National Organic Standards Board Meeting
October 18 & 20 (Comment webinars), and October 25 - 27, 2022 (NOSB meeting)

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National Organic Standards Board
Certification, Accreditation and Compliance Subcommittee (CACS)
Proposal: NOP Risk Mitigation Table Review
August 9, 2022

Background:
On November 18, 2021, the National Organic Program (NOP) sent a memo to the National Organic Standards Board (NOSB) requesting that it review and facilitate public comment on the National Organic Program's (NOP) Risk Mitigation Table. This table was developed in response to the 2020 peer review conducted by the American National Standards Institute (ANSI) National Accreditation Board and seeks to document the ways NOP safeguards impartiality in the delivery of services and oversight over accredited certifiers. In 2017 the International Standard ISO/IEC 17011; Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies was revised. This standard, along with the requirements outlined in the organic regulations themselves, is what NOP adheres to in carrying out its accreditation procedures. The new ISO standard now recommends that an organization's risk mitigation controls be reviewed by a representative body. The NOSB is serving as this "representative body" given the Board's prior interest in the NOP Peer Review process.

The CACS reviewed the table and drafted a proposal for stakeholder feedback and NOSB consideration for the Spring 2022 NOSB meeting. The CACS received several responses from stakeholders to the CACS' questions on whether the conflicts-of-interest needed to be clarified and/or if any potential conflicts of interest were missing. Based on the scope of the comments received, the Board voted to send this proposal back to subcommittee for further review.

Summary of Review:
During further review, the CACS had the opportunity to clarify the scope of the Risk Mitigation Table (NOP 1009) with the NOP. The scope of the table was meant to address how NOP can mitigate its risks in regard to the delivery of services and oversight of certifiers. It was not intended to address how the NOP manages conflicts-of-interest, or impartiality of certifiers and oversight of the operations they (certifiers) certify. Therefore, while the topic of conflicts-of- interest and impartiality of certifiers and the operations they certify is important, it is outside of the scope of this particular process.

With this in mind, CACS reviewed the Risk Mitigation Table and the public comments received during the Spring 2022 meeting. CACS and stakeholders acknowledge the work the NOP as done thus far, noting that the table was comprehensive regarding conflicts-of-interest. However, it was also noted that this isn't the only risk outlined by the governing documents NOP adheres to when carrying out their accreditation activities. Based on our review and the public comments received during the Spring 2022 meeting, the CACS recommends that the NOP revise the table to include the following areas related to the risk of impartiality in regard to delivery of the services they provide and oversight of certifiers:

- Analysis of the risk related to the steps in the accreditation process being implemented in a manner that is biased or unfair (ISO/IEC 17011:2017 §4.4.1 and §3.10)
- Analysis of the risks to impartiality created by the organizational structure of the accreditation body within a larger governmental organization, as well as certifiers that operate within larger governmental organizations (e.g., state departments of agriculture and state organic programs) (ISO/IEC 17011:2017 §4.4.2)
- Analysis of pressures created from the same agency acting as the standard setting body and the accreditation body. (ISO/IEC 17011:2017 §4.4.2)

- Analysis of risks created if top management reduced its commitment to quality (ex. Budget pressures, political pressures) (ISO/IEC 17011:2017 §4.4.3)
- Risks related to not maintaining, nor making public (not in NOP 2000) a documented Impartiality Policy (ISO/IEC 17011:2017 §4.4.3)
- Analysis of risks related to not implementing a formal, public process that allows interested parties to be involved in safeguarding impartiality (ISO/IEC 17011:2017 §4.4.5)
- Analysis of risks related to not conducting an on-going review of topics related to impartiality (ISO/IEC 17011:2017 §4.4.6)
- Procedures outlined in NOP 2000 and 1009 do not address how NOP has eliminated or minimized ALL risks. Conflicts of interest are covered but other types of risks to impartiality are not addressed. (ISO/IEC 17011:2017 §4.4.7)
- Top management to "review any residual risk to determine if it is within acceptable levels" is not addressed in Accreditation Policies and Procedures (NOP 2000). (ISO/IEC 17011:2017 §4.4.8) – see additional comments below regarding additional clarification to this area in NOP 1009
- The requirement that NOP not provide accreditation in cases of unacceptable risk to impartiality (ISO/IEC 17011:2017 §4.4.9)
- Comprehensive discrimination analyses including non-discriminatory practices related to policies and processes, as well as that access to accreditation service not be conditional (ISO/IEC 17011:2017 §4.4.10)

Additionally, the CACS recommends that the NOP clarify the following areas in NOP 1009:

- Risk evaluation scale:
  - Based on this scale, action is not a mandatory requirement and therefore introduces subjectivity. Further clarification is recommended on the criteria used to make this determination to better understand where various circumstances may fall on the scale.
  - It is unclear who is making the initial determination regarding the risk and where it falls on the scale. NOP 1009 does state that if the "potential conflict is 'possible' or 'likely'…NOP management reviews the specific circumstances…". Further clarification is recommended on who is making the initial determination. (ISO/IEC 17011:2017 §4.4.8)
  - Again, as stated previously, this scale appears only to be applied to "conflicts of interest" but not to other risks such as impartiality. Further clarification is recommended to broaden this scale to other types of risk.
- Favoritism, bias, or discrimination:
  - This potential conflict area focuses on equal access to information. However, there are other ways that favoritism, bias, or discrimination can be introduced into the certification and accreditation process. Further clarification and examples are recommended on other types of favoritism, bias, or discrimination such as policy determinations and unfair enforcement procedures.
- Undue influence
  - This potential conflict focuses on undue influence caused by "third parties." However, undue influence may also be caused by accreditation program personnel. Further clarification and examples are recommended to be included that address undue influence imparted by auditors, reviewers, or other decision makers.
  - Additionally, in the Control Measure column it is stated that the "NOP adheres to the USDA organic regulations in the decision-making process", and the Monitoring Method column says to "compare the decision with previous decisions to confirm consistency with the requirements." Achieving this goal becomes challenging when the USDA organic regulations lack clarity in some areas and are knowingly applied inconsistently

by certifiers. Further clarification and examples are recommended for how the NOP will proceed in known areas of inconsistencies.

- Due process
  - This potential conflict focuses on due process as it relates to the appeals process. However, there may be other aspects of implementing a regulatory process where due process must be incorporated. Further clarification and examples are recommended for how due process is included throughout each element of its quality system management (see Organic Produce Wholesalers Coalition (OPWC's) Spring 2022 comments for specific examples).

The CACS' discussion and some stakeholder comments included additional areas, that, as stated prior, are important but were not part of this review. The CACS would like to capture these areas for potential future work by the Board and/or NOP. These areas are:

- A tool for certifiers to compare accreditation findings
- Systemic sources of conflicts-of-interest such as organic operators choosing their own certifiers and paying them for certification, discrepancies between certifiers ins interpretation and implementation of the rule, and operators shopping for certifiers that may be more in line with the operator's preferred interpretation of organic regulations.
- Clarification and revision to the standards on a routine basis to resolve known inconsistencies and divergent certification practices in order to fully ensure strong and consistent oversight of certifiers.

Subcommittee Proposal
CACS recommends that NOP revise the Risk Mitigation Table to include the areas outlined above and that the NOP incorporate the Risk Mitigation Table (NOP 1009) into their procedures.

Subcommittee Vote
Motion to accept the proposal on the NOP's Risk Mitigation Table
Motion by: Kyla Smith
Second: Nate Powell-Palm
Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 0

National Organics Standards Board
Certification, Accreditation and Compliance Subcommittee (CACS)
Proposal: NOSB Technical Support
July 5, 2022

Background:
Much of the momentum for the initiative to seek technical support for the NOSB came from the Fall 2020 discussion document titled, *Human Capital Strategy for Organic Inspectors and Reviewers*. During its Spring 2021 meeting, the NOSB considered a discussion document on Human Capital Management: Supporting the Work of the NOSB. Additionally, the National Organic Program (NOP) released a Request for Applications (RFA) for human capital in Spring 2021, which included a request for industry stakeholders to bring forth ideas on supporting the NOSB through the public-private partnership. No proposals were made for that component of the RFA. Therefore, the CACS developed this discussion document seeking feedback for NOSB technical support specifically. The rationale for this initiative is simple. NOSB positions are not financially compensated, and many Board members have full-time jobs. The time investment and workload for NOSB members can be 10-15 hours per week and this can potentially limit the number of people willing to take on board membership.

To demonstrate the scope of work, NOSB members are tasked with the following activities:
- Review petitions to add or remove materials from the National List of Approved and Prohibited Substances (National List), and complete “Sunset” reviews of materials on the National List.
- Review and develop questions for Technical Reports to inform deliberations on materials.
- Complete materials-related checklists to assess the status of materials against the OFPA criteria for inclusion on the National List; conduct supporting research to determine the context of use of materials in the organic industry.
- Attend and participate in NOSB subcommittee calls and full Board meetings to discuss agenda items and deliberate on proposals.
- Conduct other research activities to support the development of proposals and recommendations on a range of topics of interest to the organic community.
- Review and prepare summaries of public comments in advance of public meetings.
- Write proposals and recommendations summarizing petitions, the Board’s deliberations, Technical Reports, public comments, and justifications for Board positions.

Getting outside support could significantly reduce the time that Board members have to dedicate to NOSB tasks and make tenure on the board more attractive to future members. While not all of the activities of the NOSB are amenable to support, the scope of activities and deliverables completed by the support team could involve:

- Conducting literature reviews and preparing summaries for Board members to support their work. This may include investigating the current context of material use, specific questions related to environmental or health impacts of materials, and/or research about alternative practices or materials.
- Reviewing Technical Reports.
- Preparing summaries of public comments for Board member review.
- Drafting language for proposals and recommendations based on Board member input.

Written comments from the Spring 2021 Board Meeting regarding the potential technical support for board members were supportive of the idea, but not devoid of concerns. Several commenters expressed the concern that the NOSB should be careful not to compromise the integrity of the process. Further concerns centered around not endangering the independent nature of the production and deliberation of the NOSB's proposals.

Summary of Recent Review by the CACS:

During recent Subcommittee calls, the CACS has discussed two main questions in some detail:
1. Where should the technical/advisory support come from?
2. Will the NOSB lose some of its autonomy if it receives technical support?

Source of Technical/Advisory Support
The question of where to source assistance focused on two broad categories. Technical support could come from within the government/USDA (outside of the Agricultural Marketing Service (AMS)/NOP). Alternatively, support could come from outside organizations such as universities or nonprofits. At the time of the CACS review, the group appeared to lean towards an "inside" position but was not conclusive. Further review of the question during the July 5th Subcommittee meeting resulted in the decision to formally recommend that support should come from within the USDA.

Autonomy of the NOSB
Regarding the preservation of autonomy, the Subcommittee recognizes that there are some concerns, but felt confident that independence can be maintained with proper structuring of the relationship.

Summary of Spring 2022 Written and Oral Comments

Written and oral comments resulting from the discussion document presented at the Spring 2022 Board Meeting totaled 17 respondents, with no single person or entity speaking against some form of technical support for the NOSB. The following four questions were presented to stakeholders in the discussion document. A brief summary of stakeholder answers follows each question.

1. What are the advantages or disadvantages of having support come from within the government? From a nonprofit or university?
   - Much like the CACS Subcommittee discussions, our stakeholders were passionate about this question with a slight preference towards "inside". Some suggested specific agencies such as USDA (but not AMS/NOP), EPA and FDA.

2. What NOSB tasks, if any, are critical to keep completely independent from the support team?
   - Here there were many "should nots". Technical support staff should NOT draft proposals or discussion documents, initiate polls of stakeholder groups, or communicate on behalf of the NOSB or any subcommittee, etc.

3. Should the support team be privy to all Subcommittee meetings and discussions?
   - There was universal agreement that "yes" they should be allowed to attend all meetings relating to the topics they are working on.

4. What should be the scope of the NOP's relationship with the support group, i.e., should they be able to task the group directly?
   - A unanimous "No" to the NOP being able to task the support group directly, but a very strong statement that NOP must administer the program.

Subcommittee Proposal:
CACS recommends that NOP proceed with an initiative to provide technical support to the NOSB. CACS further recommends that the source of technical support come from within the USDA but from outside the AMS/NOP. Technical support staff should NOT draft proposals or discussion documents, initiate polls of stakeholder groups, or communicate on behalf of the NOSB or any subcommittee. Technical support should attend all meetings relevant to their topics. The NOP should serve as the administrator of the support staff but not task them directly.

Subcommittee Vote:
Motion to accept the proposal on NOSB technical support
Motion by: Jerry D'Amore
Seconded by: Kim Huseman
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 1

National Organic Standards Board
Compliance, Accreditation & Certification Subcommittee (CACS)
Oversight Improvements to Deter Fraud: Acreage Reporting Proposal
August 9, 2022

Proposal

The Compliance, Accreditation & Certification Subcommittee (CACS) recommends that the National Organic Program (NOP) require certifiers to list harvested acres by crop type and the total acres of a certified organic operation on the organic certificate for domestic and international producers.

Introduction

Since the NOSB introduced the concept of production verification (listing acres by crop type on organic certificates) as a discussion document at the Spring 2022 meeting, the organic community has confirmed that continued efforts to deter fraud are of the utmost concern. While the finalizing of the Strengthening Organic Enforcement (SOE) rule will contribute significantly to the strength of the NOP standards and enforcement, more work is needed to build upon these successes. The community's questions, input, and expertise have been vital, and this stakeholder engagement gives the authors of this document great heart. Indeed, the commitment, enthusiasm, and focused energies of the organic community need to be celebrated.

In our discussions on oversight improvements to deter fraud, the consistent message from the community resonates that we need more robust mechanisms to address fraud effectively.

Specifically, three themes have remained constant since the beginning of our discussion:

1. Enforcement mechanisms need to be modernized to reflect the globalized reach of the NOP;
2. Continuous improvement in enforcement is expected from certifiers, farmers, and industry;
3. Consistency in certification leads to more effective enforcement and a fairer playing field for all involved.

Considering these three themes, we present the first of our recommendations to deter fraud.

Background

Currently, each certifier chooses the format of its organic certificates. On these certificates, certifiers typically list crops and livestock by the products for which they are certified. While exceptions exist, most certifiers do not list crops by acres.

One of the points in the supply chain where the risk of fraud is highest is when the production of multiple producers is aggregated. During an inspection, aggregators of certified products provide organic certificates from their suppliers (producers) to the inspector. In most inspections, inspectors can only verify that the supplier is certified for the crop the inspected party purchased, not the supplier's capacity. By having access to certificates that list harvested acreage by crop type, an inspector will be able to quickly check whether the capacity of the supplying operations supports amounts purchased by the aggregator.

Goals of Reporting Harvested Acreage by Crop Type and Stakeholder Support
As demonstrated by recent cases in the media, fraud can scale quickly with the simple substitution of conventional products for organic. The goal of reporting production (listing harvested acres by crop type and total acres of the operation) on all organic certificates could improve enforcement, increase the robustness of mass-balances on a granular level, allow aggregated mass-balances to function at a regional or country level and create consistency amongst the community on this topic.

Some state organizations such as the California Department of Food and Agriculture (CDFA) and select certifiers currently list harvested acres by crop type and actual acres of an operation. One commenter noted, "There are certifiers currently collecting and recording this information in the Organic Integrity Database. However, since it is not a mandatory requirement of certifiers, there are gaps in the information available to the supply chain when purchasing products and for the certifiers to determine the validity of organic crops sold. Since the Organic Foods Production Act (OFPA) and the NOP Rules are process-based standards, it is essential that there be transparency and sufficient information to ensure the integrity of the crops sold." Many stakeholders, including certifiers, farmers, and handlers, supported the concept of having acres by crop type on certificates, in one form or another, for both domestic and international organic operations. Also, most stakeholder comments indicated that the information should be housed in the Organic Integrity Database (OID).

Listing production on all organic certificates is an additional tool for certifiers and inspectors when reviewing operations. It can also assist buyers when reconciling products purchased with the certified area. This information is also beneficial when conducting mass-balances on the handler, broker, and importer operations that will be newly certified with the upcoming implementation of the SOE Rule.

The Accredited Certifiers Association (ACAs) - "Best Practices for verifying traceability in the supply chain" states that a solution to transparency is that certifiers should ALL submit data on organic acreage reports to the NOP for inclusion in the Organic Integrity Database. With acres on the organic certificate, a clearer picture of whether or not the organic land base supports production claims on small and large scales and allows for calculating a mass balance across the supply chain. Another commenter mentioned, "Including acreage on certificates would help auditors and buyers quickly assess if the volume of product being sold is reasonable given the operation's acreage." An additional commenter stated, "accurate operation-level organic acreage data that is segregated by crop would assist in conducting high-level, big picture mass balance audits, in addition to those performed during inspections, to determine if the output from a specific region matches production levels or is an indication of fraudulent activity."

Challenges of Reporting Acres by Crop Type
A few stakeholders expressed concerns about several areas: land used to grow multiple crops in one year; small acreages with a wide variety of produce crops; and the need for consistent usage of NOP's taxonomy and classifications, to name a few. Sharing best practices currently used by some certifiers could help reduce and/or alleviate concerns about finding a workable solution.

Aggregating production on small parcels with multiple vegetable crops, clear guidance on standardization for classification, and reporting on actual acreage and harvested acres to account for multiple crops grown on the same parcel in one season, are currently best practices implemented by certifiers and state agencies.

For example:

1. Practices that help decipher and not overstate acres when multiple crops are grown on the same parcel in one season can be captured by recording actual and harvested acres on the certificate.
2. To address small acreages with a wide variety of crops:
    a. Special consideration for granularity could be given to small-scale producers that direct market a wide variety of crops, such as CSAs and farmers' markets.
    b. Guidelines could be set to express the needed granularity or aggregation of produce crops grown on small parcels.

One commenter expressed that "the burden associated with tracking and documenting acreage figures by crop for use in verification of product purchases will not be balanced by benefits." Also, risk-based assessments were mentioned as another way to proceed forward.

Since organic acreage can be dynamic, in an effort to lessen the burden and make reporting more manageable, annual collection of acreage data in the Organic System Plan (OSP) could be implemented. The information could be updated and validated at the time of inspection. Reporting acres by crop type provides additional quantitative information that could further enhance the risk-based assessment process supporting certified acres with products sold.

Additional Considerations for Reporting Harvested Acreage by Crop Type

Other commenters pointed out that livestock, poultry, beehives, trays of mushrooms, etc., should also be included and reported on organic certificates. Indicating size by category of an organic operation outside of crops is important and should be considered. A follow-up to this proposal could elaborate on these additional production categories.

Public comments generally supported proceeding with declaring production by crop type on all certificates. One commenter stated, "information should be on the certificate as well as in the Organic Integrity Database since reports from the public are important in initiating investigations." While another commenter noted that there are "challenges in balancing the protection of confidential business information with making such data adequately accessible for traceability and fraud detection purposes."

The CACS understands that the treatment of confidential business information is applied differently across various USDA agencies. The driver of reporting production information is for enforcement and compliance purposes. Since the NOP is a regulatory program, transparency in reporting this production-level information would be unique and specific to the needs of the NOP.

Closing

As one commenter stated, "Currently, there are no means to accurately calculate organic acreage and/or yield estimates on a regional or country-by-country basis. This hinders the ability of NOP, State Organic Programs, certifiers, and inspectors to evaluate the total volume of organic products coming from any given region and accordingly detect whether fraud is occurring. A requirement for certifying agents to report certified organic production by crop/livestock and location, on at least an annual basis, to the NOP Organic INTEGRITY Database is one of the most impactful single actions that can be taken to increase the integrity in the global organic control systems."

The auditing process for organics is primarily process and risk-assessment driven. Integrating quantitative data into the auditing system could assist in fraud detection. Requiring the number of harvested acres on certificates by crop type and total operational acres for operations domestically and internationally will provide the needed information to begin the process of an effective mass-balance at a farm, region, or country level, which is vital in our globalized marketplace.

Lastly, as mentioned in the Spring 2022 discussion, fraud in the organic sector is often exposed by individuals reporting red flags to certifiers and the NOP. With this acknowledgment, the NOSB implores the USDA to elevate the ability of organic inspectors and buyers of organic crops to identify, in real-time, the volume of sales cross-referenced with certified production area.

Subcommittee Proposal
CACS recommends that NOP require certifiers to list a certified operations harvested acres by crop type and the total acres in the operation on the organic certificate.

Subcommittee Vote
Motion to accept the proposal on Oversight Improvements to Deter Fraud - Acreage Reporting
Motion By: Amy Bruch
Seconded By: Nate Powell-Palm
Yes: 5 No: 0 Abstain: 1 Recuse: 0 Absent: 0

National Organic Standards Board
Compliance, Accreditation & Certification Subcommittee (CACS)
Oversight Improvements to Deter Fraud -
Minimum Reporting Requirements Discussion Document
August 9, 2022

Introduction:
The administration of the National Organic Program (NOP) organic certification is a shining example of a public/private partnership going well. Freedom to collaborate, innovate, and truly understand the needs of organic producers has enabled the organic certifier community to build a strong foundation on which the trusted organic seal is based.

While the certifier's role has been consistent since the Organic Foods Production Act (OFPA) was published in 1990, the scale and complexity of the industry have changed drastically. Growing by double digits annually, the value, scale, and human capital necessary to maintain the whole system have exploded exponentially.

Initially designed for a different time and scale, systems are used to manage a larger and more complex globalized supply chain.

Background:
At the Spring 2022 NOSB meeting, the Compliance, Accreditation & Certification Subcommittee (CACS) brought forth a discussion document on “Oversight improvements to deter fraud: Modernization of organic supply chain traceability” for full board consideration. Informed by stakeholder input from across the supply chain, farmers, brokers, buyers, manufacturers, and organic certifiers all agreed that consistency is essential to creating a robust verification system to live up to the promise of total transparency. The discussion document also explored improving consistency in the commonly used bill-of-lading document.

The CACS noted several takeaways from the discussions. The first was that most commenters agreed consistency is the foundation of trust, and trust is the currency behind the organic seal. Stakeholder confidence is eroded by inconsistent expectations and the inability to identify and correct fraudulent behavior. The second highlight was that consistency is needed across all forms and procedures in the organic certification and enforcement process.

According to public comments by some organic certifiers (Oregon Tilth (OTCO) and Ohio Ecological Food and Farm Association (OEFFA), non-compliances for inadequate record-keeping are the most common non-compliances issued by their certification teams. These record-keeping issues do not reflect individual instances of fraudulent activity and take up the inspector's time, reducing a certifier's capacity to detect actual fraud. Are certifiers clearly communicating the minimum reporting elements? Are producers at a disadvantage due to the subjectivity of what constitutes sufficiency?

Consistency builds trust. Consistency allows organic farmers to trust the rules are being equally enforced.

In this current discussion document, the CACS is exploring ways to continuously improve the transparency of the record-keeping and audit systems of organic certification, by focusing on consistency and minimum reporting requirements.

Goals of Standardized Audit Forms:
With the pending release of the final rule on Strengthening of Organic Enforcement (SOE), the organic certification community is preparing for traceback audits, and mass-balance audits will become mandatory at every inspection. While these audits are common at most inspections, they are not universally conducted and, when conducted, are not always consistent. In addition, certifiers will also need to perform risk-based full supply chain audits.

When completing their basic training with the International Organic Inspectors Association (IOIA), organic inspectors are trained to conduct mass-balance and traceback audits. When inspectors go to work for a certifier, the templates or focus of the audit can vary from certifier to certifier. Some certifiers are hyper-prescriptive with the information they want inspectors to collect. At the other end of the spectrum, some provide no templates, leaving it to inspectors. This latter example places a very high expectation on inspectors to be able to construct and then execute the audits.

Suppose all certifiers collaborated and adopted a universal audit document for each scope (crop, livestock, handling). In that case, IOIA and certifiers could all focus on how to train inspectors to a consistent set of forms and free up mental space to focus on identifying red flags rather than just creating an audit that satisfies the different reporting requirements of the certifier.

We envision this move towards universal auditing documents as having the following impacts:

1. Allow certifiers to prepare for the coming SOE rule and establish a consistently agreed-upon standard for mass-balance/traceback and supply chain audits.
2. Create consistency for inspectors, allowing them to focus on audit techniques to identify fraud rather than worry about checking the right boxes on a form.
3. Empower the entire certification community to work collaboratively to improve these documents, develop best practices for training inspectors on forensic auditing, and make the certification decisions from the findings of these audits more consistent.
4. Provide relief to farmers, ranchers, and handlers, who could expect consistently thorough audits from their inspectors and adapt their record-keeping systems to make those audits more efficient and more transparent.
5. Create cost-savings while building a well-prepared pool of inspectors. By sharing the responsibility for creating and maintaining universal organic inspection audit forms, certifiers will save money by not having to create, revise, and retain staff for maintaining forms. Instead, they will be able to focus on substantive audit techniques.

In essence, by having a universal audit document, minimum reporting standards will in turn, need to be established.

Challenges of Standardized Audit Forms and Stakeholder Support:
One commenter at the Spring 2022 meeting mentioned, "right now, record-keeping systems vary widely across production and handling operations, with systems often specifically suited to the type of operation. Choosing any one system for all operators to adopt will inevitably be more or less burdensome for each operator depending on a host of variables."

We, as a subcommittee, agree with this comment; however, there are core pieces of information that are or should be "standardized" to ensure better consistency. With the implementation of SOE, certifiers are aware that additional scrutiny will be placed on assessing whether record-keeping by an operation is sufficiently auditable. Assessing what "sufficient" means will be a significant step forward in building a robust universal auditing system leading to a more robust traceability system. However, tackling this challenge leads the CACS to start the conversation surrounding the heart of the problem, as inconsistent audits make producers unsure of how to best keep records.

Closing:
The CACS would like to highlight a comment from a certifier who contributed the following, "The integrity and future success of the organic system are dependent on the awareness, collaboration, and cooperation of everyone involved--the regulators, the certifiers, and the certified operations. Similarly, the prevention, detection, and eradication of fraud must be a cooperative effort, endorsed and implemented equally by all."

By using universal auditing documents (Including consistent mass-balance and traceback templates), the organic industry will empower inspectors and certifiers to realize the opportunity to create trust, consistency, and fight fraud, all in the spirit of continuous improvement.

Questions from CACS:

1. How could the NOP engage, facilitate, and help inform certifier exploration of universal documents like mass-balance and traceback worksheets?

2. Is there any unforeseen downside to inspectors, reviewers, and certifiers all working with the same traceback and mass-balance templates?

3. Are there other forms (i.e., Dry Matter Intake (DMI) worksheet, Bills-of-Lading (BOLs), inspection report forms, etc.) that we can make universal to promote consistency for certifiers, inspectors, and operations?

Subcommittee Vote
Motion to accept the discussion document on Oversight Improvements to Deter Fraud - Minimum Reporting Requirements
Motion by: Nate Powell-Palm
Seconded by: Jerry D'Amore
Yes: 6 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
Certification, Accreditation and Compliance Subcommittee
Discussion Document: Organic and Climate-Smart Agriculture
August 9, 2022

Introduction:

Dear Dr. Tucker,
With the announcement of the Partnerships for Climate-Smart Commodities, the organic community engaged in a celebration of the forward-thinking funding and policy goals embracing our collective concern for a resilient farming future. The certified organic community has been involved in 20 years of consensus-making in a public-private partnership with the United States Department of Agriculture (USDA) National Organic Program (NOP) and the National Organic Standards Board (NOSB). The NOSB process represents countless hours of research, stewarding innumerable acts implementing a voluntary regulatory program through which producers are paid a premium for their systems-based approach (collection of climate-smart practices), by which consumers can be assured of climate-smart decision-making with transparency and the force of law.

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

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

Per the February 2022 memo assigning the NOSB a work agenda item, the NOSB will specifically address the questions to help articulate why classifying certified organic farming "climate-smart" is a sensible evolution of the hard work and resources that have gone into building the wildly successful NOP.

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

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

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

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

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

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

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

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

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

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

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

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

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

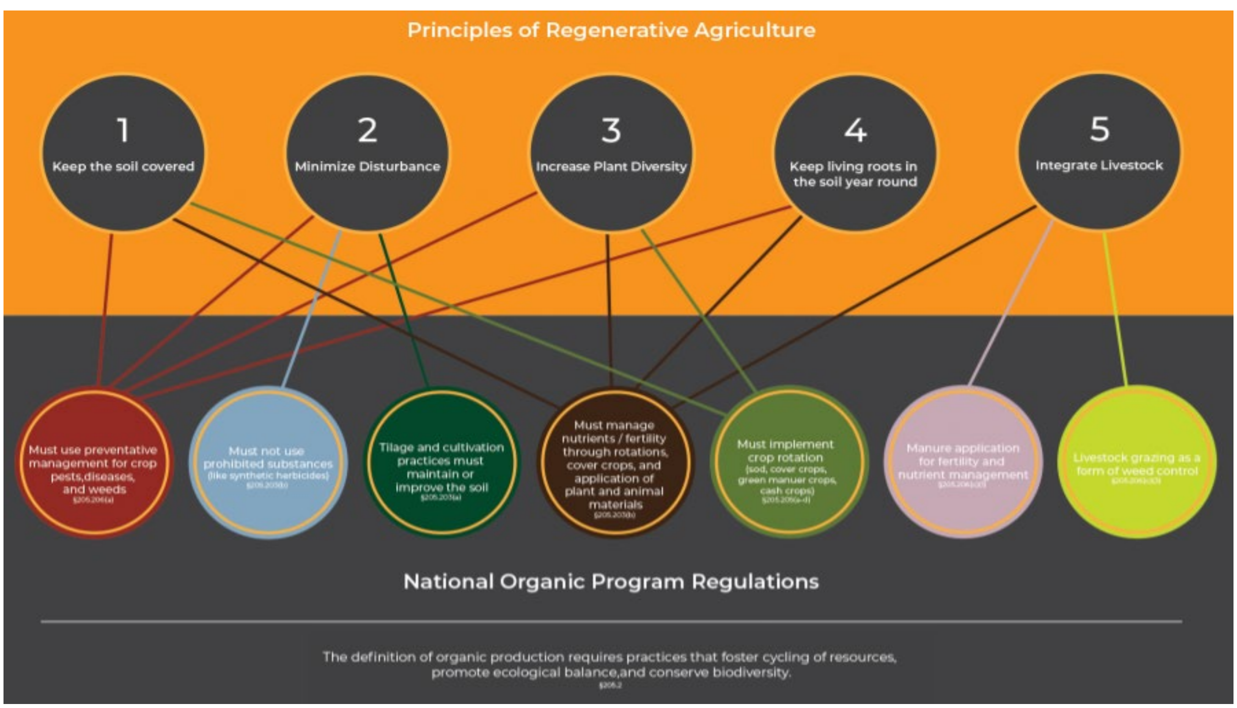

Figure -1: - Organic Agronomy Training Service (OATS).

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

- Organic farming can require less tillage (1. Moldboards and Dust Clouds: Organic Has a Tillage, OATS 2021) than conventional agriculture due to crop rotations.
  The yield gap (4. Double the Acres Half the Yield: Organic Can't Feed the World, OATS 2021) between organic and conventional production is closing (i.e., corn) or has closed (i.e., wheat).
- Certified organic farming prohibits synthetic nitrogen use, which is positive for soil health and farmers' pocketbooks.
- Crop insurance for organic is improving (attention is still needed).
- Certified organic rotations incorporating perennial crop phases such as clover or alfalfa or annual crop phases such as small grains and pulses can lead to less tillage than conventional systems.
- Organic crop rotations can fix nearly all of the fertility necessary to have robust crop yields when proactively managed.
- Organic prohibits the use of synthetic fertilizers, yet rapidly realizes yields that are consistent with conventional.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Livestock

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

Crops

1. Examination of decomposition rates, the effects of residues on soil biology, and the factors that affect the breakdown of biodegradable biobased mulch films.
2. Conduct whole farm ecosystem service assessments to determine the economic, social, and environmental impact of farming systems choices.
3. Organic no-till practices for diverse climates, crops, and soil types.
4. Develop cover cropping practices that come closer to meeting the annual fertility demands of commonly grown organic crops.
5. Development of systems-based plant disease management strategies (including specific considerations related to copper use in organic rice production) are needed to address existing and emerging plant disease threats.
6. The demand for organic nursery stock far exceeds the supply. Research is needed to identify the barriers to expanding this market, then develop and assess organic methods for meeting the growing demand for organically grown nursery stock.
7. Strategies for the prevention, management, and control of problem insects and weeds.
8. Factors impacting organic crop nutrition, and organic/conventional nutrition comparisons.
9. Side-by-side trials of approved organic inputs, both synthetic and natural, and cultural methods, with a request for collaboration with the USDA IR-4 project (Interregional Research Project No. 4), a specialty crops research program.
10. Impartial evaluation of microbial inoculants, soil conditioners, and other plant and soil amendments is needed as there is little objective evidence upon which to assess their contribution to soil health.
11. More research, extension services, and education are needed to fully understand the relationship between on-farm biodiversity and pathogen presence and abundance.
12. Clarify practices that reduce greenhouse gas emissions and that contribute to farming systems resilience in the face of climate change.

Food Handling and Processing

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

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

Coexistence with GE and Organic Crops

1. Outcome of genetically engineered (GMO/GE) material in organic compost.
2. Evaluation of public germplasm collections of at-risk crops for the presence of GMO/GE traits, and ways to mitigate small amounts of unwanted genetic material in breeding lines.
3. Develop, then implement, methods of assessing the genetic integrity of crops at risk to quantify the current state of the organic and conventionally produced non-GMO/GE seed.
4. Techniques for preventing unintended presence of GMO/GE material in organic crops, and evaluation of the effectiveness of current prevention strategies.
5. Testing for fraud by developing and implementing new technologies and practices.

General

1. Examination of the factors influencing consumer access to organically produced foods.
2. Production and yield barriers to transitioning to organic production to help growers successfully complete the transition.

Subcommittee Vote

Motion to accept the discussion document on Organic and Climate-Smart Agriculture
Motion by: Nate Powell-Palm
Second: Kyla Smith
Yes: 5 No: 0 Absent: 0 Abstain: 1 Recuse: 0

References:

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

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

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

Sunset 2024
Meeting 2 - Review
Livestock Substances § 205.603
October 2022

Introduction
As part of the Sunset Process, the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are scheduled for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list.

Request for Comments
Written public comments will be accepted through September 29, 2022 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

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

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

For Comments that Support the Continued Use of §205.603 Substances in Organic Production:
If you provide comments supporting the allowance of a substance at §205.603, you should provide information demonstrating that the substance is:

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

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

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

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

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

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

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

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

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

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

§205.603 Sunsets: Synthetic substances allowed for use in organic livestock production:

- Chlorhexidine
- Glucose
- Tolazoline
- Copper sulfate
- Elemental sulfur
- Lidocaine

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

- None

Chlorhexidine

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.

(6) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

Technical Report: 2010 TR; 2015 TR.

Petition: N/A

Past NOSB Actions: 10/1999 minutes and vote; 11/2005 sunset recommendation; 11/2009 Annotation change/clarification; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice effective 3/15/2017 (82 FR 14420); Annotation amendment effective 1/28/2019 (83 FR 66559)

Sunset Date: 01/28/2024

Subcommittee Review

Use

Used as an antimicrobial during surgery for cleansing wounds, skin, and equipment. Also used as a pre and post teat dip to aid in controlling bacteria that cause mastitis. There are numerous synthetic disinfectants currently on the National List for organic livestock production, including iodine, ethanol, isopropanol, acidified sodium chlorite, and hydrogen peroxide. Not all alternatives to chlorhexidine are useful in both a surgical environment and as a teat dip, as allowed under the chlorhexidine annotation. Chlorhexidine reportedly kills mastitis-causing pathogens faster than iodine and is more persistent in its disinfection activity. Chlorhexidine is gentler on the skin than iodine, which is especially useful in northern climates where an irritated udder and teats can be especially problematic for the animals in cold winter months. Approved legal uses of the substance include disinfection during livestock surgery, on teats pre and post milking, and on milking equipment. Chlorhexidine is also used in food processing as a hard surface disinfectant and in human dentistry as a mouth wash and to disinfect equipment.

Manufacture

Limited information is available regarding the manufacture of chlorhexidine for use in commercially available disinfectants, sanitizers, bactericides, and virucides. The general procedure for industrial-scale chlorhexidine production involves initial synthesis of the 1,6-hexamethylenebis(dicyandiamide) intermediate, followed by reaction of the intermediate with 4-chloroaniline hydrochloride. Once purified, chlorhexidine is combined with acetic acid or D-gluconic acid to generate the commercially relevant diacetate or digluconate salts of chlorhexidine.

International Acceptance

Canadian General Standards Board Permitted Substances List

The Canadian General Standards Board allows the use of chlorhexidine under Section 5.3 (Health Care Products and Production Aids) of the Permitted Substances Lists for Livestock Production (CAN, 2011). Specifically, the rule states that chlorhexidine may be used in the following ways: (1) for surgical procedures conducted by a veterinarian, and (2) as a post-milking teat dip when alternative germicidal agents and physical barriers have lost their effectiveness.

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

According to Article 23 (4) of the Commission Regulation concerning organic production and labeling of organic products, *Housing, pens, equipment, and utensils shall be properly cleaned and disinfected to* *prevent cross-infection and the build-up of disease carrying organisms. Feces, urine and uneaten or split feed shall be removed as often as necessary to minimize smell and to avoid attracting insects or rodents.*

The list of approved substances for cleaning and disinfection of building and installations for animal production includes "cleaning and disinfection products for teats and milking facilities." However, the rule does not explicitly describe the restrictions of use for available teat dip substances (EC, 2008). It is therefore uncertain whether European regulations allow the use of chlorhexidine as a topical disinfectant (e.g., teat dip) in organic livestock production.

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
Appendix 5 of the IFOAM Norms, which provides a list of "substances for pest and disease control and disinfection in livestock housing and equipment," includes iodine and "cleaning and disinfection products for teats and milking facilities." However, the standard does not explicitly describe the restrictions of use for available teat dip substances (IFOAM, 2014). It is therefore uncertain whether IFOAM guidelines permit the use of chlorhexidine as a topical disinfectant (e.g., teat dip) in the organic production of dairy animals.

Japan Agricultural Standard (JAS) for Organic Production
According to Table 4 of the Japanese Agricultural Standards for Organic Livestock Products, chlorhexidine is an allowed synthetic agent for cleaning and disinfecting livestock housing (JMAFF, 2012). However, chlorhexidine is not explicitly allowed for use in pre- or post-milking teat dips under Japanese organic regulations.

Environmental Issues
The 2015 technical report indicates that, although data is limited, chlorhexidine is readily biodegradable in the atmosphere, with limited biodegradation in the terrestrial and aquatic compartments [TR 275-277]. However, chlorhexidine is not considered to be persistent, bioaccumulative, or toxic to humans. Production and use of chlorhexidine as an antiseptic and disinfectant will result in releases to the environment through waste streams and spills. Chlorhexidine exists primarily in protonated (cationic) form in the environment, and thus is expected to adsorb strongly to organic carbon and clay despite its predicted high mobility in soil. Likewise, chlorhexidine is expected to adsorb to suspended solids and sediments when released to water [TR 433 - 436]. Despite the relatively low risk associated with chlorhexidine, environmental hazards cannot be excluded for improper handling and disposal of chlorhexidine products. Specifically, chlorhexidine salts are highly toxic to aquatic life with long lasting effects [TR 438 - 439]. Registrant-submitted studies indicate that concentrations as low as 60 parts per billion are toxic to half of the freshwater water fleas in an acute toxicity test [TR 439 - 441]. Further, 4-chloroaniline used in the synthesis of chlorhexidine is highly toxic to red blood cells and DNA, and exposure to residues of this substance in contaminated chlorhexidine solutions may lead to toxic effects in terrestrial organisms [441 – 443]. As a general antimicrobial agent chlorhexidine is potentially toxic to beneficial soil organisms, including nitrogen fixing bacteria and mycorrhizal fungi.

Discussion
Chlorhexidine is listed on the National List for two specific uses: as a teat dip; and as a disinfectant during medical procedures. There is unanimous support from the community that chlorhexidine should remain on the National List as a disinfectant used by veterinarians during medical procedures. There were several commenters from the dairy industry who use chlorhexidine in their operations and are supportive of it

remaining on the National List as a teat dip alternative when other products are not effective. They stated that it is used as a critical backup measure when alternative teat dips, such as iodine, prove to be ineffective. It was mentioned that chlorhexidine is not routinely used other than when necessary. A couple commentors urged more evidence should be obtained to weigh the need as a teat dip given the availability of products already approved. The subcommittee acknowledged that inspectors should be trained to validate there is product rotation for teat dips and ensuring chlorhexidine is not used excessively or exclusively in a program.

Justification for Vote
The Subcommittee finds that chlorhexidine continues to be compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote
Motion to remove chlorhexidine from the National List
Motion by: Kim Huseman
Seconded by: Amy Bruch
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 2

Glucose

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(13) Glucose.
Technical Report: 1995 TAP; 2022 TR
Petition: N/A
Past NOSB Actions: 10/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420); Sunset renewal notice effective 10/30/2019 (84 FR 53577).
Sunset Date: 10/30/2024

Subcommittee Review

Use
Glucose is a synthetic substance allowed in organic livestock production for medical treatment. For animal health purposes, glucose is used primarily as an aid in the treatment of ketosis in cattle. Additionally, glucose is an important remedy for dehydration, neonatal hypoglycemia, as an ingredient in formulated electrolyte solutions, and as an excipient.

Manufacture
An updated technical report published in 2022 notes that glucose is made through the hydrolysis of starches, mostly originating from corn, but could be sourced from wheat, rice, potato, barley, sago, or sorghum. In the process of hydrolysis, glucose can be formulated with enzymes or acids as the catalyst.

International Acceptance
Canadian General Standards Board Permitted Substances List
Glucose is permitted for use under section 5, Table 5.3 as a Health Care Product and Production Aide with no annotations or restrictions.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Article 14 addresses Livestock production rules, but glucose is not specifically mentioned

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Annex 1, Principles of Organic Production, Section B, subsections 20 thru 24 address Health Care in Livestock.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Section 5.6 addresses General Principles for use of Veterinary Medicines for Livestock, but glucose is not specifically mentioned.

Japan Agricultural Standard (JAS) for Organic Production
Glucose is not specifically mentioned

Environmental Issues
According to the 2022 technical report, glucose is abundant in the environment and is easily metabolized. It is not expected to accumulate in the environment, but as excreted in the urine of ruminants after treatment, is expected to be consumed by microbes in soil systems. As an important biomolecule, glucose has very low toxicity. Environmental concerns with glucose are associated with the agricultural production of starch-containing-crops used to produce glucose and the energy and materials consumed during manufacture. The technical report goes on to describe the starch industry as causing very little waste due to the effective use of all side streams as economically valuable products, noting that very little waste is sent to a landfill or incineration. Glucose is not expected to negatively impact environmental or human health from chemical interactions in organic crop, livestock, or handling systems. The use of glucose in organic systems is not expected to threaten water or soil systems.

Discussion
Glucose is an essential animal health remedy in organic systems. It is typically used to treat ketosis and dehydration when preventative measures have failed. While ketosis is a concern in most dairy herds, some producers note that due to an elevated risk of ketosis, it is necessary to maximize pre-parturition confinement in order to prevent ketosis through a low potassium diet. With glucose in the "toolbox", producers can proceed with grazing pasture closer to parturition with the confidence that they will be able to address ketosis, should it arise. Previous sunset reviews have reflected low levels of glucose usage, but farmers and inspectors have consistently commented that glucose is an essential treatment and there is a high degree of support for keeping glucose on the National List. Since glucose is used as an excipient and in electrolyte formulations (for example), retaining glucose on the National List of allowed synthetics also maintains this important tool in formulations.

Justification for Vote
The Subcommittee finds that glucose continues to be compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote
Motion to remove glucose from the National List
Motion by: Liz Graznak
Seconded by: Kim Huseman
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 0

Tolazoline

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.

(29) Tolazoline (CAS #-59-98-3)—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;

(ii) Use only to reverse the effects of sedation and analgesia caused by xylazine; and

(iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

Technical Report: 2002 TAP; 2019 TR.

Petition: 2002.

Past NOSB Actions: 9/2002 recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.

Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420); Sunset renewal notice effective 10/30/2019 (84 FR 53577).

Sunset Date: 10/30/2024

Subcommittee Review

Use

Tolazoline is limited to use only by a veterinarian prescription and is further restricted for "use only to reverse the effects of sedation caused by xylazine." Xylazine is primarily used in veterinary medicine as a sedative, tranquilizer, and analgesic. Sedation of animals is necessary for both planned medical procedures and emergency procedures to prevent pain and suffering and injury to the veterinarians performing the procedures. Tolazoline is commonly used as a reversal agent for xylazine by competing for the α2-adrenergic receptors, blocking binding events for xylazine. Structural similarities with xylazine allow tolazoline to compete with xylazine for biological binding sites, providing the mode of action for its approved use in organic livestock production as a reversal agent for xylazine.

Tolazoline is used only for veterinary applications, with no natural or USDA-approved synthetic alternatives. There are no alternative practices that would make the anesthetic agent unnecessary. Tolazoline may be made unnecessary by allowing the veterinary subject to recover from the effects of xylazine by natural metabolism of the substance, rather than its active reversal. However, the rate of xylazine metabolism is species-dependent; therefore, this may prove problematic in species with slower metabolic rates (e.g., cattle).

Manufacture

Tolazoline is a synthetic substance produced by a one-pot process (i.e., no intermediates are isolated) by the reaction of phenylacetaldehyde with ethylene diamine, with the incorporation of an iodine-based oxidation process.

International Allowance

Canadian General Standards Board Permitted Substances List

Although xylazine is listed in the CAN/CGSB-32.311-2015 — Organic production systems - permitted substances listed in Table 5.3 "health care products and production aids," as a "sedative," Tolazoline (the most commonly used substance for a reversal agent for sedatives, including xylazine) is not listed in the CAN/CGSB-32.311-2015.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Tolazoline is not listed in the EEC EC No. 834/2007 or 889/2008.

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
Tolazoline is not listed in IFOAM.

Japan Agricultural Standard (JAS) for Organic Production
Tolazoline is not listed in the JAS for Organic Production.

Environmental Issues
Tolazoline is a synthetic α2-adrenergic antagonist that also interacts with histamine and cholinergic receptors temporarily and reversibly. Tolazoline affords several physiological effects, including vasodilation (increasing arterial oxygenation), transient hypotension, and histaminic gastrointestinal effects. There are no published toxicity or carcinogenicity studies on tolazoline's toxicity or lethal dosages.
The EPA lists tolazoline as an inert ingredient of toxicological concern. There are no studies on tolazoline's environmental toxicity, persistence, or concentration.

Discussion
In 2022, Stakeholder comments supported relisting for the rare cases in which tolazoline is needed. Most commenters were unaware of substitutes; however, a few mentioned that Yohimbine is supposedly an antagonist of xylazine, but it is not used with any regularity in farm animal medicine. Additionally, atipamezole is also a potential alternative. Other comments stated that tolazoline and xylazine should sunset together since they are used together.

Although xylazine is not being reviewed for sunset at this time, for documentation purposes, there were concerns about the lack of consistency between the FDA and the American Medical Drug Use Clarification Act regarding the off-label use of xylazine in food-producing animals. The FDA prohibits it, but the American Medical Drug Use Clarification Act permits veterinarians to prescribe extra-label uses of certain approved new animal and human drugs for animals under certain conditions. The TAP and the 2015 NOSB review expressed that the lack of consistency can lead to confusion; therefore, this should be reviewed in further detail during the xylazine sunset.

Questions to our Stakeholders
None.

Justification for Vote
The Subcommittee finds that tolazoline continues to be compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote
Motion to remove tolazoline from the National List
Motion by: Amy Bruch
Seconded by: Kim Huseman
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 0

Copper sulfate

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(1) Copper sulfate.
Technical Report: 1995 TAP; 2015 TR.
Petition: N/A
Past NOSB Actions: 10/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420); Sunset renewal notice effective 10/30/2019 (84 FR 53577).
Sunset Date: 10/30/2024

Subcommittee Review

Use
Copper sulfate is listed on the National List of Allowed and Synthetic Substances for use in organic livestock production at § 205.603 as a topical treatment, external parasiticide or local anesthetic. Copper ions have been reported to have antimicrobial activity against a wide range of aerobic and anaerobic bacteria and fungi. The exact mechanisms by which copper sulfate exerts its biocidal effect is a source of numerous ongoing investigations in the scientific literature. Copper sulfate has been used as a footbath antiseptic to help control and prevent infectious hoof disease problems that affect the skin adjacent to the claw horn of dairy cattle and sheep [i.e., digital dermatitis (DD) (hairy heel warts), foot rot lesions (interdigital area and invading the subcutaneous tissue), and heel erosions]. Depending on the severity of the infection, the impact on managed cattle and or sheep ranges from minor discomfort to severe debilitating lameness, reproductive problems and in the dairy industry a reduction of milk production ranging from 20 to 50 percent [2015 TR, 93 – 98].

Manufacture
Copper sulfate is a synthetic compound produced by a chemical process. Copper sulfate is produced commercially by reacting various copper minerals and or metal with sulfuric acid [2015 TR 293 - 294].

International Acceptance
Canadian General Standards Board Permitted Substances List
Allowed as an essential nutrient (source of copper and sulfur) and for topical use (foot baths).

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

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

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

Japan Agricultural Standard (JAS) for Organic Production
Not listed.

Environmental Issues

See 2015 TR for references.

Walk-through footbaths are used to help control and prevent hoof related diseases in dairy cattle and sheep. A five-to-ten percent copper sulfate solution is commonly used as the antimicrobial agent in the footbath and is considered effective for 150 to 300 animal passes. Spent solution is mixed with manure waste and ultimately disposed by land application. Regulators in several states (Ippolito et al., 2013, Rankin, 2012) have expressed concern that soil copper could be increased to an unhealthy level by this practice and have established maximum (lifetime) loading rates of copper. An 8 ft. x 2.5 ft. x 5-inch foot footbath will contain approximately 62 gallons of water and 26 pounds of copper sulfate (charged at the 5% concentration). Since copper sulfate is 25% copper, each time the footbath is dumped, 6.5 pounds of copper is added to the disposal burden. The environmental effect of this copper depends on the volume of footbath solution disposed (a function of the number of animals and intensity of footbath use), concentration of copper sulfate, and the land area of application. Without careful attention, maximum soil copper loading rates may be exceeded in relatively short times (5 to 30 years) (Epperson et al., 2007). Depending on the agricultural crop, the annual removal rate for copper is less than 0.5 pound/acre per year. Federal, state, and local environmental regulations require the development of manure management plans to protect water resources and soil quality. The EPA has specific guidelines for copper loading to agricultural land when sewage sludge or biosolids are applied. The EPA §503.13 standard limits annual loading of copper from biosolids to 66 pounds copper per acre and limits lifetime loading to 1,339 pounds copper per acre (limits are based on biosolids land application) (EPA, 2014). Reaching these limits is almost impossible with dairy waste applications and would devastate most agricultural crops long before the lifetime loading limits were met. Some states have lower limits for copper application. New York and Illinois have set lower lifetime loading limits for copper at 75 and 250 pounds per acre, respectively, in order to avoid the potential of irreversible toxic accumulations of copper in the soil (Socha et al., 2007, Ippolito et al., 2013, Rankin, 2012). While more studies are needed, Ippolito et al. recommended that alkaline soils with greater than 50 ppm extractable copper should not have additional copper load added to soil. This value is advisable for producers' raising alfalfa for dairy cow consumption in order to avoid copper accumulation above the NRC 2005 recommendations for the maximum tolerable Cu level for cattle and sheep. Ippolito et al. suggested that soil samples be tested for extractable copper every two to three years from an accredited soil testing laboratory to determine if a copper accumulation problem exists.

Discussion

The feedback from the community during the Spring 2022 meeting was unanimous that copper sulfate use in livestock is essential as of this review. The subcommittee acknowledges the environmental impact of copper sulfate. The subcommittee received consistent feedback that it remains the goal of the community to find alternatives to copper sulfate and to conduct new research on alternatives to copper sulfate.

Questions to our Stakeholders

1. Can the consistent use of foot trimming allow for the elimination of copper sulfate on dairy farms?
2. Have other foot bath treatments of similar efficacy come on to the market?
3. Could zinc replace copper as a less environmentally toxic foot bath? If so, what are market barriers to facilitating this adoption.
4. The TR recently received by the Crop Subcommittee noted copper used in conventional hog production yields a concentrated amount of copper via hog manure. If using conventional hog manure on organic farms, should certifiers request manure tests to establish copper levels and then require corresponding soil tests to show a deficiency prior to approving the manure as an input?

Justification for Vote
The Subcommittee finds copper sulfate compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote
Motion to remove copper sulfate from the National List
Motion by: Nate Powell-Palm
Seconded by: Brian Caldwell
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 0

Elemental sulfur

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(2) Elemental sulfur—for treatment of livestock and livestock housing.
Technical Report: 2017 TR.
Petition: 2016.
Past NOSB Actions: 11/2017 recommendation to add.
Recent Regulatory Background: Added to National List on 5/30/2019 (84 FR 18133).
Sunset Date: 05/30/2024

Subcommittee Review

Use
Elemental sulfur is currently allowed for use in organic production as an insecticide, for plant disease control, as a plant or soil amendment, and as a pesticide for domestic livestock.

Elemental sulfur is granulated to a fine powder (325 mesh) for use as a pesticide (control for mites, insects, fungi, and rodents) in livestock production. The particle size for this powder is 44 microns (0.0017 inches) or less. Sulfur is dusted liberally and rubbed into feathers or hair. Sulfur dusting and or spraying is used for both the animals and their respective accommodations. Livestock species include chickens, turkeys, ducks, geese, game birds, pigeons, equine species, cattle, swine, sheep, and goats.

Manufacture
Sulfur is an abundant element on the earth. Elemental sulfur is found in volcanic sites and salt domes. Sulfur was classically mined from these using the Frasch process in the U.S. as late as the 1920s, but this is not a major source today.

Sulfur is also found in petroleum, natural gas, and fossil products from which it must be removed as a legal mandate to avoid the production of sulfur dioxide, a contaminant of the air. Hydrogen sulfide from petroleum refining and fossil fuels is converted to pure sulfur by the Claus process. The Claus process is used to produce the majority of sulfur available today. In a heating and cooling cycle, hydrogen sulfide recovered from fossil products is combusted to form water and elemental sulfur:

$$16\ H_2S + 10\ O_2 \rightarrow 2\ SO_2 + 7\ S_2 + 16\ H_2O$$

The addition of an aluminum or titanium catalyst permits the reaction of SO_2 formed during combustion with additional molecules of H_2S to yield sulfur and water:

$$2\ H_2S + SO_2 \rightarrow 3\ S + 2\ H_2O$$

In 2015, recovered elemental sulfur and its byproduct sulfuric acid were produced at 103 operations in 27 States. Total shipments were valued at about $933 million. Elemental sulfur production was 8.7 million tons; Louisiana and Texas accounted for about 52% of domestic production. Elemental sulfur was recovered, in descending order of tonnage, at petroleum refineries, natural-gas-processing plants, and coking plants by 39 companies at 96 plants in 26 States. Domestic elemental sulfur provided 64% of domestic consumption. About 11 million tons of sulfur were used in the US in 2015 (USGS, 2016; for references, please see the 2017 technical report for Elemental Sulfur: Livestock).

International Acceptance
Canadian General Standards Board Permitted Substances List
Sulfur is allowed for control of external parasites.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Commission Regulation (EC) No 889/2008 permits the use of elemental sulfur (98% pure) as a fertilizer or soil amendment and as a fungicide, acaricide and repellent in organic farming. Sulfur is not permitted for use as an insecticide in livestock.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Codex Alimentarius guidelines (GL 32-2013) permit the use of sulfur for livestock and livestock products in bee husbandry for pest and disease control. With recognition by the certification body or authority, GL 32-2103 permits the use of sulfur in soil fertilizing and conditioning, and plant pest disease control.

International Federation of Organic Agriculture Movements (IFOAM) Norms
The IFOAM norms allow the use of sulfur as a fertilizer and soil conditioner and as a crop protectant in organic crop production. IFOAM allows the use of sulfur for pest and disease control in beekeeping. Sulfur is not permitted for use as an insecticide in livestock.

Japan Agricultural Standard (JAS) for Organic Production
The Japan Agriculture Standard for Organic Production permits the use of sulfur as a fertilizer or soil improvement. Sulfur is not permitted for use as an insecticide in livestock.

Environmental Issues
Elemental sulfur seems benign unless being handled or administered in very large amounts, for instance in transport in molten form or when stored in open piles. It can also be overfed in unusual cases.

Consumption by ruminants of a high dietary percentage (>0.3%) of sulfur as elemental sulfur or sulfate can cause toxic effects. Sulfur bacteria in the rumen produce the poisonous gases, hydrogen sulfide and sulfur dioxide that eructate from the rumen and are absorbed through the lungs. Diets rich in sulfate can depress feeding. In spite of the liver's capability for detoxifying sulfide in the blood, extreme cases of sulfur toxicity can lead to death [TR 261-221].

In livestock production, hydrogen sulfide can be a hazard to human health. This colorless toxic gas with a rotten egg odor is produced during the degradation of liquid manure stored in anaerobic conditions within agricultural livestock operations. However, the contribution of elemental sulfur to the hydrogen sulfide livestock production hazard for workers is negligible [TR 314-319.

Current available U.S. Environmental Protection Agency (EPA) toxicity studies and literature searches for elemental sulfur do not indicate any systemic human toxicity associated with elemental sulfur exposure and no endpoints of toxicological concern have been identified. The acute toxicity of sulfur is low. Only the word caution or no signal word is required on the label for elemental sulfur for acute toxicity, inhalation, and dermal exposure. Sulfur is an eye and skin irritant (category III, moderate irritation (erythema) at 72 hours), but is not a skin sensitizer. The EPA's review of incident data indicates that both the relative number of reported incidents and the severity of reported health effects are low.

Discussion
In 2022, commenters were again strongly in favor of relisting this material. Commenters mentioned non-synthetic alternatives from the 2017 technical report, that were noted to be ineffective.

Justification for Vote
Because elemental sulfur is needed to control external parasites in livestock, has no effective alternatives, has low environmental impact, and is compatible with a system of organic agriculture, the Livestock Subcommittee recommends it remain on the National List at: § 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(2) Elemental sulfur—for treatment of livestock and livestock housing.

The Subcommittee finds that elemental sulfur continues to be compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote:
Motion to remove elemental sulfur from the National List
Motion by: Kim Huseman
Seconded by: Liz Graznak
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 2

Lidocaine

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(5) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 8 days after administering to livestock intended for slaughter and 6 days after administering to dairy animals.

Technical Report: N/A
Petition: N/A
Past NOSB Actions: 10/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 2016 annotation change recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice 2017 (82 FR 14420). Annotation change effective 1/28/2019 83 FR 66559
Sunset Date: 01/28/2024

Subcommittee Review

Use
Lidocaine is a local anesthetic used to reduce or prevent pain during de-budding horns in livestock, or general minor surgery on mature livestock. They numb only the area to be worked on. Humane treatment

of animals is critically important, and the public expects high standards of animal welfare for organic livestock. A lengthy withholding period after treatment may result in animals not being treated in a timely manner, or not being treated at all. Section 205.238 establishes a livestock healthcare practice standard permitting physical alterations needed to promote animal welfare in a manner which minimizes stress, and further that a producer must not withhold medical treatment in an effort to preserve its organic status.

Manufacture
Lidocaine, 2-(diethylamino)-N-(2,6-dimethylphenyl)acetamide (2.2.2), is synthesized from 2,6-dimethylaniline upon reaction with chloroacetic acid chloride, which gives α-chloro-2,6-dimethylacetanilide, and its subsequent reaction with diethylamine.

International Acceptance
Canadian General Standards Board Permitted Substances List
Use of pharmaceutical local anesthetics shall be followed by withdrawal periods of 90 days for livestock intended for slaughter, and seven days for dairy animals.

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

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

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

Japan Agricultural Standard (JAS) for Organic Production
Not listed.

Environmental Issues
Lidocaine is extensively and rapidly metabolized in the liver of mammals, followed by excretion via urine. No more than 10% of the dose is excreted as parent lidocaine. There is no excretion via feces.

Lidocaine is not readily biodegradable and is not predicted to bioaccumulate in aquatic organisms. The Predicted Environmental Concentration (PEC) / Predicted No Effect Concentration (PNEC) ratio is 6.5 x 10-2, which means use of lidocaine is predicted to present an insignificant risk to the environment.

Discussion
The subcommittee noted that animal welfare is an innate aspect of organic livestock production and lidocaine has been a consistent tool to minimize livestock pain. To this end, the subcommittee does encourage the community to think critically about ways the organic industry can further improve animal welfare via pain management.

Questions to our Stakeholders
1. Are there other, more effective anesthetics which should be considered for use in addition to or instead of lidocaine?

Justification for Vote

The Subcommittee finds lidocaine compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote

Motion to remove lidocaine from the National List
Motion by: Nate Powell-Palm
Seconded by: Amy Bruch
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 0

USDA National Organic Standards Board
Materials Subcommittee
Research Priorities Proposal
Fall 2022
Executive Summary

Overall: The National Organic Standards Board (NOSB) presents an annual list of research priorities for organic food and agriculture. The NOSB requests that integrated research be undertaken with consideration of the whole farm system, recognizing the interplay of agroecology, the surrounding environment, and both native and farmed species of plants and animals.

Livestock

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

Crops

1. Examination of decomposition rates, the effects of residues on soil biology, and the factors that affect the breakdown of biodegradable bio-based mulch film.
2. Conduct whole farm ecosystem service assessments to determine the economic, social, and environmental impact of farming systems choices.
3. Organic no-till practices for diverse climates, crops, and soil types.
4. Develop cover cropping practices that come closer to meeting the annual fertility demands of commonly grown organic crops.
5. Development of systems-based plant disease management strategies (including specific considerations related to copper use in organic rice production) are needed to address existing and emerging plant disease threats.
6. The demand for organic nursery stock far exceeds the supply. Research is needed to identify the barriers to expanding this market, then develop and assess organic methods for meeting the growing demand for organically grown nursery stock.

7. Strategies for the prevention, management, and control of problem insects and weeds.
8. Factors impacting organic crop nutrition, and organic/conventional nutrition comparisons.
9. Side-by-side trials of approved organic inputs, both synthetic and natural, and cultural methods, with a request for collaboration with the IR4 project.
10. Impartial evaluation of microbial inoculants, soil conditioners, and other amendments is needed as there is little objective evidence upon which to assess their contribution to soil health.
11. More research, extension, and education are needed to fully understand the relationship between on-farm biodiversity and pathogen presence and abundance.
12. Elucidate practices that reduce greenhouse gas emissions and that contribute to farming systems resilience in the face of climate change.

Food Handling and Processing

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

Coexistence with GE and Organic Crops

1. Outcome of genetically engineered (GMO/GE) material in organic compost.
2. Evaluation of public germplasm collections of at-risk crops for the presence of GE traits, and ways to mitigate small amounts of unwanted genetic material in breeding lines.
3. Develop, then implement, methods of assessing the genetic integrity of crops at risk to quantify the current state of the organic and conventionally produced non-GMO seed.

4. Techniques for preventing adventitious presence of GE material in organic crops, and evaluation of the effectiveness of current prevention strategies.
5. Testing for fraud by developing and implementing new technologies and practices.

General

1. Examination of the factors influencing access to organically produced foods.
2. Production and yield barriers to transitioning to organic production to help growers successfully complete the transition.

National Organic Standards Board
Materials Subcommittee Proposal
2022 Research Priorities
Fall 2022

INTRODUCTION

The National Organic Standards Board (NOSB) presents an annual list of research priorities for organic food and agriculture. The NOSB's Livestock, Crops, Handling, and Materials/GMO Subcommittees proposed an updated set of priorities at the Fall 2021 board meeting. The Board requests input from stakeholders on the 2022 research priorities and will review those comments for the Fall 2022 proposal.

BACKGROUND

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

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

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

Livestock

1. Efficiency of Natural Parasiticides and Methodologies – Nutritional programs, use of herbs, essential oils, homeopathic remedies, Diatomaceous Earth, and the genetic pool of laying hens in controlling *A. galli* and *H. gallinarum* in laying and replacement chickens intended to become hens – among other interventions – may be helpful in ensuring flock health. Ongoing research into the usefulness and viability of such innovations is consistent with NOSB action.

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

Continued research on the use of synthetic methionine in the context of a systems approach (nutrition, genetic selection, management practices, etc.) is consistent with the NOSB unanimous resolution passed at the La Jolla, California, Spring 2015 board meeting. A systems approach that includes industry and independent research by USDA/ARS, on farms, and by agricultural land grant universities is needed for (1) evaluation of the merits of natural alternative sources of methionine such as herbal methionine, high methionine corn, and corn gluten meal in organic poultry production systems; (2) evaluation of poultry breeds selection that could be adaptive to existing organic production systems – inclusive of breeds being able to adequately perform on less methionine; (3) assessment of management practices for improving existing organic poultry welfare under different conditions; and (4) with the European Union as a case study, assess how it is that EU farmers manage the methionine needs of their flocks in the absence of synthetic methionine use. Research findings and collaborations under various climates, housing types, geographical regions, and countries should be noted and researched, where applicable. Certainly, the fruition of these types of research topics could take years to achieve the expressed NOSB resolution; however, an aggressive and/or heightened research focus could lead to findings that can positively impact the organic poultry industry and the organic brand. The continued focus on methionine with a systems approach is imperative and necessary. The key research areas should include the efficacy and viability of alternatives such as: herbal methionine, corn gluten meal, potato meal, fishmeal, animal by-products, and other non-plant materials. Additional research on the more promising alternatives to bring them into commercial production is also encouraged. Additionally, management practices impacting the flock's demand for methionine should be included, such as flock management practices, access to pasture, and pasture management.

3. Prevention and Management of Parasites - Livestock production places large numbers of cattle, sheep, goats, poultry etc. into relatively close contact with each other on fields and in barns. Organic production does not allow antibiotic use and requires that livestock be raised in a manner which approximates the animal's natural behavior. The organic farmer can use synthetic parasiticides in an emergency but not prophylactically. Synthetic parasiticides have many limitations. Even if prophylactic treatment with parasiticides were possible, it is clear that parasite immunity to chemical control will inevitably occur. Thus, prevention of parasites is critical.

The research question on prevention and management of parasites must be systems-based. What farm systems, bird and animal breeds, herd or flock management systems have shown the best results with parasite control over the last twenty years? What regional differences are there in the US in parasite prevention? Are there specific herbal, biodynamic, diatomaceous earth, or other treatments that have been proven to work overtime? What are the parasite-resistant breeds? Are there plant species in pastures, hayfields, and scrublands that could be incorporated into the annual grazing system to reduce the spread of parasites or to provide prevention through the flora, fauna, and minerals ingested? Which pasture management systems appear to be best for parasite prevention in various parts of the country? Are pasture mixes being developed that include plants known to prevent parasites in various breeds?

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

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

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

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

Crops

1. Biodegradable Bio-based Mulch Film - Biodegradable mulch was recently approved by the NOSB but did not specify a required percentage of biologically derived (i.e., bio-based) content. In 2015, NOP issued a Policy Memo that states that certifiers and material organizations should review biodegradable mulch film products to verify that all (100%) of the polymer feedstocks are bio-based. This requirement makes bio-based mulches unavailable to organic producers because petroleum-based polymers are present in these mulch films. In order to provide a recommendation to the NOP addressing the presence of petroleum-based polymers in these mulches, the answers to the following questions are important to develop more clarity on mulch films and possibly develop an additional annotation to address producer needs for biodegradable mulch films even if petroleum-based polymers are used:

- How rapidly do these mulches fully decompose, to what extent does cropping system, soil type, and climate mediate decomposition rates, and does the percentage of the polymers in the mulch film affect the decomposition rate?
- Are there metabolites or breakdown products of these mulches that do not fully decompose? Do any of these mulches fully decompose?
- Do breakdown byproducts influence the community ecology and ecosystem function of soils, plants, and the livestock that graze on crops grown in these soils?
- As fragments degrade, do they pose a problem to terrestrial and aquatic wildlife? What are the environmental fates of micro- and nano-plastic fragments resulting from biodegradable mulch film degradation, and what hazards do they present to organisms that they interact with on the way to that fate?
- Do the residues of these films accumulate after repeated use?
- Are the testing protocols in place to insure decomposition standards?

2. Ecosystem service provisioning and biodiversity of organic systems - How do organic systems impact ecosystem service provisioning, both on-farm and off-farm through the materials and inputs sourced and used for production? For example, life-cycle analysis of environmental costs and benefits of inputs used for organic production, such as manure, seaweed, and fish-based soil amendments, would be beneficial. Additionally, what is the impact of diversified and agroecologically designed organic farming systems on biodiversity and ecosystem services within the farm and in its surroundings? Can farm-mapping be performed to quantify the impact of the location of a farm (in a broader landscape) and the arrangement of fields and non-crop habitat to enhance biodiversity and ecosystem service provisioning?

3. Organic No-Till and Minimum Tillage - Organic no-till can increase soil health and provide for increased biodiversity. Organic no-till preserves and builds soil organic matter, conserves soil moisture, reduces soil erosion, and requires less fuel and labor than standard organic row crop farming.

Farmers are employing several different approaches to organic no-till. Some are using a roller-crimper to terminate cover crops for in-place mulching. They then transplant or seed directly into the cover crop mulch. Others are utilizing polyethylene sheets (silage tarps) to prepare land for no-till planting. This approach often involves termination of a cover crop, as with the roller-crimper systems, but seemingly as often, or more frequently, is utilized to prepare fallow ground (for stale seed bedding, termination of crop residue and subsequent incorporation via soil fauna), or in conjunction with large applications of compost or other sources of organic matter.

Increased research is needed to develop organic no-till systems that function for a wide variety of crops in diverse climates and soil types. Annual crops such as commodity row crops and specialty crops, as well as perennial crops such as tree fruits, berries, and grapes would all benefit from these organic no-till practices. Research areas that could be covered include:

- Development of plant varieties that have specific characteristics, such as early ripening, to aid in the effectiveness and practicality of organic no-till.
- What combination of mulch crops and cultural systems sustain crop yields, provide soil health benefits, and suppress weeds?
- How does organic no-till influence pest, weed, and disease management?
- What potential pest problems can be caused or exacerbated by cover crops used as mulches, and how can those problems best be managed?
- In perennial cropping systems, such as fruits, what are the benefits or drawbacks of using this mulching system on weed, pest, and disease management, as well as soil fertility?
- What are the biodiversity benefits to living and/or killed mulches, and how does this contribute to pest, weed, and disease management?
- Do these systems affect the nutrient balance of the soil and subsequent fertilization practices, including use of outside inputs?
- Based on the improved soil health, when there is less soil disturbance and more plant decomposition resulting in higher organic matter, how does this system affect soil microbial life and nutrient availability, and does this then result in crops that are less susceptible to disease and pests?
- Research is needed on seeds, specifically for good cold germination, rapid emergence and establishment, seedling vigor, nutrient uptake efficiency, and overall weed competitiveness to crop cultivar development goals for organic conservation tillage systems.
- How can reduced tillage weed management be improved, including development of new tools and techniques that provide greater weed control for less soil disturbance?

Finally, organic farmers use whole-farm planning when deciding what will be done in each of their fields. Research that assesses the ecosystem benefits of reducing tillage in patches (field-level) across a farm is also needed. For example, the relative benefits of reducing tillage are greater in areas prone to surface water runoff. Research is needed to "inform" where reduced tillage practices are likely to have their greatest impact.

4. Managing Cover Crops for On-Farm Fertility - Growing cover crops and green manures is a foundational practice on many organic farms. In addition to conserving soil, increasing water holding capacity, and providing weed suppression, cover crops supply important plant nutrients and increase soil organic matter. As farmers seek to grow their own fertility, more research is needed on the efficacy of relying primarily on cover crops to meet production needs, particularly for horticultural crops. At present, there is inadequate data on the nutrient benefits of different cover crop mixes and how those benefits vary according to species mix, mowing practices, tillage regimes, subsequent planting time of the cash crops, and importantly the preceding practices that define the legacy of individual fields.

5. Disease Management - Disease management in organic fruit and vegetable production relies on a systems approach to succeed, but even with current systems plans in place, growers frequently struggle to manage commonly occurring blights and citrus greening. The NOSB underscores the need for systems research that addresses solutions to these and related diseases that are workable for farmers, that reduces adverse health effects on farmers and fieldworkers, and that also limits adverse effects on the soil and water in which the crops grow. To this end, we call for systems research that identifies disease resistant material while at the same time identifying biological controls that limit the use of copper-based compounds where possible.

Specifically, targeted research is needed to identify management practices and less toxic alternative materials for a wide range of crops. More research is needed on many of the crop/disease combinations, including:

- Comprehensive, systems-based approaches for managing individual crops in a way that decreases the need for copper-based materials, including researching crop rotations, sanitation practices, plant spacing, and other factors that influence disease.
- Breeding plants that are resistant to the diseases that copper controls.
- Developing alternative formulations of materials containing copper so that the amount of elemental copper is reduced.
- Developing biological agents that work on the same diseases that copper is now used on.
- Evaluating plant nutritional strategies to mitigate the impacts of plant diseases.
- Research on scum and algae control in rice and whether sodium carbonate peroxyhydrate or other materials are suitable alternatives in an aquatic environment.
- Soil management and crop cultivar development for enhanced beneficial crop-root microbe partnerships that protect organic crops from soil borne and foliar pathogens.
- Alternatives to antibiotics (tetracycline and streptomycin) for fire blight control, particularly in pears and apples.

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

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

6. Identify Barriers and Develop Protocols for Organic Nursery Stock Production

The demand for organic nursery stock far exceeds the supply. Research is needed to identify the barriers to expanding this market, then develop and assess organic methods for meeting the growing demand for organically grown nursery stock. That work could include but is not limited to assessing phytosanitary rules for shipping plants and quantifying the production and demand for organic rootstock. Research has shown that application of the correct ectomycorrhizal inoculants to roots can substantially (50% or more) enhance establishment and early growth of woody perennial horticultural crops. How can fine tuning the use of mycorrhizal inoculants make organic nursery stock production easier and more profitable, thereby helping to close the demand/supply gap? Research centered on development of practical organic methods for the nursery industry to implement is needed, including:

- Disease and insect control materials that are allowed under organic standards and may be accepted under specific phytosanitary regulatory requirements.

- New materials for controlling pests addressed by phytosanitary rules that show promise of compatibility with National List review criteria.
- Alternative protocols for phytosanitary certification of nursery stock that are based on outcomes (such as testing or inspection) rather than requirements for use of synthetic materials during production.

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

Examples are:

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

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

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

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

8. Nutritional Value of Organic Crops - How do organic soil health and fertility practices - crop rotations, cover crops, compost and other organic or natural mineral amendments, etc. - affect the nutritional value or "nutrient density" of organically produced crops? How do organic production and shipping methods (including methods of production, handling, and time in transport) influence the nutritional quality, taste, palatability, and ultimately preference for organic vegetables and fruits? There is a lack of sound, rigorously conducted studies of this kind. How can growers and handlers retain nutrition through post-harvest handling and transportation? Additionally, can providing organic producers information on soil biology and soil nutrient composition help improve nutrition? Finally, more studies are needed examining how organic crops compare to conventional crops with regards to nutritional value.

9. Side-by-Side Efficacy Comparisons Between National List Allowed and Petitioned Synthetic Inputs Versus Non-synthetic Alternative Inputs or Practices - During its five-year review of sunset materials on the National List and in the evaluation of newly petitioned materials, the NOSB often lacks sufficient information of the effectiveness of these materials as compared with other synthetics on the National List, natural materials, and cultural methods. Side-by-side trials with approved organic inputs, both synthetic and natural, and cultural methods to evaluate efficacy would strengthen the review process and provide growers with valuable information in pest and disease management decisions. The NOSB specifically requests collaboration with the Minor Crop Pest Management Program Interregional Research Project #4 (IR4) to include materials on the National List in their product trials. Such studies would help inform the NOSB review process of sunset materials and to determine if materials are sufficiently effective for their intended purpose, particularly when weighed against the natural and cultural alternatives. It should be noted that growers commonly rely on a mix of cultural practices and both non-synthetic materials and materials from the National List to produce crops of marketable quality and sufficient yield for profitability; it is understood that such studies would serve as a starting point and would form part of the comprehensive material review process.

10. Evaluation of Microbial Inoculants, Soil Conditioners, and Other Amendments – Vendors of organic amendments now offer a large and growing array of microbial inoculants, organic soil conditioners, and other materials claimed to improve soil health, crop vigor and quality, and combat weeds, pests, and diseases. There is an urgent need for impartial evaluation of these materials to help producers decide which products to use and to avoid unnecessary expenditures on products that are unlikely to yield benefits.

11. Pathogen Prevention - Third-party food safety auditors believe that some biodiversity-maintenance strategies employed by organic farmers may increase the risk for introduction of human pathogens on the field. While some research has been conducted disproving this hypothesis, more research, extension, and education are needed to fully understand the relationship between on-farm biodiversity and food safety – and this research must be communicated to third-party food safety auditors and incorporated into their audits.

12. Climate Change (Reducing Greenhouse Emissions and Sequestering Carbon) - A growing body of research demonstrates that organic farming can help prevent anthropomorphic climate change, and some strategies employed by organic farming can also help with resilience to current climate challenges such as drought and flooding. Although a number of researchers are examining this issue, additional work is needed to pinpoint specific strategies that organic farmers can take to reduce greenhouse gas emissions and respond to current climate challenges threatening the future of our food security.

Handling

1. Chlorine Materials and Alternatives - Chlorine materials currently allowed for use in organic agriculture are widely used in farming and handling to clean and disinfect equipment, surfaces, and produce. There have been some concerns raised about these materials and their impact on the environment and human health when/or if they form trihalomethanes and other toxic compounds. Chlorine materials are also acutely toxic to workers. New sanitizers and disinfectants are regularly petitioned to the NOSB for addition to the National List. FDA regulations on food safety (Food Safety Modernization Act) and best management practices for cleaning in handling operations both require a suitable level of cleanliness and disinfection to prevent pathogens from entering the food supply.

Producers and handlers are looking for alternatives to chlorine while continuing to provide a safe end-product to their customers and the consumer. Addressing food safety while adhering to the fundamental organic principles involving human health and environmental impact is a concern.

The organic industry needs better information on how either alternative materials or appropriate chlorine materials are best suited for a specific use and control measure. This is especially important in determining if the industry can move away from the use of chlorine compounds in the future.

Points of consideration for future research activities:

- Comparison of alternatives to chlorine such as: citric acid, hydrogen peroxide, ethanol, isopropanol, peracetic acid, and ozone. How would each compare to the different chlorine materials for specific uses? The strengths and weaknesses would need to be considered.
- Potential human health and environmental impacts of each chlorine material versus the possible alternative materials listed above. Are there ways that these impacts can be mitigated and still allow the material to work as needed?
- Determination of which of the above-mentioned alternatives would NOT be a suitable substitute for chlorine. What specific uses and/or conditions would this apply to?
- Identification of practices that could be used to help reduce the formation of trihalomethanes in those specific situations where chorine is the best material to use.
- Could the rotation of materials for cleaning and disinfecting help lower the risks from chlorine materials and still be effective in providing the desired control of pathogens?
- Research on the absorption of chlorine by produce from its use in wash tanks, including information about the amount of time of exposure, would help inform understanding of human exposure to chlorine and health risks. Are residues from produce washing a persistent residual effect or temporary (if temporary – how long is it a viable residue), and would it be harmful if consumed at these levels?
- 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? Does that include 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. Alternatives to Bisphenol A (BPA) - The Handling Subcommittee is examining the issue of whether to prohibit BPA in packaging materials used for organic foods in light of direct evidence that these uses result in human exposures and mounting evidence that these exposures may be harmful. There is a need for increased research about alternatives for the linings of cans and jars used for organic products that do not result in human exposures and health risks.

Materials/GMO

In previous years, the Materials Subcommittee has prioritized the Reduction of Genetically Modified Content of Breeding Lines (2013) and Seed Purity from GMOs (2014), issues which are currently being addressed through a comprehensive stream of work on Excluded Methods. The following research priorities are among the areas that the Excluded Methods work continues to elevate:

1. **Fate of Genetically Engineered Plant Material in Compost -** What happens to transgenic DNA in the composting process? Materials such as cornstalks from GMO corn or manure from cows receiving rBGH are often composted, yet there is little information on whether the genetically engineered material and traits break down in composting process. Do these materials affect the microbial ecology of a compost pile? Is there trait expression of Bt (bacillus thuringiensis) after composting that would result in persistence in the environment or plant uptake?

2. **Integrity of Breeding Lines and Ways to Mitigate Small Amounts of Unwanted Genetic Material -** Are public germplasm collections that house at-risk crops threatened by transgenic content? Breeding lines may have been created through genetic engineering methods such as doubled haploid technology, or they may have had inadvertent presence of GMOs from pollen drift. The extent of this problem needs to be understood.

3. **Assess the Genetic Integrity of Organic Crops at Risk** - Develop then implement methods of assessing the genetic integrity of crops at risk to quantify the current state of the organic and conventionally produced non-GMO seed. Such assessments are needed on the front (seed purchased by farmers) and back end (seed harvested from a farmer's field) of the production chain as well as on points of contamination in the production chain.

4. **Prevention of GMO Crop Contamination: Evaluation of effectiveness** - How well are some of the prevention strategies proposed by the NOSB working to keep GMOs out of organic crops? For instance, how many rows of buffer are needed for corn? How fast does contamination percentage go up or down if there are more or fewer buffer rows? Other examples could be whether cleanout of combines and hauling vehicles reduces contamination using typical protocols for organic cleaning, whether situating at-risk crop fields upwind from GMO crops can reduce contamination, and what the role may be of pollinators in spreading GMO pollen. Lastly, research is needed on a mechanism to provide conventional growers incentives to take their own prevention measures to prevent pollen drift and its impact on organic and identity-preserved crops. This is policy research rather than field research but is equally as important.

5. **Testing for Fraud: Developing and implementing new technologies and practices** - New technologies, tests, and methodologies are needed to differentiate organic crop production from conventional production to detect and deter fraud. Testing to differentiate conventional and organic livestock products, for example omega 3 or other indicators, is also needed. Additional tools to identify

fraudulent processed and raw organic crops require research to combat this problem. Current methodologies include pesticide residue testing, in field soil chemical analysis, and GMO testing. Areas in need of further testing methodology include phostoxin residues, fumigant residues, carbon isotope rations for traceability, validating nitrogen sources using nitrogen isotope rations, or other experimental testing instruments that can be utilized to distinguish organic raw and/or processed crops from conventional items. Additionally, there is a need to develop rapid detection technologies for adaptation to field-testing capacities.

General

1. Increasing Access to Organic Foods - What factors influence access to organically produced foods? Individual-based studies are needed to assess the constraints to accessing organic food. Research should be funded that builds on an understanding of constraints by asking what community, market, and policy-based incentives would enhance access to organic foods.

2. Barriers to Transitioning to Organic Production - What are the specific production barriers and/or yield barriers that farmers face during the three-year transition period to organic? Statistical analysis of what to expect economically during the transition is needed to help transitioning growers prepare and successfully complete the transition process.

Subcommittee Vote:
Motion to accept the proposal on the 2022 NOSB Research Priorities
Motion by: Wood Turner
Seconded by: Brian Caldwell
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 2

Approved by Wood Turner, Materials Subcommittee Chair, to transmit to NOSB, August 9, 2022

National Organic Standards Board
Crops Subcommittee Petitioned Material Proposal
Carbon Dioxide
July 5, 2022

Summary of Petition:
The NOSB received a petition requesting the addition of synthetic carbon dioxide (CO_2) at § 205.601 Synthetic substances allowed for use in organic crop production as (a) algicide, disinfectants, and sanitizer, including irrigation system cleaning systems and (j) As plant or soil amendments.

Carbon dioxide is currently allowed for use as an ingredient in organic labeled processed food products: § 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." (b) Synthetic allowed: - Carbon dioxide. This petition requests the allowance of carbon dioxide in organic crop production under the two sections listed above.

Subcommittee Review:
Carbon dioxide is understood to be a material with inherently low risk and is approved as a processing aid. Nonsynthetic sources are not available due to lack of infrastructure at ethanol plants. Because the petitioned material is synthetic, the Crops Subcommittee discussions focused on the need and benefits of using carbon dioxide over other allowed alternatives.

Some farming areas have alkaline water sources that can hinder nutrient availability and optimal crop growing conditions. Currently, organic farmers can use citric acid and sulfur burners to acidify irrigation water. It is a naturally occurring substance in the atmosphere and has no apparent negative effect on other materials used in organic farming systems. In a greenhouse environment, atmospheric CO_2 levels are depleted quickly as it is required for plants to photosynthesize. Greenhouse operations may have limiting levels of carbon dioxide and may benefit from this material as a plant and soil amendment. The Crops Subcommittee questions the potential uses of this material in other growing systems. Previous commenters have also shown interest in further information for this listing. The Crops Subcommittee understands that this product is inherently low risk and is a suitable alternative to current water acidifiers at § 205.601(a).

However, the Crops Subcommittee is seeking more information about the requested use at § 205.601(j) and has requested a limited-scope Technical Report (TR) to understand the use frequency, the application rates, and all methods of applications.

Category 1: Classification

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

Carbon dioxide (empirical formula CO_2, CAS Reg. No. 124-38-9) occurs as a colorless, odorless, noncombustible gas at normal temperatures and pressures. The solid form, "dry ice", sublimates under atmospheric pressure at a temperature of −78.5 °C.

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

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

Carbon dioxide falls under the category of production aid.

Category 2: Adverse Impacts

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

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

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

The action to dissolve carbon dioxide (CO_2) in water (H_2O) makes carbonic acid (H_2CO_3): H_20 + CO_2 -> H_2CO_3. Carbonic acid is dissociated in water to: HCO_3^- + H^+. This hydrogen lowers water pH. This is a common, naturally occurring reaction in the soil ecosystem from carbon dioxide in the atmosphere.

In soils with high pH, applying water with a reduced pH can increase nutrient availability and increase plant health. Additionally, the activity of carbon dioxide in water can help prevent clogging of irrigation systems by algae and other plant contaminants.

Carbon dioxide can also be used for pest control in storage areas, however, that is not the subject of this petition.

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

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

This characteristic makes the use of carbonic acid the safer and most secure process for water pH adjustment when compared to alternatives.

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

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

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

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

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

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

Category 3: Alternatives/Compatibility

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

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

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

Citric acid is a non-synthetic substance widely used in food processing. It is used as an ingredient, acidulant, pH control agent, flavoring, and sequestrant. It is also used as a dispersant in flavor or color additives. Citric acid is listed as GRAS (Generally Recognized As Safe) by the FDA.

As a plant and soil amendment, there are no substitutions to carbon dioxide since carbon dioxide is needed for photosynthesis. In greenhouse conditions, carbon dioxide can be a limiting resource and its replacement would be needed.

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

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

The Crops Subcommittee is seeking additional information about the requested use at § 205.601(j) and will develop a proposal for a future NOSB meeting.

National List Motion:
Motion to add carbon dioxide at § 205.601(a) algicide, disinfectants, and sanitizer, including irrigation system cleaning systems
Motion by: Logan Petrey
Seconded by: Rick Greenwood
Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 2

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Potassium Hydroxide as a production aid in the production of liquid fish products

July 20, 2022

Summary of Petition:
The petition states that the intent is to use potassium hydroxide as a processing aid to facilitate emulsion of the invasive carp species to help support extraction of soluble organic compounds from the fish by means of alkaline hydrolysis. The petitioner states that the amount of potassium hydroxide used should be limited to the amount necessary for emulsion of the fish and once the process is completed phosphoric acid will be used to stabilize the product.

Summary of Review:

Potassium hydroxide is already on the National List and is allowed as a processing aid for the extraction of aquatic plant extracts (per 7 CFR 205.601(j)(1)) and humic acids (per 7 CFR 205.601(j)(3)). It is also allowed for extraction and emulsion of algae and its use has been thoroughly reviewed when it was added to the National List.

Category 1: Classification

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

   Potassium hydroxide is a synthetic substance allowed for use in organic crop production (7 CFR 205.601).
2. Reference to appropriate OFPA category:
   Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

   The petitioner is requesting that potassium hydroxide be added to 7 CFR 205.601(j)(4) as a synthetic substance allowed for use in organic crop production to be used as a production aid for the emulsion of invasive carp to produce a liquid fish product.

Category 2: Adverse Impacts

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

Potassium hydroxide is added to a reactor vessel along with fish and water, agitated with heat, and eventually stabilized (neutralized) with phosphoric acid. The potential for chemical interactions with other materials is negligible.

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?
   For the petitioned use there will be no environmental contamination since the product will be neutralized before it is used in the environment.
3. Describe the probability of environmental contamination during manufacture, use, misuse, or disposal of such substance? [§6518(m)(3)]
   The probability that there could be environmental contamination during the manufacture of the liquid fish product is minimal because the reaction takes place in an enclosed reaction vessel.

4. Discuss the effect of the substance on human health. [§6517(c)(1)(A)(i); §6517(c)(2)(A)(i); §6518(m)(4)].
   Potassium hydroxide is a caustic chemical and can cause skin damage, but in this use there is little chance for human exposure except during the manufacturing process. Potassium hydroxide has been reviewed by the FDA (21 CFR 184.1631).

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)]
   Potassium hydroxide is used to raise the pH as part of the fish emulsion process but is neutralized when the liquid fish product is produced so no change in soil pH would be expected. Minor amounts of potassium would be added to the soil but in levels that would not be expected to change biological or chemical interactions in the soil agroecosystem.

6. Are there any adverse impacts on biodiversity? (§205.200)
   At the rates this substance is applied, no adverse impacts on biodiversity are expected.

Category 3: Alternatives/Compatibility

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

   Potassium hydroxide is the preferred chemical for raising pH and is commonly used in agriculture, fertilizer, and food products. It is also listed by OMRI in numerous products. Sodium hydroxide could be an alternative but can be harmful to plants because of increased sodium levels. Lithium hydroxide could be an alternative but would be harmful to the environment due to the toxicity of lithium.

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

   Yes. The end product, fish emulsion (liquid fish products), is widely used by organic farmers and has been recognized for years as being a beneficial fertilizer. This process will allow an invasive species of fish to be used in a beneficial way for organic agriculture. However, the

Subcommittee had remaining questions about the need to add this to the National List for just this specific fish (invasive carp species).

Classification
Potassium hydroxide is on the National List, and already classified as synthetic.

National List Motion
Motion to add potassium hydroxide to the National List as a processing aid at 205.601
Motion by: Rick Greenwood
Seconded by: Jerry D'Amore
Yes: 6 No: 1 Abstain: 0 Recuse: 0 Absent: 1

Sunset 2024
Meeting 2 - Review
Crops Substances § 205.601 & § 205.602
October 2022

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

Request for Comments
Written public comments will be accepted through September 29, 2022 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

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

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

For Comments that Support the Continued Use of §205.601 Substances in Organic Production:
If you provide comments supporting the allowance of a substance at §205.601, you should provide information demonstrating that the substance is:
1. not harmful to human health or the environment;
2. necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
3. consistent with organic crop production.

For Comments that Do Not Support the Continued Use of §205.601 Substances in Organic Production:
If you provide comments that do not support a substance at §205.601, you should provide reasons why the use of the substance should no longer be allowed in organic production. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:
1. harmful to human health or the environment;
2. unnecessary because of the availability of alternatives; and/or
3. inconsistent with organic crop production.

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

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

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

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

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

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

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

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

- Herbicides, soap-based
- Biodegradable biobased mulch film
- Boric acid
- Sticky traps/barriers
- Elemental sulfur
- Coppers, fixed
- Copper sulfate
- Polyoxin D zinc salt
- Humic acids
- Micronutrients:
    - Soluble boron products
    - Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt
- Vitamins C E
- Squid byproducts

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

- Lead salts
- Tobacco dust (nicotine sulfate)

Herbicides, soap-based

Reference: §205.601(b) As herbicides, weed barriers, as applicable.
(1) Herbicides, soap-based—for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops.
Technical Report: 1996 TAP; 2015 TR
Petition: N/A
Past NOSB Actions: Actions: 1996 recommendation; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

Use
As herbicides, soap-based herbicides are used as weed barriers, for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops as a last resort.

Manufacture
Soap-based herbicides are potassium salts of fatty acids and are produced through saponification, where aqueous potassium hydroxide is added to fatty acids commonly found in animal fats and plant oils. Ammonium salts of fatty acids, such as ammonium nonanoate, are produced through room temperature reaction of aqueous ammonia or ammonium hydroxide with fatty acids.

International Acceptance
Canadian General Standards Board Permitted Substances List
The Canadian Organic Production Systems Permitted Substances List provides several use patterns for soaps in organic crop and livestock production, as well as organic processing

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
European organic regulations allow the use of soap salts in crop and livestock production as insecticides and disinfecting agents but are not mentioned for use as herbicides.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
The use of soaps in organic productions is an allowed synthetic substance for plant pest and disease control but no mention of specific use as an herbicide.

International Federation of Organic Agriculture Movements (IFOAM) Norms
A number of uses of soaps are listed for organic crop production and disinfection but no mention of specific use as an herbicide.

Japan Agricultural Standard (JAS) for Organic Production
Soaps can be used for control of pests in organic crop production. No mention of specific use as an herbicide.

Environmental Issues
Potassium and sodium salts of fatty acids decompose rapidly and do not persist in the environment. They need to be sprayed directly on the target plant and thus, environmental contamination is not expected. Studies have not shown any negative interactions with other chemicals used for organic farming.

Discussion
In 2017, the NOSB received several comments in favor of keeping soap-based herbicides on the National List. Comments indicated that although soap-based herbicides are sometimes only marginally effective, they are a safe alternative, and some farmers rely on them for weed control on farmsteads, roadways, and other places they are approved for use. In the Spring 2020 NOSB meeting again there were no comments in favor of removing soap-based herbicides. The subcommittee discussed soap-based herbicides and considers them to be benign to the environment and human health.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds herbicides, soap-based compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote
Motion to remove herbicides, soap-based from the National List
Motion by: Rick Greenwood
Seconded by: Jerry D'Amore
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 3

Biodegradable biobased mulch film

Reference: §205.601(b) As herbicides, weed barriers, as applicable. (2) Mulches.
(iii) Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods.
Technical Report: 2012 TR; 2015 Report; NOP Policy Memorandum 15-1; 2016 Supplemental TR.
Petition: 2012.
Past NOSB Actions: Actions: 10/2012 recommendation; 11/2017 sunset recommendation; 2021 annotation change
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

Use
Biodegradable biobased mulch film (BBMF) is used to suppress weeds, conserve water, and facilitate production of row crops. Some commenters have noted that having a degradable plastic mulch is likely to be more environmentally friendly than using landfills for the non-degradable plastic mulches. The requirement for 100% biobased feedstocks to manufacture the film is articulated in the preamble of the final rule that added BBMF to the National List. Past commenters have acknowledged that there are currently very few options (other than difficult to use paper mulch) for 100% BBMF but have generally felt this listing should remain despite the fact that no 100% BBMF is available (see below). At the Fall 2021 NOSB meeting, the Board voted to allow 80% BBMF.

As noted in numerous public comments on past documents relating to BBMF, the current listing allowing the use of these films is impractical. No biobased films meet the 100% annotation and are unlikely to meet this criterion in the near future. There is also broad consensus among the Board and stakeholders that the use of allowed polyethylene mulch has serious negative environmental impacts. After input from stakeholders on the practicality and environmental impacts from biodegradable mulch, the Board passed a proposal modifying the annotation for BBMF. While there are no currently available products that meet the modified criteria, commenters noted that it is possible that materials meeting the proposed annotation could be available in the near future. The use of BBMF that meets this proposed annotation would alleviate the environmental impact of disposal of non-recyclable polyethylene mulch. The proposed language, "When greater than 80% biodegradable biobased mulch films become commercially available, producers are required to use them, given that they are of the appropriate quality, quantity, and form", also reflects the Boards intent to ensure that famers must use BBMF with biobased content greater than 80% when these materials become commercially available.

The timing of this sunset review predates the rulemaking process to implement the annotation allowing 80% BBMF. at §205.601(b) As herbicides, weed barriers, as applicable. (2) Mulches. (iii) Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods until the annotations is implemented.

Manufacture
BBMF is a synthetic plastic material manufactured from polymers using plant-based carbon sources.

International Acceptance
Canadian General Standards Board Permitted Substances List
Plastic mulches: non-biodegradable and semi-biodegradable materials shall not be incorporated into the soil or left in the field to decompose. Use of polyvinyl chloride as plastic mulch or row cover is prohibited. Biodegradable mulches: 100% of biodegradable mulch films shall be derived from bio-based sources. Biodegradable polymers and Carbon Black from GE or petroleum sources are not permitted.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Mulches are not specifically addressed in EEC. Under plant protection it states that all plant production techniques used shall prevent or minimize any contribution to the contamination of the environment.

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
Under section 4.5.1, mulches are permitted as a pest management practice under and 4.5.2 references appendix 3 as an approved list including "mulch" as a barrier. 4.6.3 states "for synthetic structure coverings, mulches, fleeces, insect netting and silage wrapping, only products based on polyethylene and polypropylene, or other polycarbonates are permitted. These shall be removed from the soil after use and shall not be burned on the farmland."

Japan Agricultural Standard (JAS) for Organic Production
Mulches are permitted for the control of noxious animals and plants in fields or cultivation sites. Mulches derived from used papers (those without chemically synthesized materials added in production) or plastic mulches (those intended to be removed after use). There is no listing of biodegradable mulches.

Environmental Issues
Concerns about BBMF have been discussed extensively in prior documents, including discussion documents, reports, and proposals for an annotation change. Concerns have been raised about incomplete degradation and migration of partially decomposed particles into the environment.

Discussion
There have been numerous public comments requesting the NOSB work with the NOP to allow a BBMF that contains unique polymers. Some noted that having a degradable plastic mulch is likely more environmentally friendly than disposing of non-degradable mulches in landfills. Previous commenters also acknowledged that there currently are no alternatives (other than difficult-to-use paper mulch) to 100% BBMF but felt the listing should remain despite the fact that 100% BBMF is not available. As noted above, at the Fall 2021 NOSB meeting, the Board voted on a recommendation to allow 80% BBMF. Subsequently, in 2022, during Subcommittee review for the sunset, there was hesitation by both the NOSB and stakeholders for relisting biodegradable mulch. Ongoing discussions include the degradation of BBMF and its unknown effects on soil health, comparisons of biodegradable mulches and bags, stickers, and other “biodegradable” products; estimates of polyethylene (PE) mulch residue; and concerns about phthalate residues.

Questions to our Stakeholders
1. At the Spring 2022 meeting the Crops Subcommittee asked about availability of 100% biodegradable biobased mulches. Commenters did not present any new information. Has there been any new development since then?
2. Mulches are critical to many organic farming operations; are those operations eager for biodegradable options?
3. How much residue is typically remaining after attempting to remove the standard polyethylene (PE) mulch?
4. If any producer has experience with trials of biodegradable mulches, please share.

Justification for Vote
The Subcommittee vote was mixed. Four members voted to remove BBMF from the National List, two voted to not remove it, and one member abstained. While the substance's manufacture, use, and disposal may have minimal impact on the environment and are done in a manner compatible with organic handling, under OFPA SEC. 2109. [7 U.S.C. 6508] Prohibited crop production practices and materials; (c) CROP MANAGEMENT - For a farm to be certified under this title, producers on farms shall not- (2), “use plastic mulches unless such mulches are removed at the end of each growing or harvest season.” Complete removal of these materials has proven to be challenging and has organic producers searching for alternatives.

Plastic mulches have been identified as a critical material category for many organic producers. The quest for an appropriate alternative has proven difficult, and stakeholders and NOSB members have conflicting opinions.

The Subcommittee would like further information on the decomposition products of BBMF, including micro-plastics, and whether they are harmful to soil microorganisms.

Subcommittee Vote
Motion to remove Biodegradable biobased mulch film (BBMF) from the National List
Motion by: Logan Petrey
Seconded by: Rick Greenwood
Yes: 4 No: 2 Abstain: 1 Recuse: 0 Absent: 1

Boric acid

Reference: §205.601(e) As insecticides (including acaricides or mite control).
(3) Boric acid - structural pest control, no direct contact with organic food or crops.
Technical Report: 1995 TAP.
Petition: N/A
Past NOSB Actions: 04/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

Use
As an insecticide, boric acid is odorless. It attacks insect nervous and metabolic systems. It can also dehydrate insects and be abrasive to insect exoskeletons. It has been used as an insecticide since 1948 and is common in household insecticides.
As a structural pest control tool, it is used as a bait which insects ingest and return to their colonies. As a result, it can eliminate entire pest colonies.
Boric acid is often used in packing sheds and other facilities. Many times, it is used as a powder introduced into cracks and crevices, and is essential for controlling ants and roaches.
It has a number of industrial and medical uses and is often used as an amendment in boron-deficient soils.

Manufacture
Boric acid is a white powder that is soluble in boiling water. It is a mined substance, occurring naturally in areas of high volcanic activity, and its primary source is the Mojave Desert of Nevada and California. It also occurs in plants, is prevalent in most fruits, and appears in rocks and soil.

Boric acid produced through the manufacturing process includes a broad range of formulations in concentrations from 1-100% in liquids (solutions, emulsifiable concentrates), granules, wettable powders, dusts, pellets, tablets, and baits.

International Acceptance
Canadian General Standards Board Permitted Substances List
The Canadian Organic Production Systems Permitted Substances List includes boric acid for structural pest control.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
European organic regulations do not reference boric acid.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
CODEX regulations do not reference boric acid.

International Federation of Organic Agriculture Movements (IFOAM) Norms
IFOAM regulations do not reference boric acid.

Japan Agricultural Standard (JAS) for Organic Production
JAS regulations allow boric acid for pest control for plants.

Environmental Issues
Boric acid is generally regarded as safe (GRAS) and of low toxicity, although it can be an eye, skin, and respiratory and nasal irritant. Ingestion by humans or pets can cause gastrointestinal distress. Long-term exposure can affect the kidneys, although it is not generally considered to be carcinogenic. There is no evidence it can be an endocrine disruptor or can create reproductive toxicity in humans (although birds may experience some reduced growth rates after ingestion). Several species of fish have been tested for impacts from boric acid, and the World Health Organization determined very low sensitivity to the material in those species. It has low toxicity to bees.

Boric acid is mined from the environment in deserts where sensitive habitats and species may exist. Boric acid is released into the environment due its wide range of applications, including borate salt laundry products, power generation, chemical manufacturing, copper smelters, rockets, mining operations, and the manufacture of glass, fiberglass, porcelain enamel, ceramic glazes, metal alloys and fire retardants.

Discussion
Boric acid, derived from the mineral borax/borate salts, is a weak acid that has long been considered a "least-toxic" pesticide because it is non-volatile when placed in bait or gel formulations and therefore eliminates risk of direct exposure. It is essentially hydrated boron.

At the Fall 2015 NOSB meeting, the Crops Subcommittee proposed to remove boric acid from §205.601(e) on the basis of not fully meeting all sub-components of OFPA criteria, particularly criteria of Impacts on Humans and the Environment, Essentiality, and Compatibility & Consistency. The motion to remove failed after receiving 1 "Yes" and 13 "No" votes. While boric acid does not fully meet the OFPA criteria of Impacts on Humans and the Environment, Essentiality, and Compatibility & Consistency, the alternatives often have equally challenging issues.

In 2017 and 2022, there was no new information provided from the stakeholder community through public comment. There was also no support for removing boric acid from the National List. Neither the Subcommittee nor the full Board recommended its removal from the National List.

The Crops Subcommittee discussed the use of this material and noted it is both common and useful for structural pest control applications.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds boric acid compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote
Motion to remove boric acid from the National List
Motion by: Wood Turner
Seconded by: Jerry D'Amore
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Sticky traps/barriers

Reference: §205.601(e) As insecticides (including acaricides or mite control).
(9) Sticky traps/barriers.
Technical Report: 1995 TAP.
Petition: N/A
Past NOSB Actions: 10/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

Use
Sticky traps/barriers are used for pest control and monitoring. They are also used with traps as a production aid.

Manufacture
This listing covers a wide range of traps and coatings made with a number of different materials, including coated paper, coated plastic, and brushed on sticky chemicals applied directly to plants. Some sticky traps are made with petroleum wax or linear hydrocarbons.

International Acceptance
None noticed

Environmental Issues
Sticky traps are used in limited quantities in confined areas such as traps or tree trunks, and have limited mobility, making it unlikely to have environmental impacts. Also, sticky traps do not come into contact with food.

Discussion
There was broad support for relisting sticky traps/barriers from farmers, certifiers, and trade organizations during the last sunset review for these materials. Based on the previous Subcommittee review and public comments from the Spring 2022 NOSB meeting, the NOSB found sticky traps/barriers compliant with OFPA criteria, and do not recommend removal from the National List.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds sticky traps/barriers compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote
Motion to remove sticky traps/barriers from the National List
Motion by: Rick Greenwood
Seconded by: Amy Bruch
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 3

Elemental sulfur

Reference: §205.601(h) As slug or snail bait.
(2) Elemental sulfur.
Technical Report: 1995 TAP; 2018 TR.
Petition: 2017.
Past NOSB Actions: 04/2018 recommendation.
Recent Regulatory Background: Added to National List on 11/22/2019 (84 FR 56673).
Sunset Date: 11/22/2024

Subcommittee Review

Use
When used to manage slugs and snails, sulfur is formulated with attractants plus other inert ingredients and extruded into pellets. These are broadcast or hand-applied near crops needing protection from these target pests. For this purpose, a 1% sulfur formulation is used at a labeled rate of up to 44 lbs. per acre, with an actual elemental sulfur application rate of up to 0.44 lbs. per acre. This application rate is much lower than labeled rates for sulfur when it is used as a fungicide in formulations of 80% or 90% elemental sulfur.

Manufacture
Elemental sulfur can come either from a natural mined source, or may be produced as a by-product from natural gas or petroleum operations and refinery processes. The latter appears to be the source of most elemental sulfur currently being used. Because the sulfur is chemically extracted from fossil-fuel feedstock, it is considered synthetic.

International Acceptance
Canadian General Standards Board Permitted Substances List
The Canadian General Standards Board (CGSB) includes elemental sulfur from either mined and reclaimed sources as permitted substances for organic production systems (CAN/CGSB-32.311-2015) for use as a soil amendment and as a foliar application. The CGSB also permits the use of sulfur for the control of external parasites and sulfur smoke bombs in conjunction with other methods used for rodent control when a pest control program is temporarily overwhelmed.

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

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
The Codex Alimentarius Commission's "Guidelines for the Production, Processing, Labelling, and Marketing of Organically Produced Foods" (GL 32-1999) lists elemental sulfur as an allowed substance for pest and disease control.

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

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

Environmental Issues
When used as a fungicide with several applications per season, sulfur can lower soil pH over time, and have negative effects on beneficial mite populations. However, application rates used for slug and snail management are much lower and would not be expected to have those effects.

Discussion
Sulfur for use as a slug or snail bait was added to the National List at §205.601(h) in 2019. This is its first sunset review. It was petitioned for use in 2017 with studies showing that a sulfur slug bait product was slightly more effective than other products approved for the same use in organic production.

Other synthetic products commonly used by organic farmers to kill slugs contain the active ingredient, ferric phosphate. It is invariably combined with a synergist, the chelator EDTA, which is an inert ingredient on the defunct EPA List 4. The EDTA + ferric phosphate combination has been implicated in harm to earthworms in soil and also pet dogs due to enhanced iron toxicity. In 2012, these products were petitioned for removal from the National List at § 205.601(h) for this reason, but the NOSB motion to remove failed. At that time, the NOSB Recommendation indicated that there were no commercial alternatives to ferric phosphate. In 2018, the listing for ferric phosphate was renewed on the National List.

In light of questions about the toxicity of ferric phosphate and the availability of relatively new sulfur alternatives, organic farmers may consider the sulfur products to be desirable. The label of one sulfur-based slug bait product states that it can be used around pets and wildlife when used as directed. The label shows 1% sulfur and 99% inert ingredients, which include iron. It is not known whether this product also contains EDTA. At labeled rates, sulfur used to target slugs and snails is thought to have little or no negative environmental impacts, even if applied multiple times per season. However, other components of a sulfur product's formulation are unknown and may have negative environmental effects.

Written and oral comments in 2022 included 5 in favor of relisting, 1 opposed, and 1 calling for further review. The point was made that farmers have little experience with sulfur for this specific use because it is relatively new. Also, some commenters noted that the goal of reducing tillage may lead to an increase of damaging slug populations. Questions about inert ingredients in product formulations, which can be 99% of total ingredients, highlight the need for more work on these products.

Based on 2022 comments, the relatively low environmental profile of sulfur for this use, and its potential as a less toxic formulation than current slug control products, the Crops Subcommittee recommends renewing the listing of sulfur at §205.601(h) as slug or snail bait.

Justification for Vote
The Subcommittee finds elemental sulfur compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote:
Motion to remove elemental sulfur from the National List
Motion by: Brian Caldwell
Seconded by: Jerry D'Amore
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

Coppers, fixed

Reference: §205.601(i) As plant disease control.

(2) Coppers, fixed —copper hydroxide, copper oxide, copper oxychloride, includes products exempted from EPA tolerance, *Provided,* That, copper-based materials must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides.

Technical Report: 1995 TAP; 2011 TR.
Petition: N/A
Past NOSB Actions: 10/1995 minutes and vote; 11/2005 sunset recommendation; 4/2011 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

Use
Fixed coppers was reviewed and approved for continued use during the October 2015 NOSB meeting. Coppers were considered to be an important tool for organic producers as part of a comprehensive approach to disease management in many crops. For example, copper products became an integrated part of fire blight control in pome fruits after antibiotics were removed from the National List. While some copper minerals and compounds occur in nature, products for agriculture are made from by-products of processing copper ores and are considered synthetic. Copper is on the list of exemptions for synthetic materials in OFPA at § 6517(c)(1)(B)(i). Copper sulfate is also undergoing sunset review, and the Crops Subcommittee has submitted a separate review.

Manufacture
Fixed coppers, such as copper hydroxide, are formed by treating copper sulfate with another compound (in this case sodium hydroxide). In another example, copper carbonate is formed by treating copper sulfate with sodium carbonate.

International Acceptance

Canadian General Standards Board Permitted Substances List

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

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

- The EEC states that, "it is appropriate to restrict the use of plant protection products containing copper compounds to a maximum application rate of 28 kg/ha of copper over a period of 7 years (i.e., on average 4 kg/ha/year) in order to minimize the potential accumulation in soil and the exposure for not target organisms, while considering agro-climatic conditions occurring periodically in Member States leading to an increase of the fungal pressure. When authorizing products Member States should pay attention to certain issues and strive for the minimization of application rates."

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

- Copper in the form of copper hydroxide, copper oxychloride, (tribasic) copper sulfate, cuprous oxide, Bordeaux mixture and Burgundy mixture are listed in Annex 2 (Permitted substances for the production of organic foods), Table 2 (Substances for plant pest and disease control) of ―Guidelines for the production, processing, labeling, and marketing of organically produced foods‖ (CODEX-GL 32, 1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms
Copper is only mentioned as a soil amendment and trace soil nutrient under IFOAM.

Japan Agricultural Standard (JAS) for Organic Production

- While the document refers to 'copper powder" repeatedly, only copper sulfate is specifically mentioned. Copper sulfate is only permitted in organic agriculture as a fungicidal spray

Environmental issues
Run-off from treated fields can contain high levels of copper. Copper is readily dissolved and suspended in the water and is lethal to fish and other aquatic organisms at fairly low concentrations. In the soil, it tends to concentrate heavily in the topsoil and leads to copper resistant fungal strains over time, as well as altering the soil microbiota and killing soil-dwelling animals such as earthworms. Copper toxicity in the soil can reduce the growth and nutrient value of crop plants, as well as damage the integrity of root systems (Van Assche and Clijsters, 1990). Because copper accumulates in the soil over time and eventually results in poor plant outcomes, its use as a sustainable practice must be questioned.

Discussion
Copper products are difficult substances to evaluate, as there appears to be broad consensus throughout the US, EU, and Canada that they are hazardous to both human health and the environment. Despite this, they have repeatedly had their use period extended in all three jurisdictions. There doesn't yet appear to be a viable organic alternative for copper in certain applications, including in the lucrative organic wine industry. Banning the use of coppers entirely could eliminate organic wine production, as there are no other widely available and effective tools for controlling downy mildew. While there is not yet a broadly accepted alternative to copper compounds for controlling downy mildew, research has pointed to plant extracts from yucca and salvia, as well as another fungus , *Trichoderma harzianum*, as a possible means of biological control (Dagostin et al., 2011). However, some organic vineyards have also withdrawn from the organic label in order to allow for use of copper alternatives in their vineyards, citing toxic copper build-up in the soil. One way to mitigate this issue would be to implement regular soil testing in organic vineyards and mandate soil remediation once a toxic threshold is approached.
One method to remove toxic copper levels from the soil of vineyards uses plants and bacteria to pull the heavy metal from the soil (Mackie et al, 2012). Phytoremediation with mustard (*Brassica juncea*) can help remove toxic copper levels from the soil (Ariyakanon and Winaipanich, 2006). There appears to be varying tolerance of crops to copper levels in the soil, suggesting that copper-tolerant crops could be rotated into place after a period of copper intensive cropping. While this would clearly not work for long-lived perennial crops like grapes, annual crops such as potatoes and melons might benefit from this type of crop rotation.

2017 NOSB Review
Fixed coppers and copper sulfate used for plant disease control (§205.601(i)(2) and §205.601(i)(3), respectively) were reviewed in 2015 ahead of the 2017 sunset date. There was strong public support for

relisting of copper materials. Although there was some discussion regarding the annotation, the final public comment was that the current annotation is adequate. Given the extensive use and documented need for copper sprays, the NOSB found coppers, fixed, compliant with OFPA criteria, and voted unanimously to not remove coppers from the list.

2022 NOSB Review
Overview: Distinguishing between fixed coppers and copper sulfate seems redundant as they are used in a similar manner and are reviewed in the same technical reports (TRs). In the scientific literature, they are grouped as CBACs (copper-based antimicrobial compounds). Copper sulfate contains more “free” copper ions vs. “fixed” and is therefore often combined with lime to bind the copper ions. The free copper ions contribute to its solubility in water and its higher uptake by plants.

Main Considerations in 2022 Review

- Copper compounds readily dissolve in water and are highly toxic to many aquatic organisms. They disperse quickly in water.
- Copper compounds bind to soil and tend to accumulate significantly in clay soils and increasingly with increasing soil pH. Soils with pH over 6.5 are particularly susceptible to metal toxicity from repeated application.
- Copper compounds can damage the plants they are applied to, as well as impact the appearance and taste of the crop.
- Widespread use of copper compounds has led to the evolution of copper-resistant disease varietals
- There is a well-studied link between dysfunctional copper metabolism and Alzheimer’s disease. Recent research finds a link between the epidemic of Alzheimer’s disease and the agricultural use of copper for disease management in plants.
- Foliar spray of copper mixtures has long been recognized to impact lung and liver function in agricultural workers

In December 2021, the Crops Subcommittee discussed the need for an updated TR. Not only have ten years passed since the previous report was written, but there are new concerns regarding human and environmental health.

The Subcommittee requested that the new TR highlight five areas that should be expanded and updated with the latest research: human health concerns, soil health and microbiota, application rates and accumulation in the soil, copper in the aquatic environment, and alternatives to copper-based products. We also asked that the future TR use consistent units of measurement when discussing rates of application and copper concentrations.

In July 2022, just prior to the deadline to submit proposals for the Fall meeting, the Crops Subcommittee received a draft copy of the copper TR, which it found comprehensive, thorough, and sufficient. The 2022 TR contained updated and expanded information regarding continued and expanded environmental and human health concerns, and the Crops Subcommittee will continue to review the TR and public comment. Although the Subcommittee found the TR sufficient, it did submit additional clarifying questions for the authors of the TR, and expects those answers some time prior to the Fall NOSB meeting.

Questions to our Stakeholders
1. Are there organic alternatives available to copper products that are more suitable for use in disease control?

2. Are there viable practices that can be used *in situ* to offset the toxic build-up of copper in the soil and water?

Justification for Vote
The Subcommittee finds coppers, fixed compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote
Motion to remove coppers, fixed from the National List
Motion by: Jerry D'Amore
Seconded by: Brian Caldwell
Yes: 1 No: 6 Abstain: 0 Recuse: 0 Absent: 1

References

1. Ariyakanon N, Winaipanich B (2006). Phytoremediation of copper contaminated soil by *Brassica juncea* (L.) Czern and *Bidens alba* (L.) DC. var. *radiate*. J Sci Res Chula Univ 31(1):49–56
2. Dagostin S, Schärer H, Pertot I, Tamm, L (2011). Are there alternatives to copper for controlling grapevine downy mildew in organic viticulture? Crop Protection. 30(7):776-788.
3. Mackie KA, Müller T, Kandeler E (2012). Remediation of copper in vineyards—a mini review. Environmental Pollution 167:16–26.
4. Van Assche F, Clijsters H (1990). Effects of metals on enzyme activity in plants. Plant Cell Environ. 13:195-206.

Copper sulfate (i)(3)

Reference: §205.601(i) As plant disease control.
(3) Copper sulfate - Substance must be used in a manner that minimizes accumulation of copper in the soil.
Technical Report: 1995 TAP; 2011 TR.
Petition: N/A
Past NOSB Actions: 10/1995 minutes and vote; 11/2005 sunset recommendation; 4/2011 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

Use
Copper sulfate was reviewed and approved for continued use during the October 2015 NOSB meeting. Coppers were considered to be an important tool for organic producers as part of a comprehensive approach to disease management in many crops. For example, copper products became an integrated part of fire blight control in pome fruits after antibiotics were removed from the National List. While some copper minerals and compounds occur in nature, products for agriculture are made from by-products of processing copper ores and are considered synthetic. Copper is on the list of exemptions for synthetic materials in OFPA at § 6517(c)(1)(B)(i). Fixed coppers is also undergoing sunset review, and the Crops Subcommittee has submitted a separate review.

Manufacture
Copper sulfate is manufactured by treating copper ore with concentrated sulfuric acid. It is also known as copper vitriol. In order to enhance its fungicidal properties, copper sulfate is mixed with calcium hydroxide to produce a “Bordeaux mixture” which is sprayed on crops for disease control.

International Acceptance
Canadian General Standards Board Permitted Substances List

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

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

- The EEC states that, “it is appropriate to restrict the use of plant protection products containing copper compounds to a maximum application rate of 28 kg/ha of copper over a period of 7 years (i.e., on average 4 kg/ha/year) in order to minimize the potential accumulation in soil and the exposure for not target organisms, while considering agro-climatic conditions occurring periodically in Member States leading to an increase of the fungal pressure. When authorizing products Member States should pay attention to certain issues and strive for the minimization of application rates.”

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

- Copper in the form of copper hydroxide, copper oxychloride, (tribasic) copper sulfate, cuprous oxide, Bordeaux mixture and Burgundy mixture are listed in Annex 2 (Permitted substances for the production of organic foods), Table 2 (Substances for plant pest and disease control) of ―Guidelines for the production, processing, labeling, and marketing of organically produced foods‖ (CODEX-GL 32, 1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms
Copper is only mentioned as a soil amendment and trace soil nutrient under IFOAM.

Japan Agricultural Standard (JAS) for Organic Production
Copper sulfate is only permitted in organic agriculture as a fungicidal spray.

Environmental Issues
Run-off from treated fields can contain high levels of copper. Copper is readily dissolved and suspended in the water and is lethal to fish and other aquatic organisms at fairly low concentrations. In the soil, it tends to concentrate heavily in the topsoil and leads to copper resistant fungal strains over time, as well as altering the soil microbiota and killing soil-dwelling animals such as earthworms. Copper toxicity in the soil can reduce the growth and nutrient value of crop plants, as well as damage the integrity of root systems (Van Assche and Clijsters, 1990). Because copper accumulates in the soil over time and eventually results in poor plant outcomes, its use as a sustainable practice may be questioned.
Copper sulfate has been shown to be toxic to bees, particularly in tropical environments. At sub-lethal levels, the heavy metal also changes behavior and movement ability. Despite this, there are multiple statements on the National Pesticide Information Center (NPIC) and in US Environmental Protection Agency Office of Pesticide Programs documents stating that copper sulfate is virtually non-toxic to bees. This is an important

point to clarify. The role that bees play in the pollination of commercial crops globally should make this a concern to farmers and the general public alike.

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

Discussion

Copper sulfate is a difficult substance to evaluate, as there appears to be broad consensus throughout the US, EU, and Canada that it is hazardous to both human health and the environment. Despite this, the use period for copper has been extended in all three jurisdictions, as there isn't yet a viable organic alternative in certain applications, including in the lucrative organic wine industry. Banning the use of copper sulfate entirely could eliminate organic wine production, as there are no other widely available and effective tools for controlling downy mildew. While there is not yet a broadly accepted alternative to copper sulfate for controlling downy mildew, research has pointed to plant extracts from yucca and salvia, as well as another fungus, *Trichoderma harzianum*, as a possible means of biological control (Dagostin et al., 2011). However, some organic vineyards have also withdrawn from the organic label in order to allow for use of copper alternatives in their vineyards, citing toxic copper build-up in the soil. One way to mitigate this issue would be to implement regular soil testing in organic vineyards and mandate soil remediation once a toxic threshold is approached.

One method to remove toxic copper levels from the soil of vineyards uses plants and bacteria to pull the heavy metal from the soil (Mackie et al, 2012). Phytoremediation with mustard (*Brassica juncea*) can help remove toxic copper levels from the soil (Ariyakanon and Winaipanich, 2006). There appears to be varying tolerance of crops to copper levels in the soil, suggesting that copper-tolerant crops could be rotated into place after a period of copper sulfate intensive cropping. While this would clearly not work for long-lived perennial crops like grapes, annual crops such as potatoes and melons might benefit from this type of crop rotation.

2017 NOSB Review

Copper sulfate and fixed coppers used for plant disease control (§205.601(i)(2) and §205.601(i)(3)) were reviewed in 2015 ahead of the 2017 sunset date. There was strong public support for relisting of copper materials and the NOSB voted 2 "Yes" and 12 "No" on the motion to remove copper. Although there was some discussion regarding the annotation, the final public comment was that the current annotation is adequate. Given the extensive use and documented need for copper sprays, the NOSB found copper sulfate compliant with OFPA criteria, and did not recommend removal from the National List.

2022 NOSB Review

Overview: Distinguishing between copper sulfate and fixed coppers seems redundant as they are used in a similar manner and are reviewed in the same technical reports (TRs). In the scientific literature, they are grouped as CBACs (copper-based antimicrobial compounds). Copper sulfate contains more "free" copper ions vs. "fixed" and is therefore often combined with lime to bind the copper ions. The free copper ions contribute to its solubility in water and its higher uptake by plants.

Main Considerations in 2022 Review

- Copper compounds readily dissolve in water and are highly toxic to many aquatic organisms. They disperse quickly in water.
- Copper compounds bind to soil and tend to accumulate significantly in clay soils and with increasing soil pH. Soils with pH over 6.5 are particularly susceptible to metal toxicity from repeated application.

- Copper compounds can damage the plants they are applied to, as well as impact the appearance and taste of the crop.
- Widespread use of copper compounds has led to the evolution of copper-resistant disease varietals.
- There is a well-studied link between dysfunctional copper metabolism and Alzheimer's disease. Recent research finds a link between the epidemic of Alzheimer's disease and the agricultural use of copper for disease management in plants.
- Foliar spray of copper mixtures has long been recognized to impact lung and liver function in agricultural workers.

In December 2021, the Crops Subcommittee discussed the need for an updated TR. Not only has ten years passed since the previous report was written, but there are also new concerns regarding human and environmental health. The Subcommittee requested that the new TR highlight five areas that should be expanded and updated with the latest research: human health concerns, soil health and microbiota, application rates and accumulation in the soil, copper in the aquatic environment, and alternatives to copper-based products. We also asked that the future TR use consistent units of measurement when discussing rates of application and copper concentrations.

In July 2022, just prior to the deadline to submit proposals for the Fall meeting, the Crops Subcommittee received a draft copy of the copper TR, which it found comprehensive, thorough, and sufficient. The 2022 TR contained updated and expanded information regarding environmental and human health concerns, and the Crops Subcommittee will continue to review the TR and public comment. Although the Subcommittee found the TR sufficient, it did submit additional clarifying questions for the authors of the TR, and expects those answers some time prior to the Fall NOSB meeting. .

Questions to our Stakeholders

1. Are there organic alternatives to copper sulfate that are more suitable for use as a fungicide?
2. Are there viable practices that can be used *in situ* to offset the toxic build-up of copper in soil and water?

Justification for Vote

The Subcommittee finds copper sulfate compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote

Motion to remove copper sulfate from the National List
Motion by: Jerry D'Amore
Seconded by: Amy Bruch
Yes: 1 No: 5 Abstain: 1 Recuse: 0 Absent: 1

References

1. Ariyakanon N, Winaipanich B (2006) Phytoremediation of copper contaminated soil by *Brassica juncea* (L.) Czern and *Bidens alba* (L.) DC. var. *radiate*. J Sci Res Chula Univ 31(1):49–56
2. Buzio L, Tondel M, De Palma G, et al. (2002) Occupational risk factors for renal cell cancer. An Italian case-control study. La Medicina del Lavoro. 93(4):303-309.
3. Dagostin S, Schärer H, Pertot I, Tamm, L (2011). Are there alternatives to copper for controlling grapevine downy mildew in organic viticulture? Crop Protection. 30(7):776-788.
4. Mackie KA, Müller T, Kandeler E (2012) Remediation of copper in vineyards—a mini review. Environmental Pollution 167:16–26.

5. Van Assche F, Clijsters H (1990) Effects of metals on enzyme activity in plants. Plant Cell Environ. 13:195-206.

Polyoxin D zinc salt

Reference: §205.601(i) As plant disease control.
(11) Polyoxin D zinc salt.
Technical Report: 2012 TR; 2017 Limited Scope TR; 2021 Lmt'd Scope TR Pending
Petition: 2016 (Addendum #1, #2, #3).
Past NOSB Actions: 04/2018 recommendation.
Recent Regulatory Background: Added to National List on 11/22/2019 (84 FR 56673).
Sunset Date: 11/22/2024

Subcommittee Review

Use
Polyoxin D zinc salt is used as an agricultural fungicide. It has a locally systemic function, meaning that it is absorbed into surface plant tissues. It currently appears on the National List as plant disease control at 7 CFR 205.601(i). Few fungicides used in organic production are systemic, and polyoxin D zinc salt products may have greater efficacy against some plant disease organisms.

Manufacture
Polyoxin D is produced by controlled fermentation of the naturally occurring (non-GMO) soil microorganism *Streptomyces cacaoi* var. asoensis. While polyoxin D might be considered a nonsynthetic product, its chemical conversion to a zinc salt makes it synthetic. The zinc salt makes this product more useful by lessening its high water-solubility, thereby preventing the product from washing off the application area too quickly.

International Acceptance
Polyoxin D zinc salt does not appear on any of the following lists:

Canadian General Standards Board Permitted Substances List

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

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

International Federation of Organic Agriculture Movements (IFOAM) Norms

Japan Agricultural Standard (JAS) for Organic Production

Environmental Issues
The 2012 Technical Review (TR) states that polyoxin D zinc salt rapidly degrades on plant surfaces, in approximately 2-3 days, and has a half-life of 16 days in soil. The 2018 NOSB review concluded there was low environmental risk, and further that there is no concern during the manufacture, use, or disposal of polyoxin D zinc salt other than that this product should not be used nearby to, or in, water since it is moderately toxic to

aquatic invertebrates and fish. The 2017 TR concurs and states "Based on the results [of numerous studies cited], polyoxin D zinc salt is presumed to carry very low environmental risk and because polyoxin D zinc salt is formed through fermentation, it is considered to be less toxic to the environment than a fungicide that was chemically manufactured such as copper, sulfur, or petroleum distillates."

Polyoxin D zinc salt has a unique, non-toxic mode of action. No other active ingredient registered for use in North America has the same mode of action (FRAC Code 19). As described in the 2012 petition (page 18): "The active portion of polyoxin D zinc salt is polyoxin D which is produced by a microorganism that is naturally occurring in the soil. Polyoxin D inhibits the growth of phytopathogenic fungal cell wall chitin by competitively inhibiting chitin synthetase. Without chitin, susceptible fungi are unable to continue growing and infecting plant cells. Polyoxin D zinc salt does not kill the fungi; it simply stops the fungal growth. The action of Polyoxin D is highly specific; it does not affect bacteria, viruses, or mammals."

In response to NOSB questions of toxicity to beneficial soil fungi, honeybees, or ladybird beetles, the petitioner commissioned their own studies and found no negative effects of polyoxin D zinc salt on any of these organisms. If directly mixed with products used by organic producers containing living beneficial fungi, the fungi could be rendered ineffective.

Human Health Issues

The 2017 TR of polyoxin D zinc salt states there is very low acute toxicity to humans by oral, dermal, or inhalation routes, and it did not demonstrate mutagenic potential. There are warnings on the label about possible skin and eye irritation effects. Polyoxin D zinc salt is poorly absorbed after ingestion with the vast majority of the product (>90%) being excreted unchanged, directly in the feces. Polyoxin D zinc salt has been in use as an antifungal agent for over 40 years in Japan on rice, without any notable, consistent, adverse human reactions being recorded. It has been approved in the USA and Mexico on food crops for over 5 and 3 years, respectively and for non-food crops in the USA for over 16 years. The direct risk to humans is considered to be extremely low.

A separate issue relates to how its agricultural use could affect anti-fungal medicines in human health. Considerable research has focused on polyoxins as less-toxic alternatives to currently available therapeutic antifungal medications in humans. These studies have led to mostly unsuccessful results, and polyoxins are not used clinically at the present time. Polyoxin D has thus far been ineffective in therapeutic exploratory studies for potential human use against fungi, except at very high concentrations. It has shown some efficacy against yeasts, but is considered unlikely to be used as a human medicine. Thus, human pathogen resistance to polyoxin D would have little or no medical impact.

It is possible that from polyoxin D use in agriculture, cross-resistance could develop to related antibiotics such as Nikkomycin Z, currently being tested as a human anti-fungal medicine. In order for such resistance to develop, polyoxin D would need to be used widely. A human fungal pathogen would need to acquire the resistance to polyoxin D, either from direct exposure or via transfer from other resistant organisms. Finally, the pathogen's resistance to polyoxin D would need to confer resistance to the to-be-developed new medicine. This seems to be a highly unlikely chain of events.

Discussion

Written and oral comments in 2022 were strongly in favor of retaining polyoxin D zinc salt on the National List. Producers reiterated that it is an effective and valuable material.
Based on its efficacy, low environmental impact, and low risk to human health, the Crops Subcommittee recommends renewing polyoxin D zinc salt at §205.601(i) As plant disease control.

Justification for Vote
The Subcommittee finds that polyoxin D zinc salt continues to be compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote
Motion to remove polyoxin D zinc salt from the National List
Motion by: Brian Caldwell
Seconded by: Amy Bruch
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 3

Humic acids

Reference: §205.601(j) As plant or soil amendments.
3) Humic acids - naturally occurring deposits, water and alkali extracts only.
Technical Report: 1996 TAP; 2006 TR; 2012 TR (oxidized lignite/humic acid derivatives).
Petition: N/A
Past NOSB Actions: 09/1996 minutes and vote; 4/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

Use
Humic acids can be soil-applied or foliar applied depending on the specific product. Humic acid affects soil fertility by making micronutrients more readily available to plants rather than contributing additional nutrients to the soil. According to the 2006 Technical Report (TR), humic substances can chelate (bind) soil nutrients, improve nutrient uptake, reduce the need for nitrogen fertilizer, remove toxins from soils, stimulate soil biological activity, solubilize minerals, improve soil structure, and improve water holding capacity.

Manufacture
According to the 2006 TR, humic substances (which includes humic acids) naturally constitute a significant fraction of the organic matter in the soil and are formed through the process known as "humification." Humification is the natural conversion of organic matter into humic substances by microorganisms in the soil (Mayhew, 2004).

Commercially available humic acids are derived from leonardite, lignite, or coal. Extracts from non-synthetic humates by hydrolysis using synthetic or non-synthetic alkaline materials are permitted, including the use of sodium, potassium, or ammonium hydroxide. The TR states that the process begins with separating organic matter from the inorganic matrix of sand, silt, and clay. The terrestrial source is leached with hydrochloric acid (HCl) to remove calcium and other positively charged ions and to increase the efficiency of extraction of organic matter with alkaline reagents. Next, a stronger sodium hydroxide solution creates a liquid solution (Weber, undated). The extracted liquid solution is incompatible with acids because it is very alkaline, in the range of 8 to 12 pH, and can be treated with an acid to precipitate out the humic acid portion (Mayhew, 2004). Alkali extraction can also be carried out using potassium hydroxide, a common reagent used by manufacturers to extract humic acid from leonardite.

International Acceptance

Canadian General Standards Board Permitted Substances List

As noted in the 2012 TR, humates, humic acids and fulvic acids are permitted if mined; produced through microbial activity; extracted by physical processes; or with: a) Table 4.2 Extractants; or b) potassium hydroxide—potassium hydroxide levels used in the extraction process shall not exceed the amount required for extraction. Levels (mg/kg) of arsenic, cadmium, chromium, lead, and mercury shall not exceed the limits (category C1) specified in Guidelines for the Beneficial Use of Fertilizing Residuals. Shall not cause a build-up of heavy metals or micronutrients in soil.

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

Humic acid derivatives and oxidized lignite do not appear on Annex I, Fertilizers, soil conditioners and nutrients referred to in Article 3(1) and Article 6d(2) (EC, 2008). The EU requires all substances used as a fertilizer, soil conditioner or nutrient in organic production in the EU appear on that Annex (EC, 2007). However, humic acids do appear on Annex VII, Products for Cleaning and Disinfection (EC, 2008).

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

No information was identified at the listed site.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Humic acid derivatives do not appear on Appendix 2: Fertilizers and Soil Conditioners. However, the use of humic acids are covered under a derogation found in §4.4.6, which reads: "Mineral fertilizers shall be applied in the form in which they are naturally composed and extracted and shall not be rendered more soluble by chemical treatment, other than addition of water and mixing with other naturally occurring, permitted inputs."

Japan Agricultural Standard (JAS) for Organic Production

The Japanese Agricultural Standard for Organic Production does not include humic acid derivatives or oxidized lignite on Table 1, Fertilizers and Soil Improvement Substances (JMAFF, 2012). Alkali extracted humic acid is banned for use on products grown for export to Japan under the Equivalency Agreement between the Japanese Ministry of Agriculture, Forestry and Fisheries and the USDA's National Organic Program, the only such substance currently to have that status (Arai, 2008).

Environmental Issues

Humic acids themselves are not known to cause environmental issues. When evaluating the manufacturing process, the TR states that there is no information available from EPA to suggest that environmental contamination results from the manufacture, use, misuse, or disposal of humic acids. Improper disposal of acids or bases used in the extraction process could be a source of environmental contamination. The mining of lignite/leonardite or other source materials may have environmental impacts.

Discussion

In 2022, the majority of the comments submitted to the NOSB regarding humic acid substances were supportive of continued listing. Various certifying bodies indicated the widespread usage on multiple crops. The Subcommittee discussed information in the TR about a lack of standardized analysis for substances marketed as humic acid substances, resulting in the marketing of some products that produce minimal to no results. However, scientists have researched and documented the benefits of using humic acid substances in agriculture. The Subcommittee reviewed concerns from stakeholders, including environmental impact, the risk of synthetic fortification of extractants, and also the Fall 2012 NOSB vote to prohibit oxidized lignite (humic acids derived from coal by oxidation with hydrogen peroxide) due to environmental and health impacts, lack of essentiality, and incompatibility with organic production.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds humic acids compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote
Motion to remove humic acids from the National List
Motion by: Amy Bruch
Seconded by: Rick Greenwood
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Micronutrients: soluble boron products

Reference: §205.601(j) As plant or soil amendments. (7) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Micronutrient deficiency must be documented by soil or tissue testing or other documented and verifiable method as approved by the certifying agent.
(i) Soluble boron products.
Technical Report: 2010 TR (Micronutrients); 2021 Lmt'd Scope TR pending
Petition: N/A
Past NOSB Actions: 04/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2015 micronutrient annotation change; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 1/28/2019 (83 FR 66559)
Sunset Date: 01/28/2024

Subcommittee Review

Use
Soluble boron is a crop micronutrient that can be soil applied or applied foliarly. According to the Technical Report (TR), boron deficiency is the most common when compared to the other recognized plant micronutrient deficiencies. Every year, boron deficiency is responsible for significant crop losses, whether in volume or quality.

Soluble boron products have appeared on the National List for use as micronutrients since it was first published in 2000.

Manufacture
The TR states that all soluble boron products are derived from mined borate mineral deposits. Borate minerals can be extracted by surface mining or solution mining (Garrett, 1998).

Borax/borate salts
Refined sodium borate salts are typically produced by crushing solid borate ores and dissolving in water alongside trona (a double salt of sodium carbonate and sodium bicarbonate), or supersaturating brine with carbon dioxide in the case of solution mining (Office of Energy Efficiency and Renewable Energy, 2002; Smith, 2000). Insoluble waste materials are filtered out of the liquid, and disodium tetraborate pentahydrate and

decahydrate are selectively crystallized by temperature control and vacuum crystallization, followed by centrifugation and drying (Smith, 2000). To prevent crystallization water loss and caking, disodium tetraborate decahydrate crystals are sometimes washed with a boric acid solution that coats the crystals with a thin layer of the pentahydrate variety (Smith, 2000).

High purity borax can also be produced by reacting boric acid with hot sodium hydroxide (Smith, 2000). Various dehydration and rehydration methods can selectively produce the different hydration states of disodium tetraborate (Smith, 2000). Boric acid reactions with sodium hydroxide can produce disodium octaborate tetrahydrate (Kutcel, 2001).

Boric acid

In the United States, boric acid is typically prepared by reacting naturally occurring solid sodium borate minerals with strong mineral acids like sulfuric acid (Smith, 2000). This results in a concentrated solution of boric acid and sodium sulfates, after which the boric acid is crystallized by evaporation.

International Acceptance

Canadian General Standards Board Permitted Substances List

The Canadian Organic Standards permit soluble boron products at CAN/CGSB 32.311-2020 Table 4.2, column 1, entry for boron. Borate (boric acid), sodium tetraborate (borax and anhydrous), and sodium octaborate are permitted only when one of the following has been established:

- soil and plant deficiencies are documented by visual symptoms
- testing of soil or plant tissue demonstrates the need
- the need for a preventative application can be documented (CGSB, 2020)

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

Several boron substances are allowed for soil management and fertilization by the European Union organic regulations. EC Regulation No. 889/2008 Article 3 permits the use of substances appearing in Annex I when the nutritional needs of plants cannot be met by certain preventative measures (European Parliament, Council of the European Union, 2008). Annex I permits the use of boric acid, sodium borate, calcium borate, and boron ethanolamine (European Parliament, Council of the European Union, 2003).

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

The Codex guidelines include “Trace elements (e.g., boron, copper, iron, manganese, molybdenum, zinc)” in Table 1, substances for use in soil fertilizing and conditioning (FAO 2007).

International Federation of Organic Agriculture Movements (IFOAM) Norms

Boric acid, sodium borate, calcium borate, and “borethanolamin” (presumably referring to boron ethanolamine) of mineral origin are permitted as fertilizers and soil conditioners in the IFOAM NORMS, where soil or plant nutrient deficiency can be documented by soil or tissue testing or diagnosed by an independent expert. Chloride and nitrate forms are prohibited, as are micronutrients used as defoliants, herbicides, or desiccants (IFOAM Organics International, 2019).

Japan Agricultural Standard (JAS) for Organic Production

Trace elements (manganese, boron, iron, copper, zinc, molybdenum, and chlorine) are permitted by the Japanese Agricultural Standard for Organic Plants as fertilizers and soil improvement substances if a crop cannot grow normally because of a micronutrient shortage (MAFF, 2017).

Environmental Issues
Mining borate minerals could cause an environmental impact. In addition, the TR states that sulfuric acid is used as a reactant to make boric acid from colemanite, and calcium sulfate is sometimes produced as a by-product. This results in a significant waste stream and can have environmental consequences related to the build-up of industrial waste. Wastewater discharge is also a source of boron pollution since boron appears in some soaps and washing chemicals.

Discussion
The Crops Subcommittee reviewed soluble boron products and discussed the role that soluble boron products play in crop development.

In 2022, the NOSB received several comments in support of relisting soluble boron on the National List. Comments indicated that boron is an essential nutrient for plant development. There was an over-arching theme stating that having the ability to correct nutrient deficiencies in organic production is critical to creating strong, healthy, resilient soils. Commenters also mentioned the final rule effective in January 2019 that specifies deficiency "must be documented by soil or tissue testing or other documented and verifiable method as approved by the certifying agent."

Justification for Vote
The Subcommittee finds soluble boron compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote
Motion to remove soluble boron from the National List
Motion by: Amy Bruch
Seconded by: Jerry D'Amore
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Micronutrients: sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt

Reference: §205.601(j) As plant or soil amendments. (7) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Micronutrient deficiency must be documented by soil or tissue testing or other documented and verifiable method as approved by the certifying agent.

(ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.

Technical Report: 2010 TR (Micronutrients).
Petition: N/A
Past NOSB Actions: 04/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 annotation change recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 1/28/2019 (83 FR 66559)
Sunset Date: 01/28/2024

Subcommittee Review

Use

Micronutrients are essential for plant growth and are used across all types of crop production, but are typically required in very small quantities. Although some forms of micronutrients are found naturally in the soil, many producers find deficiencies of some or all of the micronutrients on the National List. These deficiencies can be a limiting factor in water and macro-nutrient uptake, and can result in limited growth and vitality of crops.

Manufacture

Plant micronutrients at this listing are made up of both compounds and natural minerals. After physical processing such as breaking and grinding, these natural minerals might be used as micronutrients in agriculture. Many commercial micronutrients are manufactured as by-products or intermediate products of metal mining and processing industries.

International Acceptance

Canadian General Standards Board Permitted Substances List
The Canadian Organic Production Systems Permitted Substances List permits micronutrients with a similar annotation to the USDA.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
European organic regulations do not reference micronutrients.

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
Micronutrient use is restricted to cases where soil/plant nutrient deficiency is documented by soil or tissue testing or diagnosed by an independent expert. Micronutrients in either chloride or nitrate forms are prohibited. Micronutrients may not be used as a defoliant, herbicide, or desiccant.

Japan Agricultural Standard (JAS) for Organic Production
JAS does not reference micronutrients.

Environmental Issues

Simple inorganic compounds such as Co, Cu, Fe, Mn, Mo, Se, and Zn, are found naturally in soil. Applied micronutrients are not expected to be significantly different from naturally occurring compounds in terms of concentration and physiological activity, when applied under set limits. Micronutrients are “heavy metals”, but the annotation prevents contamination by restricting their use to correct a deficiency.

Discussion

Micronutrients are crucial for organic production and stakeholders were overwhelmingly supportive of relisting.

Questions to our Stakeholders:

None

Justification for Vote
Based on the current review and public comment, the Subcommittee finds micronutrients: sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt, compliant with the OFPA criteria, and does not recommend removal from the National List.

Subcommittee Vote
Motion to remove micronutrients: sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt from the National List
Motion by: Logan Petrey
Seconded by: Amy Bruch
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Vitamins C and E

Reference: §205.601(j) As plant or soil amendments.
(9) Vitamins C and E.
Technical Report: 1995 TAP; 2015 TR.
Petition: N/A
Past NOSB Actions: 10/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation (relist C and E, remove B_1).
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review
Vitamins, including synthetically derived C (ascorbic acid) and E (tocopherols), are generally considered non-toxic essential nutrients for terrestrial and aquatic organisms. Vitamins C and E are used to promote both growth and yields and to protect plants from oxidative stress due to salinity. During the previous sunset review (11/2017), vitamin B1 (thiamine) – which had been previously paired with the other two vitamins on the National List – was recommended for removal from the list on the basis that foliar and soil applications of the material did not stimulate root growth in transplanted crops, and it was subsequently removed.

A Technical Report was completed on these materials in 2015. While it relied on peer-reviewed scientific literature to assess its alignment with OFPA criteria, it does not include practical information regarding the use of Vitamins C and E.

Manufacture
Although Vitamins C and E are naturally occurring in commonly consumed foods, they are typically derived for commercial use from laboratory processes.

International Acceptance
Canadian General Standards Board Permitted Substances List
Vitamin C is listed for crop production; Vitamin E is not listed.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Neither substance is listed.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Neither substance is listed.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Neither substance is listed.

Japan Agricultural Standard (JAS) for Organic Production
Neither substance is listed.

Environmental Issues
It is unclear whether there are particular environmental concerns regarding the manufacture and use of Vitamins C and E for plant or soil amendments.

Discussion
The Subcommittee has had a general discussion of the historical review of these materials and what was involved in the separate, now-delisted Vitamin B1 from this section. Stakeholders and the Subcommittee are supportive of relisting vitamins C and E, and added a question about use in organic crop production to be considered for the next sunset review.

Questions to our Stakeholders
1. How are Vitamins C and E being used in organic crop production?
2. Are Vitamins C and E being used by significant numbers of organic growers?

Justification for Vote
The Subcommittee finds vitamins C and E compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote
Motion to remove vitamins C and E from §205.601(j) of the National List
Motion by: Wood Turner
Seconded by: Brian Caldwell
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Squid byproducts

Reference: §205.601(j) As plant or soil amendments.
(10) Squid byproducts—from food waste processing only. Can be pH adjusted with sulfuric, citric, or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.
Technical Report: 2016 TR.
Petition: 2015 (Amendment #1).
Past NOSB Actions: 04/2016 recommendation.
Recent Regulatory Background: Added to National List on 01/28/2019 (83 FR 66559).
Sunset Date: 01/28/2024

Subcommittee Review

Background
Squid are littoral invertebrates classified into the phylum Mollusca, class Cephalopoda and order Loligo (later renamed Doryteuthis). There are an estimated 300 squid species known throughout the world. Common to the northeastern Atlantic coast is the longfin squid, species *Doryteuthis (Loligo) pealli*. Common to the US west coast is the market squid, species *Doryteuthis (Loligo) opalescens*. The use of squid and squid byproducts in agriculture dates back to the 1800's when much of the product was shipped from California market squid fisheries to Asian countries for consumption and fertilizer applications.

Use
Squid and squid byproducts are the starting ingredients in the production of enzymatically produced hydrolysates with N-P-K values ranging from 2-2-2 to 3.3-7.3-2 or more. Seafood derived hydrolysates, including squid and squid byproducts, have been used both as foliar sprays and soil amendments for propagating cranberries, cherries, and apples.

Manufacture
Squid byproducts make up 52% of the total body weight and include the squid ink, pen, skin, milt, liver, and viscera and are typically discarded as waste. In general, squid byproducts are chopped, heated, digested with natural enzymes, and stabilized with an acid such as phosphoric, sulfuric, or citric acid to prevent microbial growth.

International Acceptance
Canadian General Standards Board Permitted Substances List
The Canadian Organic Standard allows for the use of fish products; in Canadian fisheries, the definition of fish includes marine invertebrates such as squid.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
The EU Organic Standard allows the use of molluscan (squid) products from sustainable fisheries and may be used in organic production of feeds for non- herbivores; squid products are not explicitly authorized for use in organic production.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
CODEX does not reference squid byproducts.

International Federation of Organic Agriculture Movements (IFOAM) Norms
IFOAM permits the use of fish and shell products and food processing of animal origin.

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

Environmental Issues
Squid are commercially harvested using nets directly above spawning grounds during mating season primarily for calamari. Fisherman target spawning squid because they die shortly after reproduction. There are two main squid fisheries in the US including along the Atlantic coast for long-finned squid and along the Pacific coast for market squid. The US Pacific squid fishery is managed by the California Department of Fish and Game, the National Oceanographic and Atmospheric Administration (NOAA) Fisheries, and the Pacific Fishery Management Council. Atlantic squid are managed in federal waters by NOAA Fisheries in conjunction with the

Mid-Atlantic Fishery Management Council. Management includes seasonal catch limits, timed fishery closures, administration of permit issuance, and limitations on using lights to attract squid to ensure uninterrupted spawning.

Discussion
The manufacturing and use of squid byproducts has little to no environmental impact or human health concerns and provides organic growers with another nitrogen source. Most commenters support the relisting of squid byproducts with the current annotation. No further discussion in subcommittee.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds squid byproducts compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote
Motion to remove squid byproducts from the National List
Motion by: Logan Petrey
Seconded by: Brian Caldwell
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Lead salts

Reference: §205.602(d) Lead salts.
Technical Report: N/A
Petition: N/A
Past NOSB Actions: 04/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

Use
Lead salts are used as both pesticides and herbicides.

Manufacture
Lead salts are usually produced using the following reaction, which leads to formation of the desired product as a solid precipitate:

$$Pb(NO_3)_2 + H_3AsO_4 \rightarrow PbHAsO_4 + 2\ HNO_3$$

International Acceptance
None found

Environmental Issues

Lead poisoning can cause a number of adverse human health effects but is particularly detrimental to the neurological development of children. Since lead accumulates in soils, it is important to avoid soil applications of materials containing lead, whether the lead is in synthetic materials or naturally occurring (nonsynthetic) lead salts. Notably, the Centers for Disease Control and Prevention (CDC) has found that there is no safe level of lead exposure and in 2021 lowered the reference level from 5 ug/dl to 3.5 ug/dl.

Discussion

Public comments received in previous sunset reviews were in favor of keeping lead salts on the list of nonsynthetic substances prohibited for use in organic crop production. One commenter suggested that it would be worthwhile to add more detail about the scientific and regulatory rationale (i.e., OFPA) for why lead salts should continue to be prohibited. The Crops Subcommittee consulted the Toxicological Profile from the Agency for Toxic Substances (ATSDR 2007, Toxicological Profile: Lead. P. 304. http://www.atsdr.cdc.gov/toxprofiles/tp13.pdf.) and noted the following:

Occurrence and Prevalence:

Lead (PB) occurs naturally in soils in small amounts and in ore deposits throughout the world. Lead is also given off as an emission from combustion of leaded gasoline (now banned in the US), and was used in house paint until 1978. Lead was widely used as an insect disease control in the early part of the 1900s on tree fruit, and residual lead in old orchard areas can still be detected. People can be exposed to lead in ambient air, drinking water, foods, soil, and dust.

Lead does not break down in the environment. Particles of lead can be transported through air, water, and soil. Once in soil, it does not leach. It's availability to be taken up by plants is limited but lead can be in the soil adhering to root crops.

Health and Environmental Hazards of Lead:

Toxicity of lead in humans has been known for over 2000 years and is not disputed. There is vast literature on the health effects of lead exposure. More details on the exact symptoms of too much lead, and details of the many studies, can be found in the ATSDR report cited above. There are a few treatments to facilitate removing lead from the body, but they are not easily accessible and take a lot of time. Livestock can also be exposed to high levels of lead through dust and air pollution.

While the most polluting forms of lead from auto emissions and lead paint are no longer being generated, much of the lead that they put out into the environment is still there. Additional sources of lead pollution may come from lead-acid batteries if not disposed of properly, lead in ammunition used for hunting, air pollution from aircraft using fuel with lead in it, and smelting of lead ore. Industries continue to release large amounts of lead into waterways. Sediments from these waterways can end up in agricultural soils from flooding and dredging.

Lead is very slow to leach out of soils, although it can slowly migrate down through soils. However, soils with high organic matter create conditions for the lead molecules to be bound to organic matter, thereby lessening its migration.

The Crops Subcommittee supports keeping lead salts in its prohibited status on the National List and the NOSB will vote on the proposal at the Fall 2022 meeting. The Subcommittee concurred that lead salts should stay on the National List in prohibited status.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee supports continued prohibition of lead salts and is not proposing removal from the National List.

Subcommittee Vote
Motion to remove lead salts from the National List
Motion by: Javier Zamora
Seconded by: Amy Bruch
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Tobacco dust (nicotine sulfate)

Reference: §205.602(j) Tobacco dust (nicotine sulfate).
Technical Report: N/A
Petition: N/A
Past NOSB Actions: 04/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

Use
Nicotine is a natural insecticide produced as a secondary metabolite in tobacco. Tobacco dust can be used in agriculture for pest control.

Manufacture
Tobacco dust is a by-product of agro-industrial waste from the commercial processing of tobacco products. It was noted during a previous review that tobacco dust is no longer commercially available as a crop pest control product, however it could still be homemade by mixing tobacco with water.

International Acceptance
Canadian General Standards Board Permitted Substances List
There is no reference to tobacco dust.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
There is no reference to tobacco dust.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
There is no reference to tobacco dust.

International Federation of Organic Agriculture Movements (IFOAM) Norms
There is no reference to tobacco dust.

Japan Agricultural Standard (JAS) for Organic Production
There is no reference to tobacco dust.

Environmental Issues
Classified as super toxic on the National Library of Medicine's Hazardous Substances Data Bank (HSDB) and regulated by the Environmental Protection Agency (EPA) as a pesticide. EPA published a Federal Register notice [74 FR 26695] in June 2009 indicating that as of January 1, 2014, the EPA would no longer register nicotine products.

Discussion
Tobacco dust (nicotine sulfate) has been present on the National List as a prohibited substance since the inception of the USDA organic regulations. Due to the negative human health effects caused by this material, it has been relisted as a prohibited nonsynthetic on the National List at every sunset review, with no objections from the public or from the NOSB. It is present on the Hazardous Substance list and regulated by OSHA and the EPA as well as other agencies.

Previous public comments indicated that certifiers, businesses, and public interest organizations agree that tobacco dust should remain listed as a prohibited nonsynthetic. The Crops Subcommittee supports keeping tobacco dust on the National List at §205.602.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee supports continued prohibition of tobacco dust and is not proposing removal from the National List at §205.602.

Subcommittee Vote
Motion to remove tobacco dust (nicotine sulfate) at §205.602
Motion by: Logan Petrey
Seconded by: Wood Turner
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Peroxylactic Acid (PoLA)
August 2, 2022

Summary of Petition

Peroxylactic Acid ("PoLA") is being petitioned by Zee Company, Inc. for addition to the National List as an antimicrobial processing aid for application onto meat and poultry carcasses, parts, trim, and organs at 7 CFR 205.605 (b), "Nonagricultural (nonorganic) substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients)." PoLA is a synthetic aqueous mixture for use in process water, ice, or brine for use in the production, processing, and preparation of meat and poultry. The petitioner identified PoLA to be more efficacious, safer, and less volatile than peroxyacetic acid (PAA) in the management of *Campylobacter jejuni,* a pathogen causing campylobacteriosis. A Technical Report (TR) was completed and found sufficient by the Handling Subcommittee on February 1, 2022. According to the TR, campylobacteriosis is one of the most common bacterial infections worldwide and contaminated poultry products are identified as the primary source of these infections. In the TR, other sources stated efficacy of PoLA for the reduction of *E. coli* and *Salmonella spp*. The TR recognized the scarcity of information available for PoLA at this time.

The Handling Subcommittee is bringing this petition forward for full NOSB review at its Fall 2022 meeting.

Summary of Review:
The Handling Subcommittee has reviewed the PoLA petition and TR and discussed the issues that are characteristic of most sanitizers and antimicrobials. The Handling Subcommittee is hesitant to add another synthetic antimicrobial to the list and expand the organic industry's exposure to synthetic substances. However, unlike materials like cetylpyridinium chloride (CPC), which was petitioned in 2021 and subsequently rejected by the NOSB, and chlorine materials, which are on the National List, PoLA breaks down into lactic acid and eventually carbon dioxide and water within 60 minutes of application and therefore is a benign product when considering human health and environmental impacts.

The petition and TR state that PoLA is an effective antimicrobial and could provide better efficacy to producers in managing food borne pathogens in their facilities. The TR also stated that PoLA, if used in place of other antimicrobials, could significantly reduce water use which has dramatically increased over the last couple of decades due to food safety standards.

The Handling Subcommittee is supportive of new, innovative, efficacious synthetic materials that are less harmful or impactful to human health and the environment that could replace currently listed synthetics that require more recourses for use. It is helpful to the Handling Subcommittee to hear from stakeholders and more specifically, operators who need these materials.

Reference Material:
The petition and TR were used as reference to answer the following questions:

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:

   PoLA is a non-agricultural synthetic 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:

   PoLA is not derived from an agricultural source, is not a mineral or bacterial culture, is not a microorganism, and is not derived from a crop or livestock product.

   According to the TR, "(PoLA) is a peroxycarboxylic acid is formed through an equilibrium reaction between DL-lactic acid (CAS No. 50-21-5) and hydrogen peroxide (CAS No. 7722-84-1) and both isomers of PoLA exist in equilibrium with unreacted lactic acid and hydrogen peroxide. As with other peroxycarboxylic acids, the formation of PoLA from lactic acid and hydrogen peroxide can be catalyzed by a strong mineral acid, such as sulfuric acid. The rate of formation without an added mineral acid was reported as being negligible. Once formed, peroxycarboxylic acids can be self-reactive and susceptible to exothermic degradation, releasing energy as heat as they spontaneously break down."

   Perlactic acid, like peracetic acid, is supplied as an equilibrium mixture:

   $$\text{Perlactic acid:}\quad C3H6O3 + H2O2 \leftrightarrow C3H6O4 + H2O$$

   $$\text{L-lactic acid + hydrogen peroxide} \rightleftarrows \text{perlactic acid + water}$$

   Chemical and physical properties of PoLA from the TR:

Color:	Colorless
Odor:	Odorless – low odor
Average Mass:	106.077 g/mol
Density at 20 ºC:	1.140 g/cm
Vapor pressure at 20ºC:	Not determined
Flash point:	>55 ºC (>131 ºF)
pH:	<2

   The manufacturing process listed in the petition is the primary method of manufacturing for PoLA and is described as: from hydrogen peroxide (CASRN 7722-84-1) and lactic acid (CASRN 50-21-5), both of which are allowed substances on the National List in § 205.605(a) and § 205.605 (b), respectively. The finished mixture optionally contains a sequestering agent 1-hydroxy-ethylidine-1,1-diphosphonic acid (HEDP) and an optional catalyst (sulfuric acid).

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)]

   PoLA is used as a processing aid for application onto meat and poultry carcasses, parts, trim, and organs in food processing facilities. It is applied as an antimicrobial agent in process water, ice, or brine use in the production, processing, and preparation of raw meat and poultry products, it is unlikely that that PoLA will interact with other materials used in organic farming systems.

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

   Toxicity information from the Safety Data Sheet (SDS) of NEOTOX (Zee Company) of the petitioned material:

Oral LD50:	3310 mg/kg (rat)
Dermal LD50:	1060 mg/kg (rabbit)

   The ecological toxicity information from the SDS of NEOTOX (Zee Company) reveals no further relevant information for aquatic toxicity, persistence, and degradability, bioaccumulative potential, and mobility in soil. The general notes indicate that it is a water hazard class 2, a danger to drinking water, and must not reach ground water, bodies of water, drainage ditches or sewage systems.

   Globally Harmonized System (GHS) information of NEOTOX (Zee Company) - label from the petition.

   GHS INFORMATION

Flam. Liq. 4	H227 Combustible liquid.
Skin Corr. 1A	H314 Causes severe skin burns and eye damage.
Eye Dam. 1	H318 Causes serious eye damage.
Acute Tox. 4	H302 Harmful if swallowed.
Acute Tox. 4	H312 Harmful in contact with skin.
Acute Tox. 4	H332 Harmful if inhaled.

   Stabilizers are required for PoLA solutions due to the reactivity of peroxycarboxylic acids. These stabilizers maintain shelf life by protecting from metal impurities. The decomposition of these acids would create heat production and be unsafe for transport. There are strict regulations under FDA and U.S. Department of Transportation for allowed stabilizers.

   The mode of actions for other peroxycarbolic acids are listed in the TR:
   a. The O-OH bond is highly reactive releasing compounds that oxidize.
   b. Peroxycarbolic acids reacts with phospholipids in cell membranes

   Like other oxidizing agents, PoLA's mode of action denaturates proteins, enzymes, and metabolites, and disrupts cell wall permeability and the oxidizing of sulfhydryl and sulfur bonds in proteins.

   FDA also issued a Finding of No Significant Impact (FONSI) during its evaluation of Food Contact Substance Notification (FCN) No. 1946 that PoLA does not persist in the environment.

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

   The TR confirms the petitioner's labeled use is approved under the FDA FCN 1946 as follows:

- 1000 parts per million (ppm) PLA, 2384 ppm Hydrogen Peroxide (HP), and 5.5 ppm HEDP in process water or ice that contacts meat or poultry carcasses, parts, trim, and organs; or
- 495 ppm PLA, 1180 ppm HP, and 2.7 ppm HEDP in process water, ice, or brine that contacts processed and pre-formed meat and poultry.

According to the petitioner "closed, automated injection systems are utilized to introduce concentrate into water lines that feed desired concentrations of this product to various application sites throughout the plant, including into spray cabinets and dip tanks." These injection lines deliver at or below the surface of the water to minimize splashing.

Disposal of PoLA as described in the petition: "discharge occurs from dip tanks in two ways: 1) as drag-out on the carcasses and 2) deliberately when the tank is emptied for sanitation procedures. For drag-out, there is no difference between a sprayed or a dipped carcass dripping on the line before it enters the chiller. Some antimicrobial chemistry will be introduced into drip pans under the line and that chemistry will be dumped to the waste stream in the drain or back into the dip tank. For tank emptying for sanitation, the antimicrobial-treated water left in the tank at the end of processing will be dumped directly to drain just like the water from every other processing application, including large chiller tanks."

The TR states, "the patent referenced in the petition claims that PoLA can pose a danger to drinking water if leaked into the ground. The SDS instructs users to not allow PoLA to reach ground water, watercourse or sewage systems, bodies of water, or drainage ditches if undiluted and not neutralized."

Addition of the PoLA to the wastewater stream at 1000 ppm will have no negative environmental impact. This is further supported by the FDA's FONSI evaluation of FCN No. 1946.

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

   Human health concerns of PoLA are similar to that of PAA. When used in accordance with FCN No. 1946, PoLA is completely degraded on protein surfaces within 60 minutes and therefore there is no anticipated effect to the human health of consumers of the meat or poultry treated with PoLA. As confirmed in the TR, PoLA has little or no odor and has a lower odor profile than PAA. There is no data available to suggest a safety concern.

   It states in the petition that "Considering the similarities of the chemistry and the considerably lower odor profile of PoLA, we propose that PoLA concentrations be maintained below the currently acceptable limit of PAA of 0.4 ppm PAA. At this level there might also be only 0.95 ppm hydrogen peroxide, 2.2 ppb HEDP, and 5.2 ppb sulfuric acid in the air – levels far below those that would be of concern for human health hazards. Testing of PAA vs. PoLA vapors above a drip tray apparatus has been performed to compare their volatility, and under identical conditions and amounts, the concentration of PoLA was 10 times less than that of PAA."

   Exposure to the concentrate can cause severe burns, eye damage, and respiratory distress. Effects of exposure to use dilutions should be easily controlled by washing eyes and skin with water should contact occur. Risk can be minimized by using safety glasses and latex or nitrile gloves.

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

   The substance will only be applied to meat and poultry products within the confines of a food processing facility and therefore, there will be no effect on soil organisms, crops, or livestock.

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

   There is no literature addressing the impacts on biodiversity, however, there is likely to be little to no affect since the product breaks down into carbon dioxide and water. The TR did state that the use of PoLA may increase the use of recycled water and indirectly result in a reduction of water use in the poultry industry, which has significantly increased since 1998.

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)]

   Nonsynthetic alternatives include bacteriophages, fatty acids, and essential oils.

   The petitioner compares PoLA to PAA throughout the petition. They are compatible with each other but like PAA, PoLA is not compatible with reducing agents, alkali (caustic) chemicals, or heavy metals such as iron, copper, chromium, nickel, and aluminum. PAA is also a synthetic material.

   The petition indicated the efficacy of PoLA over its alternative, PAA in control of two pathogens, *Campylobacter jejuni,* and *Salmonella infantis*. Neotox (PoLA product) resulted in a reduction of both pathogens under three concentrations (400 ppm; 500 ppm; and 800 ppm).

   Antimicrobial materials are necessary to prevent food borne illnesses. There are multiple sanitizers listed for use including organic acids, and chlorine materials. Other allowed antimicrobial agents on the National List are sodium lactate and potassium lactate. PoLA is expected to be more efficacious than these materials.

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)]

   Yes. PoLA is very similar to PAA (which is on the National List) with a potentially reduced environmental and human health effect and greater efficacy as an antimicrobial.

   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))

   PoLA is synthetic and cannot be produced from natural sources. It is manufactured by a chemical process.

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))

   It is unlikely that environmental contamination will occur from the petitioned use and from the patented manufacturing. Literature found in the patent claims that peroxycarboxylic acids are environmentally benign sanitizers since they break down into naturally occurring elements and compounds (lactic acid, carbon dioxide, and water).

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)

   The nutritional quality of the food is not affected by use of PoLA. Residues are undetectable after 60 minutes of use and have no effect on human health.

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))

   PoLA is not used as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing,. When used in accordance with FCN No. 1946, PoLA is completely degraded on protein surfaces within 60 minutes.

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))

   POLA is not designated as GRAS. As a food contact substance (FCS)(U.S. FDA, 2021a), its legal approval is 438 governed through the issuance of Food Contact Notifications [tr 437-438]

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

   Presently, PoLA is not essential, however could provide a safer, more efficacious alternative to reduce pathogens in organic meat and poultry processing facilities.

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)

   PoLA is manufactured, applied, and degrades in a manner that is in accordance with the principles of the USDA National Organic Program.

At this time, the Handling Subcommittee is seeking more information from stakeholders about the need for new antimicrobials. The Handling Subcommittee is also interested in the antimicrobial rotations and IPM strategies used in these facilities to help manage pathogens.

Questions for Stakeholders:

1. Are pathogen populations getting harder to control in meat and poultry processing facilities?
2. The petition compares PoLA to PAA; if PAA is not the dominant material used in your facility, what is?
3. Have chemical rotations aided in pathogen resistance management?
4. Are your current antimicrobial products preventing you from reducing water use in your facility?

Classification Motion:
Motion to classify peroxylactic acid (PoLA) as non-agricultural, synthetic
Motion by: Logan Petrey
Seconded by: Kyla Smith
Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 2

National List Motion:

Motion to add peroxylactic acid (PoLA) for use as an antimicrobial agent in process water, ice, or brine used in the production, processing, and preparation of meat and poultry products, at § 205.605(b) of the National List.
Motion by: Logan Petrey
Seconded by: Kyla Smith
Yes: 3 No: 3 Abstain: 0 Recuse: 0 Absent: 2

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Phosphoric acid - Annotation Change
July 26, 2022

Summary of Petition
This document reviews the petitioned annotation change of phosphoric acid, which is currently on the National List at §205.605(b): Phosphoric acid - cleaning of food-contact surfaces and equipment only.

Introduction:
In 2019, Kemin Food Technologies petitioned the United States Department of Agriculture (USDA) National Organic Standards Board (NOSB) to amend the existing annotation of phosphoric acid on the National List to include use as a synthetic substance for organic processing and handling (USDA 2019, USDA 2020a, USDA 2020b). This new petition requests the expansion of the use of phosphoric acid "as an acidifier to adjust pH of an extraction solvent to extract antioxidants or other target molecules from *lamiaceae* plants, provided the amount of acid used shall not exceed the minimum needed to lower pH to 2.5" (USDA 2020b).

Relevant Background:
In 2002, Aquatic Seaplants Limited petitioned the NOSB to expand the approved use of phosphoric acid within the National List to include production of organic aquatic plant extracts (USDA 2002). A technical report on phosphoric acid for organic processing was submitted in 2003 (USDA 2003). In 2004 the NOP contacted the petitioner and stated that phosphoric acid did not need to be petitioned for use in plant extraction "because its use as a pH adjuster in aquatic plant extracts is currently not prohibited through the inclusion of "aquatic plant extracts" in section 205.601(j)(1) of the National Organic Standards" (NOP 2013). In 2013 the NOP sent a memorandum to the National Organic Standards Board (NOSB) requesting a review on the use of phosphoric acid in plant extracts to ensure that this use is consistent with the context to the National List (NOP 2013). The petitioner subsequently withdrew the petition in January 2014.

Use:
Phosphoric acid is used in organic handling and processing as a cleaning agent for "food contact surfaces and equipment," as described in 7 CFR 205.605(b). Phosphoric acid has been approved for pH adjustment of some soil amendments (liquid fish products and squid byproducts) and as an equipment cleaner in both organic crop and livestock production. (7 CFR 205.601 and §205.603).

In addition to its appearance at 7 CFR 205.605, phosphoric acid has been used as an ingredient in plant extractions (USDA 2002, USDA 2019, USDA 2020a, USDA 2020b). When used in this manner, phosphoric acid acts as an acidifying agent and stabilizer to facilitate more efficient extraction of target compounds (Yoon et al. 2020). The purpose of the annotation would be to allow use to extract target molecules, including but not limited to antioxidants, from various plant species of the *lamiaceae* family. In order to prepare the proper extraction solvent, tap water pH will be adjusted to lower pH.

The petitioner states, "This adjustment is critical to successful extraction because such low pH inhibits enzymatic oxidation that would otherwise destroy the target molecules. Regarding use of the extract, as consumer preferences begin to change and shift away from chemically sounding ingredients, consumers are looking to purchase and consume foods made with ingredients that come from natural sources. For food manufacturers, this means finding replacements for traditionally used synthetic ingredients, such as plant-based molecules. The petition is intended to be limited to extracting target molecules from plants of the *lamiaceae* family. The extracted target molecules may be subsequently blended with appropriate carriers for help in proper dispersal across the surface of finished food products. Application depends on the finished food matrix as different extracts have hydrophilic or lipophilic properties."

In addition to organic applications, phosphoric acid is a widely-used substance in conventional agriculture, with approximately 90% of wet process phosphoric acid used in the production of fertilizers (Shriver and Atkins 2008). Phosphoric acid has uses in food and beverage processing as a pH adjuster, flavor ingredient, and processing agent in dairy products (Wolke 2002, Gilmour 2019). Phosphoric acid is also a precursor to synthetic phosphates, which have a variety of uses including as fertilizers, surfactants, and detergents (Shriver and Atkins 2008). [TR 163-179]

Manufacture:
Phosphoric acid is produced through two methods, the wet process, and the thermal process (EPA 1995, Gilmour 2019, Haghani and Daneshpazhuh 2020). Historically, the end-point use for the phosphoric acid was determined by its production method. High purity, technical and food grade phosphoric acid was produced by the thermal process (EPA 1995, Gilmour 2019). Lower purity phosphoric acid, primarily used in animal feed and fertilizer applications, was produced by the wet process (EPA 1995, Shriver and Atkins 2008, Gilmour 2019). Due to the expensive nature of the thermal process, there has been continued development of purification methods for wet process phosphoric acid, which now serve as the predominant method for the production of technical and food grade phosphoric acid (Gilmour 2019).

Thermal process
The thermal process is broken down into three major steps: combustion, hydration, and demisting (collection) (EPA 1995, Gilmour 2019). In the combustion step, elemental yellow phosphorus (P_4) is reacted with oxygen gas, which oxidizes the phosphorous from its 0 to V oxidation state, as shown below in Equation 6 (EPA 1995, Gilmour 2019). The heat of combustion for phosphorus is highly endothermic and the reaction must be carried out at high temperatures (1650 – 2760 °C) (EPA 1995, Gilmour 2019).

$$P_4 + 5\ O_2 \rightarrow 2\ P_2O_5$$

Equation 6

Once the elemental phosphorus is oxidized to P_2O_5, it undergoes the hydration process to form orthophosphoric acid, as shown below in Equation 7 (EPA 1995, Gilmour 2019). In this process P_2O_5 is generally reacted with water, although in some cases dilute solutions of phosphoric acid are used instead of water alone (EPA 1995). Once phosphoric acid has been produced, it is isolated in the demisting process. In this step, phosphoric acid is collected as a mist with high-pressure drop demisters. The thermal process produces phosphoric acid with P_2O_5 concentrations between 54 and 62%, which are sufficiently pure for use in technical and food grade applications (EPA 1995, Gilmour 2019).

$$2\ P_2O_5 + 6\ H_2O \rightarrow 4\ H_3PO_4$$

Equation 7

Wet Process

The wet process produces phosphoric acid from naturally occurring phosphate mineral sources (fluorapatite [$Ca_{10}(PO_4)_6F_2$] and hydroxyapatite [$Ca_{10}(PO_4)_6(OH)_2$]) (EPA 1995, Shriver and Atkins 2008, Gilmour 2019, Haghani and Daneshpazhuh 2020). Once mined, these minerals are converted to phosphoric acid in four main steps, as outlined in Figure 5 below (Gilmour 2019). The phosphate rock is prepped in the initial step by being milled and ground to increase its surface area (EPA 1995, Haghani and Daneshpazhuh 2020).

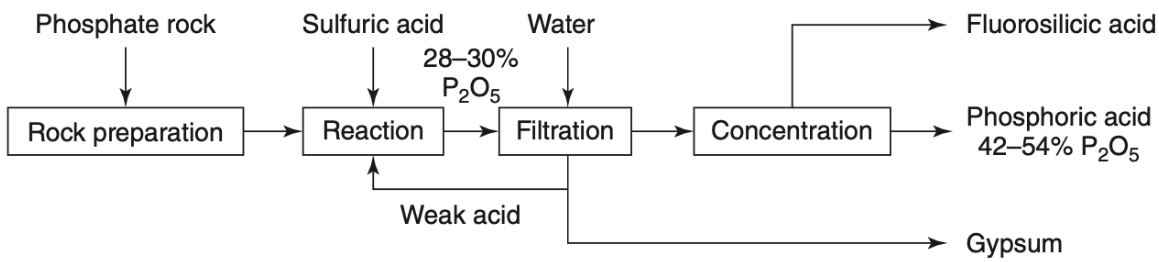

Figure 5

Once milled, the mineral phosphates are reacted with a strong mineral acid and converted to phosphoric acid, as shown in Equation 8 below (EPA 1995, Shriver and Atkins 2008, Gilmour 2019, Haghani and Daneshpazhuh 2020). While sulfuric acid is shown in both Figure 5 and Equation 8, other strong mineral acids (e.g., nitric acid [HNO_3] and hydrochloric acid [HCl]) may also be used (Jin et al. 2014, Haghani and Daneshpazhuh 2020). However, most commercial processes use sulfuric acid because it provides higher phosphoric acid yields, lower costs, and a solid form of calcium (Al-Fariss et al. 1992, EPA 1995, Shriver and Atkins 2008, Gilmour 2019). The specific reaction conditions dictate the type of calcium sulfate hydrate ($CaSO_4 \bullet n\ H_2O$) formed, with lower temperatures favoring the formation of gypsum ($CaSO_4 \bullet 2\ H_2O$), as shown in Equation 8 (EPA 1995). The prevalence of fluorapatite among mineral phosphates also produces hydrofluoric acid (HF), as shown below in Equation 8.

$$Ca_{10}(PO_4)_4F_{2\,(s)} + H_2SO_{4\,(aq)} + 20\ H_2O_{\,(l)} \rightarrow 6\ H_3PO_{4\,(aq)} + 10\ [CaSO_4 \bullet 2\ H_2O]_{\,(s)} + 2\ HF_{\,(aq)}$$

Equation 8

The gypsum formed during the reaction with the mineral acid is removed via filtration. Once removed, the gypsum solids undergo several aqueous wash cycles to remove residual phosphoric acid from the solid surface, producing phosphoric acids yields of 99.9% (EPA 1995, Gilmour 2019). As shown previously in Figure 5, the aqueous gypsum washes are sent back to the reaction vessel to aid in the conversion of mineral phosphates (EPA 1995, Gilmour 2019). The presence of mineral silicon in the initial composition reacts with hydrofluoric acid to produce less reactive forms of silicon tetrafluoride (SiF_4) and SiF_6^{2-} ions, some of which are removed as solids with the gypsum (Gilmour 2019).

The phosphoric acid isolated following the filtration process is dilute, with P_2O_5 concentrations between 26 – 30% (EPA 1995, Gilmour 2019). Vacuum evaporation is used to remove water and concentrate the phosphoric acid to 42 – 54% P_2O_5 (Gilmour 2019). Activated silica or clay is added during the concentration process to react with residual hydrofluoric acid. Silicon tetrafluoride isolated from the concentration step is hydrolyzed to fluorosilicic acid (H_2SiF_6), as shown in Figure 5 (Gilmour 2019).

Mineral impurities, including heavy metal contaminants, remain in phosphoric acid produced via the wet process, which have historically limited its use to agricultural fertilizer applications (EPA 1995, Shriver and Atkins 2008, Gilmour 2019, Haghani and Daneshpazhuh 2020). Wet process phosphoric acid results in concentrations between 42 and 54% P_2O_5, which is largely unsuitable for technical applications (Gilmour 2019). The elemental phosphorous used in the thermal process can be purified via sublimation, resulting in no carry-over of heavy metal contaminants so that thermal phosphoric acid can be used in technical and food applications (Shriver and Atkins 2008). However, the thermal process is much more expensive and energy intensive than the wet process (~2000 °C vs ~80 °C) (EPA 1995, Gilmour 2019).

Wet process purification methods

Wet process phosphoric acid is commonly purified by crystallization or solvent extraction (Gilmour 2019). Crystallization is a common purification technique, which is based on the differing solubilities of pure and impure mixtures, with pure substances selectively crystallizing at reduced temperatures (Pavia et al. 1995). When phosphoric acid is concentrated to 61% P_2O_5 or higher, it selectively forms hemihydrate crystals ($H_3PO_4 \bullet \frac{1}{2} H_2O$) when cooled to 8 – 12 °C (Gilmour 2019). The crystals are removed from the mixture and can be melted to undergo additional recrystallization cycles to improve purity, with each cycle yielding a 10 to 100 times increase in purity (Gilmour 2019).

Solvent extraction is another traditional purification method based on solubility. In solvent extraction, the target compound migrates between immiscible phases (usually aqueous [polar] and organic [nonpolar]) based on solubility (Pavia et al. 1995). The selectivity of phosphoric acid does not differ greatly compared to its impurities, requiring additional purification steps. Prior to solvent extraction, concentrated phosphoric acid undergoes precipitation with calcium or barium salts to remove sulfate (SO_4^{2-}), sodium salts to remove fluorosilicates, and sulfides to remove arsenic (Shlewitt and Alibrahim 2008, Gilmour 2019, Haghani and Daneshpazhuh 2020). Phosphoric acid extractions are performed in one or more extraction columns with many possible organic solvents, including alcohols, ethers, ketones, amines, and kerosene blends (Shlewitt and Alibrahim 2008, Jin et al. 2014, Gilmour 2019). Following extraction with an organic solvent, phosphoric acid is recovered with water. Residual organic solvents are removed via evaporation during the concentration of the recovered phosphoric acid from the aqueous solution (Shlewitt and Alibrahim 2008, Gilmour 2019). Solvent extraction of wet process phosphoric acid improves the purity of the substance from 42-54% P_2O_5 in the raw form to up to 97% P_2O_5 (Gilmour 2019). [TR 376-482]

International Acceptance:

Canadian General Standards Board Permitted Substances List

Phosphoric acid is listed in the Organic Production Systems Permitted Substances List as an approved substance for pH adjustment of "fish meal, fish powder, fish wastes, hydrolysate, emulsions and solubles" that are used for "soil amendments and crop nutrition." Phosphoric acid is also listed as a "cleaner, disinfectant and sanitizer permitted on organic product contact surfaces for which a removal event is mandatory [for use] on dairy equipment." [TR 345-351]

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

Phosphoric acid is not listed in EC No. 834/2007 or EC No. 889/2008. [TR 357-358]

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

Phosphoric acid is not listed in the CODEX. [TR 353-355]

International Federation of Organic Agriculture Movements (IFOAM) Norms
Phosphoric acid is listed in the IFOAM NORMS for organic production and processing as an "equipment cleanser and equipment disinfectant only for dairy equipment," and as a "substance for pest and disease control and disinfection in livestock housing and equipment [for] dairy equipment." [TR 364-367]

Japan Agricultural Standard (JAS) for Organic Production
Phosphoric acid is not listed in the JAS. [TR 360-361]

Summary of Review:
The Handling Subcommittee submitted a proposal to the full Board at the Spring 2022 meeting in response to the petition. At that time, the Subcommittee's review and discussion were centered around the petitioner's assertion of essentiality. The Subcommittee took note of the presence of other similarly functional acids on the National List that can be used to prepare extraction solvents. According to the petitioner, phosphoric acid's strength as an acid will assist in the creation of processed goods that meet consumer expectations. Phosphoric acid is allowed for use in crops to adjust pH in liquid fish products and squid byproducts. Phosphoric acid was in consideration for use in the extraction of aquatic plant extracts, but the submission was withdrawn by the petitioner. The Subcommittee discussed the low negative impact on the environment and human health, and noted that given the functionality of the petitioned use, it is unlikely that phosphoric acid will be present in final food products in significant amounts. The Handling Subcommittee challenged the need for an additional synthetic substance especially for use in food.

At the Spring 2022 meeting, the Board voted to send the proposal back to Subcommittee to further evaluate and better understand the intended use of phosphoric acid. The Subcommittee asked the petitioner some additional questions.

The questions and subsequent answers provided by the petitioner (in italics) are below:

1. Is this an accurate process flow?

    a. Tap water + phosphoric acid = extraction solvent with low pH
    b. PA extraction solvent + *lamiaceae* plants -> antioxidants and other target molecules of the *lamiaceae* plants
    c. Extracted antioxidants and other target molecules + organic carrier oil -> added as ingredient in finished product

    The process flow detailed in your response is mostly correct. However, one minor change to Section 1(c) is that the carrier is unlikely to be an oil. After extraction, the plant extract could be used without a carrier, or could be used with a water-soluble carrier including but not limited to water or organic ethanol. It is also possible for the lamiaceae plant extracts to be combined with a dry carrier, including but not limited to something like organic rice flour, and then added as a dry ingredient to the finished food.

2. What are some examples of finished products this extract would be used as an ingredient in? And why is this ingredient needed to be added to the finished product? Is this for food preservation?

    Finished products incorporating this extract would be any multi-ingredient product certified as organic under USDA NOP federal regulatory program.
    Lipid oxidation, a chain reaction that occurs in the presence of oxygen and lipid molecules, is responsible for deterioration in food quality and can lead to possible off-flavors or off-odors.

Oxidation can be affected by processing, packaging, storage methods, or even ingredients within a food product. Fortunately, though, antioxidants are common food ingredients today used to help prevent oxidation and thereby preserve freshness to help ensure consumers have the most appealing and fresh food. Multiple synthetic antioxidants have commonly been used throughout history, but data has shown similar effects can come from the power of plants. These plant-based antioxidants are acceptable to consumers. Consumers not only expect a product to taste fresh through its shelf life, but also demand use of ingredients they feel good about, including those that are plant-based and organic compliant. Consumers have a wide range of expectations, meaning food ingredient manufacturers must offer a wide range of product solutions, including the antioxidants or other target molecules mentioned in this petition.

3. Is this to support the production of organic rosemary extract or other organic extracts?

The intent behind his petition was not to support production of organic rosemary extract. The current need is for an extraction solvent to process spearmint. However, as many plants from the lamiaceae family contain additional beneficial molecules that might not have been discovered yet, the need to extract these new molecules may arise in the future. That being said, Kemin is not currently aware of any such additional molecule having been affirmed GRAS for its intended use, and therefore a GRAS affirmation would be required before any additional plant extract could be applied to an organically certified food. Thus, while Kemin believes phosphoric acid could be used to aid in the extraction of any target molecule from the lamiaceae family, the current request could be limited to extraction of only antioxidants from spearmint if such amendment was more acceptable to the NOSB Handling Subcommittee.

Most of the public comments during the Spring 2022 meeting were not supportive of the listing based on lack of knowledge and understanding of the intended use of phosphoric acid especially in relation to the finished product. The petitioner confirmed that phosphoric acid is solely to be used to aid extraction (i.e., processing aid). By definition a processing aid is either "…removed in some manner from the food..." or "…is present in the finished food but at insignificant levels…". This addresses some stakeholder comments about whether phosphoric acid will be present in the finished product. It would appear this would not be the case given this will be used as a processing aid (§205.2 Definitions).

The extraction ingredient (mainly spearmint extract) will be added to various finished foods to prevent oxidation. Additionally, as stated throughout the TR and the petition, phosphoric acid is a stronger acid compared to other acids resulting in lower usage rates. There are other acids on the National List, which are all "weaker acids", which would require higher rates to achieve the desired pH adjustment. Based on this the petitioner states it is not feasible to use these alternatives. This was also brought up by stakeholders, in which it was noted that there are already various organic mint family extracts on the market. There are about a dozen companies in the Organic Integrity Database (OID) with spearmint extracts listed as organic products. The Subcommittee is looking for additional information on the topic of essentiality given that there are already organic spearmint extracts available produced without the use of phosphoric acid. It seems like the acids already on the National List are "feasible" but not preferred. Is this an accurate assumption?

The Subcommittee discussed how the expanded annotation could potentially increase use of organic rosemary extracts and therefore reduce the use of tocopherols (another synthetic on the National List). However, this doesn't seem to be the intended use. Again, it appears that other acids currently listed could also be used for this purpose, which brings us back to the same question of essentiality.

Lastly, public commenters also noted the impact on the environment during the manufacturing process. The Subcommittee discussed this along with the other concerns expressed in the Spring 2022 public comments outlined above.

Overall, the Subcommittee is mostly concerned about expanding the use of a synthetic substance on the National List when it appears to not be essential (i.e., according to the OID, organic spearmint extracts are currently being produced).

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:

   Phosphoric acid is currently listed on the National List at §205.605(b).

   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:

   Phosphoric acid is currently listed on the National List at §205.605(b).

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

   N/A

Category 2: Adverse Impacts

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

The petition states “Phosphoric acid itself combines readily with many other chemicals and no known detrimental interactions within organic farming systems is known.” Additionally, this material is already listed twice on the National List, therefore the potential for detrimental chemical reactions seems unlikely.

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

The petition states "In the process of phytochemical extraction, phosphoric acid combines with water to form an acidified extraction solution. Phosphoric acid in its original form will break down quickly in the environment, so there are no toxicity issues directly related to its breakdown products. In this process, phosphoric acid will be partially neutralized by the plant components, and after extraction, the matrix has a pH of about 5.0-6.0. Consequently, the phosphoric acid will no longer exist in its acid form and the resulting liquid will not be corrosive. Therefore, while raw and concentrated phosphoric acid might be toxic to aquatic environments, the process mitigates contaminant persistence and/or concentration in the environment."

The TR states that due to the low concentration in the extraction application, as well as the prevalence of phosphates throughout biology, the likelihood of toxicity and concentration in the environment are low.

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

When used as petitioned, phosphoric acid is used in low concentrations (1 – 3%), and is a source of phosphates for incorporation to biomolecules. The low concentration in extraction applications and the prevalence of phosphates throughout biology make phosphoric acid from plant extractions unlikely to be harmful to the environment or biodiversity.

However, the production of phosphoric acid does have the potential to be harmful to the environment. The thermal process for producing phosphoric acid is energy intensive and requires high temperatures. The high energy requirements of the thermal process may contribute to atmospheric CO_2 levels if the energy is produced from fossil fuels. The thermal process also requires the treatment of combustion gases by scrubbers, cyclonic separators, mist eliminators, and electrostatic precipitators to prevent the release of phosphoric acid to the environment (EPA 1995, Gilmour 2019). The small size ($< 3\ \mu$m diameter) makes these phosphoric acid and phosphorus oxide (P_2O_5) particles difficult to capture, and contributes their release to the atmosphere at levels of "< 25 mg P_2O_5 per dry standard cubic meter of stack gas" (Gilmour 2019).

Wet process phosphoric acid is produced from chemical changes to mined mineral phosphates. There may be initial harm to the environment and biodiversity in the mining process. Once the minerals are isolated, hydrofluoric acid presents the most likely source of environmental harm (Shriver and Atkins 2008). Hydrofluoric acid is removed as a solid or as fluorosilicic acid by reaction with silica sources. These include natural silicates present within the initial mineral, as well as activated silica and clay added during the manufacturing process (Shriver and Atkins 2008, Gilmour 2019). Additionally, scrubbers are used to remove gaseous fluorine compounds from concentration steps to prevent their release to the environment (EPA 1995).

In addition to the hazards from fluorine compounds, the gypsum produced may pose a hazard to the environment. Isolated gypsum may be used for other commercial applications if it is sufficiently pure (Gilmour 2019). In other cases, gypsum is left in gypsum stacks, or pumped out to sea (Gilmour 2019). However, the gypsum may also contain silicon fluorides, acids, and other impurities from the initial mineral source, which has resulted in its designation as a hazardous substance by the EPA in 40 CFR 261.4. [TR 566-594]

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

Concentrated phosphoric acid is corrosive and can result in burning and irritation of the eyes and skin on contact (Flomenbaum et al. 2002, NJDHSS 2004, Gilmour 2019). Phosphoric acid can desiccate epithelial cells, resulting in the drying and cracking of skin where long-term exposure occurs (Flomenbaum et al. 2002, NJDHSS 2004). Inhalation of phosphoric acid may result in irritation to the nose, lungs, and throat and may induce coughing and wheezing (NJDHSS 2004, Gilmour 2019). Ingestion of phosphoric acid may damage gastric and esophageal mucus linings (Flomenbaum et al. 2002).

Phosphoric acid is frequently used in food processing and production and is a common component of food and beverages (Wolke 2002). As described in Equations 2 – 4 in the "Composition of the Substance" section, phosphoric acid is the source of several phosphates, which are important components of biomolecules (e.g., ATP, DNA, etc.) (Shriver and Atkins 2008, Timberlake 2016, Gilmour 2019). When used as petitioned, phosphoric acid is used in low concentrations (1 – 3%), making it unlikely to be harmful to human health (Gilmour 2019). [TR 599-611]

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

The petition states, "When stored, used and disposed of appropriately, phosphoric acid use during phytochemical extraction will have no negative interactions with soil organisms, crops, or livestock."

Additionally phosphoric acid is allowed at §205.601(j)(8) as a pH adjuster which makes the likelihood that phosphoric acid has negative physiological effects on soil organisms, crops, and livestock unlikely.

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

As previously stated, due to the low concentration in the extraction application, as well as the prevalence of phosphates throughout biology, there does not appear to be an adverse impact on biodiversity.

Category 3: Alternatives/Compatibility

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

There are alternative methods to extract target molecules from plant material. One of the simplest ways to improve solvent extraction processes is to increase the solvent temperature (Pavia et al. 1995, Silberberg 2003). Increased temperature improves the solvation of most solids and liquids by disrupting the intermolecular forces that prevent the target molecule from entering the solution (Silberberg 2003).

Supercritical carbon dioxide extraction offers an alternative to acidic extractions. This extraction method uses temperatures and pressures that push the solvent beyond its critical point, so that it no longer exists as a liquid or gas (Silberberg 2003, Babovic et al. 2010). Carbon dioxide is the most common supercritical fluid used in extraction applications due to its low cost and the low temperatures and pressures required to reach supercritical conditions (31.1 °C and 7.38 MPa) (Babovic et al. 2010). The selectivity of supercritical fluids can be modulated by changing its temperature and pressure to target different classes of molecules.

Subcritical extractions offer another alternative to acidic extractions. In such applications, the solvent remains in liquid form, although conditions may approach the critical point of the solvent (Ibañez et al. 2003). As with supercritical fluid extractions, the selectivity of the subcritical extractions can be manipulated by modifying temperature and pressure. Subcritical water extractions have been successful in the extraction of essential oils and antioxidants (Ibañez et al. 2003). However, some antioxidants and other compounds are sensitive to decomposition, and may not survive increased solvent temperatures or the high-pressure conditions needed in supercritical and subcritical extractions (Ibañez et al. 2003). [TR 616-634]

Many natural and currently allowed synthetic acids offer an alternative to phosphoric acid for plant extractions, such as acetic acid, citric acid, gibberellic acid, lactic acid, and tartaric acid (NOP 2016c). Polyprotic carboxylic acids (for example, ascorbic acid, citric acid, etc.) are also able to chelate positively charged species, facilitating improved extraction (Albuquerque et al. 2005).

However, the strength of the acid is important in determining the effectiveness in the extraction of the target molecules. Carboxylic acids are weaker acids than phosphoric acids (pKa ~5 vs 2.15) meaning that they may be less effective in extracting some molecules, including anthocyanin antioxidants (Silberberg 2003, Nicoué et al. 2007, Timberlake 2016). The target molecule and plant structure determine the optimal solvent conditions, although phosphoric acid solutions have been reported to be among the most effective for antioxidant extractions (Nicoué et al. 2007). [TR 640-650]

Alternatives to phosphoric acid are naturally acidic agricultural substances, including wine and vinegar. Both mixtures include natural acids that can provide an acidic extraction solution. However, as described in Evaluation Question 12, carboxylic acids are weaker than phosphoric acid and may be less effective in the extraction of some target molecules. Additionally, the complex mixture of compounds in wine and vinegar would make purification of the plant extracts more difficult. [TR 655-659]

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))

Phosphoric acid is a synthetic substance that does not exist in nature. Therefore, there are no natural sources of phosphoric acid. [TR 500-501]

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))

The petition states, "There are many environmental consequences from the manufacture, misuse, and disposal of phosphates in general and these cannot be separated out for phosphoric acid in particular. In figures from world phosphorus consumption in 1980, about 90% of phosphate consumption is for fertilizer, while 4.5% is for all detergents including other cleaners such as trisodium phosphate. There are extreme environmental impacts from mining of phosphate ore which occurs in many parts of the world. Worker safety is of prime concern in the wet-process acid and elemental phosphorous used in the thermal process because of high acidity, heat released upon neutralization and toxic gases released. Plants will be equipped with proper safety procedures and equipment to deal with these issues.

The issues of phosphate pollution from disposal are discussed above, but in general the dilution of phosphoric acid will minimize disposal problems in the food processing or livestock facility."

The TR, as previously stated, indicates that the use of phosphoric acid is relatively benign regarding its impact on the environment. However, it does state that thermal production process is energy intensive and uses high temperatures, which could contribute to CO_2 levels if the energy is produced from fossil fuels. That said, as stated previously, due to the expensive nature of the thermal process, there has been continued development of purification methods for wet process phosphoric acid, which now serve as the predominant method for the production of technical and food grade phosphoric acid (Gilmour 2019).

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)

When used as petitioned, phosphoric acid will be used in the extraction of target molecules from plant material. The extraction of antioxidants and other compounds from the initial plant material will reduce the nutritional quality of the material from which they are extracted. However, the purpose of plant extracts is to improve the quality of other products to which they are added (Nicoué et al. 2007, Proestos 2020). Phosphoric acid is a source of phosphates, which are important nutrients in human health, and can be found in many biomolecules, including ATP and DNA (Shriver and Atkins 2008, Timberlake 2016, Gilmour 2019). However, phosphoric acid is typically used in low concentrations (1 – 3%) in extraction processes and is unlikely to contribute directly to improved nutritional quality. [TR 540-547]

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))

When used as petitioned, the primary function of phosphoric acid is to improve the extraction of target molecules, not to act as a preservative. However, in some cases, the addition of phosphoric acid stabilizes target molecules from decomposition, as described above in the "Action of the Substance" section, thus the ingredient (e.g., *lamiaceae* plant extracts such as spearmint extract) will act as an antioxidant in the finished food product.

Phosphoric acid is also used as an equipment sanitizer in organic agriculture in 7 CFR 205.605 and §205.603. The low pH of phosphoric acid solutions makes it an antimicrobial substance, as high acid content is not tolerated by microorganisms (Winniczuk and Parish 1997, Prado et al. 2015). The antimicrobial nature of phosphoric acid may result in some preservative characteristics if incorporated into food and beverage products (Winniczuk and Parish 1997). [TR 518-526]

When used as petitioned, the primary function of phosphoric acid is to improve the extraction of target molecules, not to improve or recreate flavors in processed food products. However, phosphoric acid has been used as a flavoring agent in conventional food and beverage production, as described above in the "Specific Uses of the Substance" and "Historical Use" sections. [TR 532-535]

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))

As described in the "Approved Legal Uses of the Substance" section, the FDA has designated phosphoric acid generally recognized as safe (GRAS) for several uses. Phosphoric acid is listed as a "multiple purpose GRAS food substance" in 21 CFR 182. 1073, and as a GRAS "general purpose food additive" in §582.1073. Additionally, the FDA lists phosphoric acid as a substance used in the production of the GRAS substances monobasic ammonium phosphate in §184.1141, dibasic ammonium phosphate in §184.1141, magnesium phosphate in §184.1366, and hydrogen peroxide in §184.1366. [TR 507-512]

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

The petition states, "Since effective extraction is a critical step in the ability to use biomolecules, the ultimate benefit of the applicable organic management program, and since phosphoric acid appears among the best and safest pH adjusters, this material seems compatible with an organic production and processing system."

However, as discussed above in the Summary of Review section, the Handling Subcommittee questions the essentiality of phosphoric acid as a pH adjuster as there are already acids on the National List that perform this function and there are organic spearmint extracts (and other *lamiaceae* plant extracts) commercially available (determined via a search of the OID).

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)

Based on essentiality, availability of alternatives, as well as potential negative environmental impacts during manufacturing, the Handling Subcommittee finds that phosphoric acid is not compatible with a system of sustainable agriculture,

Questions to stakeholders:

1. Is expanding the use of phosphoric acid as petitioned necessary given that there are currently organic spearmint extracts (and likely other extracts from the *lamiaceae* plant family) commercially available?

National List Motion:

Motion to amend the annotation of phosphoric acid to (underlined verbiage is the proposed addition) "cleaning of food-contact surfaces and equipment, and as an acidifier to adjust pH of an extraction solvent to extract antioxidants or other target molecules from *lamiaceae* plants, provided the amount of acid used shall not exceed the minimum needed to lower pH to 2.5." at 205.605(b).

Motion by: Kyla Smith
Seconded by: Dilip Nandwani
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

National Organic Standards Board
Handling Subcommittee Proposal
Review of Ion Exchange Filtration Process – Recharge Materials
July 26, 2022

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

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

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

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

A simplified summary of ion exchange, provided in the past from OMRI is as follows:

> Ion exchange is based on the principle that a solid mass with immobilized charges can attract the mobile ions of the opposite charge in a fluid media. In practice, this involves a column that is like a large pipe packed with an exchanger, which may be in the form of beads, crystals, gels, or granules. The fluid can pass through, but the ions in solution will be pulled out and held to the exchanger. The process chemically changes the resulting fluid.
>
> Techniques used to produce various sweeteners offer a good example of how the process works. Minerals, salts, proteins, and color bodies occur naturally in grape juice, cane juice, beet juice, and corn syrup. The refinement process seeks to remove these "impurities". They are also naturally present or—in case of color bodies—are formed between naturally present components during heating. These can be removed by a number of techniques. Some are physical, some are chemical, and some use both. However, the use of synthetic cross-linked polymeric resins—such as styrene-divinylbenzene (S-DVB)—to remove certain constituents of

liquids based on their chemical properties is a chemical process. The liquified sweetener stream chemically reacts with the ions present on the ion exchange resin to purify and concentrate the desired sugar (Cantor and Spitz, 1956).

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

Th Board presented a discussion document at the Spring 2020 meeting, and voted on a proposal at the Fall 2020 meeting, which recommended that the recharge materials be listed, and the resins not be listed. This vote failed (9 yes, 6 no). The board requested to be able to keep this as a work agenda item and presented a proposal at the Spring 2021 meeting. This proposal basically outlined the complexity of this material but didn't take a stance on whether recharge materials and/or resins should be listed. The proposal passed with the inclusion of a request on the cover letter for the NOP to exchange with FDA on this topic and how they categorize resins – as secondary food additives or food contact substances. The NOP held this meeting and sent a memo to the board with a summary of the discussions. The findings from this meeting were inconclusive on a specific path forward for ion exchange resins as the FDA expressed that ion exchange resins can be both secondary food additives and food contact substances (determined on a case-by-case basis). This is further discussed in the discussion document on ion exchange resins, as this is where the inconsistency lies.

However, there has been a unified approach to the recharge materials used in the ion exchange filtration process. When reviewing ion exchange filtration as a substance, certifiers are aligned in their review of the recharge materials and are presently requiring these materials to be listed on the National List. Examples of substances on the National List that may be used as an ion exchange recharge material include, but are not limited to, sodium chloride, potassium chloride, and hydrogen perioxide.

Subcommittee Review:
Since there is consensus on the listing of the recharge materials used in the ion exchange filtration process on the National List (based on the public comments, discussions of previous proposals and current review practices by certifiers), the Handling Subcommittee decided to decouple the review and recommendation of recharge materials from the resins.

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

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

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

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

Subcommittee Recommendation:
The inherent nature of ion exchange leads us to the conclusion that recharge materials used to recharge ion exchange resins must be on the National List if they are used in the processing of organic product. These recharge materials leave ions on the resins and those ions will ultimately end up in the final organic product. The public comments on previous discussion documents and proposals, as well as current review practices by certifiers, support this recommendation.

Subcommittee vote
Motion to approve the recommendation that recharge materials used in the ion exchange filtration process must be listed on the National List.
Motion by: Kyla Smith
Seconded by: Kim Huseman
Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 2

National Organic Standards Board
Handling Subcommittee Discussion Document
Ion Exchange Filtration Process - Resin Materials
August 2, 2022

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

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

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

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

A simplified summary of ion exchange, provided in the past from OMRI is as follows:

> Ion exchange is based on the principle that a solid mass with immobilized charges can attract the mobile ions of the opposite charge in a fluid media. In practice, this involves a column that is like a large pipe packed with an exchanger, which may be in the form of beads, crystals, gels, or granules. The fluid can pass through, but the ions in solution will be pulled out and held to the exchanger. The process chemically changes the resulting fluid.
>
> Techniques used to produce various sweeteners offer a good example of how the process works. Minerals, salts, proteins, and color bodies occur naturally in grape juice, cane juice, beet juice, and corn syrup. The refinement process seeks to remove these "impurities". They are also naturally present or—in case of color bodies—are formed between naturally present components during heating. These can be removed by a number of techniques. Some are physical, some are chemical, and some use both. However, the use of synthetic cross-linked polymeric resins—such as styrene-divinylbenzene (S-DVB)—to remove certain constituents of

liquids based on their chemical properties is a chemical process. The liquified sweetener stream chemically reacts with the ions present on the ion exchange resin to purify and concentrate the desired sugar (Cantor and Spitz, 1956).

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

The Handling Subcommittee presented a discussion document at the Spring 2020 meeting, and presented and voted on a proposal at the Fall 2020 meeting, which recommended that the recharge materials be listed, and the resins not be listed. This vote failed (9 yes, 6 no), and the NOSB requested to keep this as a work agenda item. The Handling Subcommittee then presented a proposal at the Spring 2021 meeting that outlined the complexity of this material but didn't take a stance on whether recharge materials and/or resins should be listed. The Spring 2021 proposal passed with the inclusion of a request on the cover letter for the NOP to engage with FDA on this topic about how FDA categorizes resins – as secondary food additives or food contact substances. The NOP sent a memo to the Board with a summary of the discussions. The findings from this meeting were inconclusive as the FDA expressed that ion exchange resins can be both secondary food additives and food contact substances (determined on a case-by-case basis). A clear result of the meeting between NOP and FDA is that it is dangerous territory for the NOSB to rely on the FDA definitions of secondary food additives and food contact substances to determine whether substances should be listed on the National List, as this would result in substances not on the National List needing to be petitioned and substances that are listed that would not need to be listed.

Since there is consensus on the listing of the recharge materials used in the ion exchange filtration process on the National List (based on the public comments, discussions of previous proposals, and current review practices by certifiers), the Handling Subcommittee decided to decouple the review and recommendation of recharge materials from the resins. The Handling Subcommittee drafted a separate proposal for consideration by the full Board at the Fall 2022 meeting recommending that the recharge materials used in ion exchange filtration be listed on the National List.

Subcommittee Review and Discussion:
The Handling Subcommittee is still evaluating whether resins used in ion exchange must be on the National List.

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

As noted in the 2020 TR, ion exchange filtration differs from physical filtration processes in that there is an actual chemical change in the ensuing product due to the recharge materials used in this process.

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

Based on past NOP guidance, substances categorized as food contact substances may be used unless explicitly prohibited; whereas if categorized as secondary food additives, then they must appear on the National List. This position comes from a policy statement issued on December 12, 2002, which states:

> "Accredited certifying agents, food processors, and food manufacturers have contacted the National Organic Program (NOP) regarding under what conditions synthetic substances used as ingredients in processed food products are subject to review and recommendation by the National Organic Standards Board (NOSB).
>
> 7 CFR 205.2 defines ingredient as "any substance used in the preparation of an agricultural product that is "still present" (quotations added) in the final commercial product as consumed." This definition arose from an April 25, 1995, NOSB recommendation on good manufacturing practices in certified organic handling operations.
>
> The NOP defines "still present" as those ingredients regulated by the Food and Drug Administration (FDA) as food additives permitted for direct addition to food for human consumption under:
>
> 1. 21 CFR Part 172, Food additives permitted for direct addition to food for human consumption.
> 2. 21 CFR Part 173, Secondary direct food additives permitted in food for human consumption: *Except,* That, substances classified by the FDA as food contact substances are not subject to this definition.
> 3. 21 CFR Part 180, Food additives permitted in food or in contact with food on an interim basis pending additional study: *Except,* That, substances classified by the FDA as food contact substances are not subject to this definition.
> 4. 21 CFR Part 181, Prior-sanctioned food ingredients: *Except,* That, substances classified by the FDA as food contact substances are not subject to this definition.
> 5. 21 CFR Part 182, Substances generally recognized as safe.
> 6. 21 CFR Part 184, Direct food substances affirmed as generally recognized as safe.
>
> The NOP also defines "still present" as those materials approved by the Bureau of Alcohol, Tobacco, and Firearms (ATF) as being acceptable for use by proprietors in the production of alcohol beverages under:

1. 27 CFR Part 24, Section 24.246, Materials authorized for the treatment of wine and juice: *Except,* That, substances classified by the FDA as food contact substances are not subject to this definition.
2. 27 CFR Part 24, Section 24.247, Materials authorized for the treatment of distilling material: *Except,* That, substances classified by the FDA as food contact substances are not subject to this definition.
3. The Brewers Adjunct Reference Manual: *Except,* That, substances classified by the FDA as food contact substances are not subject to this definition.

Accordingly, substances listed in 21 CFR Parts 172, 173, 180, 181, 182, and 184; 27 CFR Part 24; and the Brewers Adjunct Reference Manual, **except those substances classified by the FDA as food contact substances,** must be on the National List of Allowed and Prohibited Substances to be used in the production of an "organic" or "made with organic (specified ingredients or food group(s))" processed product.

Handlers must include in their organic systems plan a list of all synthetic substances to be used in the production of processed products. Each synthetic substance must be identified as an ingredient or a contact substance. Any substance identified as a contact substance must be accompanied by documentation that substantiates the claim."

This memo was archived when the NOP Program Handbook was created, however it has never been formally rescinded and remains in use by some certifiers.

To aid in evaluation, the NOSB requested that the NOP meet with FDA to inform how resins should be categorized: as secondary food additives or food contact substances. Because food additives are listed on the National List and due to the precedent set by the December 2002 policy memo, we believed this distinction would help us to determine if the resins should be listed or not. This meeting took place on June 7, 2021. Unfortunately, the conclusion was that ion exchange resins can be classified both as food contact substances and secondary food additives and are evaluated on a case-by-case basis, and therefore didn't provide information to guide us in either direction.

The NOSB received a number of public comments on its Spring 2020 discussion document, Fall 2020 proposal, and Spring 2021 proposal with a number of different viewpoints.

Some commenters stated that even though a material might be listed both ways, the fact that they are listed by FDA as a food contact substance, exempts those materials from needing to be reviewed by the NOSB and placed on the National List. Other commenters making the counterargument that if a substance is listed as a secondary food additive, regardless of its listing as a food contact substance, that it is under the purview of OFPA, and the resins would therefore need to appear on the National List.

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

On a less technical level, there is a procedural context as well. Since some physical filtration materials are listed and resins are not, there are arguments that there is a disparity in the review of materials.

There is also some disparity as to the level of scrutiny certifiers apply to reviews of food contact substances. Some certifiers require listing all the food contact substances and others may not.

Given all of the above information the below options are being presented. These are essentially the same options that were included in the Spring 2021 proposal.

Option 1: Resins do not need to be listed

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

However, since resins are currently being used in organic production this is the least impactful option.

Option 2: Require listing of Resins – Categorically

An alternative to allowing all resins without review would be to create a listing on the National List that includes all resins used in ion exchange filtration (similar to other broad categories on the List). Petitions to the NOSB could be used to annotate this broad listing to exclude problematic resins. This process, however, puts the onus on stakeholders to recognize which resins are being used and to act to exclude particular resins. A petition to remove a resin by annotation takes considerable time and forces the petitioner to provide documentation as to how the resin does not comply with OFPA. While this process is in action the resin would continue to be used. This is opposite the more normal procedures of the NOSB whereby the burden is put on the petitioner to document why something should be added to the List and that substance is not allowed to be used until it is added. In the past, removal of substances already being used from the National List becomes difficult due to economic impacts of that removal.

Option 3: Require listing of Resins – Individually

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

Requiring the listing of these resins could cause significant economic impact and disruption of current organic supply chains.

Questions to Stakeholders

1. Has there been new information since the NOP policy statement from December 2002, that would indicate a change in policy position about what types of substances are required to be listed on the National List in accordance with OFPA?
2. Does the fact that resins are listed by FDA as a food contact substance exempt these materials from needing to be reviewed by the NOSB and placed on the National List? If so, why?
3. Does the fact that since resins are listed as a secondary food additive, regardless of their listing as a food contact substance place them under the purview of OFPA and therefore need to appear on the National List. If so, why?
4. How and to what extent do resins degrade? Does the degradation occur during the recharge process or during the food filtration process?

5. Which option listed above (Options 1-3) would you choose and why?
6. Is there another option the NOSB should consider in regard to resins?

Subcommittee vote
Motion to accept the discussion document on ion exchange - resins.
Motion by: Kyla Smith
Seconded by: Mindee Jeffery
Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Sunset 2024
Meeting 2 - Review
Handling Substances § 205.605(a), § 205.605(b), § 205.606
October 2022

Introduction
As part of the [Sunset Process](), the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are scheduled for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list.

Request for Comments
Written public comments will be accepted through September 29, 2022 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review, which demonstrated that the substances were: (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.

§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)).’’:

- Attapulgite
- Bentonite
- Diatomaceous earth
- Magnesium chloride
- Nitrogen
- Sodium carbonate

§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)).’’:

- Acidified sodium chlorite
- Carbon dioxide
- Sodium phosphates

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

- Casings
- Pectin
- Potassium acid tartrate

Attapulgite

Reference: §205.605(a) *Nonsynthetics allowed:*

Attapulgite—as a processing aid in the handling of plant and animal oils.

Technical Report: 2010 TR.
Petition: 2009.
Past NOSB Actions: 4/2011 recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use

Attapulgite is used as a natural bleaching clay for the purification of vegetable and animal oils. The function of a bleaching clay is to remove undesirable by-products (impurities) for the vegetable oil and animal fat, thus improving the appearance, flavor, taste, and stability of the final product.

Manufacture

Attapulgus is the principal mineral of attapulgus clay, which is surface mined by open-pit method with stripping by scrapers, draglines, or bulldozers and extraction by shovels, backhoes, small draglines, or front-end loaders. The clay is then loaded onto trucks and transported to the processing plant. The clay is then dried, milled, and sieved to obtain a desired range of particle sizes [TR 143-146].

International Acceptance

Note: In the United States, the term attapulgite is used in place of palygorskite; however, the International Nomenclature Committee determined that palygorskite is the preferred name.

Canadian General Standards Board Permitted Substances List
Canadian Food Inspection Agency, Feed Program— Schedule IV of the Feeds Regulations, 1983, lists ingredients approved for use as livestock feed. Attapulgite clay (Schedule IV Number 8.111) is listed under Class 8. Miscellaneous Product of the Feeds Regulations. It stated, —Attapulgite clay (IFN6 8-14-008) is hydrated aluminum-magnesium silica, a naturally occurring mineral mined in Attapulgus, Georgia… It shall be labeled with the following statement: This product is for use in non-medicated feeds only as an anticaking agent or pelleting aid in an amount not to exceed 0.25% of the finished feed or as an emulsifier in liquid feed supplements at a level not to exceed 2.5% of the supplement.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Regulation (EC) 1831/2003— —Attapulgite (clay) CAS No. 12174-11-7‖, under silage additives functional group, listed in Community Register of Feed Additives. The date of first entry in the Register is July 11, 2005.

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
Attapulgite/palygorskite is not specifically listed.

Japan Agricultural Standard (JAS) for Organic Production
Attapulgite/palygorskite is not specifically listed.

Environmental Issues
Attapulgite is surface mined, and, in most countries, the mining company is required by law to reclaim the land. Common practice is to open a cut, mine the clay, and then spoil the overburden from the next cut into the mined-out area. The spoil is leveled or sloped to meet the standards prescribed by the government, and grasses and/or trees are planted. Sometimes the topsoil is put back on top of the spoil and is used for agriculture. The major environmental issue is air quality from the dust generated during manufacture, use, or disposal. Repeated or prolonged inhalation of dust may cause delayed lung injury.

Discussion
During the Spring 2022 meeting commentors brought forward a couple concerns regarding the listing of attapulgite. As listed, only non-synthetic forms of attapulgite should be used at 205.605(a). Attapulgite that is acid-activated, which is treated with sulfuric or hydrochloric acid, should be listed at 205.605(b) if allowed. Without clarity, certifiers may be inconsistent with allowing certain forms of attapulgite. One certifying agency responded that they do verify that attapulgite is not acid-leaching, acid-activated, or acid-treated and prohibits the synthetic form. There were a few requests by commenters to annotate the listing. The Handling Subcommittee acknowledges that only non-synthetic forms should be used, as allowed by the listing.

A couple commenters said that the material does not appear to be in widespread use and may not be necessary for the industry especially as both bentonite and kaolin are also approved as effective non-synthetic bleaching agents. The Board did not receive public comments from stakeholders currently using attapulgite. One Subcommittee member cast a vote to remove the material based on this discussion.

Based on this review and public comment, the Handling Subcommittee finds attapulgite compliant with OFPA criteria.

Justification for Vote
The Subcommittee finds attapulgite compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote
Motion to remove attapulgite from the National List
Motion by: Kim Huseman
Seconded by: Mindee Jeffery
Yes: 1 No: 6 Abstain: 0 Recuse: 0 Absent: 1

Bentonite

Reference: §205.605(a) *Nonsynthetics allowed:*
Bentonite.
Technical Report: 1995 TAP.
Petition: N/A
Past NOSB Actions: 4/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use

Bentonite is used as a processing aid, not an ingredient. Its adsorptive qualities make it useful for removing impurities in edible oils like soy, palm, and canola. It can also be used to clarify beer, fruit juice, wine, sugar, and honey and is not present in the final product.

Manufacture

It is a naturally occurring porous rock of clay materials that derives from weathered volcanic ash. It is mined and thus subject to environmental mitigation and monitoring by other agencies. It is a fine white to yellowish white or graphic aluminum silicate clay with limited shrink-swell features. It darkens and takes on a distinct clayey smell in the presence of liquid. It is insoluble in water, alcohol, dilute acids, and alkali solutions.

International Acceptance

Canadian General Standards Board Permitted Substances List
The material is allowed in food handling.

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

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
The material is allowed in food handling.

International Federation of Organic Agriculture Movements (IFOAM) Norms
The material is not listed.

Japan Agricultural Standard (JAS) for Organic Production
The material is not listed as a food handling aid.

Environmental Issues

While mining activities are regulated by other agencies, bentonite does derive from mining activities, which do produce negative impacts by definition.

It is generally regarded as safe (GRAS) and does not produce human toxicity, although if consumed in large quantities, particularly during pregnancy, can produce iron deficiency.

Historically, there has been strong public support for the continued use of bentonite.

Discussion

The Handling Subcommittee discussed the longstanding support for keeping bentonite on the National List for this use. At the same time, the Subcommittee did note the similarity of bentonite as a food processing aid to other listed substances (for example, diatomaceous earth) and indicated a desire to understand more fully how, why, and to what extent the material is being used in organic applications.

The Subcommittee continues to seek public comment to specifically address the ongoing need for bentonite, given other similar (although perhaps not identical) substances.

During the Spring 2022 meeting commenters expressed specific but limited issues regarding the listing of bentonite, that were similar to those conveyed about attapulgite. Commenters maintain that, as listed, only non-synthetic forms of bentonite should be used at §205.605(a) and that acid-activated bentonite, which is treated with sulfuric or hydrochloric acid, should be listed at §205.605(b) if allowed. Without clarity, certifiers may be inconsistent with allowing certain forms of bentonite, which could be remedied with clarity provided by an annotation, as some commenters requested. The Handling Subcommittee acknowledges that only non-synthetic forms should be used, as allowed by the listing.

Justification for Vote
Based on the Subcommittee review and public comment, the Handling Subcommittee finds bentonite compliant with OFPA criteria, and does not recommend removal from the National List.

Subcommittee Vote
Motion to remove bentonite from the National List
Motion by: Wood Turner
Seconded by: Mindee Jeffery
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

Diatomaceous earth

Reference: §205.605(a) *Nonsynthetics allowed:*
Diatomaceous earth—food filtering aid only.
Technical Report: 1995 TAP.
Petition: N/A
Past NOSB Actions: 4/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use
Used as a filtering aid in food production of syrups, juices, beer, beverages, and other products.

Manufacture
Diatomaceous earth is made from the fossilized remains of diatoms, whose skeletons are made of a natural substance called silica. Diatoms accumulate in the sediment of rivers, streams, lakes, and oceans, and diatomaceous earth is mined in quarries or open-pits.

International Acceptance
Diatomaceous earth is permitted for use in organic processing by:
International Federation of Organic Agriculture Movements (IFOAM) Norms,

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

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

Unsure if it is allowed by [Canadian General Standards Board Permitted Substances List or Japan Agricultural Standard (JAS) for Organic Production]

Environmental Issues
Dust produced during processing can be a human health concern for workers and would be subject to OSHA requirements (1995 TAP pg. 5). Waste material can, in some states, be considered a hazardous waste requiring special disposal requirements (1995 TAP pg. 5). The 1995 Technical Advisory Panel was made up of three people. One TAP reviewer expressed concern for possible concentrations of mercury, lead, cadmium, arsenic, thallium, and antimony and the need to verify "food grade" quality of diatomaceous earth.

Discussion
The NOSB reviewed diatomaceous earth (DE) in November 2005, April 2010, and October 2015, and recommended relisting each time. Diatomaceous earth does not exist within the final organic product and is classified as a processing aid and not an ingredient. At the Spring 2022 NOSB meeting, numerous stakeholders expressed strong support for the relisting of DE as a filtering aid in the production of organic food. The use of filter aids is necessary to help remove insoluble materials from finished products to ensure consistent quality. One commentor mentioned that stakeholders have experimented manufacturing with and without the use of filter aids and cannot guarantee quality without their use. Stakeholders have also experimented with alternatives to DE, such as using organic rice hulls or cellulose as filter aids, but none have been successful in application. For example, when using organic rice hulls instead of DE, the resulting product contained insoluble materials, in addition to changing the color from colorless to amber which was not acceptable to meet quality standards or customer expectations. A couple commentors suggested the need to review the impact of mining activities, although no new information was provided regarding mining concerns. Diatomaceous earth was found to satisfy the OFPA evaluation criteria in previous reviews.

Justification for Vote
The Subcommittee finds diatomaceous earth compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote
Motion to remove diatomaceous earth from the National List
Motion by: Kim Huseman
Seconded by: Mindee Jeffery
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Magnesium chloride

Reference: §205.605(a) *Nonsynthetics allowed:*
Magnesium chloride.
Technical Report: 1995 TAP; 2016 TR.
Petition: N/A
Past NOSB Actions: 10/1995 minutes and vote; 10/1999 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.

Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577); Classification change from synthetic to nonsynthetic effective 11/22/2019 (85 FR 56673).
Sunset Date: 11/22/2024

Subcommittee Review

Use
Magnesium chloride is used in organic food processing as a processing aid, used in tofu production as a coagulant/firming agent, and used in certified organic dietary supplements. It can also be used to dress cotton fibers, or as a color retention agent and as a source of essential mineral magnesium in infant formula.

The EPA regulates magnesium chloride as a pesticide on List D, pesticides of less concern (EPA 1998). Magnesium chloride has also been used to treat bovine hypomagnesemia (low blood magnesium levels).

Manufacture
Natural commercial sources of magnesium chloride can be classified as: (a) sea water; (b) terminal lake brines; (c) subsurface brine deposits; and (d) mineral ore deposits. Magnesium chloride produced from each of these natural sources is the product of a brine comprising soluble ions of various mineral elements, primarily sodium, potassium, magnesium, calcium, chloride, and sulfate (TR 2016, 186-189).

(a) Sea Water

Sea water is processed in solar ponds to produce concentrated brines from which specific minerals crystallize and are recovered. These specific minerals, called “evaporites,” crystallize in a sequence based on the concentrations of anions and cations in the brine and their innate solubility in water (TR 192-194).

(b) Terminal lake brines

A terminal lake is a lake where water is flowing in, but no water flows out, so that the dissolved salts concentrate and form brine as the water evaporates. The Great Salt Lake in Utah is a familiar example. Great Salt Lake brine is the primary source of magnesium chloride in North America. The Great Salt Lake contains sodium-magnesium-chloride-sulfate brine with low alkalinity (Domagalski, Orem, and Eugester 1989). Like solarization of seawater, the first evaporite of Great Salt Lake brine to form is halite (sodium chloride), followed by schoenite (magnesium-potassium sulfate), kainite (potassium chloride-magnesium sulfate double salt), and carnallite (potassium-magnesium chloride), resulting in a magnesium chloride brine (Neitzel 1971). Evaporating the water in this magnesium chloride brine creates crude solid magnesium chloride (TR 2016, 221-234).

(c) Subsurface brine deposits

Brine deposits in Midland, Michigan, have been a source of magnesium chloride since the 1890s. The Dow company originally obtained its bromine, chlorine, sodium, calcium, and magnesium from the brine of ancient seas under Midland (TR 2016, 264-266).

(d) Mined mineral deposits

The two major mined mineral sources of magnesium chloride are bischofite and carnallite, both of which were formed during prehistoric solar evaporation of sea water (Butts 2004). Solution mining of these ore bodies creates a brine that is processed on the surface. Water is pumped into the ore body to dissolve these soluble minerals, forming a brine which is pumped to the surface. Most of the patented processes for purification and concentration of these brines rely on water and evaporation, without any additional chemicals However, because magnesium chloride is soluble in alcohol while potassium chloride is not, several patented processes for separating pure magnesium chloride from carnallite employ a low molecular weight alcohol, such as methanol, to recover pure magnesium chloride (TR 2016, 291-297).

Synthesis of magnesium chloride by the reaction of a magnesium compound such as the oxide, hydroxide, or carbonate with hydrochloric acid is a chemical process, which involves chemical reaction of an acid and an alkali to form a salt. (TR 2016, 340-342).

GRAS: Magnesium chloride hexahydrate is affirmed by the FDA as Generally Recognized As Safe (GRAS) as a food ingredient (21 CFR 184.1426). It is allowed by the FDA as a flavoring agent, adjuvant, nutrient supplement, and may be used in infant formula (TR 2016, 94-96).

Ancillary substances: Magnesium chloride hexahydrate is commercially available as colorless, odorless flakes, crystals, granules, or lumps. Both JECFA and FCC require that the material assays at 99% to 105% $MgCl_2 \cdot 6H_2O$. Commercial sources contain no additional or ancillary ingredients (e.g., inert ingredients, stabilizers, preservatives, carriers, anti-caking agents or other materials) (TR 2016, 110- 113).

International Acceptance

Canadian General Standards Board Permitted Substances List

Magnesium chloride is a permitted processing substance listed in CAN/CGSB-32.311-2015, Table 6.3, "ingredients classified as food additives," with the annotation, "derived from seawater."

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

The European Community regulation permits the use of the magnesium chloride (or "nigari") in processing organic foods of plant origin as a coagulation agent (EC No. 889/2008 Annex VIII, Section B – Processing Aids).

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

The Codex organic guidelines permit the use of magnesium chloride (INS 511) in food category 06.8, soybean products (excluding soybean products of food category 12.9 and fermented soybean products of food category 12.10); food category 12.9.1, soybean protein products; and food category 12.10, fermented soybean products

International Federation of Organic Agriculture Movements (IFOAM) Norms

The IFOAM Norms, Appendix 4, Table 1, permit the use of magnesium chloride (INS 511) as an additive and also as a processing and post-harvest handling aid for soybean products only.

Japan Agricultural Standard (JAS) for Organic Production

Article 4, Table 1, Food Additives permits the use of food additive INS 511, magnesium chloride, and also "crude seawater magnesium chloride," for processed foods of plant origin as a coagulating agent or for processed bean products.

Environmental Issues

The historical process of solar evaporation of sea water to obtain salt and additional minerals such as magnesium chloride creates saline ponds and infertile soil. Solar salt ponds have been reused for several millennia in the Eastern Mediterranean so that the environmental damage is localized. With respect to terminal lakes such as the Great Salt Lake, the major environmental threat here is not related to mineral extraction operations; it is the reduction of water flow into this terminal lake caused by agricultural and other diversions (Wurtsbaugh et al. 2016). Winds blowing over dry lake beds cause dust storms and urban pollution. An environmental risk with solution mining is surface subsidence, as the underlying mineral is dissolved and removed, effectively creating a cavern. (TR 414-423).

Discussion

Magnesium chloride is currently allowed under the USDA organic regulations at 7 CFR 205.605(a) as a nonagricultural nonsynthetic substance for use as an ingredient in or on processed products labeled "organic" or "made with organic (specified ingredients or food group(s))." Magnesium chloride was previously listed at §205.605(b) with the annotation "derived from sea water." However, during the Spring 2018, the Board put forth a proposal to reclassify magnesium chloride as non-synthetic and to remove the annotation "derived from sea water" since there are multiple sources from which non-synthetic magnesium chloride can be derived. This proposal passed unanimously, went through the rulemaking process, and became effective on November 22, 2019.

During the Spring 2022 meeting, most if not all commenters were in favor of relisting. However, several commenters suggested annotating to limit the use to tofu production and dietary supplements. Similar comments were made during previous sunset reviews. We didn't receive direct answers to the questions posed for the Spring 2022 meeting, however, based on the comments suggesting an annotation to limit the use, it might be inferred that those comments indicate that perhaps the use of color enhancement is not consistent with organic principles. The Handling Subcommittee will evaluate this annotation change suggestion as a potential work agenda item.

We also didn't receive comments on our question regarding other substances on the National List (e.g., glucono delta-lactone and calcium sulfate) and whether they perform the same or similar function in tofu production. The Subcommittee is still interested in this information.

Justification for Vote

Based on this review and public comment submitted during the Spring 2022 meeting, the Handling Subcommittee finds magnesium chloride compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote

Motion to remove magnesium chloride from the National List
Motion by: Kyla Smith
Seconded by: Allison Johnson
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

Nitrogen

Reference: §205.605(a) *Nonsynthetics allowed:*

Nitrogen—oil-free grades.

Technical Report: 1995 TAP.
Petition: N/A
Past NOSB Actions: 4/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use
Nitrogen is used to displace oxygen and thereby reduce oxidation of product during processing, storage, and packaging. It can be used in the flash freezing of foods. It also functions as a propellant when used under pressure and doesn't have ozone-depleting properties.

Manufacture
Nitrogen is a colorless, odorless gas. Cryogenic distillation, where air is compressed, cooled, and then filtered, is the most economic and highest purity method for separating nitrogen from air.

International Acceptance
The use of nitrogen is permitted in organic processing in Canada, CODEX, EU, IFOAM, and Japan.

Canadian General Standards Board Permitted Substances List
The material is allowed in food handling.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
The material is allowed in food handling.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
The material is allowed in food handling.

International Federation of Organic Agriculture Movements (IFOAM) Norms
The material is allowed in food handling.

Japan Agricultural Standard (JAS) for Organic Production
The material is allowed in food handling.

Environmental Issues
None. Nitrogen is a naturally occurring inert atmospheric gas.

Discussion
During the spring 2022 meeting, all commenters expressed support in relisting.

Based on this review and public comment submitted during the spring 2022 meeting, the Handling Subcommittee finds nitrogen compliant with OFPA criteria.

Justification for Vote

The Subcommittee finds nitrogen compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote

Motion to remove nitrogen from the National List
Motion by: Kyla Smith
Seconded by: Allison Johnson
Yes: 0   No: 5 Abstain: 0   Recuse: 0 Absent: 3

Sodium carbonate

Reference: §205.605(a) *Nonsynthetics allowed:*
Sodium carbonate.
Technical Report: 1995 TAP.
Petition: N/A
Past NOSB Actions: 4/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use

Sodium carbonate is used as a raising (leavening) agent. Sodium carbonate (also referred to as washing soda or soda ash) can also be used as an anti-caking agent, as an acidity regulator, or as a stabilizer, as well as a neutralizer for butter, cream, fluid milk, and ice cream. Sodium carbonate is the material used to give pretzels and lye rolls their brown crust without burning. Sodium carbonate is also used in the processing of olives prior to canning, in the making of ramen noodles, and in cocoa products.

Manufacture

Sodium carbonate is produced in North America from natural deposits of trona ore (sodium sesquicarbonate) that is heated and then mixed with water to dissolve the soda ash and separate out the impurities. This solution is then concentrated by evaporation to crystallization. This method is considered to be the most sustainable form of producing sodium carbonate. Additionally, in California, sodium carbonate can be produced from a similar method using natural brine (Searles Lake).

International Acceptance

Sodium carbonate is permitted for use in organic processing in the following International Standards:

International Federation of Organic Agriculture Movements (IFOAM) Norms,

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

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

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

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

Ancillary Substances
None

Discussion
Public comments during prior sunset reviews have stated that sodium carbonate is essential for use as a leavening agent, neutralizer in baked goods, frozen desserts, and soy base extraction. It is also used as a pH adjuster in organic laundry detergents. One certifier commented that it is also used to clean fruit and remove mold. Past public comments have been supportive of sodium carbonate remaining on the National List. Prior comments have raised concerns about possible hazards during mining and manufacturing and requested a technical report to evaluate the synthetic/non synthetic status of this material, essentiality, and research potential alternatives.
During the spring 2022 NOSB meeting, most commenters were in favor of relisting of Sodium carbonate as this is an important tool for producers. Stakeholders supporting relisting of this material included three trade groups, a farmer group, and a manufacturer. One trade group, a material review organization, and several certifiers submitted data on the number of users who list this material on their organic system plans. This material is essential for organic handling and processing and there are no alternatives available that can replace sodium carbonate. Removal of any materials allowed for cleaning can be problematic.

According to the TAP review, sodium carbonate may be produced from mined deposits or by chemical reaction (Solvay process). In written submissions for the Spring 2022 NOSB meeting, a certifier commented:

Based on the original 1995 TAP Reviews, the reviewers considered sodium carbonate produced via the Trona process to be non-synthetic and that produced via the Solvay process to be synthetic. However, based on NOP Guidance 5033-1, it appears that both processes result in a synthetic classification for the sodium carbonate. QAI currently permits sodium carbonate produced via the Trona process based on 1995 TAP Review, but encourages the NOSB to examine the prevalent manufacturing processes to ensure appropriate classification and/or annotation. It appears sodium carbonate would be more appropriately listed at 205.605(b) with an annotation to only permit forms produced via the Trona process.

The Handling Subcommittee will evaluate this as a future work agenda item.

Questions to our Stakeholders

1. Is this material still essential for organic handling and processing?
2. Are there alternative materials that can replace sodium carbonate?
3. What are the relative environmental impacts of trona mining or brine extraction during production of sodium carbonate?
4. Is sodium carbonate produced from trona or brine extraction non-synthetic?

Justification for Vote
The Subcommittee finds that sodium carbonate continues to be compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote:
Motion to remove sodium carbonate from the National List
Motion by: Dilip Nandwani
Seconded by: Kyla Smith
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

Acidified sodium chlorite

Reference: §205.605(b) *Synthetics allowed:*
Acidified sodium chlorite—Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.
Technical Report: 2008 TAP; 2013 TR (livestock).
Petition: 2006.
Past NOSB Actions: 2009 recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use
Acidified sodium chlorite (ASC) solution is used as a processing aid in wash and/or rinse water, in accordance with the FDA limitation, for direct food contact and indirect food contact:
- Direct Food Contact (Secondary Direct Food Additive) – Poultry carcass, organs, and parts; red meat carcass, organs and parts, seafood (finfish and crustaceans), and fruits and vegetables (raw and further processed); processed, comminuted, or formed meat products; and
- Indirect Food Contact – Hard surface food contact sanitation.

Manufacture
ASC solutions are made on-site and on-demand by mixing a solution of sodium chlorite with natural citric acid. Sodium chlorite (25%) and citric acid (50%) solutions are stored separately in bulk on site. Both solutions are pumped by proportional pumps and a water dilution module to make the final use dilution product, which typically contains 0.1% sodium chlorite and 0.6% citric acid and 99.3% water. Sodium chlorite is made by the reduction of chlorine dioxide, which is, in turn, from the reduction of sodium chlorate in the presence of sulfuric and hydrogen peroxide or sulfuric acid and sodium chloride. The resulting solution may be dried to a solid and the sodium chlorite content may be adjusted to about 80% by the addition of sodium chloride, sodium sulfate, or sodium carbonate. Sodium chlorite is marketed as a solid or an aqueous solution (such as 25% by weight).
The acid used to acidify sodium chlorite is natural citric acid, which was specified in the [year?] petition. However, there was no information in the petition regarding how the natural citric acid was manufactured.

International Acceptance
Canadian General Standards Board Permitted Substances List
Acidified sodium chlorite is not specifically listed.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
There is no specific listing for acidified sodium chlorite in handling.

[CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)]
There is no specific listing for acidified sodium chlorite in handling.

[International Federation of Organic Agriculture Movements (IFOAM) Norms]
There is no specific listing for acidified sodium chlorite in handling.

[Japan Agricultural Standard (JAS) for Organic Production]
Limited to the use for disinfecting meat and poultry at slaughter, or washing eggs.

Environmental Issues
While the manufacture and use of acidified sodium chlorite solutions have resulted in releases to the environment, the risk of environmental contamination from released acidified sodium chlorite is minimal. Certain manufacturing facilities have reported releases of chlorine dioxide, a portion of which was generated through reaction of chlorite with a strong acid, to air, water, and soil (ATSDR, 2004). Strong acids (e.g., hydrochloric acid) and bases (sodium hydroxide) are used in the commercial production of sodium chlorite, and their release due to improper handling/disposal could lead to serious environmental impairments. Likewise, the release of strong oxidizing agents in large quantities may lead to ecotoxicity in both terrestrial and aquatic environments. This is true of both the chemical feedstocks (e.g., hydrogen peroxide) used in the manufacture of acidified sodium chlorite precursors and the chemicals in acidified sodium chlorite solutions (i.e., chlorous acid, chlorine dioxide, chlorite). Regarding the former, several lower reactivity sulfur-containing and carbonaceous substances have been evaluated for the conversion of chlorine dioxide to sodium chlorite.

The acid used to acidify sodium chlorite is natural citric acid. The petitioner did not provide information about how natural citric acid is manufactured.

Discussion
In the 2017 sunset review, public comment regarding acidified sodium chlorite was mixed. Those in favor stated that this is an essential tool in the fight against food borne pathogens. Those opposed to relisting stated that the NOSB should do a comprehensive review of sanitizers. The NOSB believes a review of sanitizers is beyond the scope of the sunset review process.

In the 2022 sunset review, there were few comments on this material. A couple of commenters reminded the NOSB about the need for an overall review of sanitizers as a class, but no specific objections were raised regarding this product. Use of acidified sodium chlorite is not widespread, and delisting was not recommended by any commenters.

Justification for Vote
The Subcommittee finds acidified sodium chlorite (ASC) compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote
Motion to remove acidified sodium chlorite (ASC) from the National List.
Motion by: Carolyn Dimitri
Seconded by: Kyla Smith
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

Carbon dioxide

Reference: §205.605(b) *Synthetics allowed:*
Carbon dioxide.
Technical Report: 1995 TAP; 2006 TAP.
Petition: 2005.
Past NOSB Actions: 10/1995 minutes and vote; 2007 recommendation; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use
Carbon dioxide is used in modified atmosphere packaging, modified atmospheric storage, the freezing of foods, beverage carbonation, as an extracting agent, and for pest control in grain and produce storage.

Manufacture
Carbon dioxide is available in limited supplies from underground wells and as a byproduct of various manufacturing processes. All of the processes require purification of carbon dioxide before being used in food processing and handling.

International Acceptance
Canadian General Standards Board Permitted Substances List
Carbonation of wine or mead is prohibited. Carbon dioxide is allowed for controlled atmosphere storage and for pest control during storage.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Carbon dioxide is listed as an allowable processing aid for ingredients of agricultural origin from organic production.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Carbon dioxide is allowed for use as a pest control method in storage facilities and as a processing aid.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Carbon dioxide is approved as a processing and post-harvest handling aid (for flavoring agents, e.g.). It is also approved as an additive.

Japan Agricultural Standard (JAS) for Organic Production
Carbon dioxide is approved for use a fumigant in storage facilities.

Environmental Issues
According to the 2006 TAP report, the production of carbon dioxide is a byproduct of environmentally damaging processes via air pollution, solid waste streams, and drilling underground wells.

Carbon dioxide is a greenhouse gas and its use in organic food production means there may be a delayed release to the atmosphere in some cases.

Discussion
Carbon dioxide is on the FDA list of generally recognized as safe (GRAS) products. The EPA allows carbon dioxide for use as a fumigant, insecticide, and rodenticide.

In the previous [year?] sunset review, there was no substantive discussion about this material. No public comment supported delisting carbon dioxide. There was support for its continued use by food manufacturers and associations.

Response to the questions posed to stakeholders
Questions posed: Is the substance essential for organic food production? Since the material was last reviewed, have additional commercially available alternatives emerged?

Response summary: In the comments for the April 2022 meeting, only a few comments were made on this material. The commenters indicated that carbon dioxide is essential for organic handling and there were no available organic alternatives. Loss of this product would be problematic for those using it.

Justification for Vote
The Subcommittee finds carbon dioxide compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote
Motion to remove carbon dioxide from the National List
Motion by: Carolyn Dimitri
Seconded by: Kim Huseman
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

Sodium phosphates

Reference: §205.605(b) *Synthetics allowed:*
Sodium phosphates—for use only in dairy foods.
Technical Report: 2001 TAP; 2016 TR (phosphates).
Petition: 2001.
Past NOSB Actions: 10/1995 minutes and vote; 10/2001 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use
Sodium phosphates are salts used as pH control agents and buffers, acidulants, sequestrants, texturizers, and nutrients in organic dairy products. They act as stabilizers in milk and as emulsifiers in cheese. Disodium phosphate can be used as a processing agent in heavy whipping cream, where it binds to milk minerals to prevent the milk from coating the equipment during processing. Sodium phosphates are used in some organic milk products, such as half-and-half and heavy whipping cream, to stabilize the milk protein and to ensure the products do not separate or lose protein prior to consumer use.

Sodium phosphates are generally recognized as safe (GRAS) across multiple regulatory entities.

Manufacture
Finely ground, mined phosphate rock is mixed with sulfuric acid to form phosphoric acid. It is then reacted with sodium hydroxide to form sodium phosphate. There is a purification step in each reaction to remove substances like arsenic and fluorine.

International Acceptance
Canadian General Standards Board Permitted Substances List
Permitted for dairy use only.

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

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

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

Japan Agricultural Standard (JAS) for Organic Production
Not listed.

Environmental Issues
Phosphates, including sodium phosphates, can pollute water bodies and lead to eutrophication and there have been global efforts to remove phosphates from detergents. That said, there is no widespread concern about adverse impacts of these substances in food uses (specifically dairy) on the environment.

Also, since sodium phosphates derive from the mining of phosphate rock, there are environmental impacts associated with the manufacture.

Discussion
Public comment regarding sodium phosphates has historically been mixed. During the previous sunset review, stakeholders in support of the material's use in organics stated that sodium phosphate is essential in organic cheese products, including liquid and powdered forms, specifically as an emulsifier and stabilizer for shelf-stable cheese products. Opposing stakeholders have expressed concern about potential human health impacts (the 2016 technical report was inconclusive) and material essentiality. Prior subcommittee review concluded that since there are four phosphates on the National List at § 205.605(b), no single phosphate food additive or ingredient can be implicated for inordinate and isolated risk. Some studies have indicated that high levels of phosphate consumption can accelerate aging and vascular damage, although sodium phosphate itself also has use among athletes for performance enhancement.

Comments from stakeholders in written and verbal form at the Spring 2022 NOSB meeting were limited and did not advance a strong position in favor of removal from the National List. While the Handling Subcommittee is reiterating its stakeholder questions for the coming meeting, it does not expect to recommend removal of sodium phosphates at this time.

Questions to our Stakeholders

1. How essential are sodium phosphates to your operations or the operations of your stakeholders? Are there other natural substances or synthetic substances on the National List that could perform the same essential functions as sodium phosphates?
2. Do you have any new and compelling evidence that demonstrates health impacts from sodium phosphates are significant?

Justification for Vote

The Subcommittee finds sodium phosphates compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote

Motion to remove sodium phosphates from the National List
Motion by: Wood Turner
Seconded by: Kim Huseman
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

Casings

Reference: §205.606(b) Casings, from processed intestines.
Technical Report: N/A
Petition: 2006
Past NOSB Actions: 4/2007 recommendation; 10/2010 sunset recommendation; 10/2015 sunset review.
Recent Regulatory Background: Added to National List on 06/21/2007 (72 FR 35137); Sunset renewal notice 03/21/2017 (82 FR 14420); Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use

The intestines of beef, lamb, and pork are used to make natural casings for sausage. The alternative material for casings is synthetic cellulose or synthetic collagen.

Casings have not received a Generally Recognized as Safe (GRAS) status, according to the 2019 Technical Report (TR).

Manufacture

Intestines are washed in pure water with no chemicals, and salted using sodium chloride (NaCl) and water. No other ingredients or processing aids are used. Animal intestines may be from organic or nonorganic animals as slaughterhouses do not separate certified organic and non-organic offal.

International Standards

Canadian General Standards Board Permitted Substances List
Collagen casings are allowed for poultry sausages

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

Environmental Issues
There are no published reports of heavy metals and other contaminants present in formulations of collagen gel and casings. According to the TR, there are no published studies on environmental impacts of casings, but "the manufacture of collagen may result in reductions to livestock and fish wastes".

Discussion
Since 2007, all sunset reviews of this material have considered limitations on the availability of casings produced from organically raised livestock and agreed that the current listing is appropriate. Echoing earlier comments, commenters at the Spring 2017 meeting raised concerns about the limited availability of organically produced casing material. Comments were in favor of retaining use of non-organically produced casings as an option for production of organic sausage meat. Concerns were raised about the need to incentivize production of organic casings but that was viewed as a long-term effort.

In Spring 2022, there was strong public support for the continued use of casings, with a few areas suggested for discussion. One group noted that non-organic casings rely on chemically intensive livestock production, which in turn relies on chemically intensive corn and soy production. This comment specifically asked NOSB (via TR process) to identify the barriers to organic casing production. Another group requested a work agenda item and a discussion document on the topic of organic casing; reasoning that if organic meat is being slaughtered, then organic casings exist and should be required. One certifier reflected that most organic sausage makers use cellulose as an alternative, but this does not meet consumer expectations.

Barriers to organic production of casing were well documented in one producer's comments. The extensive description included an overview of the scale of animal processing and the necessary infrastructure developments that would need to occur for intestines from organic hogs to be segregated at that stage of processing. Additionally, the producer's comments described the need for industrial infrastructure development that would have to occur in the final stages of processing to produce an organic casing.

Justification for Vote
The Subcommittee finds casings compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote
Motion to remove casings from the National List
Motion by: Mindee Jeffery
Seconded by: Kyla Smith
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Pectin

Reference: 205.606(o) Pectin (non-amidated forms only).
Technical Report: 1995 TAP; 2009 TR; 2010 TR (supplemental); 2015 Limited Scope TR.
Petition: 2005 (low methoxy).
Past NOSB Actions: 4/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

Use
Pectin is extracted from citrus and pome fruits but so far there is limited organic supply of extracted pectin. It is used as a gelling agent in jams, preserves, fillings and other products. It is a desirable ingredient in organic food because it allows food to gel with less sugar than would be used without it. Excess sugar has the potential for more negative human health effects than pectin.

Manufacture
The most common production of non-amidated pectin is by treatment of pectin-containing byproducts (pome fruit cores, citrus peels) with acidified water. Insoluble materials are filtered and removed, and the pectin is precipitated out with alcohol.

International Standards
Canadian General Standards Board Permitted Substances List
Compliant with the Canadian organic standards (both high and low methoxy allowed)

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Pectin allowed in all products but meat-based products

Japan Agricultural Standard (JAS) for Organic Production
Pectin allowed in all products but meat-based products

International Federation of Organic Agriculture Movements (IFOAM).
Unmodified forms only

Environmental Issues
According to the most recent Technical Report (TR), the FDA "suggest that the petitioned substance is not harmful to human health or the environment. Since the manufacture of pectin is a by-product of the fruit juice industry, its production therefore serves to reduce the waste streams generated from the making of fruit juices."

Ancillary Substances
Ancillary substances used in pectin as stabilizers/standardizing agents include sugar (and dextrose), and buffering agents trisodium citrate (or other salt buffers described in the 2015 TR).

Discussion
During the Spring 2022 sunset review, public comments submitted by organic manufacturers, trade associations, material suppliers and certifiers detailed pectin's extensive use and necessity in organic production. One commenter emphasized that pectin is routinely used as a stabilizer, a thickener and a gelling agent, and that organic alternatives are not available or do not function at the same quality. Comments from a trade association representing the pectin industry spoke to constraints in commercializing organic pectin due to commingled raw materials and the limited availability and functionality of organic pectin. Another commenter noted that pectin is essential to low sugar jams and there are no alternatives for that specific function at this time. A comment from an interest group stated pectin should be limited to high methoxyl pectin (HMP), extracted from citrus peel and apple pomace.

Overall, there is strong public support for the continued use of pectin. Previous Board discussion noted the desire for the development of greater supplies of organic pectin and noted the lack of commercial availability.

Justification for Vote
The Subcommittee finds pectin compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote
Motion to remove pectin from the National List
Motion by: Mindee Jeffery
Seconded by: Kyla Smith
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Potassium acid tartrate

Reference: §205.606(p) Potassium acid tartrate.
Technical Report: 1995 TAP; 2017 TR.
Petition: N/A
Past NOSB Actions: 10/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420); Classification changed from non-agricultural to agricultural 5/30/2019 (84 FR 18133).
Sunset Date: 5/30/2024

Subcommittee Review

Use
Potassium acid tartrate is a by-product of wine making. It is commonly known as Cream of Tartar. It is used in baked goods, a component of baking powder, for stabilizing egg whites or other food uses, pH control, and as an antimicrobial agent (TR 2017). A detailed discussion of the historical documents relevant to potassium acid tartrate is provided in the 2017 TR.

Potassium acid tartrate was previously allowed under the National Organic Program (NOP) regulations at 7 CFR 205.605(b) as a "nonagricultural, synthetic substance for use as an ingredient in or on processed products labeled "organic" or "made with organic (specified ingredients or food group(s))." However, during the 2017 sunset review, a number of commenters noted that it should be listed at § 205.606 as a non-organically produced agricultural substance. The NOSB agreed with this assessment and passed a recommendation for the change of listing. That recommendation underwent subsequent rulemaking and potassium acid tartrate is now listed under § 205.606.

Manufacture
During the winemaking process, sediments form that must be removed to produce a clear wine. "Lees" is the name of the sediment consisting of dead yeast cells, grape pulp, seed, and other grape matter that accumulates during fermentation. "Argol" and "tartar" are synonyms used to describe the crust that builds up in wine vats and casks. Argol is defined as crude potassium hydrogen tartrate, deposited as a crust on the sides of wine vats. Tartar is defined as a substance consisting essentially of cream of tartar that is derived from the juice of grapes and deposited in wine casks together with yeast and other suspended matter as a pale or dark reddish crust or sediment. Tartar consists of about 80% potassium acid tartrate. Potassium acid tartrate is only slightly soluble in cold water but highly soluble in hot water (6.1g/100 mL at 100°C). Extracting wine lees with hot water dissolves the potassium acid tartrate. When the filtered

extraction solution is cooled, potassium acid tartrate precipitates as very pure crystals (>99.5% pure). No other reagents or solvents are involved in the extraction (TR 2017, 58-69).

Potassium acid tartrate is Generally Recognized as Safe (GRAS) (TR 2017, 350).

Ancillary Substances
There are no ancillary substances associated with potassium acid tartrate.

International Use
According to the 2017 TR, international guidance and regulations include use of potassium acid tartrate (INS 336i) in organic processing and are generally consistent with the limited uses described by FDA at 21 CFR 184.1077(c). The European-focused regulations and guidance – CODEX, IFOAM and the EU – also include dipotassium tartrate (INS 336ii) as an allowed potassium tartrate.

Canadian General Standards Board Permitted Substances List
Potassium acid tartrate ($KC_4H_5O_6$) is a permitted processing substance listed in Table 6.3, ingredients classified as food additives, with the following annotation: "If the non-synthetic form is not commercially available, the synthetic form is permitted."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Consistent with the Codex guidelines, the European Community regulation permits the use of the potassium tartrates (i.e., both potassium acid tartrate E 336i and dipotassium tartrate E 336ii) in processing organic foods of plant origin (EC No. 889/2008 Annex VIII, Section A Food Additives).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
The Codex organic guidelines permit the use of potassium acid tartrate (INS 336i) and dipotassium tartrate (INS 336ii) in plant foods, specifically confectionary, flours and starches, and cakes, but not in animal foods.

International Federation of Organic Agriculture Movements (IFOAM) Norms
The IFOAM Norms, Appendix 4, Table 1, permit the use of INS 336 (i.e., both potassium acid tartrate E 336i and dipotassium tartrate E 336ii) as an additive and as a processing and post-harvest handling aid, without limitation.

Japan Agricultural Standard (JAS) for Organic Production
Article 4, Table 1, Food Additives permits the food additive INS 336i, potassium acid tartrate, for limited use for grain processed foods or confectionary only.

Environmental Issues
Since potassium acid tartrate is a byproduct of the winemaking process, the environmental issues are limited to those associated with the production of conventional grapes. There are increasing quantities of organically produced grapes and wines available.

Discussion
Public commenters confirmed that potassium acid tartrate is currently used as a pH adjuster in winemaking and in baked goods. Commenters largely supported relisting of this substance during the public sunset review process in 2022. One commenter supported removal because nonorganic potassium acid tartrate is a product of chemical-intensive agriculture.

No commenters identified any organic potassium acid tartrate in production or use or commented on its commercial availability. The labeling requirements for wine produced with organic grapes are likely to remain a barrier to commercial availability of organic potassium acid tartrate; production of "organic" wine (as opposed to wine “made with organic grapes”) remains relatively limited, and only potassium acid tartrate produced from “organic” wine production could be sold as organic potassium acid tartrate.

Questions to our Stakeholders

1. Is there currently any organic potassium acid tartrate on the market? If so, is it in sufficient quantities for commercial uses?

Justification for Vote

The Subcommittee finds that potassium acid tartrate continues to be compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) and is not proposing removal.

Subcommittee Vote

Motion to remove potassium acid tartrate from the National List
Motion by: Allison Johnson
Seconded by: Kyla Smith
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2