparison with natural (Nonsynthetic alternatives)
The 2024 TR did not list any natural alternatives to sucrose octanoate esters for use in the management of Varroa mites in honeybee hives. In the absence of research studies that compare SOEs to nonsynthetic alternatives, the 2024 TR covered the performance and characteristics of nonsynthetic pesticides used in managing pests in crop production. Alternatives listed include neem extract, Pyrethrins, *Bacillus thuringiensis* (Bt), Spinosad, miscellaneous botanicals such as essential oils derived from thyme and eucalyptus, garlic extracts and biological control agents. Even though neem extracts were reported to be effective against listed insect pests, cases of neem oil poisoning in humans were reported (2024 TR, lines 299-300). Pyrethrins can harm beneficial insects such as bees and aquatic organisms if used improperly (2024 TR, lines 312-314). *Bacillus thuringiensis* affects a broader range of organisms than SOEs (2024 TR, line 332). There are reports of non-targeted adverse effects on several groups of insects that are closely related or have an affinity to targeted insects (2024 TR, lines 337-339). At regular field application rates, Bt has been reported to impair the growth and developmental time of non-target true flies such as *Drosophila melanogaster* (common fruit fly) larvae (2024 TR, lines 341-344). There are also reports of insect pest resistance to Bt products (2024 TR, line 352). Spinosad breaks down quickly in the environment and is considered safe for humans and most beneficial insects. It can, however, be toxic to bees if applied directly to flowering plants. Spinosad application has also been demonstrated to have adverse effects on genes associated with energy production in honeybees (2024 TR, lines 367-368).

Discussion

Public Comments
There were no substantive comments from beekeepers during the Spring 2018 public comment period on the continued listing of SOEs at §205.603(b); nevertheless, there were comments from other livestock producers who stated that they were aware that SOEs are an important tool for beekeepers in controlling Varroa mites in honeybees.

In 2018, a public health advocacy organization commented that in view of the restrictive use of SOEs and the difficulty that beekeepers are experiencing in maintaining the health of honeybee colonies, they supported keeping SOEs on the National List.

Rationale for Previous NOSB Recommendation
During the sunset review of sucrose octanoate esters (SOEs) in 2018, information at the time indicated that there were no EPA registered products formulated using SOEs as an ingredient. There were also no public comments received from beekeepers stating the need for this material. Alternatives that are more effective have become available since SOEs were first placed on the National List. Based on the information at the time, the NOSB determined that SOEs were not essential. Additional clarification was provided during a

Subcommittee meeting in January 2025. The absence of public comments from organic beekeepers on SOEs was explained to be because organic honey is sourced mainly from outside the United States. The views of these international organic honey producers were not captured because they do not participate in NOSB meetings.

Questions to our Stakeholders

1. Is there current information on the use of SOE formulations by farmers? Is there a large demand for SOE formulations by livestock producers?

EPA List 4 Inerts

Reference: §205.603(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with non-synthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
(1) EPA List 4 - Inerts of Minimal Concern
Technical Report: 2015 Limited Scope TR - Nonylphenol Ethoxylates (NPEs) (one group only of List 4 inerts)
Petition(s): N/A
Past NOSB Actions: 02/1999 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review
As explained below, the LS expects this listing to be fully replaced before its next sunset review.

Use
Inert ingredients in pesticide formulations are added to enhance functionality and efficacy. Any of the pesticides approved for organic use may contain inert ingredients. For example, surfactants may improve the solubility and half-life of active pesticide ingredients. As described in Shistar (Shistar, T. “Inert” Ingredients Used in Organic Production, Beyond Pesticides, Washington, D.C., 2017), “The relatively few registered pesticides allowed in organic production are contained in product formulations with so-called “inert” ingredients that are not disclosed on the product label. The “inerts” make up the powder, liquid, granule, or spreader/sticking agents in pesticide formulations. The “inerts” are typically included in products with natural or synthetic active pesticide ingredients recommended by the National Organic Standards Board (NOSB) and listed by the National Organic Program (NOP) on the National List of Allowed and Prohibited Substances.”

Manufacture
Since this listing covers many different materials, the manufacture of these substances cannot be specifically stated.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Formulants used in crop production aids may only be used with substances listed in Column 2 of this table. Only formulants classified as List 4A or 4B by the Pest Management Regulatory Agency (PMRA) or derived from biological or mineral sources may be used with substances in Table 4.2 (Column 2). Formulants classified as List 3 by PMRA may be used with passive pheromone

dispensers. Formulants classified as List 4A, 4B or 3 by PMRA are not subject to 1.4 or 1.5 of CAN/CGSB-32.310. Formulants classified as List 1 or 2 by PMRA are prohibited (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).

- Formulants (inerts, excipients) shall be used in conjunction with substances listed in Table 5.3. Formulants are not subject to 1.4 or 1.5 of CAN/CGSB-32.310 or 5.1.2 of this standard (Table 5.3 – Health care products and production aids, CAN/CGSB-32.311-2020).
- Formulants may only be used with substances listed in Table 8.2. Only formulants classified as List 4A or 4B by the Pest Management Regulatory Agency (PMRA) or derived from biological or mineral sources may be used with substances in Table 8.2. Formulants classified as List 3 by PMRA may be used with passive pheromone dispensers. Formulants classified as List 4A, 4B or 3 by PMRA are not subject to 1.4 or 1.5 of CAN/CGSB-32.310. Formulants classified as List 1 or 2 by PMRA are prohibited (Table 8.2 – Facility pest management substances, CAN/CGSB-32.311-2020).
- Formulants may only be used with substances listed in Table 8.3. Only formulants classified as List 4A or 4B by the Pest Management Regulatory Agency (PMRA) or are non-synthetic may be used with substances in Table 8.3. Formulants classified as List 3 by PMRA may be used with passive pheromone dispensers. Formulants classified as List 4A, 4B or 3 by PMRA are not subject to 1.4 or 1.5 of CAN/CGSB-32.310. Formulants classified as List 1 or 2 by PMRA are prohibited (Table 8.3 – Post-harvest substances, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- The following products and substances referred to in Article 2(3) of Regulation (EC) No 1107/2009 shall be allowed for use in organic production, provided that they are authorised pursuant to that Regulation: (a) safeners, synergists, and co-formulants as components of plant protection products; (b) adjuvants that are to be mixed with plant protection products (General production rules, EC No. 2018/848).
- In accordance with Article 9(3) of Regulation (EU) 2018/848, safeners, synergists, and co-formulants as components of plant protection products, and adjuvants that are to be mixed with plant protection products shall be allowed for use in organic production, provided that they are authorised pursuant to Regulation (EC) No 1107/2009. The substances in this Annex may only be used for the control of pests as defined in Article 3(24) of Regulation (EU) 2018/848 (Annex I: Active substances contained in plant protection products authorised for use in organic production, EC No. 2021/1165).

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

- Inerts are not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Organic crop production ensures that co-formulants (e.g. inerts and synergists) in formulated farm input products are not carcinogens, mutagens, teratogens or neurotoxins (Crop Production, IFOAM NORMS 2014).
- Recommendation: In case operators need to use commercial formulated inputs, preference should be given to formulations approved for use in organic agriculture by a specialized organic material review organization/program (Pest, Disease, and Weed Management, IFOAM NORMS 2014).
- Any formulated input shall have only active ingredients listed in Appendix 3. All other ingredients shall not be carcinogens, teratogens, mutagens, or neurotoxins (Pest, Disease, and Weed Management, IFOAM NORMS 2014).

Japan Agricultural Standard (JAS) for Organic Production

- Inerts are not explicitly mentioned in the regulations.

Human Health and Environmental Issues
As noted below, some of the materials listed on EPA List 4 may have negative environmental and human health consequences, while others may be relatively benign. A complete review of materials listed as to environmental issues is not possible without Technical Reviews of each material.

Discussion
Inerts are not necessarily biologically or chemically inert. They may be relatively benign or may be documented as harmful to the environment or human health. Without a way to individually evaluate each substance listed on EPA List 4 or to evaluate substances as a group, it is difficult to discern the acceptability of each substance for use in organic agriculture.

Presently, the National List, under §205.601(m), references the EPA List 4 – Inerts of Minimal Concern, as acceptable in organically approved pesticide formulations. List 4, however, is outdated and no longer maintained by EPA. The list of inerts that is referenced for review of products for organic certification was last updated in August 2004 (EPA website https://www.epa.gov/pesticide-registration/epas-national-organic-program-guidance) and may include materials that some stakeholders believe are inappropriate for organic agriculture. For example, nonylphenol ethoxylates (NPEs) are included on List 4. These materials are endocrine disruptors, may adversely impact fauna and flora, and have been identified by the California Department of Toxic Substances Safer Consumer Products program as a likely high priority chemical that should be formally phased out https://www.ams.usda.gov/sites/default/files/media/NPE%20Technical%20Evaluation%20Report%20%282015%29.pdf. If evaluated on an individual basis, NPEs would likely not meet OFPA criteria for acceptability.

The NOSB and NOP have struggled with how to evaluate the EPA List 4 – Inerts of Minimal Concern during sunset review. OFPA has specific criteria for inerts which states: "*(ii) … contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern"* (§6517 C.1.B.ii). Due to EPA changes in its categorization of inerts and discontinued support for List 4, the NOSB (starting in 2010) adopted a series of recommendations to revise this sunset listing.

Most recently, the Agricultural Marketing Service (AMS) published an Advance Notice of Proposed Rulemaking (ANPR) incorporating several of these recommendations on September 2, 2022, which received extensive stakeholder feedback on updated references for inert ingredients in organic production. Subsequently, based on that feedback, the NOP requested that the NOSB evaluate four options for updating the National List. The NOSB has recommended two of them, plus "hybrid" versions of those two, at the Fall 2024 meeting. At the time of this review, the NOP is moving forward with the rule-making process based on this recommendation.

National List Motion, approved by NOSB, Fall 2024 (shown with changes from current language)**:**

> Motion to add individual substances identified in Appendix A] at 205.601(m)
>
> (m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
> ~~(1) EPA List 4 Inerts of Minimal Concern~~

~~(2) EPA List 3-Inerts of unknown toxicity-for use only in passive pheromone dispensers~~
(1) 1,2,3-Octadecenoate (CAS 9007-48-1)
(2) 12-Hydroxystearic acid-polyethylene glycol copolymer (CAS 70142-34-6)
(3) …

Motion to add individual substances identified in Appendix A] at 205.603(e)

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
~~(1) EPA List 4-Inerts of Minimal Concern~~
~~(2) EPA List 3-Inerts of unknown toxicity-for use only in passive pheromone dispensers~~
(1) 1,2,3-Octadecenoate (CAS 9007-48-1)
(2) 12-Hydroxystearic acid-polyethylene glycol copolymer (CAS 70142-34-6)
(3) …

OR

Motion to amend 205.601(m)

(m) ~~As s~~Synthetic inert ingredients as classified by the Environmental Protection Agency (EPA) and exempted from the requirement of a tolerance, for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances, except for:
~~(1) EPA List 4-Inerts of Minimal Concern~~
~~(2) EPA List 3-Inerts of unknown toxicity-for use only in passive pheromone dispensers~~
(1) Alkylphenol ethoxylate substances
(2) Per- and polyfluoroalkyl substances

Motion to amend 205.603(e)

(e) ~~As s~~Synthetic inert ingredients as classified by the Environmental Protection Agency (EPA) and exempted from the requirement of a tolerance, for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances, except for:
~~(1) EPA List 4-Inerts of Minimal Concern~~
~~(2) EPA List 3-Inerts of unknown toxicity-for use only in passive pheromone dispensers~~
(1) Alkylphenol ethoxylate substances
(2) Per- and polyfluoroalkyl substances
(3) …

The Crops Subcommittee expects an improved listing to be implemented by the NOP in the next two years, replacing the reference to List 4. In the meantime, in order to maintain continuity in pesticide formulations used by organic farmers, we recommend that List 4 Inerts be relisted in this review at 205.601(m) on the National list.

Questions to our Stakeholders

1. Do stakeholders agree that List 4 Inerts should be relisted until they are replaced with a new listing via the rulemaking process currently underway?

Excipients

Reference: §205.603(f) Excipients—only for use in the manufacture of drugs and biologics used to treat organic livestock when the excipient is:

(1) Identified by the FDA as Generally Recognized As Safe;
(2) Approved by the FDA as a food additive;
(3) Included in the FDA review and approval of a New Animal Drug Application or New Drug Application; or
(4) Approved by APHIS for use in veterinary biologics.

Technical Report: 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/2002 NOSB minutes and vote; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 12/27/2018 (83 FR 66559); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
There are more than 8,000 food, drug, and cosmetic excipients available for conventional production; however, excipients currently appear in the USDA National Organic Program (NOP) regulations at §205.603 for use in the manufacture of drugs used to treat organic livestock when the excipient is identified by the FDA as: 1) Generally Recognized As Safe (GRAS); 2) approved by the FDA as a food additive; 3) included in the FDA review and approval of a New Animal Drug Application or New Drug Application; or 4) Approved by APHIS (Animal and Plant Health Inspection Service) for use in veterinary biologics. Additionally, excipients are allowed in "nutritive supplements" listed at §205.603(a)(21).

Excipients are defined in §205.2 as "any ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (e.g., enhancing absorption or controlling release of the drug substance)." Excipients are used in New Animal Drug Applications (NADAs) approved by FDA, and in animal health care products that do not carry NADA registration. They are also used in New Drug Applications (NDAs) in drugs marketed for human consumption that may be administered to animals (2015 TR, lines 38-41).

Excipients are used for a great number of applications in animal drug and health care products but are delineated into broad categories based on the major reasons the excipient is used (2015 TR, lines 75-77). "Examples of such ingredients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents" (§205.2).

Manufacture
Excipients are common in almost all therapeutic products for veterinary use, and, in some cases, the total amount of excipients used is greater than the active substances in the dose. They are derived from natural sources or are synthetically manufactured by chemicals, derived from genetically modified organisms, or manufactured by other means. They range from simple, whole food products to highly characterized organic and inorganic molecules, to complex materials that are difficult to fully characterize chemically (2015 TR, lines 46-50).

Excipients can be added to the active substance individually or together in a formulated excipient package, depending on the drug. Excipients serve many functions but are typically comprised of suspending and viscosity-modifying agents, pH modifiers and buffering agents, preservatives, antioxidants, chelating agents, sequestrants, colorants, flavors, fillers, and diluents. While it is clear the functions that excipients serve, very few of them have been chemically described in any detail (2015 TR, lines 51-55).

Because excipients are manufactured for a wide variety of purposes, the source and origin are highly variable. They range from whole food products, such as wheat middlings and yeast, to synthetic food additives such as sodium benzoate and sodium lauryl sulfate. They may be agricultural, non-synthetic, or synthetic. Some are extracted or produced from plants, animals, minerals or microorganisms, and others are manufactured entirely from chemicals (2015 TR, lines 60-64).

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Formulants used in crop production aids may only be used with substances listed in Column 2 of this table. Only formulants classified as List 4A or 4B by the Pest Management Regulatory Agency (PMRA) or derived from biological or mineral sources may be used with substances in Table 4.2 (Column 2). Formulants classified as List 3 by PMRA may be used with passive pheromone dispensers. Formulants classified as List 4A, 4B or 3 by PMRA are not subject to 1.4 or 1.5 of CAN/CGSB-32.310. Formulants classified as List 1 or 2 by PMRA are prohibited (Table 4.2 – Substances for crop production, CAN/CGSB-32.311-2020).
- Formulants (inerts, excipients) shall be used in conjunction with substances listed in Table 5.3. Formulants are not subject to 1.4 or 1.5 of CAN/CGSB-32.310 or 5.1.2 of this standard (Table 5.3 – Health care products and production aids, CAN/CGSB-32.311-2020).
- Formulants may only be used with substances listed in Table 8.2. Only formulants classified as List 4A or 4B by the Pest Management Regulatory Agency (PMRA) or derived from biological or mineral sources may be used with substances in Table 8.2. Formulants classified as List 3 by PMRA may be used with passive pheromone dispensers. Formulants classified as List 4A, 4B or 3 by PMRA are not subject to 1.4 or 1.5 of CAN/CGSB-32.310. Formulants classified as List 1 or 2 by PMRA are prohibited (Table 8.2 – Facility pest management substances, CAN/CGSB-32.311-2020).
- Formulants may only be used with substances listed in Table 8.3. Only formulants classified as List 4A or 4B by the Pest Management Regulatory Agency (PMRA) or are non-synthetic may be used with substances in Table 8.3. Formulants classified as List 3 by PMRA may be used with passive pheromone dispensers. Formulants classified as List 4A, 4B or 3 by PMRA are not subject to 1.4 or 1.5 of CAN/CGSB-32.310. Formulants classified as List 1 or 2 by PMRA are prohibited (Table 8.3 – Post-harvest substances, CAN/CGSB-32.311-2020).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Excipients are not explicitly mentioned in the regulations.

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

- Excipients are not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Excipients are not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Excipients are not explicitly mentioned in the regulations.

Environmental Issues

The primary mechanism through which excipients appear in the environment is via manure application to cropland. There is little known about the actual effects, adverse or not, on the environment from excipients. Only a handful of studies have even identified the presence of specific excipients in the environment, while most studies focus on pharmaceuticals without making a distinction between active and excipient ingredients. Since most excipients used in organic livestock production are GRAS or FDA-approved food additives, the potential for environmental and human health effects has been evaluated by the FDA as part of their legal status. No literature was found to show definitive harmful effects on the environment when excipients are used in animal health care products (2015 TR, lines 542-552).

On the other hand, there are environmental concerns related to the manufacture of excipients. Because of the great variety of substances permitted for use as excipients and the methods of manufacture, some of the excipients could have detrimental environmental effects. Raw material extraction of petroleum products, solvents, and mined minerals pose negative environmental effects; the FDA has gone as far as recommending that the pharmaceutical industry avoid certain solvents (e.g., benzene, carbon tetrachloride, 1,2-dichloroethane, 1,1-dichloroethane, 1,1,1-trichloroethane) that pose exceptional environmental and human health risks. Further processing of certain ingredients, like starches and starch derivatives, can lead to environmental degradation, air pollution, and exploitation of resources. A great number of excipients may be derived from GMOs, i.e., soy, corn, cotton, etc. (2015 TR, lines 554-563).

Health Issues

There is no literature to indicate specific human health effects through the use of excipients in livestock healthcare products, but there is significant literature to show that certain excipients can have detrimental and even lethal consequences when administered directly to human beings, especially infants (2015 TR, lines 571-573). This is one reason the FDA assesses the safety of excipients as part of each NADA application, rather than individually in a separate program. New excipients undergo a series of preclinical tests recommended by FDA and the International Pharmaceutical Excipients Council that includes acute oral and dermal toxicity, teratology, genotoxicity assays, and skin sensitization studies in rodents. These tests may be conducted on the excipient in combination with the active ingredient, or as a stand-alone ingredient (2015 TR, lines 581-586).

The most likely route of exposure of humans to excipients in animal drugs is through consumption of residues in milk and meat products of treated animals. Most of the research on contamination has focused on traces of antibiotics, but formulations specifically allowed in §205.603 can also appear in milk and meat (2015 TR, lines 589-592). Presumably, both the active ingredient and the excipients are cleared from commercial products by the withdrawal times dictated by the NOSB on the active ingredients (2015 TR, lines 594-595). However, since the majority of excipients used in organic livestock production are GRAS or food additives, the FDA assessment would include human and animal effects of ingestion of such ingredients, including their metabolism and breakdown pathways. Adulterated excipients pose some potential risk to human health; as a result, the FDA identified a partial list of excipients and active ingredients that may also be adulterated and need further testing (2015 TR, lines 608-613, 615-617).

Discussion

In the previous sunset review, the NOSB heard resoundingly that the public desired that excipients remain on the National List. Several certifiers sent results of surveys that they had conducted with their clients, and the results showed that the numbers of uses of excipients in livestock health products were in the thousands. Based on prior Subcommittee review and public comments, the NOSB found excipients compliant with OFPA criteria, and did not recommend removal from the National List.

Questions remain as to how excipients are reviewed. Parts 3) and 4) of the annotation allow for myriad excipients to be used in livestock products subject to APHIS and FDA approval, without necessarily complying with OFPA criteria. While this could present a problem, most livestock veterinary treatments are administered in small doses, and there is a significant withdrawal period. This minimizes any effect that the active ingredients or excipients can have on the consumer or the environment. Compared to review and possible disallowance of hundreds or thousands of needed veterinary treatments, the current approach may be optimal in the real world.

Questions to our Stakeholders

1. Is the current annotation sufficient for effective use by certifiers?
2. Is the current review process sufficient to ensure that excipients meet OFPA criteria? If not, are there alternative methods, lists, or classifications that could comply?

Strychnine

Reference: §205.604 Nonsynthetic substances prohibited for use in organic livestock production.
(a) Strychnine
Technical Report: None
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (crops only); 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2020 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice published 03/21/2017 (82 FR 14420); Sunset renewal notice published 08/03/2021 (86 FR 41699)
Sunset Date: 3/15/2027

Subcommittee Review

Use
Strychnine is a toxic alkaloid that is a transparent crystal or white, crystalline powder. It is colorless, odorless, and has a bitter taste. It was widely used in poison (toxic) baits to kill rodents and other mammals and is a common adulterant of many illicit (street) drugs. Exposure to strychnine can be fatal.

Strychnine can be absorbed into the body by inhalation or ingestion. It can also be injected into the body when mixed with a liquid. Strychnine is rapidly metabolized and detoxified by the liver. This substance is also well-absorbed and acts quickly to produce muscular hyperactivity, which can quickly lead to respiratory failure and death.

Strychnine has been placed in Toxicity Category I by the EPA, indicating the greatest degree of acute toxicity for oral and ocular effects; inhalation toxicity is also presumed to be high.

According to the USDA, above-ground uses were canceled in 1988; however, it remains registered for below-ground use to control damage caused by pocket gophers.

Manufacture
The main natural source of the alkaloid is extraction from the strychnine tree (*Strychnos nux-vomica*). This plant is found in southern Asia (India, Sri Lanka, and East Indies) and Australia.

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

- Strychnine is not explicitly mentioned in the regulations.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

- Strychnine is not explicitly mentioned in the regulations.

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

- Strychnine is not explicitly mentioned in the regulations.

International Federation of Organic Agriculture Movements (IFOAM)

- Strychnine is not explicitly mentioned in the regulations.

Japan Agricultural Standard (JAS) for Organic Production

- Strychnine is not explicitly mentioned in the regulations.

Human Health and Environmental Issues

According to the EPA, acute toxicity of strychnine to birds is assumed to be very high. Subacute dietary data indicates that strychnine ranges from slightly to highly toxic to avian species. Strychnine may pose a threat to birds that are subject to repeated or continuous exposure from spills.

Mammalian studies indicate that strychnine is highly toxic to small mammals on both an acute oral basis and dietary basis. The signs of toxicity, including death, occurring within one hour. Acute freshwater fish data reveal that strychnine ranges from moderately to highly toxic to freshwater fish. Aquatic invertebrate acute toxicity data indicates that strychnine is moderately toxic to aquatic invertebrates.

Discussion

In 2017, the Crops Subcommittee determined that strychnine did not meet OFPA criteria and saw no reason to remove it from its prohibited status on the National List. Both the Crops Subcommittee and the full NOSB voted to not remove strychnine from §205.604 - non-synthetic substances prohibited for use in organic crop production.

Based on prior Subcommittee reviews and public comments, the NOSB found strychnine non-compliant with OFPA criteria, and does not recommend removal from the National List at §205.604.

Questions to our Stakeholders

None

National Organic Standards Board
Materials Subcommittee
2025 Research Priorities Discussion Document
Spring 2025

Executive Summary

INTRODUCTION

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 in multiple regions, recognizing the interplay of agroecology, the surrounding environment, and both native and farmed species of plants and animals. As part of this year's process, the Livestock, Crops, and Handling Subcommittees have made an effort to categorize and differentiate highest priority topics from ongoing topics.

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. We especially encourage university researchers to non-intrusively study working organic farms.

The NOSB encourages integrated, whole farm research into the areas described below.

CROPS

Top priorities for organic crop research, in brief. See below for detail.

The extent and impact of plastic use in organic crop production, and how organic producers can lead in reducing it and align with consumer concerns.

Side-by-side trials of approved organic pesticide products, both synthetic and natural, and cultural methods, in multiple regions, with a request for collaboration with the IR4 project.

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

Assessing the extent, economic impact, and compensation mechanisms of GMO contamination and prohibited pesticide drift, such as from Dicamba, on organic crops.

Conduct whole farm ecosystem service assessments to determine the economic, social, and environmental impact of farming system choices.

Ongoing organic crop research topics

Inputs

Examination of decomposition rates, the effects of residues on soil biology, and the factors that affect the breakdown of biodegradable bio-based mulch film.

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.

Holistic soil research to quantify soil life.

The demand for organic nursery stock far exceeds the supply. Research is needed to identify the barriers to expanding this market. This information will inform the development and assessment of organic methods for meeting the growing demand for organically grown nursery stock.

Comprehensive review of positive and negative impacts of the use of copper products in pest management.

How to increase the availability and supply of organic seeds. Also, comparative trials to evaluate performance and quality of organic seeds and planting stock.

Research on the fate of prohibited substances such as antibiotics, heavy metals, and pesticides in compost piles.

Contaminants

Investigate contaminated inputs from non-organic sources, including compost approved for use on organic farms.

Systems

Conduct whole farm ecosystem service assessments to determine the economic, social, and environmental impact of farming systems choices.

Elucidate practices that reduce greenhouse gas emissions and that contribute to farming systems' resilience in the face of climate change.

Factors impacting organic crop nutrition, and organic/conventional nutrition comparisons.

Organic no-till and low-till practices for diverse climates, crops, and soil types.

Develop cover cropping practices that come closer to meeting the annual fertility demands of commonly grown organic crops.

More research, extension, and education are needed to fully understand the relationship between on-farm biodiversity and pathogen presence and abundance.

Strategies for the prevention, management, and control of problem insects, diseases, and weeds that reflect a changing climate, and how to anticipate or predict new pest problems. Systems-based approaches are emphasized.

Top priorities for organic crop research

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 Crops 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 U.S. and major production areas such as Mexico, Spain, Chile, Holland, Canada, etc.
- What are the effects of breakdown products, airborne releases, and microplastics on soil organisms and crop plants? What is the fitness cost to beneficial microbial/fungal communities due to the presence of plastics, resins, and other breakdown substances in soil and compost?
- 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?
- What are the best first steps to reduce plastic use in organic production?

Efficacy Comparisons of Inputs and Practices for Organic Production

Organic farmers need to have information from side-by-side trials between 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.

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 is 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 utilize tools to identify, measure, and remediate PFAS contamination that has already occurred in the environment and on organic and non-organic farmland. Explore measuring total organic chlorine to ensure that all PFAS variants are captured.
- To identify viable programs for addressing the financial and emotional costs of land that must be removed from production due to PFAS contamination.

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. In addition, dicamba drift from sources further away can damage crops.

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? Are there avenues for compensation for organic crops damaged or with reduced sale value due to contamination from other farms?

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 habitats to enhance biodiversity and ecosystem service provisioning?

Ongoing organic crop research topics

Inputs

Biodegradable Bio-based Mulch Film

Biodegradable mulch film was recommended in 2012 for addition to the National List by the NOSB, but it did not specify a required percentage of biologically-derived (i.e., bio-based) content. The NOP regulations require that all (100%) of the polymer feedstocks be 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. Data from Europe, where BBMF mulches are allowed for organic production, may be particularly useful.

- How rapidly do these mulches fully decompose, to what extent do 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 ensure decomposition standards?

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.

Holistic Soil Research to Quantify Soil Biology

Organic farmers are presented with many alternative ways of assessing the health of their soil and its biological components. Which assessments give the most accurate and useful information to help farmers best manage soil over the short and long term?

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.

Comprehensive Review of Copper
Systems research that identifies disease-resistant material and biological controls that can reduce the use of copper-based compounds where possible is needed. Use of copper has documented negative effects on human and ecosystem health. Continued strong efforts need to be made to reduce the reliance on copper in organic production.

- Develop alternative formulations of materials containing copper so that the amount of elemental copper is reduced.
- Develop biological agents that work on diseases that copper is now used on.
- Research on tadpole shrimp and algae control in rice, and whether sodium carbonate peroxyhydrate or other materials are suitable copper alternatives in an aquatic environment.
- Research on movement and fate of applied copper in aquatic and field environments.
- Establish available and total copper threshold levels above, and identify which soil organisms are harmed, for different regions and soil types.
- Breeding plants that are resistant to the diseases that copper influences.

How to increase the availability and supply of organic seeds. Also, comparative trials to evaluate performance and quality of organic seeds and planting stock.
Investigate barriers to production and adoption of organic seed. Identify specific gaps and suggest solutions. In addition, rigorous, unbiased trials are needed to compare performance of different sources of organic and conventional varieties. These can reflect a range of common organic production practices, such as high or low nitrogen status or with and without plastic mulch.

Research on the fate of prohibited substances in compost piles – antibiotics, heavy metals, pesticides, etc.
Can composting reduce or eliminate some undesired contaminants? Are some recalcitrant? Research is needed on the fate of what may be unavoidable contaminants in compost feedstocks.

Contaminants

Investigate contaminated inputs from non-organic sources
In addition to PFAS and GMO drift, there are many other sources of contamination that can negatively impact organic farms and crops. Examples would be contaminants in manures and other fertilizers, irrigation water, etc. Research to identify these and whether they are avoidable needs to be ongoing.

Systems

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 habitats to enhance biodiversity and ecosystem service provisioning?

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 several 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. Life cycle analysis of organic inputs and practices is critical. In particular, work is needed on comparing soil-based and soil-less systems, as well as the effects of farm scale on greenhouse emissions.

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 with information on soil biology and soil nutrient composition help improve nutrition? Finally, more studies are needed to examine how organic crops compare to conventional crops with regards to nutritional value.

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.

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 the preceding practices that define the legacy of individual fields. Further, there need to be more programs to breed seeds for cover crops.

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.

Management of Problem Insects, Diseases, and Weeds

There is a large pool of research on the control of insects, diseases, 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.

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 and biological controls that limit the use of copper-based compounds and other fungicides 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.
- 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.
- Evaluate plant nutritional strategies to lessen disease impacts.

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 diseases affecting organic crops that require mitigations such as approved fungicides or the increased use of copper.

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 water hemp), 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 vegetables 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, arthropod, disease, 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.

LIVESTOCK

Top priorities for organic livestock research, in brief. See below for detail.

Elucidate the barriers to increased organic pork production and markets.

Develop balanced organic livestock rations that incorporate high percentages of diverse, regionally adapted grain crops to complement corn and soybeans, and allow farmers to realize more marketing opportunities for a robust crop rotation.

Ongoing organic livestock research topics

Evaluate ways to prevent and manage parasites in all species of livestock, in each region. This includes determining 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, pasture species, mixed species grazing, and utilizing the genetic pool within and between breeds.

Evaluate natural alternatives to DL-methionine in a system approach for organic poultry feed program.

Develop a dairy program to address climate change mitigation strategies where production capabilities are not hindered, and effective forage rotations are maximized.

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

Top priorities for organic livestock research

<u>Elucidate the barriers to increased organic pork production and markets</u>
Production of organic pork has lagged behind chickens, eggs, and dairy. We request holistic investigations into what the barriers are including, but not limited to, markets, pricing, input costs, processing facilities, and production constraints such as lack of hardy breeds and housing/humane standards (including indoor and outdoor space standards as well as outdoor soil and vegetation requirements) and effective parasite

management. Competition from non-organic pasture-raised, local, and other production claims should be included, as should evaluation of methods to avoid the need for farrowing crates.

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.

Ongoing organic livestock research topics

Prevention and Management of Parasites

Livestock production places large numbers of cattle, sheep, goats, poultry, etc. in 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, and 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 are 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 *Ascaridia galli* and *Heterakis gallinarum* in laying and replacement chickens.

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 1950s, poultry and pigs were fed a plant and meat-based diet without synthetic amino acids such as methionine. One former NOSB member stated, in compliance with NOP regulations §205.237(5)(b) which prohibits organic operations from feeding mammalian or poultry slaughter by-products to mammals or poultry, "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[1] passed at

the Spring 2015 Board meeting in La Jolla, California. 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 and safety 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 including insect protein in organic poultry production systems. Additional research on the more promising alternative methionine sources with the goal of bringing them into commercial production is also encouraged.
B. Evaluation of poultry breeds selection that could be adapted 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. Using the European Union as a case study, assessing how 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.

[1]The National Organic Standards Board is committed to the phase-out of synthetic methionine for organic poultry production and encourages aggressive industry and independent research on natural alternative sources of methionine, breeding poultry that perform well on less methionine, and management practices for improved poultry animal welfare.

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 provide the most profitable outcome for the dairy producer.

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 is 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 utilize tools to identify, measure, and remediate PFAS contamination that has already occurred in the environment and on organic and non-organic farmland. Explore measuring total organic chlorine to ensure that all PFAS variants are captured.
- To identify viable programs for addressing the financial and emotional costs of land that must be removed from production due to PFAS contamination.

FOOD HANDLING AND PROCESSING
(prioritized order within categories; categories not ordered by priority)

Improving methods and practices for organic handling and processing

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.

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.

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.

Expanding market opportunities for organic products – e.g., consumer expectations, products based on rotational crops, etc.

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.

Alternatives to conventional celery powder for curing organic meat.

Consumer food product development research for crops integral to organic farming systems (e.g., rotational crops).

Complete (or full) materials review

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.

Handling Subcommittee 2023 Research Priorities

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 but should also include sanitizers such as quaternary ammonia compounds).
- 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.

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.

Handling Subcommittee 2022 Research Priorities

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, but should also include sanitizers such as quaternary ammonia compounds.)
    - 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.

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/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.

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?

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.

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.

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 incentive 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.

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.

Improving our understanding of the (1) potential threats and (2) costs to the organic sector that result from the use of excluded methods
First, identify the set of potential threats the use of excluded methods presents to organic businesses (farms and handlers). The potential threats include crop damage and cross contamination, but we recognize there might be others not yet identified. Second, estimate the costs the threats present to organic farms and organic handlers.

GENERAL

Increasing Access to Organic Foods
What factors influence access to organically produced foods? Individual-based studies are needed to assess the constraints to accessing 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.

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 2025 NOSB Research Priorities
Motion by: Franklin Quarcoo
Seconded by: Brian Caldwell
Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 2

Approved by Franklin Quarcoo, Materials Subcommittee Chair, to transmit to NOSB on February 13, 2025.

National Organic Standards Board
Policy Development Subcommittee
Sunset Review Efficiency Discussion Document
February 12, 2025

Summary:
The Policy Development Subcommittee (PDS) is considering options on how to more efficiently carry out the National Organic Standards Board's (NOSB) statutory duties to review and make recommendations on substances scheduled for sunset. The PDS recommends voting on sunset consent agendas by certification scope (i.e. crops, livestock, and handling) for substances that have strong and consistent support for relisting and if the NOSB has not received new information suggesting that substances do not comply with OFPA criteria. Under this approach, any NOSB member would retain the power to call for an individual discussion and vote for any sunset substance.

Discussion:

The NOSB dedicates significant time at each Fall meeting to reviewing and voting on substances scheduled for sunset. Numerous National List substances have been reviewed by the NOSB several times and have received unanimous support for relisting. The NOSB has an ongoing obligation to review these materials and determine whether they continue to meet National List criteria, particularly in light of any new information. In recent years, the NOSB's sunset process has included subcommittee discussions, full Board discussion at the Spring meeting, further subcommittee discussions, and a second full Board discussion and vote at the Fall meeting.

In 2020, the PDS approved a discussion document on sunset reviews, proposing the development of a consent document that would group similar substances into a single sunset review and vote; since then, the PDS has continued to explore options that would allow for thorough discussion and analysis of each material, while improving the efficiency of the sunset review process at the Board meetings.

At the Fall 2024 meeting, the NOSB trialed a 'fast track' approach, with an abbreviated discussion and an individual vote for minimally controversial sunset substances. Unfortunately, this approach did not result in significant improvements to efficiency.

Accordingly, the PDS recommends that the NOSB use consent agendas for voting on substances that have previously been relisted unanimously and for which there is no new information available regarding compliance with the Organic Foods Production Act of 1990, using the following process:

- Subcommittees complete initial review and discussion of sunset materials.
- Subcommittees present sunset materials for discussion at the Spring meeting; substance leads will note which materials may be candidates for the consent agenda based on the subcommittee discussions, new TRs, and public comments.
- Subcommittees will discuss and vote on sunset materials and determine which materials will be placed on the subcommittees' proposed consent agendas for the Fall meeting.
- At the Fall meeting, the materials on each subcommittee's consent agenda will be voted upon as a group, rather than individually, and without further discussion. Prior to that vote, any Board member will have an opportunity to remove any material from the proposed consent agenda for any reason (e.g., new information comes to light in public comments, the Board member finds the written discussion incomplete or disagrees with the Subcommittee's recommendation); all materials that are not voted on as part of the consent agenda will be discussed and voted on individually.

The NOSB will initiate a trial of this process at the Spring 2025 meeting.

Subcommittee Vote:
Motion to accept the discussion document on sunset review efficiency.
Motion by: Nate Lewis
Second by: Carolyn Dimitri
Yes: 4 No: 0 Abstain: 0 Recuse: 0 Absent: 0