

FALL 2021 NOSB MEETING SUMMARY OF PROPOSALS & DISCUSSION DOCUMENTS

The fall 2021 National Organic Standards Board (NOSB) Meeting will be held October 19-21 via <u>live online webinar only</u> instead of in-person. The <u>Meeting Agenda</u> and <u>Meeting Packet</u> (all proposals, discussion documents, and sunset reviews to be considered at the meeting) are posted, and the public comment period is open. The deadline to submit written comments and/or sign up for oral comments is **Sept 30**th at midnight Eastern. The full Board will vote on the proposals at the meeting. Check out <u>OTA's NOSB Meeting Webpage</u> for more information.

PUBLIC COMMENT OPPORTUNITIES

WRITTEN COMMENTS may be submitted via Regulations.gov (Docket AMS-NOP-21-0038) by Sept 30th

ORAL COMMENTS (3-minute slot) may occur during one of two webinar sessions on October 13 & 14 between Noon – 5:00 pm Eastern. <u>Click here to register</u> **by Sept 30**th

AT-A-GLANCE LIST OF TOPICS [Use the PDF Bookmarks to Navigate Between Topics]

PROPOSALS (vote)

- Climate Change Letter letter to USDA about importance of organic agriculture as a climate solution
- Chitosan (Crops) petition to allow chitosan (from seafood shells) as plant disease control
- **Biochar (Crops)** petition to allow cow manure derived biochar as a soil amendment
- Ammonia Extract (Crops) petition to prohibit nonsynthetic ammonia extract fertilizer
- Kasugamycin (Crops) petition to allow kasugamycin (antibiotic) for fire blight control
- Hydronium (Crops) petition to allow it (sulfuric acid + calcium hydroxide) as a manure processing aid
- Carbon Dioxide (Crops) petition to allow as pH adjuster of irrigation water sources
- Lithothamnion (Crops) proposal to classify as nonagricultural and not eligible for wild crop certification
- Biodegradable Biobased Mulch (Crops) proposal to allow biodegradable mulches that are 80% biobased
- Sodium Nitrate (Crops) proposal to reinstate the restricted listing of sodium nitrate fertilizer
- Zein (Handling) petition to allow zein (corn protein) as food coating on organic foods
- Fish Oil Annotation (Handling) proposal to restrict sources of fish oil to minimize environmental harm
- **2023 Sunset Review (Crops, Livestock, Handling)** NOSB is will review **30 inputs** currently included on the National List of Allowed and Prohibited Substances to determine if the listing should expire by 2023
- **2021 Research Priorities** NOSB's annual list of research priorities for organic food and agriculture

DISCUSSION (no vote)

- **Oversight improvements to deter fraud** discussion about modernizing organic traceability technology
- **Excluded Methods** discussion about emerging technologies to be classified as excluded methods (prohibited)
- **Public Comment Process** discussion about the format of providing public oral comments for NOSB meeting



AT-A-GLANCE LIST OF SUBCOMMITTEE VOTES

PROPOSAL	SUBCOMMITTEE VOTE
Climate Change Letter	Motion to adopt the proposal: 7 Yes , 0 No.
Chitosan (CROPS)	To classify as synthetic: 8 Yes, 0 No.
	To allow at §205.601(j) for disease control: 4 Yes, 4 No.
Biochar (CROPS)	To classify as nonsynthetic: 8 Yes, 0 No.
	To add exemption "unless derived as part of the production of biochar from pyrolysis of cow manure" to the prohibition of manure ash at §205.602: 5 Yes , 3 No .
Ammonia Extract	To classify as nonsynthetic: 8 Yes, 0 No.
(CROPS)	To prohibit at §205.602: "Stripped Ammonia – created by separating, isolating and/or capturing ammonia or ammonium from an agricultural feedstock or other natural source using methods such as, but not limited to, steam stripping, pressurized air, heat, condensation, and/or distillation." 8 Yes, 0 No.
	To prohibit at §205.602: "Concentrated Ammonia – contains greater than 3% ammoniacal nitrogen and the total nitrogen content is predominately (i.e., >50%) in the ammonia or ammonium form." 7 Yes, 1 No.
	To add at §205.203(f): "Nitrogen products with a C:N ratio of 3:1 or less, including those that are components of a blended fertilizer formulation, are limited to a cumulative total use of 20% of crop needs." 7 Yes, 1 No.
Kasugamycin	To classify as synthetic: 8 Yes, 0 No.
(CROPS)	To allow at §205.601(j) for disease control: 0 Yes, 8 No.
Hydronium	To classify as synthetic: 8 Yes, 0 No.
(CROPS)	To allow at §205.601(j) as processing aid: 0 Yes, 8 No.
Carbon Dioxide	To classify as synthetic: 7 Yes, 0 No, 1 Absent.
(CROPS)	To allow at §205.601: 7 Yes, 0 No, 1 Absent.
Lithothamnion (CROPS)	To classify as a nonagricultural: 8 Yes, 0 No.
	<i>Lithothamnion</i> does not meet wild crop criteria and is not eligible to be certified to the wild crop standard: 8 Yes , 0 No.
Biodegradable Biobased Mulch (CROPS)	To add "at least 80%" biobased content to the definition of biodegradable biobased mulch film at §205.2: 7 Yes, 1 No.
Sodium Nitrate (CROPS)	To reinstate the listing of sodium nitrate at §205.602(g) as prohibited unless use is restricted to no more than 20 percent of the crop's total nitrogen requirement: 8 Yes, 0 No.
Zein (HANDLING)	To classify as nonsynthetic: 7 Yes , 0 No.
	To allow at §205.605(a) only for use in nutraceuticals or pharmaceuticals as a micro encapsulation acting as a moisture barrier and taste masker: 4 Yes , 3 No .
Fish Oil (HANDLING)	Motion to adopt the proposed restriction: "Sourced from fishing industry by-product only and certified as sustainable against a third-party certification that is International Social and Environmental Accreditation and Labeling (ISEAL) Code Compliant or Global Seafood Sustainability Initiative (GSSI) recognized." 6 Yes , 0 No, 1 Absent.
Research Priorities	Motion to adopt the proposal: 6 Yes, 0 No.



AT-A-GLANCE LIST OF SUBCOMMITTEE VOTES, CONT.

SUNSET REVIEW	SUBCOMMITTEE VOTE
Copper sulfate (CROPS) – algicide and tadpole shrimp control in aquatic rice systems	6 to relist, 2 to remove
Oxone gas (CROPS) – irrigation system cleaner	6 to relist, 0 to remove, 2 absent
Peracetic acid (CROPS) – disinfectant, disease control	8 to relist, 0 to remove
EPA List 3 Inerts (CROPS) – passive pheromone dispensers	7 to relist, 1 to remove
Chlorine materials (CROPS) – sanitizer, disinfectant	8 to relist, 0 to remove
Magnesium oxide (CROPS) – viscosity control in humates	8 to relist, 0 to remove
Calcium chloride (CROPS) – foliar spray for physiological disorders	8 to relist, 0 to remove
Rotenone (CROPS) – prohibited	8 to relist, 0 to remove
Agar-Agar (HANDLING) – gelling agent, emulsifier, thickener	7 to relist, 0 to remove
Animal enzymes (HANDLING) – catalysis for biological processes, e.g. cheesemaking	7 to relist, 0 to remove
Calcium sulfate (HANDLING) – tofu coagulant	6 to relist, 0 to remove, 1 absent
Carrageenan (HANDLING) – gelling agent, emulsifier, thickener	1 to relist, 5 to remove, 1 absent
Glucono delta-lactone (HANDLING) – tofu coagulant	5 to relist, 0 to remove, 2 absent
Tartaric acid (HANDLING) – acidulant	5 to relist, 0 to remove, 2 absent
Cellulose (HANDLING) – regenerative casings, anti-caking agent, filtering aid	6 to relist, 0 to remove, 1 absent
Chlorine materials (HANDLING) – sanitizer, disinfectant	6 to relist, 0 to remove, 1 absent
Potassium hydroxide (HANDLING) – pH adjuster	5 to relist, 0 to remove, 2 absent
Silicon dioxide (HANDLING) – defoamer	6 to relist, 0 to remove, 1 absent
Potassium lactate (HANDLING) – antimicrobial agent, pH regulator	7 to relist, 0 to remove
Sodium lactate (HANDLING) – antimicrobial agent, pH regulator	7 to relist, 0 to remove
Activated charcoal (LIVESTOCK) – adsorbent	3 to relist, 0 to remove, 2 absent
Calcium borogluconate (LIVESTOCK) – milk fever treatment	3 to relist, 0 to remove, 2 absent
Calcium propionate (LIVESTOCK) – milk fever treatment	4 to relist, 0 to remove, 1 absent
Chlorine materials (LIVESTOCK) – sanitizer, disinfectant	4 to relist, 0 to remove, 1 absent
Kaolin pectin (LIVESTOCK) – adsorbent, antidiarrheal, and gut protectant	4 to relist, 0 to remove, 1 absent
Mineral oil (LIVESTOCK) – intestinal compaction treatment	3 to relist, 0 to remove, 2 absent
Nutritive supplements (LIVESTOCK) – injectable vitamins and minerals	4 to relist, 0 to remove, 1 absent
Propylene glycol (LIVESTOCK) – ketosis treatment	4 to relist, 0 to remove, 1 absent
Acidified sodium chloride (LIVESTOCK) – teat dip	3 to relist, 0 to remove, 2 absent
Zinc sulfate (LIVESTOCK) – hoof treatment	3 to relist, 0 to remove, 2 absent



COMPLIANCE, ACCREDITATION, & CERTIFICATION SUBCOMMITTEE

Letter to Secretary re: Climate Change initiatives (PROPOSAL)

- **BACKGROUND:** The Compliance, Accreditation & Certification Subcommittee drafted a letter to USDA Secretary Vilsack communicating the importance of organic agriculture as a tool for mitigating climate change. The Subcommittee's letter is a direct responses to <u>USDA's-90 Day Progress Report on Climate-Smart Ag</u> which failed to mention the potential contributions to climate change mitigation that certified organic production systems may offer. An earlier draft of this letter was made available for public comment in July 2021.
- **PROPOSAL:** The Subcommittee's letter stresses the importance of explicitly including organic production systems in the USDA's climate-smart strategy. The letter cites research to demonstrate that organic farming systems have significant potential to contribute to climate change, and lists other policy items related to supporting transition to organic, such as: market development for organic and transition-to-organic products, expanding technical assistance, updating RMA crop insurance policies, increase research and data collection, providing transition payments to farmers in transition, and allowing transitioning farmers to be eligible for USDA organic programs like RCCP and EQIP. The letter urges USDA to portray organic farmers and ranchers as models of agriculture that is both economically viable and climate friendly in its farming practices. The letter is signed by all 14 current NOSB members.

Read the full proposal in the NOSB Meeting Packet (p. 1-5)

• SUBCOMMITTEE VOTE: Motion to adopt the proposal: 7 Yes, 0 No.

Oversight improvements to deter fraud: Modernization of organic traceability infrastructure (DISCUSSION)

- **BACKGROUND:** As NOP is working on the Strengthening Organic Enforcement (SOE) rulemaking, as well as Human Capital Capacity Building projects, the NOSB Compliance, Accreditation & Certification Subcommittee is exploring technology tools that can modernize organic verification and traceability systems to best match the size and scale of today's industry, standards, technology, and future needs. The SOE rule points to technology and electronic tracking (e.g. import certificates) as playing an essential role in supply chain traceability and enforcement strategies. SOE also requires certifiers to create fraud prevention procedures to identify high-risk operations, conduct risk-based unannounced inspections, supply chain trace-back and mass-balance audits, and share information with other certifying agents to verify supply chains and conduct investigations.
- **DISCUSSION DOCUMENT:** The Subcommittee is exploring an "organic link system" (OLS), an electronic centralized database that captures business-to-business transactions, providing continuity in verification and traceability across the supply chain. The OLS could provide a bi-directional transparency across different product transactions and could prevent sales duplication of a specific parcel or co-mingling organic and non-organic products.

Specific data to be captured in the OLS would include the date, NOP certificate number, year product was grown, the quantity of organic goods exchanged, etc. The data would be recorded by certified organic businesses involved in the transactions within the organic supply chain. The information would be accessible to certifiers and inspectors through a variety of different permission levels.

The Subcommittee's discussion document explores several barriers that exist for this type of technology and



suggests possible solutions. Barriers include: inadequate access to technology and connectivity; expense of implementing an electronic system; and human capital.

The Subcommittee seeks stakeholder comments in response to the following questions:

- 1. How can technology efficiently and effectively be deployed to enhance supply chain traceability?
- 2. What form does an organic link system (OLS) must take to be non-burdensome for organic stakeholders, including certifiers, inspectors, handlers, operations, importers, etc.?
- 3. What challenges exist with the implementation of an organic link system (OLS)?
- 4. Is there value in AMS, certifiers, and inspectors getting more granular with transaction-level detail to gain transparency throughout the complex supply chain?
- 5. What other methods exist for enhancing transparency?
- 6. Are there additional areas that need to be considered for improvement to prevent fraud or react to fraud?
- 7. Should the industry require the registration of land 36 months before certification?

Read the full discussion document in the NOSB Meeting Packet (p. 7-12)

• SUBCOMMITTEE VOTE: Motion to adopt the discussion document: 7 Yes, 0 No.

CROPS SUBCOMMITTEE

Chitosan, plant disease control (PROPOSAL)

- BACKGROUND: A <u>petition</u> has been submitted to allow chitosan as an active ingredient in plant disease control inputs for use in organic crop production. Chitosan has a similar structure to cellulose and is derived from chitin which forms structures that strengthen cell walls, insect skeletons, crustacean shells, and internal mollusk body parts. Most commercial chitosan is manufactured through chemical treatment of shrimp, prawn, and crab waste. Chitosan acts as a bio-fungicide, bio-bactericide, and bio-virucide, which spurs plant defense system against pathogens. EPA-registered labels (ARMOUR-ZEN®) indicate chitosan active ingredients target early and late blight, downy and powdery mildew and grey mould. The petitioner stated that chitosan is an alternative to sulfur-based pesticides, which can be phytotoxic to plants. A <u>technical report</u> was published in 2020.
- **PROPOSAL:** The Crops Subcommittee is split down the middle (4-4) on whether to accept the petition. Technical information demonstrates that chitosan use at low levels readily degrades and does not pose adverse impacts to the environment or humans. Although relatively benign and a tool for recycling waste streams, the Subcommittee questions whether there is a need for an additional synthetic plant disease control product on the National List. There are also consideration of the energy-intensive and toxic chemicals (chlorine and sodium hydroxide) used in the manufacturing of chitosan. The Subcommittee also identifies other inputs that are already allowed for disease control and other cultural management practices that can reduce the need for disease control substances.

Read the full proposal in the <u>NOSB Meeting Packet</u> (p. 13-16)



• SUBCOMMITTEE VOTE:

To classify chitosan as synthetic: 8 Yes, 0 No.

To add chitosan to the National List at §205.601(j)(4) for plant disease control: 4 Yes, 4 No.

Biochar, Cow Manure Derived (PROPOSAL)

 BACKGROUND: A <u>petition</u> has been submitted to NOP for an amendment to the current prohibition on manure to allow that would <u>exempt (allow)</u> biochar derived from pyrolysis of cow manure. The petitioner intends for manure-derived biochar to be allowed in organic crop production for its potential crop benefits as a soil amendment and for the unique role it can play in sequestering carbon and reducing climate-polluting substances such as N₂O emissions. A new <u>technical report</u> was commissioned in response to the petition.

"Ash from manure burning" is currently listed at §205.602(a) as a non-synthetic substances <u>prohibited</u> for use in organic crop production. The listing has been renewed at every previous sunset review based on its incompatibility with organic production because burning these materials is not an appropriate method to recycle organic wastes.

• **PROPOSAL:** The proposal is to add the following annotation (bold text is new) to the existing listing of ash from manure burning at §205.602(a) as a non-synthetic substances prohibited for use in organic crop production:

§205.602(a) Ash from manure burning – unless derived as part of the production of biochar from pyrolysis of cow manure

Most of the Crops Subcommittee members (5 of 8) voted in favor of the petitioned allowance of cow manure derived biochar. The remaining 3 members opposed the petition. Recycling of manure-based feedstocks into biochar soil amendments can have net positive carbon benefit, but more data is needed to understand the fuel sources used to produce cow manure derived biochar. The petitioned substance can improve soil quality such as cation exchange capacity, however there is a lack of data to compare cow manure derived biochar to other alternatives inputs and soil building practices like cover cropping and manure or compost applications.

The Subcommittee agrees that biochar derived from pyrolysis of cow manure is nonsynthetic. The question of whether pyrolyzed manure is the same as "ash" produced from burning manure is more complex. For the petitioned material, what is being consider as "ash" is actually part of the substance and is contained by the substance and is not a byproduct of the substance.

Read the full proposal in the NOSB Meeting Packet (p. 17-21)

• SUBCOMMITTEE VOTE:

To classify cow manure derived biochar as nonsynthetic: 8 Yes, 0 No.

To add "unless derived as part of the production of biochar from pyrolysis of cow manure" to the listing of ash from manure burning at§205.602(a): **5 Yes, 3 No.**



Ammonia Extract (PROPOSAL)

BACKGROUND: Ammonia extract has been <u>petitioned</u> for inclusion on the National List as a <u>prohibited</u> nonsynthetic input in organic crop production. Synthetic ammonia fertilizers are already prohibited, so this petition challenges the allowance of ammonia that is isolated, captured, extracted, and/or concentrated from natural sources such as manure through physical, mechanical, and/or biological processes that are ultimately classified as <u>nonsynthetic</u>. The petitioner identifies concerns that these types of ammonia fertilizers do not align with organic production principles, pose risks to the integrity of organic products, and increase the risk of fertilizer fraud. The petition also raises concerns about uncertainty and inconsistent determinations of material review organizations regarding the classification of ammonia extract technologies as nonsynthetic or synthetic.

The Subcommittee presented its first <u>discussion document</u> in fall 2020 to solicit stakeholder input on a series of questions about the ability to distinguish synthetic ammonia sources from non-synthetic sources through testing, the impacts on soil health, and other questions about the classification and other issues related to ammonia extract. The Subcommittee presented a second <u>discussion document</u> in spring 2021 that builds on comments received from the last meeting and solicited additional stakeholder feedback on the topics of soil health and the potential for fraud. A third-party <u>Technical Report</u> was published in February 2021.

Based on the Technical Report and public comments, there are two common methods of manufacturing nonsynthetic ammonia extracts: "stripping" or "concentration." The output of the stripping method produces a near pure ammonia that would be similar to that produced by the Haber-Bosch process whereas the product of ammonia concentration retains more of the original compounds of the feedstock.

• **PROPOSAL:** The Crops Subcommittee presents a proposal that seeks to <u>prohibit</u> ammonia extracts. Given the conflicting information on soil health impacts and the long-time concern for the use of highly soluble plant nutrients, an abundance of caution warrants a prohibition of these extracts.

The effectiveness of a prohibition or limitation is dependent on an exact definition of ammonia extracts. The proposal defines the two common manufacturing methods for ammonia extracts and proposes to list them individually on the National List at §205.602, non-synthetic substances prohibited for use in organic crop production, under a new sub-section for prohibited ammonia fertilizers. If both definitions are passed, the NOP could combine them into a single listing during rulemaking.

- <u>"Stripped Ammonia</u> created by separating, isolating and/or capturing ammonia or ammonium from an agricultural feedstock or other natural source using methods such as, but not limited to, steam stripping, pressurized air, heat, condensation, and/or distillation." Stripped ammonia is intended to encompass a wide variation of novel thermo-mechanical derivations of steam stripping technology that result in ammonia-containing condensate, aqua ammonia, ammonium-compound solutions, or any products thereof, such as further isolation of ammonium compounds into a solid by precipitation or solvent evaporation, and/or treatment with nitrifying bacteria.
- <u>"Concentrated Ammonia</u> contains greater than 3% ammoniacal nitrogen <u>and</u> the total nitrogen content is predominately (i.e., >50%) in the ammonia or ammonium form." Concentrated ammonia is intended to focus on products with substantial levels of Ammonical N and avoids products with minimal N. The limit on % ammoniacal nitrogen (greater than 3%) aligns with the OMRI category description for "Fertilizers with High Ammoniacal Nitrogen."



Additionally, the Subcommittee proposes another amendment to the NOP regulations at §205.203, soil fertility and crop nutrient management practice standard, that takes a broader approach to limiting any other ammonia extracts that might fall outside of the aforementioned definitions as well as for all highly soluble sources of Nitrogen.

 "Nitrogen products with a C:N ratio of 3:1 or less, including those that are components of a blended fertilizer formulation, are limited to a cumulative total use of 20% of crop needs." This approach will resolve the concerns about the practice of "stacking" restricted application rates of multiple highly soluble N fertilizers that could allow for higher applications than any individual substance. This approach also alleviates the burden of certifiers to identify whether the total use of these highly soluble products violates the requirement to maintain or build soil organic matter.

The proposal includes a comprehensive analysis of the adverse impacts, alternatives, and compatibility of ammonia extracts in accordance with the Organic Foods Production Act criteria. Some of the highlights include:

- Soil Health & Biodiversity: Arguments can be made that these materials have a positive effect or a negative effect on soil health. There is a lack of consistent research to conclusively demonstrate positive soil health benefits from the applications of ammonia extracts. Ammonium extracts alone do not enhance the soil's biological properties, do not positively contribute to plant health over the long term, and do not encourage or enhance preventative techniques for crop management. Applications to soil can retard natural nitrogen fixation processes and reduce natural efficiency of the soil. Long-term applications of nitrogen fertilizer can result in a long-term loss of nitrogen while altering other soil components like decreasing soil pH and C:N ratio and beneficial enzymatic activity. Purified ammonia compounds require the removal of the carbon value of organic waste. There is conflicting information regarding biodiversity impacts and there is a very likely chance they decrease biodiversity.
- Total Use of High N Fertilizers: Inputs that are immediately plant bioavailable mimic conventional nitrogen sources. It is a slippery slope when using large amount of highly soluble fertilizer in a fertility program with little or no attention to other organic fertilizer inputs.
- *Fraud Potential:* The risk of adulteration (e.g. spiking with synthetic nitrogen) exists with many fertilizers. High Nitrogen Liquid Fertilizers (HNLF's) are subject to additional inspections and mass-balance calculations which serve as a risk mitigation measure. Overlap in isotopic ratios between synthetic and natural nitrogen makes it difficult to rely only on isotope testing for fraud detection.
- *Environmental Impacts:* Release of ammonia to the environment as gas during manufacture leads to ozone depletion and global warming. Nitrogen leaching from field applications into water ecosystems causes eutrophication. There are potential issues with the material that remains after the ammonia has been removed (e.g. phosphorous) from the original feedstock.
- *Alternatives:* Manure, crop residues, compost, sodium nitrate, and other substances derived from natural products such as fish meal, liquid fish residues, feather meal, bird or bat guano, alfalfa meal, bone meal, kelp, seaweed, and meat meal. Crop rotation and intercropping, especially with legumes, are practices that promote soil health and plant available nitrogen.
- *Renewable Resources:* Ammonia extracts are made from renewable materials (animal manures and crop wastes) and can increase the efficiency of using and transporting these materials.
- *International:* Inconsistencies with international standards (Canada and Europe) reduces export market potential.



- *Compatibility with Organic Principles:* Given the conflicting information on soil health impacts and the long-time concern for the use of highly soluble plant nutrients, an abundance of caution warrants a prohibition of these extracts.

Read the full proposal in the NOSB Meeting Packet (p. 23-48)

• SUBCOMMITTEE VOTES:

To classify as nonsynthetic: 8 Yes, 0 No.

To prohibit at §205.602: "Stripped Ammonia – created by separating, isolating and/or capturing ammonia or ammonium from an agricultural feedstock or other natural source using methods such as, but not limited to, steam stripping, pressurized air, heat, condensation, and/or distillation." **8 Yes**, 0 No.

To prohibit at §205.602: "Concentrated Ammonia – contains greater than 3% ammoniacal nitrogen and the total nitrogen content is predominately (i.e., >50%) in the ammonia or ammonium form." **7 Yes**, **1 No.**

To add at §205.203(f): "Nitrogen products with a C:N ratio of 3:1 or less, including those that are components of a blended fertilizer formulation, are limited to a cumulative total use of 20% of crop needs." **7 Yes, 1 No.**

Kasugamycin (PROPOSAL)

• **BACKGROUND:** Kasugamycin is an aminoglycosidic antibiotic (bactericide) that has been <u>petitioned</u> for allowance to control fire blight in apples, pears, and other pome fruits. Kasugamycin is manufactured through bacterial fermentation and isolated as hydrochloride. Kasugamycin hydrochloride hydrate is the technical grade active ingredient in EPA-registered products Kasumin 2L and Kasumin 4L. These products were registered with a number of restrictions including: applications are prohibited where animals are grazing or in areas where crops have been fertilized with animal or human waste; users are also required to follow a resistance management plan; applications are limited to four per year with California limiting applications to two per year.

A third-party <u>Technical Report</u> was commissioned to support the NOSB review of this petitioned material. The Report identifies some level of resistance which is why EPA-registered labels require a resistance management plan and limits on frequency of applications. A <u>discussion document</u> was presented at the spring 2021 NOSB meeting to collect information from stakeholders about the necessity, efficacy, and availability of alternatives.

• **PROPOSAL:** The Crops Subcommittee proposes to <u>reject</u> the petition to allow kasugamycin for disease control. Given the history that antibiotics used in agriculture create microbial resistance, and that the NOSB has voted to remove other antibiotics in the same family, such as streptomycin, from the National List, the Crops Subcommittee finds that kasugamycin is not compatible with a system of sustainable agriculture under OPFA criteria. Adverse impacts on biodiversity are documented, specifically regarding negative changes in soil microflora that develop kasugamycin resistance. The alternative to kasugamycin is an integrated organic program that attacks fire blight at every point in its life cycle, including cultural controls and use of other permitted materials such as copper sprays, lime sulfur sprays, and/or biological control.

Read the full discussion document in the NOSB Meeting Packet (p. 49-53)

• SUBCOMMITTEE VOTE:

To classify kasugamycin as synthetic: **8 Yes**, 0 No.

To add kasugamycin to the National List at §205.601(j)(4) for plant disease control: 0 Yes, 8 No.



Hydronium (PROPOSAL)

- BACKGROUND: Hydronium is a compound made from a mixture of sulfuric acid and calcium hydroxide. It has been <u>petitioned</u> for use as a processing aid for pH adjustment not below 5.0 and as a stabilizer in the production of animal manures to reduce malodorous properties of manure.
- **PROPOSAL:** The Crops Subcommittee unanimously rejected the petitioned use of hydronium in manufacturing manure products for organic crop inputs because it is not compatible with a system of sustainable agriculture. The petitioner indicates that the substance has biocide activity and it has not yet been approved by the EPA. Also there are many alternatives that are already allowed for pH adjustment of manure.

Read the full proposal in the NOSB Meeting Packet (p. 55-57)

• SUBCOMMITTEE VOTE:

To classify hydronium as synthetic: 8 Yes, 0 No.

To add hydronium to the National List at §205.601(j)(7) as an organic processing aid: 0 Yes, 8 No.

Carbon Dioxide (PROPOSAL)

- BACKGROUND: Carbon dioxide has been <u>petitioned</u> for allowance in crop production as an algicide, disinfectant, and sanitizer as well as a plant or soil amendment. Carbon dioxide is used to adjust the pH of alkaline water sources that are used for plant irrigation and foliar spray.
- **PROPOSAL:** The Crops Subcommittee supports the petitioned use of carbon dioxide in crop production. It has no apparent negative effect on the environment or human health when used as petitioned, and is already allowed as an organic processing aid on §205.605. Carbon dioxide is less harmful and more secure than other currently allowed pH adjusters such as sulfur burners or citric acid.

Read the full proposal in the NOSB Meeting Packet (p. 59-61)

• SUBCOMMITTEE VOTE:

To classify carbon dioxide as synthetic: **7 Yes**, 0 No, 1 Absent.

To add carbon dioxide to the National List at §205.601: 7 Yes, 0 No, 1 Absent.

Lithothamnion (PROPOSAL)

- BACKGROUND: Lithothamnion (a.k.a. maerl, calcified seaweed, or seaweed-derived calcium) is a taxonomic genus of coralline marine red algae containing calcareous deposits within its cell walls. NOP sent a <u>memo</u> to NOSB in March 2021 asking for NOSB to provide recommendations regarding the classification of *lithothamnion* as "agricultural" or "nonagricultural" and if it may be certified as a "wild crop" under the USDA organic regulations. NOP will use NOSB's recommendations to help address inconsistencies between certifiers about the eligibility of *lithothamnion* to be certified organic.
- **PROPOSAL:** The Crops Subcommittee proposes that *lithothamnion* is classified as a <u>nonagricultural</u> substance, in accordance with <u>NOP Guidance 5033</u> (Classification of Materials) and the <u>Decision Tree 5033-2</u> (Agriculture and



Nonagricultural Materials Classification). *Lithothamnion* is not a product of agriculture and consists of dead parts of algae. The fact the dead parts of *lithothamnion* are harvested for mineral content is distinctively different from kelp (classified as agricultural) which is harvested live. *Lithothamnion* is more similar to diatomaceous earth, peat, or limestone—originally living tissues that after death are accumulated into deposits that can be mechanically harvested.

The Subcommittee also recommends that *lithothamnion* is <u>not</u> eligible for organic certification as a wild crop. According to <u>NOP Guidance 5022</u> (Wild Crop Harvesting), the Subcommittee finds that *lithothamnion* is not a wild crop since it is not a live plant, or part of a live plant, and is not fixed to a defined location by a species part.

Read the full proposal in the NOSB Meeting Packet (p. 63-66)

• SUBCOMMITTEE VOTE:

To classify Lithothamnion as a nonagricultural: 8 Yes, 0 No.

Lithothamnion does not meet wild crop criteria and is not eligible to be certified to the wild crop standard: **8** Yes, 0 No.

Biodegradable Biobased Mulch Film (PROPOSAL)

• **BACKGROUND:** Biodegradable biobased mulch film is currently listed on the National List of allowed materials for crop production as a weed barrier. The final rule to add BBMF to the National List was published September 30, 2014, in response to an NOSB Recommendation in fall 2012.

NOP published a Policy Memo in January 2015 to specify that biodegradable biobased mulch films must not contain any non-biobased content (i.e., no petroleum). NOP rescinded the Policy Memo in October 2019, but the requirement for 100% biobased content remains in effect because it is articulated in the preamble to the final regulations adding this material to the National List.

However, products that might meet the 100% biobased requirement are either not biodegradable or are not used in production due to brittleness or other production issues. Most biodegradable mulch films only contain about 20% biobased content (or less) with the remaining portion petroleum-derived. Therefore, there are no commercially viable products on the market that meet the NOP requirement for 100% biobased content. Since this conflict arose, the topic has returned to the NOSB work plan for possible resolution. In the meantime, NOSB has renewed this listing at sunset review to allow time to identify a suitable solution

A <u>Technical Report</u> was commissioned in 2016 to evaluate long-term biodegradability of petroleum-derived biodegradable mulch films, and was inconclusive due to limited research available at the time. NOSB has continued to track new research by commissioning an expert panel at the spring 2016 NOSB Meeting. NOP also commissioned a <u>new report</u> from Michigan State University, which was made available in October 2019. A <u>discussion document</u> was presented at the spring 2020 meeting, and <u>reissued</u> in fall 2020, with questions for stakeholder feedback regarding a potential future annotation amendment that would allow biodegradable mulch films that are not 100% biobased. A <u>proposal</u> was presented in spring 2021 that proposed a minimum requirement of 80% biobased content and that 100% be required if and when these materials become available, but that proposal was sent back to subcommittee for further work.

• **PROPOSAL:** The Crops Subcommittee proposes to <u>amend</u> the definition of biodegradable biobased mulch film to



allow products that are at least 80% biobased by weight, with the remaining 20% by weight consisting of materials that meet one of the following composting standards: ASTM D6400, ASTM D6868, EN 13432, EN 14995, or ISO 17088. The proposed minimum requirement of 80% biobased content for biodegradable mulch films is the same minimum requirement that NOSB recommended for paper-based planting aids. The 80% limit is aspirational in the sense that no commercially viable products current meet this criteria. The Subcommittee retains this limit due to ongoing concerns about the possibility of these films to decompose thoroughly, the comparative risk to soils and environment from these films versus risk from Polyethylene (plastic) mulch, and concerns about the precedent of allowing petroleum-derived products to be added directly to soils.

The Subcommittee proposes to revise the definition at §205.2 Terms Defined (bold text added):

Biodegradable biobased mulch film. A synthetic mulch film that meets the following criteria:
(1) Meets the compostability specifications of one of the following standards: ASTM D6400, ASTM D6868, EN 13432, EN 14995, or ISO 17088 (all incorporated by reference; see §205.3);
(2) Demonstrates at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, according to one of the following test methods: ISO 17556 or ASTM D5988 (both incorporated by reference; see §205.3); and

(3) Must be <u>at least 80%</u> biobased with content determined using ASTM D6866 (incorporated by reference; see §205.3).

No changes are being proposed to the current listing at §205.601(a)(2) Mulches:

(iii) Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods.

Read the full proposal in the NOSB Meeting Packet (p. 67-72)

• SUBCOMMITTEE VOTE: Motion to adopt the proposal: 7 Yes, 1 No.

Sodium Nitrate (PROPOSAL)

BACKGROUND: Sodium nitrate (a.k.a. Chilean nitrate) is a mined mineral of high solubility. In the early years of developing the National List, it was added to §205.602 as a prohibited nonsynthetic substance with the following annotation: "use is restricted to no more than 20 percent of the crop's total nitrogen requirement; use in spirulina production is unrestricted until October 21, 2005." The 20% restriction was a common restriction found in private certifier standards prior to the implementation of the NOP.

In spring 2011 during the Sunset Review of sodium nitrate, NOSB <u>recommended</u> by unanimous vote to relist sodium nitrate <u>without</u> the annotation, thereby entirely prohibiting its use, due to environmental and human health concerns and the lack of international harmonization of standards regarding this material. NOP never took action to renew the listing, therefore the listing became <u>invalid</u> on its sunset date of October 12, 2012. NOP issued a <u>memo</u> explaining the unusual circumstances of dealing with the invalid listing until NOP can complete rulemaking to prohibit sodium nitrate. NOP still not acted on the NOSB's recommendation, so the listing with the annotation still physically appears on the National List at §205.602 even though it is invalid.

Currently, sodium nitrate is permitted for use without specific restriction beyond the general requirements for organic operations to maintain or improve the natural resources of the operation, including soil and water



quality (§205.200) and to manage crop nutrient and soil fertility to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water (§205.203).

- PROPOSAL: In order to remedy and clarify the regulatory status of sodium nitrate, the Crops Subcommittee
 presents a technical correction to reinstate the listing for sodium nitrate as it appears on §205.602, nonsynthetic substances prohibited for use in organic crop production. The goal of the Subcommittee's proposal is
 to reinstate the sunset review of this material and to ensure that sodium nitrate isn't allowed for unlimited use.
 - §205.602(g) Sodium nitrate unless use is restricted to no more than 20 percent of the crop's total nitrogen requirement; use in spirulina production is unrestricted until October 21, 2005.

Read the full proposal in the NOSB Meeting Packet (p. 73-74)

• SUBCOMMITTEE VOTE: Motion to reinstate the listing of sodium nitrate at §205.602: 8 Yes, 0 No.

Crops 2023 Sunset Review

BACKGROUND: NOSB is reviewing whether to continue the allowance of several substances currently included on the National List of Allowed and Prohibited Substances to determine whether the substances should continue to be listed or should be relisted or removed from the list. These substances are undergoing Sunset Review this year in advance of their sunset date in 2023. These inputs may not be renewed if new information indicates they are harmful to human health or the environment, are not necessary because natural or organic alternatives are available, and/or are incompatible with organic production.

Public comments should clearly indicate the commenter's position on the allowance or prohibition of the substance and explain the reasons for the position. Comments should focus on providing relevant <u>new</u> information about a substance since its last NOSB review, including research or data that may inform NOSB's determination (e.g., scientific, environmental, manufacturing, industry impact information, etc.). Comments should also address the continuing need for the substance, and if there are viable alternatives such as: alternative management practices or natural substances that would eliminate the need for the specific substance; other substances that are nonsynthetic or are on the National List that are better alternatives, which could eliminate the need for this specific substance. Comments should address when alternatives have a function and effect equivalent to or better than the substance under review.

Please complete OTA's Sunset Surveys to provide information about the necessity of these inputs.

Read the full proposals in the NOSB Meeting Packet (p. 75-103)

Copper sulfate - §205.601(a)(3) & (e)(4)

- **Background:** Allowed for use as an algicide and tadpole shrimp control in aquatic rice systems. It is broadcast aerially into the flooded rice fields by plane control growth of algal matting in flooded fields which can dislodge young seedlings, and also to control tadpole shrimp which are detrimental to very young seedlings. Use is restricted to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a time frame agreed upon by the producer and accredited certifying agent.
- **Subcommittee Review:** The Subcommittee indicates that it may be time to reconsider copper sulfate as an algicide and means of controlling tadpole shrimp. It appears there is sufficient evidence to



conclude that use of copper sulfate in rice fields is environmentally detrimental, alternative seeding practices could eliminate the need for the chemical as both algae and tadpole shrimp cease to be problematic once seedlings are established, and international standards do not allow for spraying of copper sulfate for organic rice production.

However, organic rice farmers, certifying agencies, and public commenters all indicated ongoing need for copper sulfate until alternatives are available. Abrupt de-listing would have tremendous negative impact on US-grown organic rice. The Crops Subcommittee recommends re-listing copper sulfate and has called for a comprehensive review of copper sulfate as part of its Research Priorities for 2021.

- Subcommittee Vote: 6 to relist, 2 to remove

Oxone gas - §205.601(a)(5)

- **Background:** Allowed for use as an irrigation system cleaner. Ozone gas is a strong oxidant and has been allowed in organic production since 2003.
- **Subcommittee Review:** Ozone is widely by the organic community and public comments have supports its continued use and necessity in organic production systems. Human health and environmental issues are minimal. Ozone systems that inject directly into irrigation lines use relatively low concentrations of ozone and there is little potential for off-gassing.
- Subcommittee Vote: 6 to relist, 0 to remove, 2 absent

Peracetic acid - §205.601(a)(6) & (i)(8)

- Background: Allowed for use in controlling fire blight bacteria and for disinfecting equipment, seed, and asexually propagated planting material. Also allowed in hydrogen peroxide formulations at a concentration of no more that 6% as indicated on the pesticide product label. Peracetic acid is a very strong oxidizing agent that it is made from, and decomposes back to, acetic acid, oxygen, and water (and may contain synthetic stabilizers and chelating agents).
- **Subcommittee Review:** Peracetic acid is widely used in the organic community because it works well in cold conditions, it does not give off chlorine into the environment, it is used as part of a rotation process in fire blight disease control, it is the more benign of the sanitizers and disinfectants, and is a no-rinse material. Organic producers consider peracetic acid essential to ensure food safety and compliance with the Food Safety Modernization Act.
- Subcommittee Vote: 8 to relist, 0 to remove

EPA List 3 Inerts of Unknown Toxicity – §205.601(m)(2)

- **Background:** Allowed for use only in passive pheromone dispensers used for insect management, either to trap and monitor insect populations or to control a pest through pheromone mating disruption. When they are placed in the production area, the pheromone dispensers are not in contact with the organic crop and the List 3 inerts are not dispersed into the atmosphere. EPA List 3 is outdated and no longer maintained by EPA. An alternative review system has not yet been implemented by NOP.
- **Subcommittee Review:** These materials have a long history in organic farming and are considered an essential component of passive pheromone dispensers which have a long history of use in organic farming and have reduced the use of many other pest control inputs. The specificity of the annotation leads to limited use in very controlled situations and there are no human health or environmental



concerns. The prohibition of List 3 inerts prior to establishment of a new system for reviewing inerts would cause significant disruption to the availability of essential pest control tools for organic production. NOSB strongly recommends and asks the National Organic Program to develop an alternative to the List 4/List 3 references that would allow for review (and addition or removal) of inerts and that would not rely on an antiquated list.

- Subcommittee Vote: 7 to relist, 1 to remove

Chlorine materials - §205.601(a)(2)

- **Background:** Includes Calcium hypochlorite, Chlorine dioxide, Hypochlorous acid, Sodium hypochlorite. Allowed for use as a sanitizer and disinfectant. For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions. Chlorine materials are strong oxidants that have been allowed (under restricted conditions) in organic production since 2001.
- Subcommittee Review: The Subcommittee acknowledges that chlorine materials have been judged essential to ensure food safety and to comply with food-safety regulations under the Food Safety Modernization Act and generally support continued listing of chlorine materials. The Subcommittee also supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.
- **Subcommittee Vote: 8 to relist,** 0 to remove (Note: Subcommittee voted separately on each of the 4 chlorine materials and all resulted in 8-0 subcommittee vote).

Magnesium oxide - §205.601(j)(5)

- **Background:** Allowed for use only to control the viscosity of a clay suspension agent for humates in order to prevent crystallization of any fertilizer or micronutrient salts that may be in solution and prevent the plugging of spray nozzles during spray applications. Magnesium oxide acts as a as a buffering agent when in an aqueous solution. It was added to the National List in December 2018 as a result of a petition.
- **Subcommittee Review:** Low application rates and insolubility of magnesium oxide make environmental contamination unlikely. Nonsynthetic alternatives are not commercially available or do not meet chemical or physical specifications for suspending humates in the solution.
- Subcommittee Vote: 8 to relist, 0 to remove

Calcium chloride – §205.602

- **Background:** Prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake such as bitter pit in apples, fruit cracking on developing figs, blossom end rot on tomatoes, and dozens of other issues. Calcium chloride produced through the brine is nonsynthetic, and is restricted to prevent potential overuse of high solubility materials.
- **Subcommittee Review:** Calcium chloride is a material needed to combat physiological disorders of many crops that typically cannot be resolved with other calcium products. The current restrictions and low concentration of use do not pose environmental or human health threats.
- Subcommittee Vote: 8 to relist, 0 to remove



Rotenone - §205.602

- Background: Prohibited. Rotenone is a potent botanical pesticide that is prohibited in organic production due to adverse health effects. In the U.S. rotenone is only registered for piscicidal (fish killing) purposes. The prohibited listing ensures that it will not be used in other countries where it might be available as an insecticide.
- **Subcommittee Review:** Rotenone was found to have adverse environmental and health impacts, a lack of essentiality, and an incompatibility with organic principles.
- Subcommittee Vote: 8 to relist, 0 to remove

HANDLING SUBCOMMITTEE

Zein (PROPOSAL)

- BACKGROUND: Zein (corn protein) has been <u>petitioned</u> for allowance as a non-organic ingredient for use in organic food processing as a food coating. Zein is applied to foods as an alcohol solution; once the alcohol evaporates, the zein layer acts as protective moisture barrier. It is used as a confectioner's glaze or a coating on nuts and fruit, among other applications. Zein is derived from corn gluten meal. The petitioner states sourcing from certified organic corn gluten meal for the production of organic zein is not currently possible. NOSB has previously evaluated the question of whether the end products of the corn wet-milling process can be considered non-synthetic and precedent has been established to consider these end products as non-synthetics. A new technical report was commissioned to support the NOSB review of this petitioned material. A discussion document was presented in spring 2021 that focused on the environmental impacts of zein manufacturing (specifically the corn wet-milling process), its classification as non-synthetic, and the suitability of other already allowed substances as alternatives.
- **PROPOSAL:** The Handling Subcommittee voted 4-3 on a motion to allow limited uses of zein only as a coating for pills, specifically "Only for use in nutraceuticals or pharmaceuticals as a micro encapsulation acting as a moisture barrier and taste masker." There are concerns about the environmental impacts of the wet-milling process used to create the corn gluten meal that is the starting material for zein, and a possibility of an alternative process that bypasses the need for sulfur dioxide or other caustic chemicals used during the wet-milling process. By further limiting the use of zein only in nutraceuticals and pharmaceuticals, zein will not impact human health nor the agroecosystem. In terms of alternatives, zein has a unique functionality because it offers a vegan/vegetarian option to replace shellac and beeswax as coatings and is also hypoallergenic (replacing wheat).

Read the full proposal in the NOSB Meeting Packet (p. 105-110)

• SUBCOMMITTEE VOTE:

Motion to classify zein as nonsynthetic: **7 Yes**, 0 No.

Motion to add zein at §205.605(a), annotated as: "Only for use in nutraceuticals or pharmaceuticals as a micro encapsulation acting as a moisture barrier and taste masker": 4 Yes, 3 No.



Fish Oil Annotation (PROPOSAL)

• **BACKGROUND:** Fish oil is currently on the National List at §205.606(e) as an agricultural substance allowed for use in organic processed foods only when the product is not commercially available in organic form. It is used as a nutritional supplement to increase the content of omega-3 fatty acids in a variety of food products such as milk. Because there are no NOP standards for organic aquaculture, non-organic forms are the only option for organic processors. During the last Sunset Review of fish oil in 2019, concerns were raised about the environmental impacts of harvesting fish directly for their oil. NOSB is exploring additional restrictions on the sourcing of fish oil to ensure its use is not harmful to the environment.

The Handling Subcommittee presented its first <u>discussion document</u> in spring 2020 to explore new restrictions on fish oil that would prohibit the use of fish caught directly for the sole use of its oil, and prohibit fish oil from species and regions that are overfished or exploited. A second <u>discussion document</u> was presented in sprint 2021 that contained three possible fish oil annotations and requested input from organic stakeholders on the merits and feasibility of each approach.

- **PROPOSAL:** The Subcommittee proposes to revise the annotation for fish oil at §205.606 to read (bold text added):
 - §205.606 (e) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8) -stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606. Sourced from fishing industry by-product only and certified as sustainable against a third-party certification that is International Social and Environmental Accreditation and Labeling (ISEAL) Code Compliant or Global Seafood Sustainability Initiative (GSSI) recognized.

This annotation would prevent the use of fish caught solely for oil production. Although there are concerns with National List annotations that rely on third party certifications, there are advantages for consulting existing certification schemes that cover complex issues related to fish that don't currently exist under NOP regulations. <u>GSSI</u> and <u>ISEAL</u> help to define and ensure programs demonstrate their continual compliance in upholding best practice for seafood sustainability certifications and sustainability systems at a global level.

Read the full proposal in the NOSB Meeting Packet (p. 111-116)

• **SUBCOMMITTEE VOTE:** Motion to accept the proposed fish oil annotation: **6 Yes**, 0 No, 1 Absent.

Handling 2023 Sunset Review

• **BACKGROUND:** NOSB is reviewing whether to continue the allowance of several substances currently included on the National List of Allowed and Prohibited Substances to determine whether the substances should continue to be listed or should be relisted or removed from the list. These substances are undergoing Sunset Review this year in advance of their sunset date in 2023. These inputs may not be renewed if new information indicates they are harmful to human health or the environment, are not necessary because natural or organic alternatives are available, and/or are incompatible with organic production.

Public comments should clearly indicate the commenter's position on the allowance or prohibition of the substance and explain the reasons for the position. Comments should focus on providing relevant <u>new</u> information about a substance since its last NOSB review, including research or data that may inform NOSB's determination (e.g., scientific, environmental, manufacturing, industry impact information, etc.). Comments



should also address the continuing need for the substance, and if there are viable alternatives such as: 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. Comments should address when alternatives have a function and effect equivalent to or better than the substance under review.

Please complete OTA's Sunset Surveys to provide information about the necessity of these inputs.

Read the full proposals in the NOSB Meeting Packet (p. 117-154)

Agar-Agar – §205.605(a)

- **Background:** Allowed for use in food processing as a stabilizer, thickener, gelling agent, texturizer, moisturizer, emulsifier, flavor enhancer, and absorbent. Used in various foods including bakery products, confections, jellies and jams, dairy products, canned meat and fish products, and vegetarian meat substitutes. Agar-agar has the ability to withstand high temperatures and doesn't interfere with taste profiles. Agar-agar is derived from red algae and has been permitted in organic processing since 2003.
- **Subcommittee Review:** Agar-agar continues to be an essential tool in the development and innovation of organic foods. There continues to be questions about the classification of different forms of agar-agar as nonsynthetic or synthetic, but that nonsynthetic forms are not commercially available and are not effective for some applications.
- Subcommittee Vote: 7 to relist, 0 to remove

Animal enzymes – §205.605(a)

 Background: Includes: Rennet (animals derived); Catalase (bovine liver); Animal lipase; Pancreatin; Pepsin; and Trypsin. Used as catalysts for biological processes that are useful in the processing of food products or ingredients, e.g. as a coagulant to curdle milk to be made into cheese or sour cream. Enzymes are used in very small amounts to achieve the desired effect. To prevent the loss of enzyme activity, ancillary substances such as stabilizers are added (see table).

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

- **Subcommittee Review:** There are no true alternatives to enzymes and organic enzymes are non-existent due to inability to achieve a reliable organic supply.
- Subcommittee Vote: 7 to relist, 0 to remove



Calcium sulfate - §205.605(a)

- **Background:** Mined sources only are allowed for various uses in food processing such as: coagulate in tofu manufacturing (soft and silky tofu types), yeast food and dough conditioner, water conditioner, firming agent (in canned foods), jelling ingredient, and baking powder ingredient.
- Subcommittee Review: Calcium sulfate is critical for production of tofu and soy cheese, and is also used in the brewing industry to adjust mineral content of water. There are some concern about environment impact of mining calcium sulfate (as gypsum or alabaster). The Subcommittee seeks feedback from stakeholders if there is clear evidence of unacceptable environmental or human health impacts from minim of calcium sulfate.
- Subcommittee Vote: 6 to relist, 0 to remove, 1 absent

Carrageenan - §205.605(a)

- **Background:** Allowed for use in food processing as a gelling agent, emulsifier, and thickener/ Used primarily in meat and dairy products, and also is a vegan alternative to animal-sources gelatin. Sourced from seaweed (red algae).
- Subcommittee Review: There are some concerns about environmental impact of farming seaweed used to extract carrageenan. Most of the seaweed used in carrageenan production are farmed in the Philippines and China. There are also concerns about human health impacts from numerous anecdotal reports from people who find relief from digestive complaints when they remove carrageenan from their diet, although scientific evidence is debatable. During the last sunset review, NOSB recommended removal of carrageenan from the National List based on lack of essentiality because alternative materials, such as gellan gum, guar gum, or xanthan gum, are available for use in organic products. There were also concerns about the substance at the last sunset review. NOP did not implement the past NOSB recommendation because of public comments indicating that potential substitutes do not adequately replicate the functions of carrageenan across the broad scope of use. During this sunset review, there has been general support within the stakeholder community to keep carrageenan on the National List, but the Subcommittee deems it unnecessary as there are alternative products that serve the same functionality.
- Subcommittee Vote: 1 to relist, 5 to remove, 1 absent

Glucono delta-lactone - §205.605(a)

- **Background:** Allowed for use in food processing. Primarily used as a coagulant in the production of silken tofu. Also used as a curing or pickling agent, leavening agent, pH control agent and sequestrant. Production by the oxidation of D-glucose with bromine water is prohibited.
- **Subcommittee Review:** There does not appear to be any environmental or human health issues with this material. Glucono-delta lactone continues to be critical for silken jelly-like tofu, and alternative substances are not sufficient for this particular tofu texture of flavor. At this time, this material satisfies the OFPA evaluation criteria, and the Subcommittee supports the relisting of glucono delta-lactone.

The Subcommittee continues to seek input from stakeholder on the following questions:

How widespread is the use of GDL in organic applications?



- Is there evidence that GDL being used in organic applications may derive from genetic modification of any kind?
- Have alternatives to GDL emerged in recent years that deliver the same product quality and functionality?
- Is the lack of International acceptance significant?
- How is organic silken tofu produced in the EU, Japan, etc. without the use of GDL?
- Subcommittee Vote: 5 to relist, 0 to remove, 2 absent

Tartaric acid – §205.605(a)

- Background: Nonsynthetic forms of tartaric acid are isolated from the undesirable wastes created during the winemaking process (grape pomace, etc.), which naturally contain a significant amount of tartaric acid. Includes tartaric acid and its salts (i.e. potassium acid tartrate, sodium potassium tartrate acid). Allowed for various uses in food processing including as an acidulant, pH control agent, preservative, emulsifier, chelating agent, flavor enhancer and modifier, stabilizer, anti-caking agent, and firming agent. Used in the preparation of baked goods and confectionaries, dairy products, edible oils and fats, tinned fruits and vegetables, seafood products, meat and poultry products, juice beverages and soft drinks, sugar preserves, chewing gum, cocoa powder, and alcoholic drinks.
- **Subcommittee Review:** Due to low impacts on human health and the environment and the advantageous qualities that tartaric acid lends to baked goods, wines, and other organic products, the Subcommittee supports relisting. There is a question of whether tartaric acid can be made from organic wine in the future as the organic wine market continues to grow. The Subcommittee encourages the inclusion of an analysis of the availability of tartaric acid from organic grapes during the next sunset review, and also encourages the organic wine industry to move towards production of tartaric acid from organic grapes.
- Subcommittee Vote: 5 to relist, 0 to remove, 2 absent

Cellulose - §205.605(b)

- **Background:** Allowed for use in regenerative casings (peelable/non-edible hot dog and sausage casings). Powdered cellulose is allowed for use as an anti-caking agent (e.g. for use in shredded cheese) and filtering aid (e.g. for filtration of juices). Non-chlorine bleached only. Microcrystalline cellulose is prohibited. Most commercially available powdered cellulose is produced from wood pulp or other plant sources, e.g., corn cobs, soybean hulls, oat hulls, rice hulls, sugar beet pulp, etc. Some forms of cellulose might use ancillaries listed in the chart below.

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

- **Subcommittee Review:** Cellulose remains essential to organic handling for a few products. There are some concerns about environmental impacts from sourcing and manufacturing cellulose. Overall, there continues to be support for relisting cellulose.
- Subcommittee Vote: 6 to relist, 0 to remove, 1 absent



Chlorine materials - §205.605(b)

- Background: Includes: Calcium hypochlorite, Chlorine dioxide, Hypochlorous acid, Sodium hypochlorite. Allowed for use in disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.
- Subcommittee Review: The Subcommittee acknowledges that chlorine materials have been judged essential to ensure food safety and to comply with food-safety regulations under the Food Safety Modernization Act and generally support continued listing of chlorine materials. The Subcommittee also supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.
- **Subcommittee Vote:** 6 to relist, 0 to remove, 1 absent (Note: Subcommittee voted separately on each of the 4 chlorine materials and all resulted in 6-0-1 subcommittee vote).

Potassium hydroxide - §205.605(b)

- **Background:** Allowed for various uses in food processing including as a pH adjuster, cleaning agent, stabilizer, thickener, and poultry scald agent. Prohibited for use in lye peeling of fruits and vegetables.
- **Subcommittee Review:** Potassium hydroxide is needed for pH adjustment and potassium fortification, and there are no management practices that would eliminate the need for this potassium hydroxide, and there are differences in solubility as compared to possible alternatives. There are some environmental and human health concerns related to corrosivity of potassium hydroxide and the disposal of large amounts of water with soluble potassium and alkali ions. While the Subcommittee recognizes these concerns, the removal of this material would be disruptive to organic handlers and at this point in time it is still essential for organic handling.
- Subcommittee Vote: 5 to relist, 0 to remove, 2 absent

Potassium lactate – §205.605(b)

- **Background:** Allowed for use as an antimicrobial agent and pH regulator only. Potassium lactate has been allowed for use in organic processing since 2004 although it was not added to the National List until 2019 due to procedural issues.
- **Subcommittee Review:** Potassium lactate is widely used and the Subcommittee supports relisting. There are certain uses such as "low sodium" meat alternatives that require potassium lactate specifically.
- Subcommittee Vote: 7 to relist, 0 to remove

Silicon dioxide – §205.605(b)

- **Background:** Allowed for use as a defoamer. Allowed for other uses when organic rice hulls are not commercially available in the appropriate quality, quantity, and form. Other uses may include: anticaking agent, stabilizer in beer production, adsorbent in tableted foods, or a carrier.



- **Subcommittee Review:** Public comments noted that alternatives, such as organic rice hulls, are not able to be used to achieve suitable functionality in all applications. The subcommittee supports relisting.
- Subcommittee Vote: 6 to relist, 0 to remove, 1 absent

Sodium lactate - §205.605(b)

- **Background:** Allowed for use as an antimicrobial agent and pH regulator only. Sodium lactate has been allowed for use in organic processing since 2004 although it was not added to the National List until 2019 due to procedural issues.
- Subcommittee Review: Sodium lactate is widely used and the Subcommittee supports relisting.
- Subcommittee Vote: 7 to relist, 0 to remove

LIVESTOCK SUBCOMMITTEE

Livestock 2023 Sunset Review

BACKGROUND: NOSB is reviewing whether to continue the allowance of several substances currently included on the National List of Allowed and Prohibited Substances to determine whether the substances should continue to be listed or should be relisted or removed from the list. These substances are undergoing Sunset Review this year in advance of their sunset date in 2023. These inputs may not be renewed if new information indicates they are harmful to human health or the environment, are not necessary because natural or organic alternatives are available, and/or are incompatible with organic production.

Public comments should clearly indicate the commenter's position on the allowance or prohibition of the substance and explain the reasons for the position. Comments should focus on providing relevant <u>new</u> information about a substance since its last NOSB review, including research or data that may inform NOSB's determination (e.g., scientific, environmental, manufacturing, industry impact information, etc.). Comments should also address the continuing need for the substance, and if there are viable alternatives such as: alternative management practices or natural substances that would eliminate the need for the specific substance; other substances that are nonsynthetic or are on the National List that are better alternatives, which could eliminate the need for this specific substance. Comments should address when alternatives have a function and effect equivalent to or better than the substance under review.

Please complete OTA's Sunset Surveys to provide information about the necessity of these inputs.

Read the full proposals in the NOSB Meeting Packet (p. 155-180)

Activated charcoal - §205.603(a)(6)

- **Background:** Allowed only from vegetative sources (e.g. hardwoods, grain hulls, corn cobs). The material undergoes pyrolysis at a very high heat and the resulting charcoal may activated using chemicals under pressure and heat, or by steam or oxygenated gas. Activated charcoal is used in livestock production as an antidote to poisons and other toxic substances and for removing various mycotoxins. It acts as a



detoxifier to cure upset stomachs in livestock that have ingested mold or something unknown which is causing upset or to be off feed. Has been allowed in organic livestock production since 2019.

- **Subcommittee Review:** The use of activated charcoal can reduce or prevent livestock distress and death. It is used infrequently in relatively small amounts and has little environmental impact.
- Subcommittee Vote: 3 to relist, 0 to remove, 2 absent

Calcium borogluconate - §205.603(a)(7)

- **Background:** Allowed only for treatment of milk fever in cattle, sheep, and goats. Milk fever is the result of metabolic stress occurring only at or near parturition (giving birth). Calcium borogluconate is an electrolyte that was added to the National List in 2019 separately from the existing listing of electrolytes on the National List. NOP has clarified that this substance is not in conflict with FDA regulations.
- **Subcommittee Review:** The substance provides relief from unnecessary animal suffering, it is compatible with a sustainable system of agriculture.
- Subcommittee Vote: 3 to relist, 0 to remove, 2 absent

Calcium propionate - §205.603(a)(8)

- **Background:** Allowed only for treatment of milk fever in cattle, sheep, and goats. Milk fever is the result of metabolic stress occurring only at or near parturition (giving birth). Calcium propionate is an electrolyte that was added to the National List in 2019 separately from the existing listing of electrolytes on the National List. NOP has clarified that this substance is not in conflict with FDA regulations.
- **Subcommittee Review:** A majority of livestock dairy producers, veterinarians, and the organic industry at large stated it was an essential treatment for milk fever.
- Subcommittee Vote: 4 to relist, 0 to remove, 1 absent

Chlorine materials - §205.603(a)(10)

- **Background:** Includes: Calcium hypochlorite, Chlorine dioxide, Hypochlorous acid, Sodium hypochlorite. Allowed for disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
- Subcommittee Review: The Subcommittee acknowledges that chlorine materials are an essential part for maintaining hygiene in livestock facilities and generally supports continued listing of chlorine materials. The Subcommittee supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.
- Subcommittee Vote: 4 to relist, 0 to remove, 1 absent

Kaolin pectin - §205.603(a)(17)

- **Background:** Allowed for use as an adsorbent, antidiarrheal, and gut protectant. It is made from made from aluminum silicate dust (Kaolin) and pectin from plant material. Has been allowed in organic livestock production since 2019.



- **Subcommittee Review:** It is a vital tool used for gastrointestinal disorders in livestock production. Kaolin pectin does not seem to be overused, but rather being used on an as-needed basis.
- Subcommittee Vote: 4 to relist, 0 to remove, 1 absent

Mineral oil - §205.603(a)(20)

- **Background:** Allowed for treatment of intestinal compaction. It is administered internally to lubricate the intestinal tract and dislodge intestinal obstructions in cattle and other ruminants. Prohibited for use as a dust suppressant.
- **Subcommittee Review:** Commenters stated that mineral oil is used infrequency but when it is needed, there is no alternative that is sufficient because natural oils do not work, as they get digested and do not move or break up the compaction. If the material were prohibited, there would be huge negative effects on cow health.
- Subcommittee Vote: 3 to relist, 0 to remove, 2 absent

Nutritive supplements - §205.603(a)(21)

- **Background:** Includes injectable supplements of trace minerals, vitamins, and electrolytes per §205.603, with excipients per §205.603(f). Must be used in accordance with FDA and restricted to use by or on the order of a licensed veterinarian.
- Subcommittee Review: Injectable forms of vitamins and minerals, allowed strictly on an as-needed basis, provide valuable support to an animal's immune system and work to assist livestock health, well-being, and animal welfare. With the prohibition of the use of antibiotics in certified organic livestock, farmers and veterinarians need as many of the remaining tools as possible to prioritize animal health.
 Commenters agreed that the removal of nutritive supplements would hobble organic livestock producers' ability to effectively manage their stock and provide the best care in acute illness scenarios.
- Subcommittee Vote: 4 to relist, 0 to remove, 1 absent

Propylene glycol – §205.603(a)(27)

- **Background:** Allowed for use only for treatment of ketosis in ruminants. Ketosis is a metabolic disease that can result from energy imbalance in early lactation. Has been allowed in organic livestock production since 2019.
- **Subcommittee Review:** Dairy producers and veterinarians see propylene glycol as the gold standard for treatment of ketosis in ruminants. In the treatment of ketosis, propylene glycol is used in small volumes and presents a very low risk for environmental contamination. There are some concerns about the concerns about environmental impacts from manufacturing propylene glycol. The Subcommittee has determined that the limited use of the substance as a medical treatment for ketosis is necessary and recommends relisting.
- Subcommittee Vote: 4 to relist, 0 to remove, 1 absent

Acidified sodium chlorite - §205.603(a)(28) & (b)(9)

- **Background:** Allowed for use only as a disinfecting pre-milking and post-milking teat dip for the purpose of preventing mastitis. Acidified sodium chlorite solutions are made by mixing an aqueous solution of



sodium chlorite with a food-grade acid, such as citric acid. Has been allowed as a teat dip since 2019. At §205.603(a) Sodium chlorite is allowed as a pre-milking sanitizer while at §205.603(b) it is used for postmilking as a preventative topical treatment.

- **Subcommittee Review:** Acidified sodium chlorite satisfies the OFPA criteria related to impact on humans and the environment and is compatible with organic agriculture. Acidified sodium chlorite breaks down in the environment to water and salt and is more benign than other teat dip materials currently listed on the National List. The use of pre-milking and post-milking teat dips is a normal practice and may be the most critical factor in preventing mastitis.
- Subcommittee Vote: 3 to relist, 0 to remove, 2 absent

Zinc sulfate - §205.603(b)(11)

- **Background:** Allowed only for use in hoof and foot treatments for the control of foot rot in dairy cattle, sheep, and goats. Has been allowed since 2019.
- **Subcommittee Review:** The amount of zinc sulfate used for foot rot control is a small proportion of its total use. Zinc sulfate is considered less environmentally damaging than copper sulfate, which is on the National List for the same use. Copper compounds are toxic to sheep and goats, so the presence of zinc sulfate on the National List allows for its use for these species as an alternative to copper sulfate.
- Subcommittee Vote: 3 to relist, 0 to remove, 2 absent

MATERIALS SUBCOMMITTEE

Research Priorities 2021 (PROPOSAL)

- **BACKGROUND:** Since adopting its Research Priorities Framework in 2012, NOSB has presented an annual list of research priorities for organic food and agriculture. The priorities are proposed by NOSB's Livestock, Crops, Handling, and Materials/GMO Subcommittees and are revisited and updated each year to ensure accurate reflection of existing need for new knowledge.
- **PROPOSAL:** The Materials Subcommittee presents the following list of research priorities. The <u>NOSB Meeting</u> <u>Packet</u> (p. 181-191) contains full descriptions of each research priority.

Livestock

- 1. Determine the efficiency of natural parasiticides and methodologies, including but not limited to, nutritional programs, use of herbs, essential oils, homeopathic remedies, Diatomaceous Earth, and the genetic pool of laying hens in controlling *A. galli* and *H. gallinarum* in laying and replacement chickens intended to become hens.
- 2. Evaluate natural alternatives to DL-Methionine in a system approach for organic poultry feed program.
- 3. Evaluate ways to prevent and manage parasites in livestock, examining breeds, geographical differences, alternative treatments, and pasture species.
- 4. Research and develop livestock breeding programs resulting in livestock that are adapted to outdoor life and living vegetation.



Crops

- 1. Examination of decomposition rates, the effects of residues on soil biology, and the factors that affect the breakdown of biodegradable bio-based mulch film.
- 2. Conduct whole farm ecosystem service assessments to determine the economic, social, and environmental impact of farming systems choices.
- 3. Organic no-till practices for diverse climates, crops, and soil types.
- 4. Develop cover cropping practices that come closer to meeting the annual fertility demands of commonly grown organic crops.
- 5. Development of systems-based plant disease management strategies are needed to address existing and emerging plant disease threats.
- 6. The demand for organic nursery stock far exceeds the supply. Research is needed to identify the barriers to expanding this market, then develop and assess organic methods for meeting the growing demand for organically grown nursery stock.
- 7. Strategies for the prevention, management, and control of invasive insects and weeds.
- 8. Factors impacting organic crop nutrition, and organic/conventional nutrition comparisons.
- 9. Side-by-side trials of organic synthetic materials, natural materials, and cultural methods, with a request for collaboration with the IR4 project.
- 10. Impartial evaluation of microbial inoculants, soil conditioners, and other amendments is needed as there is little objective evidence upon which to assess their contribution to soil health.
- 11. More research, extension, and education are needed to fully understand the relationship between onfarm 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 & Processing

- 1. Evaluation of alternatives to chlorine materials in processing: impact mitigation, best management practices, and potential for chlorine absorption by produce.
- 2. Suitable alternatives to BPA (Bisphenol-A) for linings of cans used for various products.
- 3. Chlorine sanitizers pose potential occupational health risks in food handling and processing environments. Given anecdotal reports of health problems associated with exposure to chlorine sanitizers by food workers, the Handling Subcommittee recommends additional research, including monitoring for chlorine breakdown products, chlorine gas, and chloroform in organically certified food handling and processing facilities to quantify worker exposures and health risks.

Coexistence with GE and Organic Crops

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



5. Testing for fraud by developing and implementing new technologies and practices.

General

- 1. Examination of the factors influencing access to organically produced foods.
- 2. Production and yield barriers to transitioning to organic production to help growers successfully complete the transition.
- SUBCOMMITTEE VOTE: Motion to adopt proposal: 6 Yes, 0 No.

Excluded Methods Determinations (DISCUSSION)

• **BACKGROUND:** The NOP regulations require that organic products must be produced and handled without the use of *excluded methods*, defined at §205.2: *"A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, <i>microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture."*

In 2016, NOSB passed a <u>recommendation</u> that would establish guidance for interpreting the excluded methods provision of the organic regulations. The recommendation includes definitions, principles, criteria that help address the increased diversity in types of genetic manipulations performed on seed, livestock and other inputs used in agriculture. The criteria that NOSB uses to evaluate individual technologies are:

- 1. The genome is respected as an indivisible entity and technical/physical insertion, deletions, or rearrangements in the genome is refrained from (e.g. through transmission of isolated DNA, RNA, or proteins). *In vitro* nucleic acid techniques are considered to be invasion into the plant genome.
- 2. The ability of a variety to reproduce in species-specific manner has to be maintained and genetic use restriction technologies are refrained from (e.g. Terminator technology).
- 3. Novel proteins and other molecules produced from modern biotechnology must be prevented from being introduced into the agro-ecosystem and into the organic food supply.
- 4. The exchange of genetic resources is encouraged. In order to ensure farmers have a legal avenue to save seed and plant breeders have access to germplasm for research and developing new varieties, the application of restrictive intellectual property protection (e.g., utility patents and licensing agreements that restrict such uses to living organisms, their metabolites, gene sequences or breeding processes are refrained from.

Subsequent recommendations identify specific technologies and whether they are prohibited under the existing regulatory definition of excluded methods. The <u>2016 recommendation</u> identified these prohibited methods: Targeted genetic modification including CRISPR; Gene silencing; Accelerated plant breeding techniques; Synthetic biology; Cloned animals and offspring; Plastid Formation. And it also identified Marker assisted selection and Transduction as allowed. The <u>2017 recommendation</u> identifies cisgenesis, intragenesis, and agro-infiltration as prohibited under the regulatory definition of excluded methods. The <u>2018 recommendation</u> identifies embryo rescue in plants as not prohibited under the regulatory definition of excluded method. The <u>Spring 2019 recommendation</u> identifies transposons developed via use of in-vitro nucleic acid techniques as prohibited under the regulatory definition of excluded methods.



of cisgenesis and intragenesis. The <u>Fall 2019 recommendation</u> identified induced mutagenesis as prohibited under the regulatory definition of excluded methods, and allows embryo transfer in livestock (not prohibited under the regulatory definition of excluded methods). Other technologies remain as "to be determined" (TBD) for future consideration by NOSB. In spring 2021, the Subcommittee presented a <u>discussion document</u> to re-establish the community's understanding of the rapidly expanding presence of biotechnology in the food system and to continue the NOSB's work on this topic.

- **DISCUSSION DOCUMENT:** The Materials Subcommittee is seeking feedback on seeking feedback on remaining TBD items, specifically cell fusion and protoplast fusion. In 2013, the NOP clarified its position on both techniques in <u>Policy Memo 13-1</u> allowing for both techniques to be used solely within taxonomic plant families. These technologies are also both included as "to be determined" (TBD) items in the NOSB Excluded Methods Determination list with the following notes:
 - Cell Fusion with a Plant Family: "Subject of an NOP memo in 2013. The Crops Subcommittee will continue to explore the issue"
 - Protoplast Fusion: "There are many ways to achieve protoplast fusion, and until the criteria about cell wall integrity are discussed and developed, these technologies cannot yet be evaluated"

The other TBD items are: TILLING (a type of mutagenesis that stands for "Targeted Induced Local Lesions in Genomes), Double Haploid Technology (DHT), Induced mutagenesis (developed through exposure to UV light, chemicals, irradiation, or other stress), and Transposons (Produced from chemicals, ultraviolet radiation, or other synthetic activities).

The Subcommittee is seeking answers to the following questions:

- 1. Should the NOSB prioritize developing additional criteria for excluded methods determinations before continuing to work on the remaining TBD list techniques?
- 2. Is Policy Memo 13-1 complete and applied consistently in organic systems, i.e., do cell fusion and protoplast fusion need to remain on the TBD list or can they be moved to the excluded method section with the notes that allowance is made for these techniques when employed within taxonomic plant families?
- 3. As the NOSB makes excluded methods determinations on the remaining TBD list techniques, should this organic system include allowance for historical use and a time frame for phasing out excluded uses?

Read the full discussion document in the NOSB Meeting Packet (p. 193-199)

• SUBCOMMITTEE VOTE: Motion to adopt the discussion document: 5 Yes, 0 No, 1 Absent



POLICY DEVELOPMENT SUBCOMMITTEE

Public Comment Process (DISCUSSION)

- BACKGROUND: NOSB public comment procedures are governed by the <u>Federal Advisory Committee Act</u> and are documented in the <u>NOSB Policy and Procedures Manual</u>. Written comments are accepted during a 30-day comment period prior to each NOSB meeting. Before the pandemic, oral comments were heard both virtually prior to the in-person meeting as well as in-person during the meeting. After the pandemic restricted travel, NOSB moved to an entirely virtual format for oral comments taking place the week before the meeting. The Policy Development Subcommittee (PDS) is reviewing procedures on written and oral comments and seeks to hear feedback on how it might modify established procedures to maximize community engagement practices that facilitate fair and equal access to National Organic Standards Board members by all stakeholders.
- DISCUSSION DOCUMENT: Written and oral public comments are foundational to the NOSB's informed decisionmaking process. Given the shift and emergence of virtual resources, the Subcommittee is considering making the virtual pre-meeting format the standard for oral comments.

The Subcommittee seeks stakeholder comments in response to the following questions:

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

Read the full discussion document in the NOSB Meeting Packet (p. 201-205)

• SUBCOMMITTEE VOTE: Motion to adopt the discussion document: 4 Yes, 0 No, 1 Absent