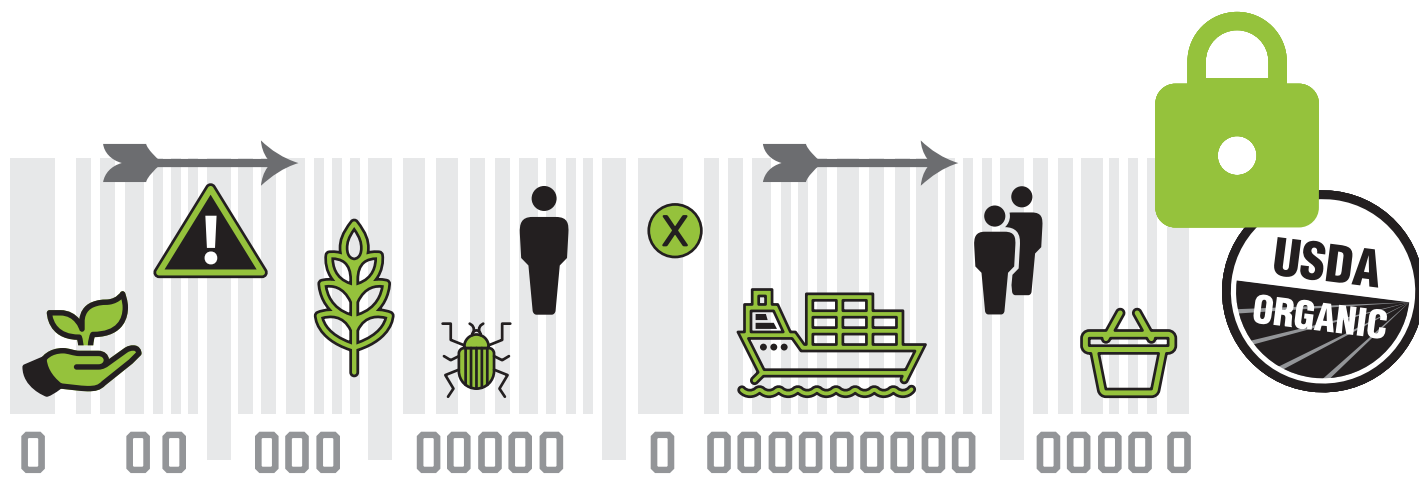


NATIONAL ORGANIC STANDARDS BOARD

FALL 2019 MEETING

October 23–25 | Pittsburgh, PA



 **INSIDE:**

- Continuous Improvement in Organic Standards
- Organic Fraud Prevention Solutions Program
- NOSB: The Cornerstone of Continuous Improvement
- The Restricted Organic Toolbox
- Get To Know Your National List
- National List Criteria: Inside the Review Process
- Guidance on Sourcing Organic Flavors
- Summary of NOSB Agenda Items
- Organic Trade Association Positions



ORGANIC TRADE ASSOCIATION RESOURCE BOOKLET

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WEDNESDAY • OCTOBER 23	THURSDAY • OCTOBER 24	FRIDAY • OCTOBER 25
8:30 a.m.: Call to Order	8:30 a.m.: Call to Order	8:30 a.m.: Call to Order
<ul style="list-style-type: none"> • Welcome/Introductions • Secretary's report • NOSB Report • USDA/AMS/NOP update • Marine Materials panel 	<ul style="list-style-type: none"> • Public comments continued 	<ul style="list-style-type: none"> • Crops Subcommittee • Materials Subcommittee
12:00 p.m.: Lunch Break	12:15 p.m.: Lunch Break	12:00 p.m.: Lunch Break
<ul style="list-style-type: none"> • Public comments 	<ul style="list-style-type: none"> • Handling Subcommittee 	<ul style="list-style-type: none"> • Policy Development Subcommittee • Compliance Accreditation & Certification Subcommittee • Deferred proposals/Final Votes • Officer Elections • Work agendas/Materials update • Closing remarks
5:45 p.m.: Recess	5:30 p.m.: Recess	5:00 p.m.: Adjourn

There will be two 15-minute breaks (mid-morning & mid-afternoon) and a 90-minute lunch break mid-day. Breaks, recess and adjournment times may vary based on completion of business.

Face-to-Face Meeting Format

- The Designated Federal Officer calls the meeting to order and adjourns the meeting. The NOSB Chair presides over the meeting.
- USDA and National Organic Program (NOP) provide NOSB with updates, and an overview of petitioned substances, sunset materials, and technical reports.
- The Board hears public comments.
- NOSB members present Subcommittee proposals, reports and discussion documents, and discuss public comment prior to voting on proposals. Final votes may be deferred to the last day of the meeting if more deliberation is needed.
- Agenda items may be withdrawn or votes postponed at the discretion of the Board.

Look for USDA's detailed NOSB Meeting Agenda that is available at the sign-in table outside the entrance of the meeting room. If you have questions, please contact the Advisory Committee Specialist Michelle Arsenault at Michelle.Arsenault@ams.usda.gov.

CONTINUOUS IMPROVEMENT IN ORGANIC STANDARDS

Welcome to the 56th meeting of the National Organic Standards Board (NOSB). NOSB has a long-standing legacy as the cornerstone of continuous improvement. These meetings are a valuable opportunity for public stakeholders to participate in shaping the organic standards. Although some recommendations may take years in the making, the passionate, opinionated and sometimes rowdy community of organic stakeholders manage to work together through the NOSB process to protect and strengthen the standards. When NOSB reaches consensus on an issue and passes a final recommendation, it is up to the U.S. Department of Agriculture (USDA) to implement the recommendations through formal rulemaking. Support from USDA's National Organic Program (NOP) is critical to advancing NOSB recommendations and ensuring uniform and robust standards. A healthy market for organic products requires a clear market distinction backed by a level playing field and a trusted, verified, and enforced claim.

IMPROVING THE PUBLIC-PRIVATE PARTNERSHIP

When Congress created the National Organic Program (NOP) housed under USDA nearly 30 years ago, the industry envisioned a process by which public and private stakeholders would work together via the NOSB process to make recommendations to USDA on advancing and developing the organic standards. As the organic industry grew and matured and new innovations, agricultural production systems and technologies emerged along with rapidly changing consumer demands, the industry would be able to evolve the standards and ensure that the organic label would continuously improve.

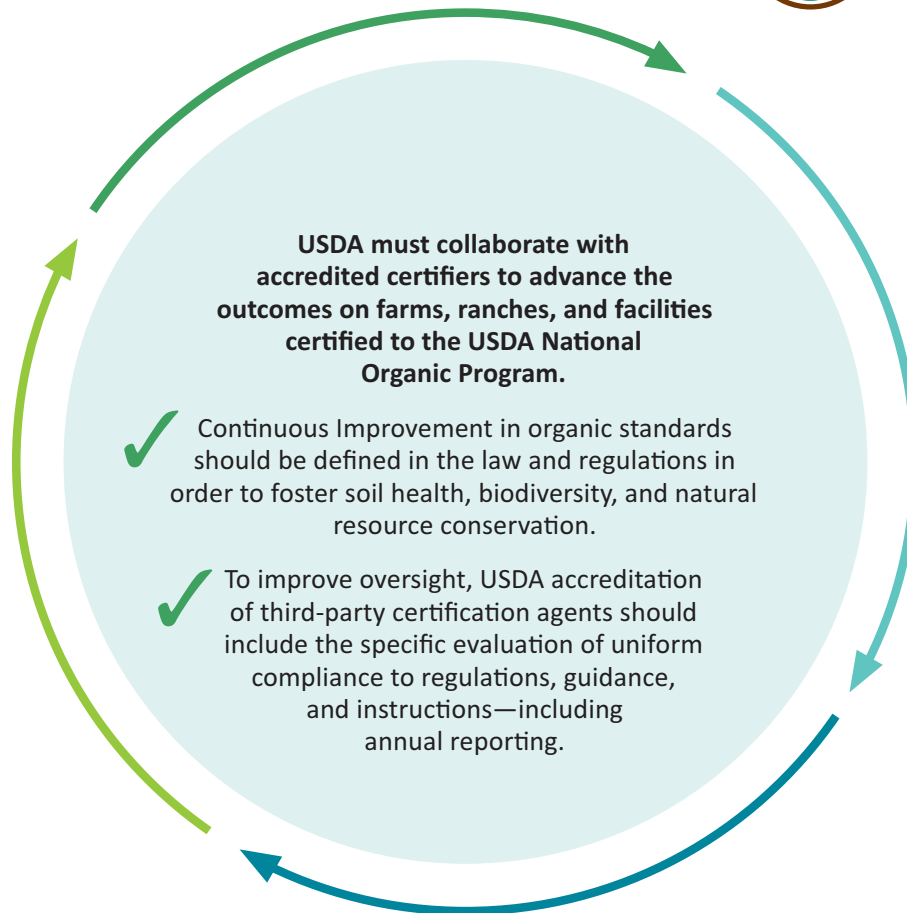
But in the past decade, the advancement and implementation of NOSB's recommendations by USDA have stalled. **In the past 10 years, the National Organic Standards Board has passed 20 final recommendations to advance the organic practice standards, yet USDA has not completed rulemaking on a single one of them.** These recommendations include animal welfare standards, strengthening organic seed usage and creating organic production standards for aquaculture, pet food, apiculture, personal care products and greenhouses. The failure of government to keep pace with consumers and the industry is harming and fragmenting the market. Inconsistent standards are becoming the status quo. Advancing organic standards is essential to a healthy market and credibility of the USDA Organic seal. The future of organic depends on fixing this partnership and getting USDA to work better for the organic community.

ACCOUNTABILITY IN VOLUNTARY ORGANIC STANDARDS

The cumbersome and time-consuming federal rulemaking process is not built for a voluntary regulatory program like organic. A new framework must be set for advancing organic standards in a way that is different than mandatory regulations, and relies on NOSB's recommendations as representations of industry consensus and priority.

The Organic Trade Association is working with Congress on legislation to add **transparency and accountability** to the federal regulatory process for organic, and to require USDA to act in a timely and transparent manner when the industry comes together to make recommendations to advance the organic standards. For instance, USDA must have an **affirmative obligation** to advance NOSB recommendations to the Unified Regulatory Agenda for rulemaking within a published timeline for action. Removal from the Unified Agenda must require public and congressional notification with the rationale as to why the agency is not moving forward on widely supported recommendations. The **cost benefit analysis** for voluntary organic standards should also be redefined to account for the costs when standards are inconsistent or not robust enough to meet market demand. Continuous improvement is also a responsibility of certifiers and certified operations. USDA must collaborate with accredited certifiers to improve oversight and **focus on outcomes** related to standards implementation and protecting natural resources.

CONTINUOUS IMPROVEMENT IS A BEDROCK OF ORGANIC





On Oct. 1, 2019, the U.S. Department of Agriculture reopened the comment period for the proposed rule on Origin of Livestock that was originally published on Apr. 28, 2015. The new comment period is open until Dec. 2, 2019 to give interested parties an additional opportunity to comment on the proposed rule.

→ **TAKE ACTION NOW:** <https://ota.com/take-action>

It is critical that USDA hears a unified voice from the organic community that we support rulemaking that clarifies and narrows the allowance for transitioning dairy animals to organic milk production. USDA especially needs to hear from organic dairy farmers that are new entrants to the organic dairy market since the last proposed rule was issued in 2015.

BACKGROUND RESOURCES

- [Organic Trade Association Origin of Livestock Fact Sheet](#)
- [Organic Trade Association 2015 comments on the Proposed Rule](#)
- [Organic Trade Association 2019 Dairy Council Letter to USDA](#)
- [National Organic Program Q&A on the Proposed Rule](#)
- [Full text of Proposed Rule published on Federal Register](#)
- [Notice from USDA to reopen the comment period](#)

KEY TALKING POINTS

- I/We support the Origin of Livestock Proposed Rule to clarify and narrow the allowance for transitioning dairy animals to organic milk production, while still allowing for a one-time transition of a conventional herd.
- Inconsistent interpretation and enforcement of the current regulations is causing economic harm to organic farmers and threatens the integrity of the organic seal. Rulemaking is critical to bring consistent enforcement and a level playing field to all organic dairy producers.
- USDA must immediately implement a final rule based on the original proposed rule issued in 2015. The organic industry, the National Organic Standards Board and Congress all agree that USDA must issue a final rule that reflects the policies contained in the original proposed rule issued in 2015 and limits the allowance for transitioning dairy animals to organic milk production as a one-time event.

OUR ASKS

→ **TAKE ACTION NOW:** <https://ota.com/take-action>

1. [Submit a unique comment](#) (using our talking points if it is helpful) directly to the Federal Register (Docket AMS-NOP-11-0009). We suggest that you attach any previously submitted comments from the original comment period as an addendum to your new comments.
2. If you don't have 5 minutes to craft a unique comment, organic farms can [take 1 minute to use our comment template](#).
3. Encourage others in your network to also [submit comments](#).

THE CORNERSTONE OF CONTINUOUS IMPROVEMENT

From its start, NOSB has been the cornerstone of continuous improvement and public input for U.S. organic standards. As we engage in this meeting and give voice to the process, it is important to take a moment to reflect on the genesis of NOSB and the importance of protecting and strengthening this foundational institution going forward.

As the growing awareness of ecological, health and welfare consequences of conventional farming systems became increasingly apparent from the 1960s through the 1980s, so did the demand for organic food and the need for organic standards. By the late 1980s, there was a patchwork of inconsistent or nonexistent state and private organic standards alongside inadequate enforcement programs. These caused a great deal of consumer confusion and threatened the meaning and value of the organic label. As a result, a coalition of organic farmers, consumers, animal welfare and environmental organizations recognized the need for establishing one common federal standard to ensure consistency, build consumer trust, and allow the sector to flourish. This diverse group of stakeholders united and persuaded Congress to pass the Organic Foods Production Act (OFPA) in the 1990 Farm Bill.

The passage of OFPA provided the foundation for uniform national organic standards for the production and handling of foods labeled as “organic.” The Act authorized a new USDA National Organic Program (NOP) to set national standards for the production, handling, and processing of organically grown agricultural products and to oversee the certification of organic operations. The Act also established the National Organic Standards Board (NOSB) to ensure an open, balanced and transparent process for setting and revising organic standards.

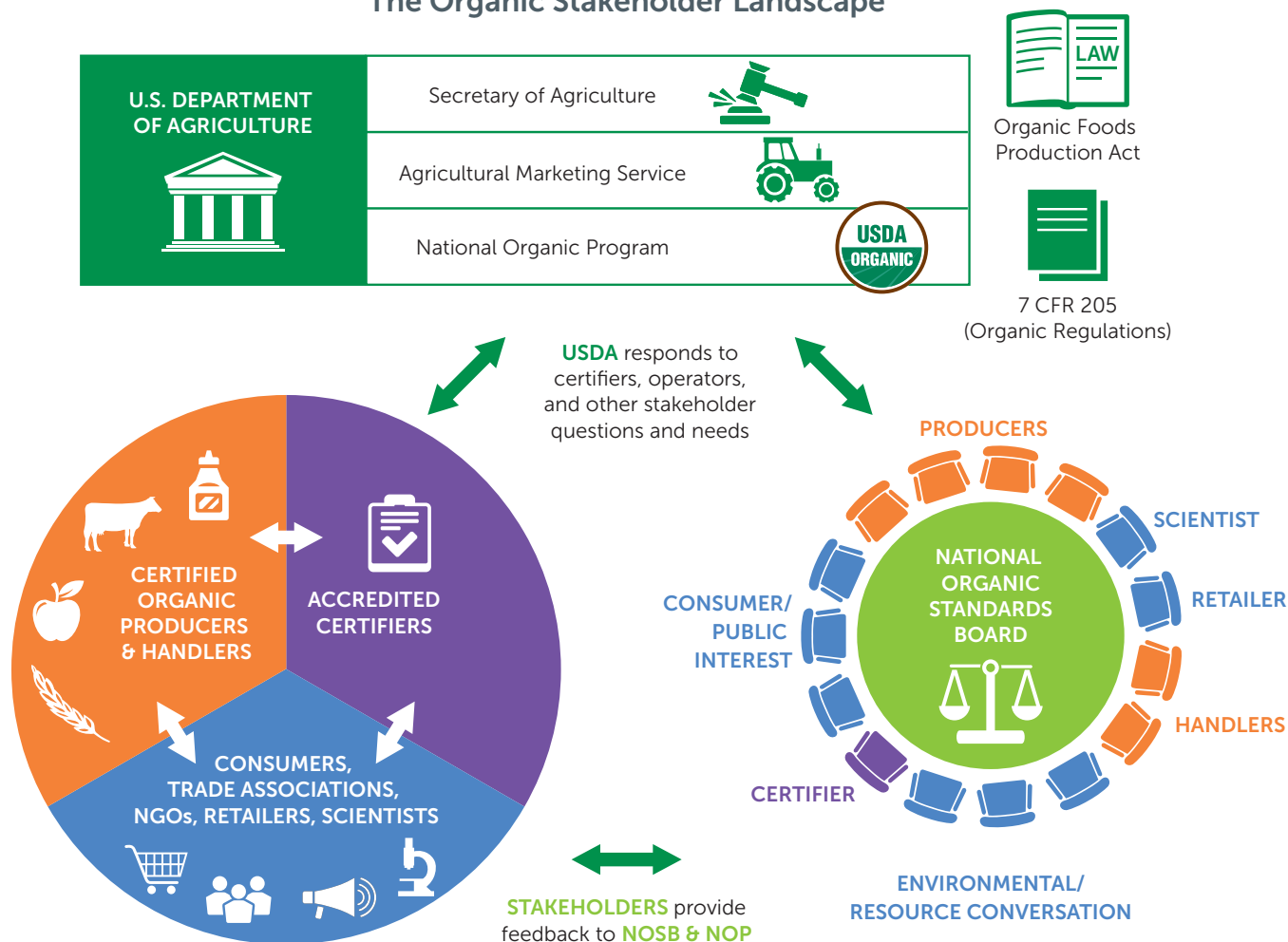
NOSB’S BALANCING ACT

NOSB plays a critical role in the organic rulemaking process because it advises USDA on which production inputs should be allowed or prohibited in organic farming and processing. NOSB also makes recommendations on a wide variety of other standards issues, such as organic pet food standards, aquaculture standards, animal welfare standards, and organic inspector qualifications.

The composition of NOSB, as detailed in OFPA, was carefully designed to ensure balanced stakeholder input into the rulemaking process. At the time the law was under development, there was debate that the Board should be industry-dominated to ensure continuation of the kind of high-quality standards associated with organic farming, which make sense from a production viewpoint. Others argued that industry representation on the Board would be inappropriate and create conflict of interest problems. As a result, Congress structured the Board so that farmers and handlers involved in organic production receive six representatives, equal to the consumer and environmental organizations, which together would receive six representatives. A single retail, certifier and scientist designation raised the membership to fifteen.

This 15-member volunteer citizen advisory board is designed to represent the diversity of the organic community across the United States to help ensure that all perspectives are considered before final recommendations are presented to the Secretary of Agriculture. The number and ratio of seats were allocated intentionally so that sectors must achieve consensus to pass a recommendation, ensuring balance of interest, with none predominating. And, in order for any motion to carry, a two-thirds vote is required to prevent any one interest from controlling the Board. It is this construct that helped give the organic label the credibility that it has today as well as the platform for its exponential growth.

The Organic Stakeholder Landscape



KEY



The Organic Foods Production Act passed in 1990. It takes an act of Congress to change the law.



7 CFR 205 are the organic standards that describe the requirements that must be verified before a product can be labeled as USDA organic.



U.S. Department of Agriculture (USDA) is responsible for administering federal regulations related to farming, agriculture, forestry and food.



The Secretary of Agriculture appoints and consults with NOSB in the formation of organic standards, policy and guidance.



USDA Agricultural Marketing Service (AMS) administers and enforces NOP's regulatory framework.



USDA (AMS) National Organic Program (NOP) establishes and enforces organic standards, oversees certifiers and supports transitioning and current organic producers and handlers.



National Organic Standards Board (NOSB) is a 15-member board of volunteer citizens that assists in the on-going development of the organic standards.



Accredited Certifiers are third party organizations that certify organic operations to protect the integrity of the USDA organic seal.



Certified Organic Producers and Handlers are farmers, ranchers, processors, retailers, traders, distributors and others that are able to sell, label and represent products as organic.



Consumers, trade associations, NGOs, retailers, scientists and other stakeholders with an interest in organic agriculture and products provide feedback to USDA and NOSB.

KEEPING NOSB STRONG

NOSB meets twice a year in a public forum to discuss and vote on subcommittee proposals related to the National List or other organic standards issues. NOSB first publishes proposals with a request for public comments. Prior to the meeting, NOSB members review literally thousands of pages of comments. During NOSB meetings, the full Board listens to oral public comments, discusses the proposals, and then votes on whether to pass the subcommittee proposals. NOSB subsequently submits its final recommendations to USDA.

The NOSB stakeholder feedback process allows substantial and diverse input from organic stakeholders continually to improve the organic standards. The process is challenging, it can be messy and it certainly can be difficult to watch. Is there room for improvement? Of course. Most anyone who has attended an NOSB meeting could point to areas to improve the process. The Organic Trade Association, for one, would like to see a less politicized and more respectful environment for public discourse at NOSB, and we would like to see Board members receive more regulatory and technical support from USDA on material analysis and proposal writing. Displeasure with the Board's controversial discussions on various topics or on the challenging decisions they make, however, should not be interpreted as a failure on the part of NOSB, but instead its members' diligence in addressing many viewpoints on multiple topics given the limited time and resources that the Board is provided.

Just like a healthy ecosystem, the strength in the organic sector always has been and always will be in its diversity. There is much at stake for organic in the 2018 Farm Bill, and the organic community's greatest weakness is the threat of division. Now more than ever, we need to stand together for policies and protections that strengthen the integrity of the USDA Organic seal, boost investment in organic research and support expansion of organic acres. With respect to NOSB, we must secure critical funding to make sure the Board receives the resources necessary to do its job so it can conduct the scientific analyses required under OFPA and write solid proposals which USDA can move through the system. OTA strongly believes that all of the opportunities to evolve the NOSB and the organic standards can happen within the public-private partnership, but we must stay united and live up to this unique structure we built. NOSB was designed to develop consensus, not pick winners and losers.

NOSB, while not a perfect system, is a solid one that has proven its worth and served the organic sector well for almost three decades. It is a process that is far more inclusive and transparent than turning over standards decisions to lawmakers and USDA staff and leaders. The public expects the process of establishing and revising USDA organic standards to be fully transparent with full opportunity for public participation, as envisioned by the procedures established in OFPA. In reality, there is no place in our food system that is more transparent than in organic production, and the role of the NOSB is central to that transparency.

WHO ARE THE CURRENT NOSB MEMBERS?

Farmers/Growers: Steve Ela (CO), Ashley Swaffar (AR), Jesse Buie (MS), Emily Oakley (OK)

Handlers/Processors: Tom Chapman (CA)

Retailer: Lisa de Lima (MD)

Scientist: Dave Mortensen (NH)

Consumer /Public Interest: Sue Baird (MO), Dan Seitz (MA), A-dae Romero-Briones (HI)

Environmentalists/Resource Conservationists: Asa Bradman (CA), Harriet Behar (WI), Rick Greenwood (CA)

Accredited Certifying Agent: Scott Rice (OR)

Every household needs a good toolbox and a well-stocked first aid kit to deal with unexpected challenges that can't be handled in the usual way. And so it is with organic agriculture.

Many consumers believe that absolutely no synthetic substances are used in organic production. For the most part, they are correct and this is the basic tenet of the organic law. But there are a few limited exceptions to this rule, and the National List is designed to handle these exceptions. The National List can be thought of as the "restricted tool box" for organic farmers and handlers. Like the toolboxes or first aid kits in our cupboards to deal with critical situations when all else fails, the organic toolbox is to be used only under very special circumstances.

The organic farmer's toolbox contains materials that have been traditionally used in organic production. By law, they are necessary tools that are widely recognized as safe and for which there are no natural alternatives. This toolbox is much smaller than the "full-toolbox" used in conventional farming.

Organic farmers have restricted access to 27 synthetic active pest control products while over 900 are registered for use in conventional farming.

How do the synthetic pest control products allowed in organic farming compare to the pesticides allowed in conventional farming?

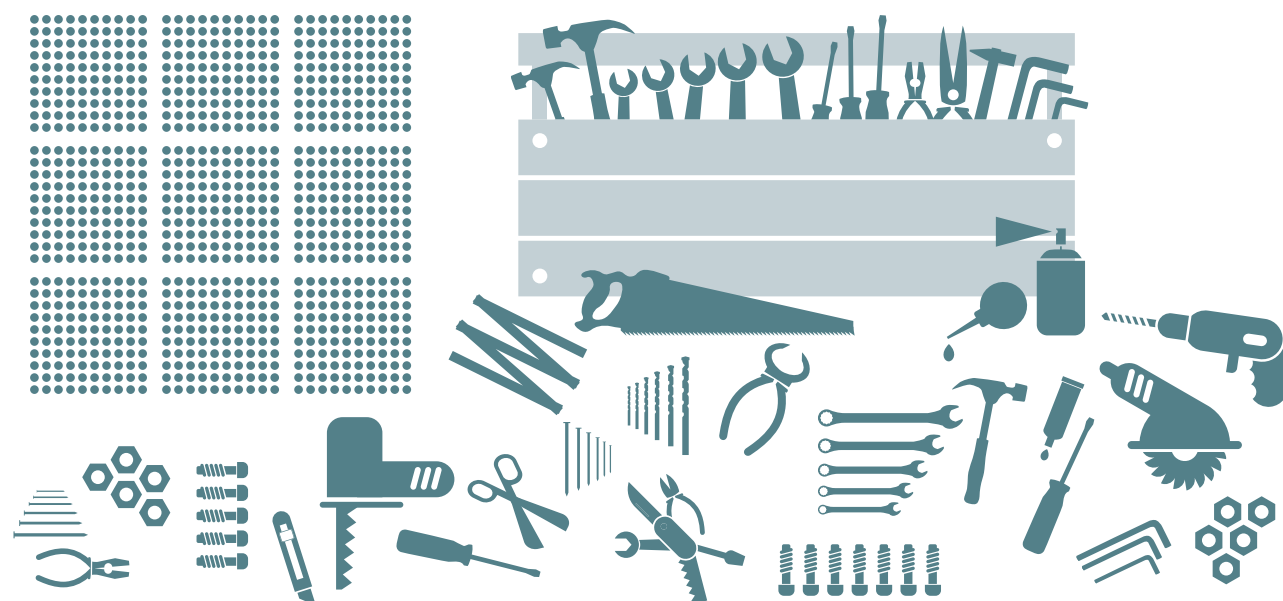
27 synthetic active pest control products allowed in organic crop production

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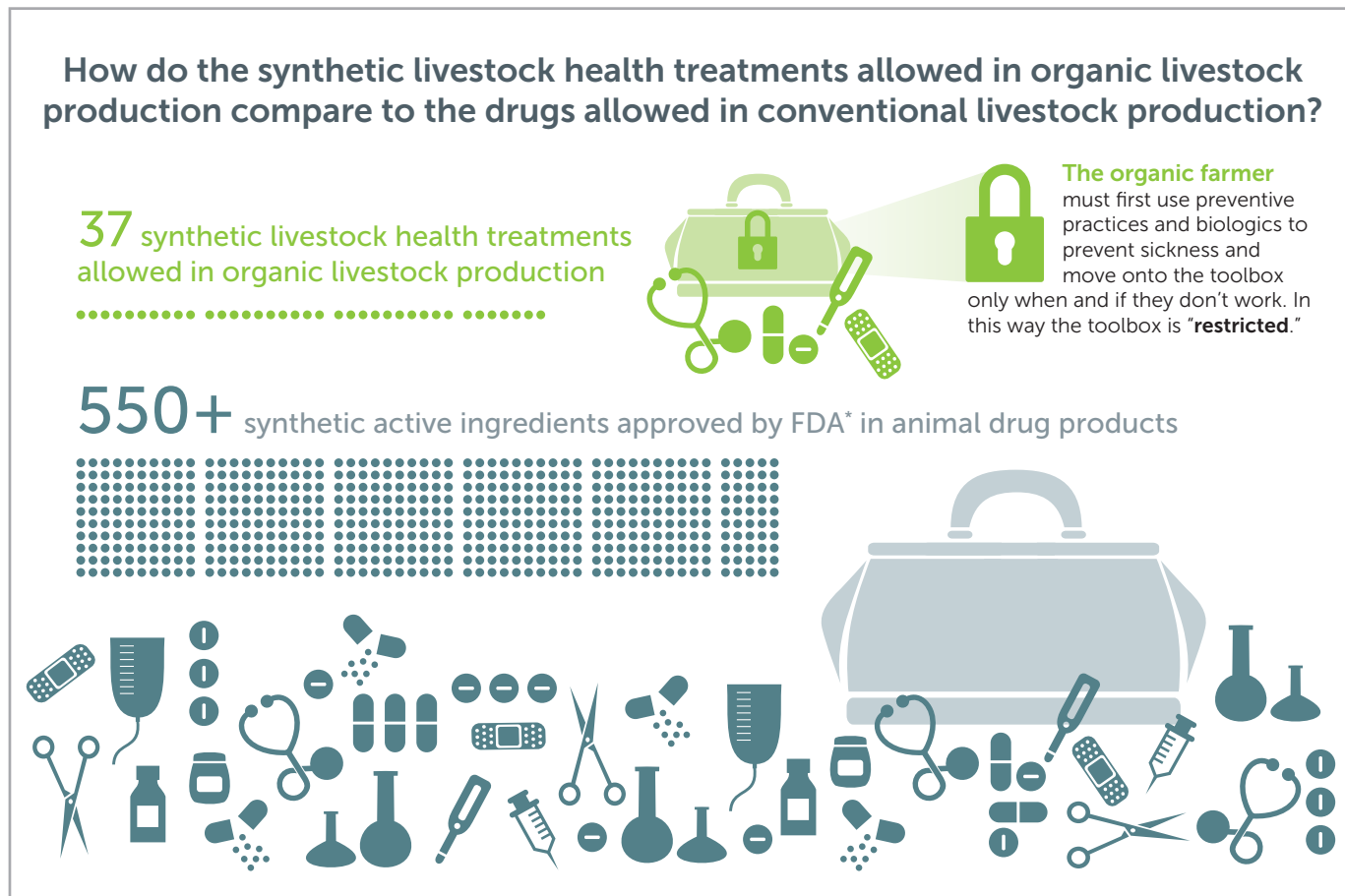
The organic farmer must first use mechanical, cultural, biological and natural materials and move onto the toolbox only when and if they don't work. In this way the toolbox is "restricted."

900+ synthetic active pesticide products registered for use in conventional farming by EPA*



*Ware, George W and Whitacre, David M. The Pesticide Book 6th Edition. 2004

Organic ranchers have restricted access to 37 synthetic livestock health treatments, while over 550 synthetic active ingredients are approved in conventional animal drug products.



*FDA Approved Animal Drug Products (Green Book)

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Before organic farmers can use any of these substances, however, they must develop a pest and disease management plan that describes how they will first prevent and manage pests without the use of National List inputs.

The restricted toolbox can only be opened when mechanical, cultural, and biological controls are insufficient to control pests, weeds and disease. This is foundational to organic farming.

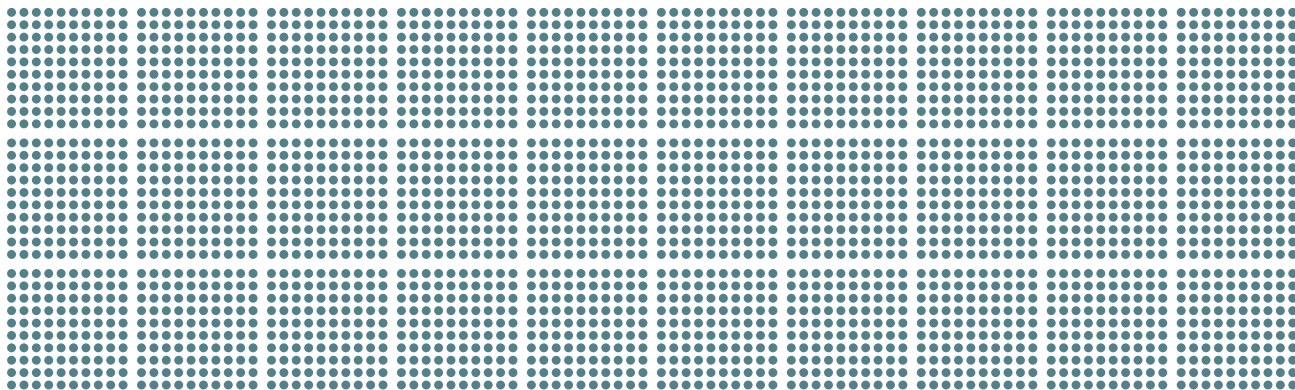
The National List is also designed to cover the up to 5% non-organic minor ingredients allowed in organic food processing. These ingredients are essential in organic food processing but difficult or impossible to obtain in organic form, either because the supply is very limited or the ingredient is a non-agricultural, like baking soda, and cannot be certified organic. A total of 67 non-agricultural minor ingredients are allowed in an organic processor's "pantry," while the conventional food processor's pantry is bulging with more than 3,000 total allowed substances.

How do the materials allowed in organic processed foods compare to the materials allowed in all other food?

67 non-agricultural minor ingredients allowed in organic processing



3000+ substances comprise Everything Added to Food in the United States (EAFUS)



Compared to the 67 non-agricultural minor ingredients allowed in organic processing, more than 3,000 total substances comprise an inventory often referred to as Everything Added to Food in the United States (EAFUS), and this is only a partial list of all food ingredients that may be lawfully added to conventional food.

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The restricted toolbox used in organic production and handling represents the best and least-toxic technology our food system has developed.

NOSB regularly reviews the tools in the organic toolbox to assure they still meet the organic criteria set forth in the law. Under the rigorous Sunset process, NOSB and organic stakeholders review the contents of the toolbox every five years to make sure that organic's allowed tools continue to be safe for humans, safe for the environment, and necessary because of the lack of natural or organic alternatives. There is no other regulation like this in the world.

Now more than ever, organic agricultural practices are needed on more acres to address significant environmental challenges for our planet. Now more than ever, the supply of organic ingredients, particularly grains and animal feed, is falling behind consumer demand. We face the dual challenges of encouraging more farmers to convert to organic and making our food production more sustainable. NOSB's challenge is to protect the integrity of organic, while at the same time providing producers and handlers with enough flexibility to allow them to comply with organic standards and to also expand organic acreage.

Like the toolboxes and first aid kits of households that are prepared for unexpected emergencies should they arise, the organic toolbox provides the tools to safely meet the challenges of today's organic world.

Here's a long list of chemicals you should never have to read.

• Acephate • Acetamidprid • Aldrin • Aldicarb • Aluminum • Aminopyralid • **Atrazine** • Avermectin • Anhydrous Ammonia • Ammonium Chloride • Ammonia • Ammoniated Micronutrients • Azadirachtin • Azoxytrobin • **Monoammonium Phosphate** • Bendiocarb • Bifenthrin • Calcium Nitrate • Calcium Oxide • Carbamates • Carbofuran • Carbaryl • Cresote • Cryolite • Calcium Cyanamide • Calcium Nitrate • Carbamates • Carbaryl • Difenapyr • Chlorothalonil • Chlorpyrifos • Clopyralid • Clothianidin • Creosote • Cryomazine • Cyflumetofen • Cyfluthrin • Cypermethrin • Cyprodinil • Deltamethrin • Diazinon • **Dicamba (Banvel)** • 1,3-dichloropropene (Telone II) • Dicloran • Dicrotophos • Dimethoate • Dimethoate • Disulfoton • 1,4-DMSO • Dinotefuran • Ethoprop • Ethoxyquin • Etoxazole • Fenpropathrin • Fenpyroximate • Fenazaquin • Folpet • Ferric Phosphate • Ferric Chloride • Ferrous Sulfate • Fenoxycarb • Fenpropanthrin • Flame Retardants • Fluvalinate • Fipronil • Fluzifop • Fludioxonil • Fluoxastrobin • Floridone • **Glyphosate (Roundup)** • Hydramethylnon • Hydrochloric Acid • Hydroperene • Iba (Indol-3-butylacetic Acid) • Imidacloprid • Iprodione • Iron Chloride • Iron Phosphate • Kinoprene • Lambda-cyhalothrin • Lambda-cyhalothrin • Magnesium Hydroxide • Magnesium Oxide • Mancozeb • Maneb • Manure Ash • Malathion • Mefenoxam • Metolachlor • Metalaxyl • Metaldehyde • Metam • Methyl Bromide • Methyl Iodide • Metolachlor • Myclobutanil • Mkg-264 • Nabam • Naled • Naphthalene • **Neonicotinoids** • Nickel Salts • Nicotine Sulfate • Nithiazine • Novaluron • Organophosphates • Oxyfluorfen • Parachlorobenzene • Pendimethalin • Pentachlorophenol • **Permethrin** • **Phenylamides** • Picaridin • Picloram • Piperonyl Butoxide • Potassium Carbonate • Potassium Permanganate • Potassium Phosphate • Potassium Nitrate • **Potassium Sorbate** • Propamocarb • Propazine • Pyraclostrobin • Pyriproxyfen • Pyridaben • Resmethrin • Rockwool • **Sewage Sludge** • Spiromesifen • Spirotetramat • Sulfur Dioxide Smoke Bombs • Sulfuryl Fluoride • Sulfoxaflo • **Streptomycin** • Strychnine • Sodium Fluoroaluminate • **Tetracycline** • **Triple Superphosphate** • Tebuconazole • Thiabendazole • Thiacloprid • Thiamethoxam • Triclopyr • Trifloxystrobin • Tolfenoyrade • Toxaphene • **Urea** • *Prohibited From Use With Organic Livestock: Antibiotics* • **Recombinant Bovine Growth Hormones (Rbgh)** • Bha (Butylated Hydroxyanisole) • Bht (Butylated Hydroxytoluene) • Butane • **Gmo Feeds** • Plastic Feed Pellets • **Slaughter Byproduct Feeds** • **Sulfa Drugs** • Strychnine • Urea • Ascorbyl Palmitate • Benzoic Acid • Calcium Aluminosilicate • Calcium Formate • Calcium Sorbate • Dilauryl Thiodipropionate • Dexamethasone • Disteryl Thiodipropionate • Erythroboric Acid • Ethoxyquin • Methylparaben • Propionic Acid • Propylparaben • Sodium Benzoate • Sodium Nitrile • Sodium Propionate • Sodium Sorbate • Sorbic Acid • Stanoic Chloride • Tertiary Butyl Hydroquinone (Tbhq) • Thiodipropionic Acid • Carnitine • Glycine • Lysine • Threonine • Tryptophan • Taurine • Acepromazine • Maleate • Acetazolamide Sodium • Afloxolaner • Albendazole • Albuterol Sulfate • Alfaxalone • Altrenogest • **Amikacin Sulfate** • Aminopentamide • Aminopropazine • Amitraz • Ammonium Bituminosulfonate • Amoxicillin • Amphomycin • Ampicillin • Amprolium • Apramycin • Arsenamide • Atipamezole • Atropine • Trichlorfon • Avilamycin • Azaperone • Bacitracin • Bambermycins • Betamethasone • Boldenone Undecylenate • Somatotropin • Bunamide • Hydrochloride • Bupivacaine • Buprenorphine • Butacaine Sulfate • Butamisol Hydrochloride • Cambendazole • Capromerlin • Carbadox • Carnidazole • Carprofen • Cefadroxil • Cefovecin Sodium • Cefpodoxime Proxetil • Ceftiofur • **Cephalosporin** • **Cephalexin** • Cephapirin • Chloramine-t Trihydrate • Chloramphenicol • Chlorobutanol • Chlorothiazide • Chlorphenesin Carbamate • Chymotrypsin • Clindamycin • Clomipramine • Clotidol • Cloprostenol • Clorsulon • Clotrimazole • Cloxacillin • Colistimethate • Corticotropin • Coumaphos • Cyclosporine • Cythioate • Danofloxacin • Decoquinat • Deraoxib • Deslorelin • Desoxycorticosterone • Detomidine • Dexmedetomidine • Dichlorophene • Dichlorvos • Diclazuril • Diclofenac • Dicloxacillin • Diethylcarbamazine Citrate • Difloxacin • Dihydrostreptomycin • Dimethyl Sulfoxide • Dinoprost Tromethamine • Dipiperazine Sulfate • Diprenorphine • Dirlotapide • Dithiazanine • Domperidone • Doramectin • Doxapram • Doxycycline • Doxylamine • Droperidol • Efrotomycin • Emodespide • Enalapril Maleate • Enrofloxacin • Eprinomectin • **Erythromycin** • Estradiol • Ethylisobutrazine • Etodolac • Famphur • Febantel • Pyrantel • Fenprostalene • Fentanyl • Fenthion • Firocoxib • Florfenicol • Flumethasone • Fluocinolone • Fluoxetine Hydrochloride • Fluprostenol Sodium • Fluralaner • Fomepizole • Formalin • Furazolidone • Gamithromycin • Gentamicin • Miconazole Nitrate • Gleptoferron • Glycopyrrolate • Gonadorelin • Grapiprant • Griseofulvin • Guaifenesin • Halofuginone • **Lincomycin** • Halothane • Haloxon • Hetaicillin • Hyaluronate • Hydrochlorothiazide • Hydrocortisone • Hydrowinoline Sulfate • Imidacloprid • Imidocarb • Insulin • Iodochlorhydroxyquin • Isoflupredone • Isoflurane • Isopropamide • Itraconazole • Kanamycin Sulfate • Ketoprofen • Laidlomycin • Lasalocid • Lasalocid • Levamisole • Levofloxacin • Lincocin • Lithiorynine • Lotilaner • Lufenuron • Luprostol • Maduramicin • Marbofloxacin • Maropitant • Mebendazole • Medetomidine • Megestrol Acetate • Melarsomine • **Melengestrol** • Meloxicam • Mepivacaine • 2-mercaptopbenzothiazole • Methocarbamol • Methylprednisolone • Metoserpate • Milbexone • Miconazole Nitrate • Milbemycin Oxime • Milbemycin • Mirtazapine • Mometasone • Monensin • Morantel Tartrate • Mupirocin • Naloxone • Naltrexone • Naproxen • Narsin • Neomycin • Nequinat • Nicarbazin • Nitenpyram • Nitrofurazone • Novobiocin • Novobiocin • Oclacitinib • Orbifloxacin • Orgotein • Oxendazole • Paclitaxel • Pegbovigrastin • **Penicillin** • Pentobarbital • Phenothiazine • Phenylbutazone • Phenylpropanolamine • Phosmet • Pimobendan • Piperazine • Pirlimycin • Ponazuril • Pradofloxacin • Pralidoxime • Praziquantel • Praziquantel • Prednisolone • Prednisone • Primidone • Progesterone • Promazine • Propioproazine • Propofol • Prostaline • Pyrantel • Maleate • Pyrimethamine • Rabacfosadine • **Ractopamine** • Robenacoxib • Robenidine • Romifidine • Salinomycin • Sarolaner • Selamectin • Selegiline • Selenium Disulfide • Semduramicin • Sevoflurane • Spectinomycin • Stanozolol • Streptomycin • Sulfadiazine • Sulfadimethoxine • Sulfaethoxyxypyridazine • Sulfamerazine • Sulfaquinoxaline • Sulfoxazole • Sulfomycin • Telmisartan • Tepoxalin • Tetracycline • Thiabendazole • Thialbaitone • Thiampyl • Thiopental • Tiamulin • Ticarcillin • Tildipirosin • Tiletamine • Tilimicosin • Tilduradone • Tioxdazole • Tolnaftate • Trenbolone • Triamcinolone • Trichlorfon • Triflupromazine • Trilostane • Tripelennamine • Triptorelin • Tulathromycin • Tylosin • Tyvalosin • Virginiamycin • Zeranol • Zoalene • Zilpaterol (Zilmax) • *Prohibited Ingredients In Organic Products: Acesulfame-k (Acesulfame Potassium) • Acetic Ether • Acetylated Esters Of Mono- And Diglycerides • Acetone • Acetylaldehyde • Acid Potassium Sulfate • Acrylonitrile Copolymers • Acrolein • Acrylates • Acrylamides • Adenosine • Adipic Anhydride • Adrenal • Advantame • Alpha-acetolactate Decarboxylase • Aluminum Caprate • Aluminum Calcium Silicate • Aluminum Disulfate • Aluminum Laurate • Aluminum Myristate • Aluminum Nicotinate • Aluminum Oleate • Aluminum Phosphate • Aluminum Sodium Sulfate • Aluminum Stearate • Amidated Pectin • Ammonium Chloride • Ammonium Gluconate • Ammonium Isovalerate • Ammonium Sulfide • Anoxomer • Arabinogalactan • Arsanilic Acid • **Artificial Colors** (Red 40, Blue 1, Blue 2, Citrus Red 1 & 2, Green 3, Yellow 5 & 6, Red 2 & 3, Orange B, Bixin, Norbixin) • **Artificial Flavors** • **Artificial Preservatives** • **Artificial Sweeteners** • **Artificial Fragrances** • Ascorbyl Palmitate • Ascorbyl Stearate • Aspartame • Astaxanthin • Azodicarbonamide • Avobenzone • Benzophenone • Bapa • **Benzoates** • Benzyl Alcohol • Benzoyl Peroxide • Brominated Vegetable Oil (Bvo) • Butylated Hydroxyanisole • Butylated Hydroxytoluene • Butyl Alcohol • Butyl Stearate • Butyric Acid • Calcium Benzoate • Calcium Bromate • Calcium Caprylate • Calcium Caprylate • Calcium Disodium Edta • Calcium Oleate • Calcium Palmitate • Calcium Peroxide • Calcium Propionate • Calcium Saccharin • Calcium Sorbate • Calcium Stearyl-2-lactylate • Caprocaprylobehenin • Carmine • Cephapirin Benzathine • Chloriform • Chlorophenols • Chlorinated Benzenes • Coal Tar Dyes • Cupric Sulfate • Cyclamates • Cyclohexane • Cysteine (L-cysteine) • Datem (Diacyl Tartaric And Fatty Acid Esters Of Mono And Diglycerides) • Dichlorodifluoromethane • Dibutyl Phthalate • Diethanolamine • Diethylenetriamine • Dimethylpolysiloxane • Dioctyl Sodium Sulfosuccinate (Dss) • Disodium Calcium Edta • Disodium Cyanodithioimidocarbonate • Disodium Dihydrogen Edta • Disodium Guanylate • Disodium Inosinate • Edta • Ethylene Oxide • Ethoxyquin • Ethoxycinnmate • Erythrobic Acid • Formaldehydes • Formaldehyde Releasers • Foie Gras • Fumaric Acid • Glutaraldehyde • **Gmos (Genetically Modified Organisms)** • Gmp (Disodium Guanylate) • Hexa-, Hepta- And Octa-esters Of Sucrose • Hexane • Homosalate • Hydrazine • Hydrochloric Acid • Hydroquinone • Hydroxypropyl Methylcellulose • Imp (Disodium Inosinate) • **Irradiation** • Lactylated Esters Of Mono- And Diglycerides • Lactylic Stearate • Lead Acetate • Magnesium Silicate • Magnesium Glycophosphate • Mannitol • Methyl Alcohol • Methyl Silicon • **Methylparaben** • Methylsynephrine • Microparticulated Whey Protein Derived Fat Substitute • Mineral Oil • Monoammonium Glutamate • **Monosodium Glutamate (Msg)** • Monopotassium Glutamate • Naphtha • Natamycin • Octyl Gallate • Olestra • Oxystearin • Paraben • Phthalates • Phenoxethanol • Pelargonic Acid • Petrolatum • Polyacrylamide • Propyl Alcohol • Propylene Glycol • Polydextrose • Polyvinyl Alcohol • Polyvinyl Pyrrolidone • Potassium Benzoate • Potassium Bromate • Potassium Sorbate • Potassium Nitrate • Potassium Persulfate • Potassium Sorbate • Potassium Sorbate • Polyethylene Glycol • Polypropylene Glycol • Polysorbates • Polyvinyl Acetate • Polyvinylpyrrolidone • Propane • Propionates • Propyl Gallate • Propyl Paraben • Propylene Chlorohydrin • Propylene Oxide • Quaternary Ammonium Chloride • Quinine Hydrochloride Or Sulfate • Retinyl Palmitate • Retinoic Acid • Saccharin • Sewage Sludge • Siloxanes • Sodium Lauryl Sulfate (Sls) • Sodium Laureth Sulfate (Sles) • Sodium Myreth Sulfate • Sorbitol Anhydride Esters • Sodium Aluminum Sulfate • **Sodium Benzoate** • Sodium Caseinate • Sodium Carboxymethyl Cellulose • Sodium Diacetate • Sodium Glutamate • Sodium Glucoheptonate • Sodium Hexametaphosphate • Sodium Humate • Sodium Hypophosphite • Sodium Metasilicate • Sodium Mono- & Dimethylnaphthalenesulfonates • Sodium Myristate • Sodium Nitrate/nitrite • Sodium Propionate • Sodium Silicoaluminate • Sodium Sorbate • Sodium Stearyl-2-Lactylate • Sodium Stearyl Fumarate • Sorbic Acid • Sorbitan Monoleate • Sorbitan Monostearate • Stearic Acid • Stearyl Citrate • Monoglyceride Citrate • Sucralose • Sucroglycerides • Sucrose Polyester • Sulfuric Acid • **Synthetic Nitrates/nitrites** • Tbhq (Tertiary Butylhydroquinone) • Tert Butylhydroquinone • **Theobromine** • Thiodipropionic Acid • **Titanium Dioxide** • Tetrasodium Ed Ta • Toluene • **Triclosan** • Triclocarban • Trichloroethylene • Tridodecyl Amine • Triethanolamine • Trimethylamine • Urea • Vinyl Acetate • Volatile Fatty Acids • **Yellow Prussiate Of Soda***

And if you buy organic, you'll never have to.

Organic keeps these chemicals off the farm and out of your food. For more information about what's not allowed in organic production and handling go to ams.usda.gov



It was 1997 and the National Organic Program (NOP) as we now know it was still evolving. On December 16 of that year, the first proposed rules to establish national organic standards were published by the NOP, erupting a roar of public discourse. The Department of Agriculture, which had just begun overseeing the National Organic Program, was swamped with over 275,000 public comments on the proposal, and the public interest in organic has only intensified since.

Today's strict and comprehensive network of federal requirements and regulations that monitor and check the organic industry, from the farm gate to the dinner plate, was born out of a public outcry that started rumbling in the 1970s for a healthier and safer agricultural system that would not endanger the environment or pose risks to human health. That public sentiment culminated in the Organic Foods Production Act in the 1990 Farm Bill, which ultimately created the current rules for the entire system of certified organic agriculture in the United States.

A historical review of the National List



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Organic production systems encourage a healthy environment with as few inputs as possible. Organic agriculture is governed by the basic rule of allowing natural substances and not allowing synthetic materials. But in the real world, sufficient quantities of an input essential to organic production and processing — and not harmful to humans or the environment — are not always available in an organic form, so exceptions to this rule have been made. These exceptions make up the “National List of Allowed and Prohibited Substances,” or simply the “National List.”

The National List identifies the synthetic substances that may be used in organic crop and livestock production, and prohibits the use of certain natural toxic substances in organic production. The list also identifies synthetic materials such as carbon dioxide, non-synthetic non-agricultural substances such as yeast, and non-organic agricultural substances such as Turkish bay leaves that may be used in organic handling and processing.

LEARNING FROM OTHERS AND COMPILING A LIST THAT WORKS

It took five years for the National Organic Standards Board (NOSB), a group of fifteen public volunteers appointed by the Secretary of Agriculture who represent various sectors of the organic industry, to complete a massive review of the inputs in use by organic producers and processors, and of state, private, and foreign organic certification programs to help craft the final organic regulations.

It was from this extensive research and engagement with everyone in the organic chain, and following thousands of comments to federal regulators, that the National List was compiled, reworked and reworked again, and then officially established on Dec. 21, 2000. The list mirrored most of the standards that organic producers and handlers were already abiding by through the various certification programs of the time, and was formulated to be flexible enough to accommodate the wide range of operations and products grown and raised in every region of the United States.

What are some of the allowable substances on the National List? For crop producers, the list includes things like newspapers for mulch and sticky traps for insect control. For livestock producers, it includes vaccines, an important part of the health regimen of an organic animal for which antibiotics are prohibited, and chlorine for disinfecting equipment. For organic processors, the list includes ingredients essential to processed products that can't be produced organically, like baking soda, and certain vitamins and minerals and non-toxic sanitizers.

Of course, not all the allowed items on the National List are non-controversial. But all of the substances on the list are required to fulfill three critical criteria as specified by the Organic Foods Production Act: 1) Not be harmful to human health or the environment; 2) Be necessary to production because of unavailability of natural or organic alternatives, and 3) Be consistent with organic principles.

A NO-GROWTH TREND IN SYNTHETICS

The first several years of the implementation of the list were a period of fine-tuning, adjustment and just plain learning. Some materials essential to safe organic production had been overlooked and were added, like ozone gas for cleaning irrigation systems and animal enzymes for organic cheese production — both put on the list in 2003.

In 2007, the number of non-organic agricultural ingredients allowed in organic processed products was dramatically tightened. Processed products with the organic label must contain 95 percent certified organic ingredients. Before 2007, the agricultural ingredients that could be used in the remaining 5 percent category were not spelled out; ANY non-organic agricultural ingredient could be used if it was not available in organic form. In 2007, 38 specific substances were defined and added to the National List of non-organic ingredients allowed in a processed organic product. So with the addition of 38 materials to the National List, what had been an unlimited number of non-organic agricultural ingredients allowed in organic processed foods was reduced to a closed list of just several handfuls.

For a decade since 2008, an even greater shift away from synthetics occurred, with just six synthetics added to the list, and a total of 77 during that same time period removed, denied from the list, or further restricted.

Allowed synthetics 2008–2018: What is the trend?**No-Growth**

with a strong preference for the use and development of nonsynthetic and organic alternatives.

6

synthetics have been added



Examples of synthetics added include a sanitizer used in processing facilities that is allowed only for secondary and indirect food contact surface sanitizing, a cheese wax used for organic mushroom production, a mite control product for honeybees for organic honey production.

77

have been removed, denied, or further restricted.



Removals:	17
Petitioned and denied:	59
Further restricted:	1

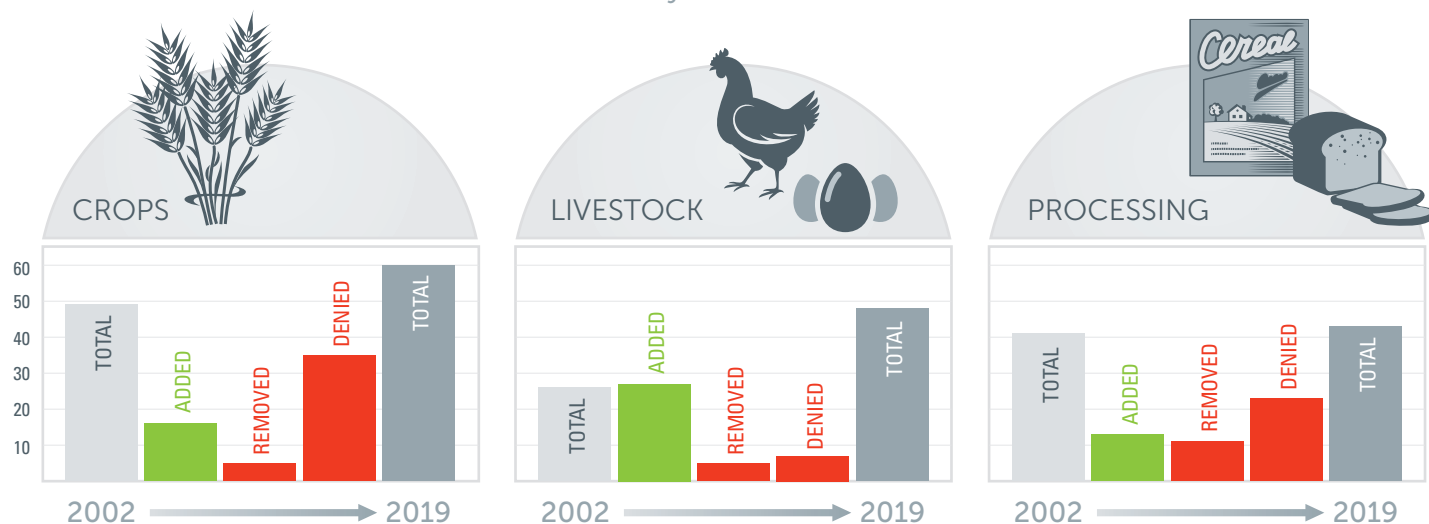
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The synthetics added include a sanitizer in processing facilities used only for secondary and indirect food contact, a cheese wax used for organic mushroom production, a mite control product for organic honey production, and biodegradable mulch. Substances no longer allowed in organic products or denied permission to be added include non-organic hops in organic beer, bleached lecithin, unmodified rice starch, antibiotics for pears and apples, and dozens of synthetic substances and other materials. Additional restrictions recently added include a requirement to use organic yeast in certified products for human consumption and a requirement to use organic colors.

The no-growth trend in synthetics from 2008-2018 shows a strong preference for the use and development of non-synthetic and organic alternatives.

A real-life example of a determined individual working within the NOSB system to replace an allowed synthetic material on the National List with a certified organic substitute occurred in 2013. The head of the company, which makes rice-based ingredients that food manufacturers use as alternatives to synthetic ingredients, submitted a petition in 2010 to remove silicon dioxide from the National List since his company had developed a rice-based certified organic alternative to the synthetic. In 2013, the NOSB amended the use of silicon dioxide and weighed in favor of organic rice hulls when available.

National List Scorecard: Synthetics Added, Removed or Denied



	Synthetics on the National List in 2002	Synthetics Added	Synthetics Removed	Synthetics Petitioned and Denied*	Synthetics on the National List in 2019
CROPS	49	16	5	35	60
LIVESTOCK	26	27	5	7	48
PROCESSING	41	13	11	23	43

* Requested for addition to the National List but denied

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ENABLING ORGANIC TO GROW AND PRESERVING THE SYSTEM'S INTEGRITY

The system was more arduous and took longer than expected, but it worked. It was proof that the National List has the foresight to include synthetic ingredients when there are no organic or natural alternatives, and thereby enabling the organic industry to evolve and grow, but more importantly, the system provides a method to retire a synthetic substance and implement the organic alternative when it becomes available.

And in the particular case of the maker of the rice-based organic alternative, it was a win-win deal for the company, with sales growing by over 150 percent!

The National List represents a process that is rigorous, fair and one that works. It reflects realistic organic practices, while taking into account current obstacles to ideal production. It encourages public scrutiny, comment and engagement.

Organic food sales in the United States have jumped from slightly more than \$18.1 billion in 2007 to nearly \$50 billion in 2018. According to USDA's National Agricultural Statistics Service's 2016 Certified Organic Survey, the number of certified organic farms in the country totaled 14,217 farms in 2016 compared to 3,000 tops in the mid-1990s. Today, the total number of certified organic operations exceeds 26,000 nationwide.

More certified organic farmers, more organic products, more organic processors and handlers, an organic farm-to-table supply chain that is growing every day, but still adhering to a tight set of stringent guidelines—that's what the National List has made possible.

ORGANIC TRADE ASSOCIATION PETITIONS TO REDUCE SYNTHETICS AND STRENGTHEN ORGANIC REQUIREMENTS

Acting on extensive feedback and input from its members, the Organic Trade Association has filed petitions to amend the National List of Allowed and Prohibited Substances in organic production and processing.

➤ **Removing the exemption for synthetic lignin sulfonate in post-harvest handling of organic pears**

At the time of the petition (2014), there were two substances on the National List that can be used as floating agents in the handling of organic pears: lignin sulfonate and sodium silicate. As the pear industry modernized its equipment, the use of floating agents declined. The trade association contacted certified organic pear packers and found that those still using a floating agent are using sodium silicate exclusively. Thus, lignin sulfonate fails to meet the criteria that it is essential for organic production, and we petitioned that it be removed as an allowable post-harvest floating agent. In fall 2017, NOSB recommended to remove listing, and the NOP final rule to amend the National List was published on July 6, 2017.

➤ **Strengthening the requirement for organic flavors in processed products**

Natural flavors are allowed in certified organic processed foods in the 5 percent non-organic portion, provided they are produced without synthetic solvents, synthetic carriers and artificial preservatives. They must also be made without the use of genetic engineering and irradiation. Natural flavors have been included on the National List since it was first implemented in 2002. Since that time, however, many organic flavors have been developed and are being successfully used by many companies. The number of organic flavors in the marketplace has become substantial, so we petitioned (2014) to revise the current listing of natural flavors to require the use of organic flavors when they are commercially available in the necessary quality, quantity or form. In fall 2015, NOSB voted unanimously in favor of the petition, and NOP final rule to amend the National List was published December 27, 2018. The new requirement becomes effective on December 27, 2019.

➤ **Protecting the continued production and availability of NOP certified encapsulated dietary supplements**

On January 31, 2018, we submitted a petition on behalf of our National List Innovation Working Group to add pullulan to the National List as an allowed non-agricultural, non-synthetic ingredient used in tablets and capsules for dietary supplements made with organic ingredients. The need for this petition is due to a recent interpretation change to classify pullulan as “non-agricultural” instead of “agricultural.” Under the previous interpretation, pullulan was allowed in the non-organic portion of dietary supplement labeled “made with” organic ingredients, which significantly contributed to the growth of NOP certified supplements. Under the new interpretation, pullulan would be required in certified organic form unless it is added to 205.605(a) as an allowed non-agricultural minor ingredient. Unfortunately, there are no other NOP compliant vegetarian options available for producing NOP certified vegetarian encapsulated supplements, and organic pullulan is currently not commercially available for use in the United States. Thus, if pullulan is not added to the National List, the production of NOP certified encapsulated vegetarian supplements will not be possible. The purpose of the Organic Trade Association’s petition is to protect the continued production and availability of USDA-NOP certified encapsulated dietary supplements, and to support the commercial development of certified organic pullulan. NOSB unanimously passed this petition at the spring 2019 meeting. NOP will need to implement this decision through rulemaking.

THE ORGANIC TOOLBOX IS SUPPORTED BY A THREE-LEGGED STOOL

A primary function and responsibility of the National Organic Standards Board (NOSB) is to determine the suitability of the inputs that may be used in organic farming and handling. NOSB was in fact designed by the Organic Food Production Act (OFPA) to advise the U.S. Department of Agriculture (USDA) as to which inputs should be allowed. The organic law and regulations specify the evaluation criteria NOSB must use when it makes its recommendation to USDA.

The evaluation criteria and review process used by NOSB when voting on the suitability of inputs can be likened to a three-legged stool. The National List, which we often refer to as the “Restricted Organic Toolbox,” is supported by three legs, each one representing criteria to be met for an input to be added or removed. If any one of the three legs is missing, the stool falls over and the action on the input fails.

The organic law (OFPA) and the organic regulations include a number of factors NOSB must consider when deciding on the suitability of an input. If one takes a look at the sum of all parts, the conditions that must be met fall into three main clearly stipulated criteria: 1) the input is necessary or essential because of the unavailability of natural or organic alternatives; 2) the input is not harmful to human health or the environment; and 3) the input is suitable with organic farming and handling. These three criteria comprise the three legs of the stool. Let’s take a closer look.

ALTERNATIVES

Perhaps the simplest of the three main criteria is researching whether there are natural or organic alternatives. The organic law clearly states the National List may allow the use of an input in organic farming or handling if it is “necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products.” The law also states NOSB shall consider alternatives in terms of practices or other available materials. The organic regulations at § 205.600(b) also bring in additional but similar criteria for synthetic processing aids and adjuvants, allowing their use only when there are no organic substitutes and when they are essential for handling or processing.

While this leg of the stool is arguably the most simple of the three, NOSB and organic stakeholders have long struggled with this criteria because of the terms “necessary,” “essential,” and “availability.” How much of something is needed to consider it available in the volume needed? What if a natural alternative is available but the quality is not sufficient? What if the alternative works in one region of the country but not another? What if there is an alternative but it’s important to have more than one option? Determining whether there are natural or organic alternatives continues to be more challenging than one might think, and for this particular criteria, NOSB relies heavily on the feedback from organic stakeholders, especially the organic farmers and handlers growing and making organic food, and using the inputs and practices in question.

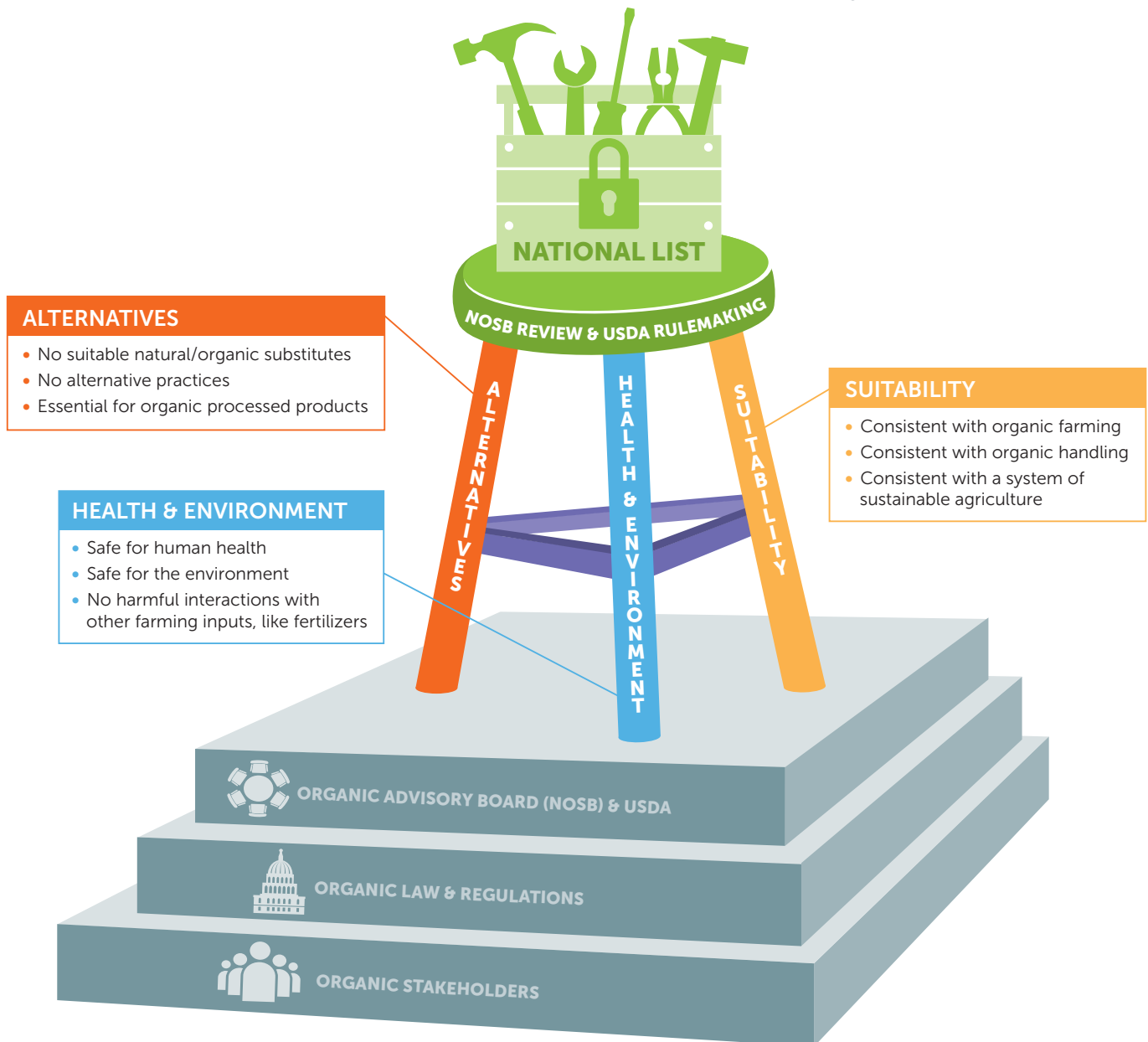
HUMAN HEALTH AND THE ENVIRONMENT

The restricted organic toolbox used in organic farming and handling represents the best and least toxic technology our food system has developed. That is exactly how we want to keep it. This principle is bound by the organic law, which states specifically that inputs that otherwise would be prohibited can be added to the National List only if their use is not harmful to human health or the environment. The law also requires the final decision made by USDA to be done so in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency.

To help NOSB advise USDA on this complex topic, the organic law provides NOSB with evaluation criteria to consider in order to explore the toxicity of the input during manufacture, use and disposal, and the

BALANCING THE THREE-LEGGED STOOL

How “National List” Criteria Support the Restricted Organic Toolbox



Synthetic Processing Aids & Adjuvants Have Additional Criteria...

- Use and disposal don't harm the environment
- Recognized as safe by the Food and Drug Administration
- Primarily not a preservative or used to recreate qualities lost during processing

REFERENCES

- Organic Foods Production Act (OFPA)
 - National List Criteria (OFPA 6517)
 - National Organic Standards Board (NOSB) Evaluation Criteria (OFPA 6518)
- USDA Organic Regulations
 - Processing Aids and Adjuvants Criteria (7 CFR 205.600(b))

potential interactions the input may have with other inputs or within the farming ecosystem. The organic regulations bring in additional but similar criteria for synthetic processing aids and adjuvants that consider the impact their use has on the environment and the safety status under the Food and Drug Administration (FDA).

Evaluating whether an input may be harmful to human health and the environment is no easy task. Members of the Board represent several areas of the organic sector and hold advanced degrees in different scientific disciplines, but they may lack the expertise or time to adequately address the needs of a petition. It is for this reason NOSB may request the assistance of a third party to evaluate a material. This comes to NOSB in the form of a Technical Review that is made available to NOSB and the public. In addition to the Technical Review, NOSB looks to the scientific experts in the community to provide meaningful input.

SUITABILITY WITH ORGANIC FARMING AND HANDLING

In addition to alternatives, human health and the environment, NOSB must determine the suitability of an input with organic practices. This is arguably the most nebulous of the three criteria, prompting NOSB to pass a guidance recommendation in spring of 2004 that includes a series of questions to assist the Board in its evaluation process. This guidance is now incorporated into NOSB's Policy and Procedures Manual, and plays a central role in NOSB's review process.

The questions in the guidance are largely tied to the definition of "organic production" codified in the organic regulations emphasizing practices that foster cycling of resources, promote ecological balance, and conserve biodiversity. Questions are also asked about the influence the input may have on animal welfare, the consistency the input has with items already on the National List and with international standards, and whether the input satisfies the expectations of organic consumers regarding the authenticity and integrity of organic products.

The third leg of the stool can be viewed as the "equalizing" leg of the stool, helping NOSB balance its evaluation of alternatives, human health and the environment. For example, if the information provided on human health raises some concerns, but the science is insufficient, or alternatives are available but they do not work in all regions of the country or in all types of products, NOSB will evaluate how suitable the input is overall with the foundations of organic production and handling. One leg of the stool may not fail the criteria altogether but it might be shorter than another leg, creating concern ... and a tilted stool. The suitability criteria help NOSB adjust and balance the stool. Similarly, the input may pull up short in the suitability department, causing the stool to topple. Either way, NOSB's final recommendation must deliver a balanced three-legged stool that firmly supports the restricted organic toolbox.

THE THREE-LEGGED STOOL STANDS ON A SOLID YET DYNAMIC FOUNDATION

The three-legged stool holding up the National List stands on a firm foundation made up of organic stakeholders, the organic law, the organic regulations, NOSB and USDA's National Organic Program. The organic law was created in response to the needs of organic stakeholders, and the law in turn created NOSB and the USDA organic regulations. Today, the entire process we use to shape the National List continues to be powered and driven by stakeholders throughout the supply chain and the organic community. The National List criteria are tough, the process is rigorous, the discussion and decisions are thoughtful and transparent, and everyone is welcome.

LEVERAGING OUR SUCCESS

As the sector evolves and grows, so does its contribution to more sustainable approaches in food production. Organic is a leader in finding ways to effectively manage agricultural systems by integrating cultural practices such as crop rotation, biological practices like introducing beneficial insects and increasing microorganisms in the soil, and mechanical practices such as tractor cultivation and hand weeding. Organic is also a leader in developing natural and organic farm inputs and food ingredients.

For the organic sector, innovation is a necessity. The strict requirements of organic regulations and the very limited toolbox producers and handlers have to work with make creativity and innovation absolutely essential to succeed. Our success, in turn, depends on biological farming practices and healthier soils that help mitigate climate change, and on a label consumers trust and are increasingly seeking out. This has practitioners from all sides looking over the fence to see what they can learn.

The challenge we face is keeping up with demand, not only on the production side, but also on the research and extension side. Over the years, despite the growing demand for organic, investment in organic research has lagged dramatically behind the funds devoted to research for conventional agriculture. Organic's growing success in developing effective alternatives, however, has put today's organic sector in an advantageous position. Organic has the opportunity now to further leverage our contributions to creating better farming practices and a healthier environment, and to build support for specific research that will benefit the entire agricultural sector.

LESSONS LEARNED

The National List process requires organic farmers and processors to be innovative, tenacious, and to embrace new ideas and blaze new trails. The process requires organic stakeholders to be proactive and on constant watch to discover or develop organic or natural alternatives to replace the synthetic materials now allowed in organic food production. But the path to developing natural and organic alternatives is not easy, it is not cheap, and it doesn't happen overnight.

The recipe for successfully developing National List alternatives includes a tremendous public-private effort to foster the adoption of new techniques and inputs and develop new supply chains. In 2015, the Organic Trade Association formed the National List Innovation Working Group consisting of members interested in investing in applied research to identify alternatives to materials currently on the National List including organic, natural, or more compatible synthetics. The group realized that in order to proactively remove materials from the National List, it would take time, money, involvement and collaboration with public and private research institutions and extension personnel. The experience to-date of the group combined with other lessons learned from National List inputs, such as antibiotics for tree fruit, methionine for poultry and celery powder for cured meat, have created an extremely helpful model that can be used to help develop organic and allowed natural alternatives.

A MODEL FOR DEVELOPING ORGANIC AND NATURAL ALTERNATIVES

The process for developing natural and organic farm inputs and food ingredients can be viewed as a four-phase intensive participatory process: 1) Design; 2) Research; 3) Commercialization and 4) Market Launch. The process on the short end normally takes at least six years. On the upper end, it can take 15 years or more. At a minimum, it takes more than five years.

Design: The design of a project sets the stage for success or failure. During this process, the situation and need are identified, a working group with all of the essential partners including industry, universities, government, institutions and consumers is formed, and the project concept, goal and objectives are developed. A key activity at this stage is something known as “asset and resource mapping,” an activity often undertaken in food systems planning, where the complexities of the supply chain are accounted for and the available resources are mapped by region. This creates a visualization of what is available and what is still needed in product and partner supply. The design of a project can take from six months to a year.

Research: The research phase is the greatest hurdle in the process, and it will not advance without adequate support and funding. For the organic sector, the funding options are limited but, thankfully, some funds are available through USDA, private foundations, industry donations and other private efforts. Simply securing the funding typically takes a couple years or more. A good starting point can be a planning grant through the Organic Research and Extension Initiative (OREI) under USDA’s National Institute of Food and Agriculture. A \$50,000 planning grant provides the dollars often needed to complete the asset and resource mapping process that will provide the information and data needed to submit a grant for a full \$2 million OREI grant.

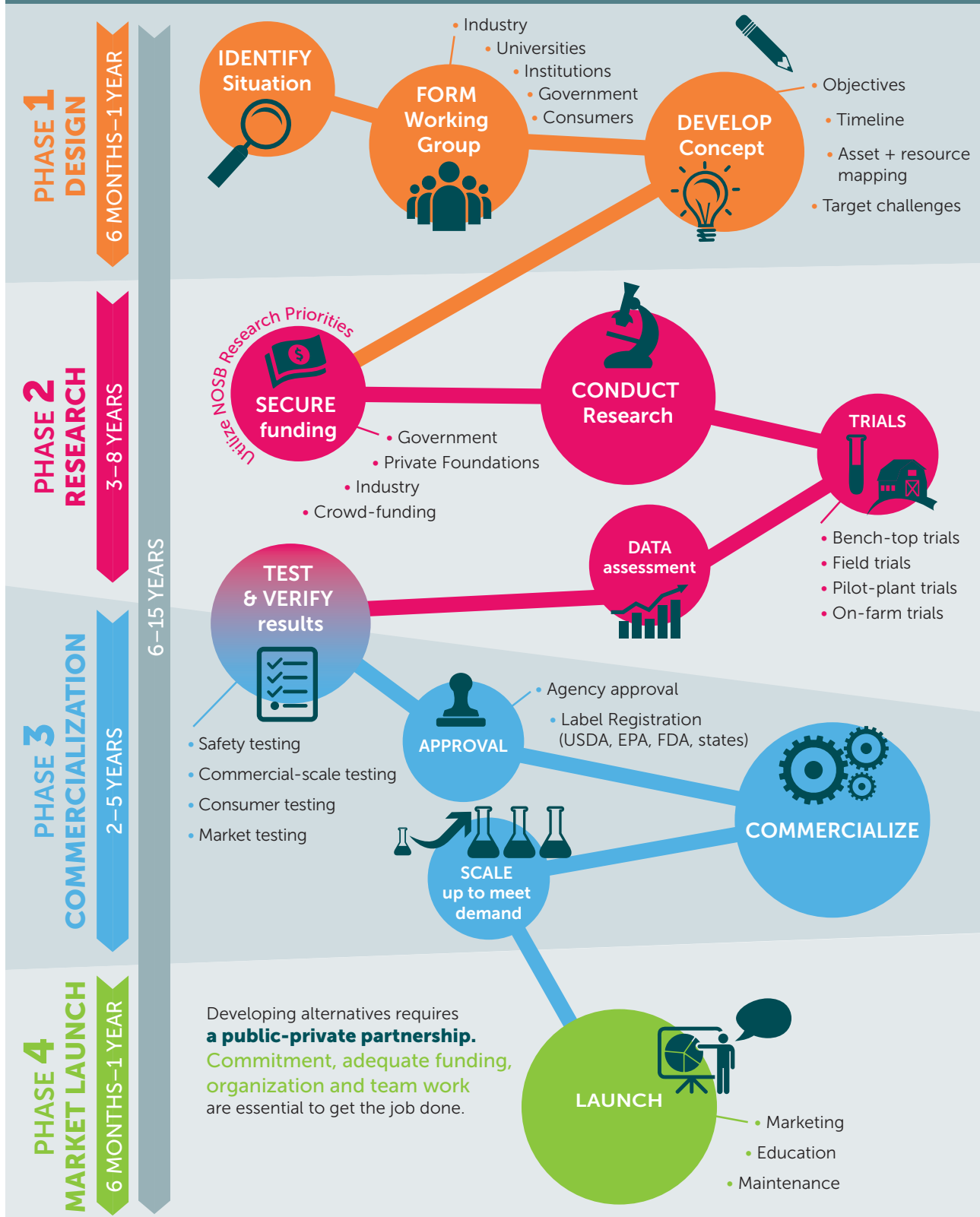
The research phase takes an additional two to five years at least to carry out bench-top trials, field trials, and/or pilot-plant trials as well as conduct data collection and assessment. Research trials then need to be scaled up to on-farm or commercial-scale testing. Results must be tested and verified, and if found to be successful at the research level, the commercialization process may start.

Commercialization: The time it takes to commercialize a farm input or new ingredient is often underestimated. There are significant time and resources that must be spent on additional commercial scale validation, followed by consumer, market and safety testing. Materials on the National List cannot be replaced overnight. New farm inputs or food ingredients must also undergo agency approval and label registration that can take two to three years. Agency support of organic interests is critical at this point. The organic sector can weigh in during this time, emphasizing the importance of prioritizing agency approval, and help to shorten these approval timelines. Once the testing and agency approval are granted, the product must be scaled up to meet market demand. This will ultimately determine the commercial availability of an ingredient or product.

Market Launch: Lastly, there is a necessary a period of education and experience for growers and handlers to refine their use of a new material in the diverse settings and environments encountered in commercial settings. As in the case of organic tree fruit growers adopting new materials and practices to prevent fire blight, a significant amount of education and outreach was necessary to convince producers to adopt these alternatives when faced with this devastating plant disease. Growers and handlers have to be confident the alternatives will work. Also, consumers must be willing to accept the new food ingredient in their organic products. The consumer commitment to organic is based on trust that the organic product is the best choice, and that trust has to hold true for any new organic ingredient or product.

The process of moving from concept of an alternative ingredient or input, and then to proving its efficacy and integrating or implementing its use into an organic production or handling system represent a multi-year effort that rarely occurs in a timeline shorter than five years.

A model for developing ORGANIC AND NATURAL INPUTS for use in organic food and farming



COMMUNICATING WITH POLICYMAKERS: A CALL TO ACTION

Successfully developing alternatives to the National List requires time and significant funding. To strengthen the organic sector's ability to defend and solicit funds for research that benefits organic production and handling, organic needs to have a voice at the table, and be represented on USDA and other applicable federal research boards and committees.

The organic sector can work with USDA and other federal agencies to ensure fair representation on appropriate research boards by identifying and bringing forth qualified nominees for those boards. Our goal is that all USDA appointed research boards include at least one member representing the interests of organic.

The organic sector has specific and unique research needs regarding production and organic regulatory compliance, and federal agencies need to respond to those needs with the appropriate policies. Government agencies (particularly USDA) need to include organic production as a component of its studies comparing the effects of different agricultural production systems when appropriate (e.g., investigation of climate change adaptation practices). Organic production models provide alternative solutions to current agricultural challenges. We encourage USDA to increase its efforts to develop diversity in research and alternatives for all producers and handlers.

Great strides have been made in the organic sector, but the work is not done. Organic stakeholders have to continue advocating, working, pressing and staying engaged in the process to enable organic to reach its full potential. The Organic Trade Association encourages everyone in the organic sector to help make sure the U.S. Department of Agriculture fulfills its leader's directive. In this regard, we urge NOSB to draft a letter to USDA requesting mandatory organic representation on USDA research boards and committees.

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ENSURING GLOBAL ORGANIC SUPPLY CHAIN INTEGRITY

Food fraud, or the act of defrauding buyers of food or ingredients for economic gain, has plagued the food industry throughout history. Although it is not known conclusively how widespread food fraud is in the United States or worldwide, it is now estimated to be a \$50 billion industry for the total food market --about the same size as the entire 2017 U.S. organic market. Although the act of adulterating food for economic gain dates back to at least the Middle Ages, its presence in the global organic supply chain is more recent, and poses a significant threat to the integrity of the organic brand.

Simply put, fraud cannot be tolerated in the organic system, inside or outside of the United States. Anytime there is fraud anywhere in the organic system, it takes value out of the organic chain, and hurts organic farmers wherever they farm. The oversight of foreign and domestic organic suppliers and the enforcement of organic standards must be rigorous and robust. The integrity of the organic certification process and the commitment to compliance and enforcement are the lifeblood of the organic industry, and ensure a level playing field for U.S. organic farmers.

To adequately address the situation, several approaches are needed. The Organic Trade Association's position is that everyone has a role in preventing organic fraud, and both the private and the public sector must engage on several fronts. The Organic Trade Association applauds the actions taken to date by USDA's National Organic Program and other agencies to help prevent the occurrence of organic fraud --such efforts must continue and more must be done. We also commend the National Organic Standards Board (NOSB) for its outreach to organic stakeholders to help inform NOP on the list of actions that will build a better compliance and enforcement system. The ongoing work of the USDA-NOP to strengthen the enforcement of the organic standards and to deepen the rigor of oversight across the supply chain is critical as is the need for industry and certifiers to take heightened measures of vigilance when unusual trends or anomalies organic trade are suspected. A risk-based approach to detecting fraud is a fundamental component to any kind of effective fraud prevention program.



BUILDING AN ORGANIC FRAUD PREVENTION PROGRAM

For the past two years, the Organic Trade Association has prioritized significant time and resources into organic fraud prevention solutions that will help mitigate and prevent the occurrence inside and outside of the United States. Our work to address organic fraud is taking place on several fronts ranging from our legislative efforts and priorities for the 2018 Farm Bill, to our work with NOSB and our member task force to shape a major piece of NOP enforcement rulemaking slated for fall 2019, to our major private-sector initiative that has evolved into an industry-wide fraud prevention program that launched March 5, 2019. The new program is based on the Organic Trade Association's Organic Fraud Prevention Guide that provides businesses engaged in organic trade with a comprehensive training on organic fraud mitigation and a risk-based process for developing and implementing an organic fraud prevention plan. It also provides detailed information on what to do when you suspect or detect fraud, and the process for filing a complete and effective complaint to USDA's National Organic Program.

Before diving into the details of the organic fraud prevention program, let's take a look at the steps the Organic Trade Association and its members took to get here.

TASK FORCE AND BEST PRACTICES GUIDE

In May 2017, the Organic Trade Association convened a Global Organic Supply Chain Integrity (GOSCI) Task force of 48 member companies to develop a best-practices guide to preventing fraud specifically for the organic industry. In an effort to both acknowledge and utilize the extensive fraud prevention strategies already developed by Michigan State Food Fraud Think Tank and the Global Food Safety Initiative (GFSI), the task force adopted a model that highlights the motivation behind fraud (i.e. the root cause) to better understand the detection and prevention activities that need to be developed based on a company's susceptibility or exposure to food fraud risk. The GFSI model is a smart and practical approach because it was built to be a starting point consistent with other quality management practices such as HACCP (Hazard Analysis and Critical Control Points), lending itself to a fraud prevention program that can be adopted into existing internal quality management systems. While the traditional HACCP-type food safety approach is applied at manufacturing steps, food fraud vulnerabilities are company-wide, and must be applied cross-functionally and within the overall organization. The name of the game is to think like a criminal!

The Organic Fraud Prevention Guide developed by the task force is aimed at buyer responsibility and the assessment of factors that create vulnerabilities in an organic supply chain. Accordingly, the Guide provides businesses engaged in the organic trade with a systematic risk-based approach for identifying appropriate fraud mitigation measures, and developing and operationalizing a written Organic Fraud Prevention Plan. It also includes information on what to do when you suspect or detect fraud, along with resources and helpful tools for identifying and deterring fraud.

ORGANIC FRAUD PREVENTION PILOT PROGRAM

Following the creation of the Guide, the trade association launched a pilot program. The pilot was an intensive-focused exercise running from June – September 2018 in which 13 OTA member companies "test drove" in their specific businesses the fraud prevention strategies described in the Guide. Participants concentrated on one product or ingredient, and developed fraud mitigation measures based on the results of a vulnerability assessment that identifies weak points in a supply chain that increase exposure to fraud. Pilot participants informed the final version of the Guide, and helped set the stage for implementing a corresponding program. Collaborating partners in the project include USDA-NOP, the Accredited Certifiers Association (ACA) and NSF International.

ORGANIC FRAUD PREVENTION SOLUTIONS

With a tested and completed fraud prevention guide in hand, the Organic Trade Association has developed an organic fraud prevention program in which organic businesses may voluntarily enroll. The name of the program is Organic Fraud Prevention Solutions. The mission of the program is to assure the authenticity of organic products by mitigating the occurrence of organic fraud. The goal of the program is to establish a framework and formal process for businesses to create continuously improving internal programs for achieving organic integrity throughout their associated supply chains. The program requires training, registration and the development of an organic fraud prevention plan, followed by confirmation by an accredited certifier. Companies that complete the annual enrollment process are publicly acknowledged in the Organic Trade Association's [find.organic](#) business directory. Collaborating partners include USDA-NOP and Michigan State University's Food Fraud Initiative Program.

BUT WAIT, ISN'T ENFORCEMENT USDA'S JOB?

The National Organic Program is, in fact, responsible for oversight and enforcement of the organic regulations. Organic Fraud Prevention Solutions, however, is not a certification or verification program nor is it a product label. Instead, the program serves as a business-to-business marketing advantage designed to improve internal quality assurance programs. It is also designed to complement and reinforce USDA's organic standards and the work of the accredited certifying agencies.

It is critical that organic businesses have robust systems and measures in place that adequately support the promise of providing organic products that people can trust. Organic Fraud Prevention Solutions, as adopted by businesses engaged in organic trade, will become the industry standard reference for excellence and achieving integrity across complex organic global supply chains. Organic companies that want to prevent organic fraud in their supply chain and be publicly recognized for having implemented an Organic Fraud Prevention Plan now have an opportunity to voluntarily pre-enroll in the program. The Organic Trade Association is excited to work with certified organic companies across the United States and help build a stronger system. Leadership and commitment from organic businesses will drive adoption of the program. The more companies that join, the stronger the organic supply chain will become. To date, over 45 member companies have pre-enrolled in the program.

To learn more about the program, download our [Frequently Asked Questions](#) or contact Gwendolyn Wyard, Vice President of Regulatory and Technical Affairs.

THE SUNSET PROCESS

Once a material has been added to the National List, NOSB must re-review the material every five years to confirm that the material continues to meet the National List criteria. This re-review process is known as the “Sunset Review” process. Through this process, NOSB can remove inputs from the National List based on any new information regarding adverse impact on human health or the environment, or the availability of a natural or organic alternative. After NOSB completes its Sunset Review and provides a recommendation, USDA either renews or removes the input to complete the Sunset Review process. The Sunset Review process must be completed prior to the material’s Sunset Date, which is the five years from its initial listing or most recent renewal on the National List. Therefore, NOSB reviews these materials well in advance to ensure there is time to complete the entire Sunset Review process prior to the material’s Sunset Date.

SUNSET REORGANIZATION

NOSB has adopted a reorganization process that will result in a more evenly distributed Sunset Review workload over the five-year Sunset Review cycle. The process is the result of an NOSB recommendation unanimously passed at the fall 2016 NOSB meeting. As explained in the NOSB recommendation, National List inputs that are reviewed early under the reorganization plan should be allowed to sunset on their original timeline.

TWO-STAGE PUBLIC COMMENT PROCESS

There are two public comment opportunities that inform the Sunset Review process. The first opportunity occurs at the spring meeting when NOSB accepts public comments on material undergoing Sunset Review that year. NOSB uses the information collected through the first round of public comment periods to inform the subcommittee proposals that are presented for a second public comment at the fall meeting. The full Board takes the feedback from both comment periods into consideration along with its own research, and votes at the fall meeting on whether to renew their allowance on the National List for another five years.

ORGANIC TRADE ASSOCIATION’S ONLINE SURVEY SYSTEM

To help facilitate a thorough comment and review process, OTA creates electronic surveys for each sunset material under review. The surveys are available to every NOP certificate holder, and include 7-10 questions addressing the necessity (crop and livestock) or essentiality (handling) of each material. The names of the companies submitting the information are confidential (not disclosed to OTA). To ensure wide distribution of the surveys beyond OTA membership, OTA works with Accredited Certifying Agencies and the Organic Materials Review Institute (OMRI) to distribute the survey links to all of their clients as well as to targeted clients they know are using the inputs under review. OTA also works through its Farmers Advisory Council to help assist in distribution to NOP certified farmers. OTA hopes these efforts and the feedback gathered from certified farmers and handlers will help to inform NOSB in its review process as it relates to the necessity or essentiality of the National List inputs undergoing their five-year Sunset Review.

NOSB VOTING PROCEDURES

NOSB MOTIONS AND VOTES

As specified in the Organic Foods Production Act (OFPA), two-thirds of the votes cast at an NOSB meeting at which a quorum is present shall be decisive of any motion [§2119(i)].

Based on a 2013 NOP clarification of the NOSB sunset voting procedure, the full NOSB must vote on a motion to remove a substance from the National List (instead of voting on a motion to renew the substance). This procedure ensures that changes to the National List are based on a decisive vote of the Board. For sunset materials, this means that two-thirds of NOSB members must vote in favor of removing a material for USDA to have the authority to amend the National List. As there are 15 NOSB members, 10 votes in favor are needed to pass any recommendation to remove a material from the National List.

Materials can only be renewed or removed from the National List during the sunset process. Any other changes, clarifications, or restrictions to listed materials must be conducted through the petition process, and be recommended by the subcommittee through a proposal that is separate from the Sunset Review process.

WHY DO THE SUNSET SUBCOMMITTEE PROPOSALS INCLUDE A “MOTION TO REMOVE?”

Even if a subcommittee intends to renew a sunset material, the subcommittee will still put forward a “motion to remove.” The purpose is to introduce the topic for consideration while the vote from the entire Board determines the final recommendation. Even if the Subcommittee “motion to remove” fails to receive a simple majority, the motion will still be put forward to the full Board for review. The “motion to remove” is then considered and voted on by the full Board, and needs a decisive vote (two-thirds majority) to recommend removal.

EXAMPLE VOTING PROCESS FOR A “MOTION TO REMOVE”

Subcommittee Vote (simple majority is needed to pass a motion)

- Yes = in favor to delist No = in favor to renew
- If majority vote yes, the recommendation to the full Board is to remove the material
- If majority vote no, the recommendation to the full Board is to renew the material
- Subcommittee proposal is forwarded to the full Board for a vote regardless of whether the motion failed/passed

Full Board Vote (2/3 majority (10 of 15)) is needed to remove a material)

- The full Board votes on the subcommittee’s motion to remove
- Yes = in favor to remove No = in favor to renew
- 2/3 of the 15 member board would need to vote YES to remove the material
 - Example: 10 yes, 5 no would mean that the motion passes, and the final recommendation would be to remove the material
 - Example: 8 no, 7 yes would mean the motion fails, and the material would remain on the National List.

2021 SUNSET REVIEWS

BACKGROUND

At this meeting, NOSB will vote on whether to continue the allowance of several of the fertilizers, pest control products, livestock treatments, processing aids, and ingredients currently included on the National List of Allowed and Prohibited Substances to determine whether the substances should continue to be listed or should be removed from the list. These National List inputs will be reviewed and voted on by NOSB based on their Sunset timeline (five-year renewal date cycle), and may not be renewed if new information indicates these substances are incompatible with organic production, are not essential, or are harmful to human health or the environment. The specific inputs included in this sunset cycle are listed below.

NOSB SUBCOMMITTEE SUMMARY & ORGANIC TRADE ASSOCIATION'S POSITION

The list below includes a description of material, highlights of the NOSB Handling Subcommittee discussion, and a summary of the Organic Trade Association Sunset Survey responses for the material.

Citric Acid – Allowed as an ingredient or processing aid. Used as an acidulant, pH control agent, flavoring, sequestrant, dispersant in flavor or color additives, antioxidant, firming agent, raising agent, emulsifying salt, and as a stabilizer. §205.605(a)

- **NOSB Subcommittee Discussion:** Long history of safe use. Are there any commercially available sources of citric acid derived from organically grown crops?
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0
- **OTA Survey Results:** **Essential**

Lactic acid – Allowed as an ingredient or processing aid. Used as an acidulant, pH regulator, and preservative. §205.605(a)

- **NOSB Subcommittee Discussion:** Widely used and important tool. No indication of harm.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0
- **OTA Survey Results:** **Essential**

Calcium chloride – Allowed as an ingredient or processing aid. Used as a firming agent for sliced apples and other fruits and in certain cheeses to aid coagulation of the milk (turns liquid into thick gel for cutting into curds). §205.605(a)

- **NOSB Subcommittee Discussion:** No new information to warrant removal.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0
- **OTA Survey Results:** **Essential**

Dairy cultures – Allowed as an ingredient or processing aid. Used to make yogurt, cheese, cultured sour cream and other fermented milk products. §205.605(a)

- **NOSB Subcommittee Discussion:** Widespread support for continued allowance. However, the subcommittee believes that the listing of dairy cultures is redundant and is covered by the existing listing of “microorganisms” on the National List. Subcommittee proposes removing dairy cultures and does not expect there to be any negative impact since dairy cultures would continue to be allowed under the microorganisms listing.
- **NOSB Subcommittee Vote:** Motion to remove from National List — **Yes: 5** No: 0 Abstain: 0 Absent: 2 Recuse: 0
- **OTA Survey Results:** **Essential**
- **OTA Position:** The Organic Trade Association supports the retention of dairy cultures as a separate listing on the National List, and does not support folding the allowance into the broader listing of microorganisms. 1) The continued listing of dairy cultures on the National List supports the interests of food manufacturers and shoppers focused on food label literacy and transparency; a separate listing of dairy cultures on the National List that can be easily cross-referenced with the listing on an ingredient label and vice-versa. 2) The unique application of dairy cultures, the composition of the starter cultures, and the process to grow the starter cultures, in combination with a distinct listing on the National List, provide an opportunity to create and/or tailor an annotation that could address certain specifications or restrictions such as organic preference or use of ancillary substances. 3) Removing dairy cultures from the National List for the purpose of folding its continued allowance into a separate listing (microorganism) is not an appropriate action during the Sunset Review process.

Enzymes – Allowed as an ingredient or processing aid. Used to carry out naturally occurring biological processes that are useful in the processing of food products or ingredients. Also used to reduce the length of time required for aging foods such as cheese, clarify or stabilize food products, and control the content of alcohol and sugar in certain foods. §205.605(a)

- **NOSB Subcommittee Discussion:** No environmental or human health concerns. No opposition.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0
- **OTA Survey Results:** **Essential**

L-Malic acid – Allowed as an ingredient or processing aid. Used as a pH adjuster, flavor enhances and food acidulant. §205.605(a)

- **NOSB Subcommittee Discussion:** Supportive of continued allowance. Based on new information, substance is improperly classified as non-synthetic. Will address the reclassification as synthetic and placement on 205.605(b) in a separate proposal at a future meeting. Forms actually classified as non-synthetic are not available.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0
- **OTA Survey Results:** **Essential**

Magnesium sulfate – Allowed as an ingredient or processing aid. Used as a mineral supplement, leavening agent and pH control agent. §205.605(a)

- **NOSB Subcommittee Discussion:** The Subcommittee is still seeking comment on the specific use and essentiality of this material.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0
- **OTA Survey Results:** No responses were received.

Microorganisms – Allowed as an ingredient or processing aid. Used as starter cultures for the benefit of the metabolites produced during fermentation. Commonly used in dairy products, baked goods, and fermented food and beverages. §205.605(a)

- **NOSB Subcommittee Discussion:** Essential to production of many foods. Several comments about the definition of microorganisms and critical need to determine which materials are considered under the listing of microorganisms.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0
- **OTA Survey Results:** **Essential**

Perlite – Allowed as a filter aid in food processing. §205.605(a)

- **NOSB Subcommittee Discussion:** Supported for relisting.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0
- **OTA Survey Results:** **Essential**

Potassium iodide – Allowed as an ingredient or processing aid. Used as a nutrient in table salt and in dietary supplements. Also used as a sanitizing agent for food processing equipment. §205.605(a)

- **NOSB Subcommittee Discussion:** No new information to warrant removal.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0
- **OTA Survey Results:** **Essential**

Yeast – Allowed as an ingredient or processing aid. Organic forms of yeast must be used when commercially available. Used for flavoring, as a protein source (nutritional yeast), and various fermentation applications such as bread, wine and beer. §205.605(a)

- **NOSB Subcommittee Discussion:** Commonly used. Organic forms not always available.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0
- **OTA Survey Results:** **Essential**

Alginic acid – Allowed as an ingredient or processing aid. Used as a stabilizer in many products such as beverages, cheese and dressings. Also used as a defoaming agent. §205.605(b)

- **NOSB Subcommittee Discussion:** No indication that material is in use. No comments received from manufacturers or certifiers that the material is used or needed. Not essential.
- **Subcommittee Questions:**
 1. Is alginic acid essential for handling operations? If so, why?
 2. The 2015 TR cites possible hydrocolloids alternatives including agar agar, carrageenan, gellan gum and xanthan gum. Please comment on whether or not these alternatives have been used successfully in place of alginic acid.
- **NOSB Subcommittee Vote:** Motion to remove from National List — **Yes: 5** No: 0 Abstain: 0 Absent: 2 Recuse: 0
- **OTA Survey Results:** No responses were received.

Activated charcoal – Allowed as a filtering aid. §205.605(b)

- **NOSB Subcommittee Discussion:** Minimal impact to human and environmental health.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0
- **OTA Survey Results:** **Essential**

Ascorbic acid – Allowed as an ingredient or processing aid. Used as a dietary supplement, nutrient, flavor ingredient, curing and pickling agent, antioxidant, and a wide variety of other food processing uses. §205.605(b)

- **NOSB Subcommittee Discussion:** Widespread presence and importance in food production. Alternatives have significant limitations.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0
- **OTA Survey Results:** **Essential**

Calcium citrate – Allowed as an ingredient or processing aid. Used to provide calcium in nutritive supplements, and as a pH adjuster and chelator. §205.605(b)

- **NOSB Subcommittee Discussion:** No natural sources or alternatives. No new information in terms of harm to environmental or human health.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0
- **OTA Survey Results:** **Essential**

Ferrous sulfate – Allowed for iron enrichment or fortification of foods when required by regulation or recommended. Used for iron enrichment or fortification of flour and baby food. §205.605(b)

- **NOSB Subcommittee Discussion:** No new information to warrant removal.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0
- **OTA Survey Results:** **Essential**

Hydrogen peroxide – Allowed as an ingredient or processing aid. Used as a disinfectant and bleaching agent, and for sanitizing of aseptic packaging. §205.605(b)

- **NOSB Subcommittee Discussion:** Strong support for relisting. No new information in terms of harm to environmental or human health.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 4 Abstain: 0 Absent: 3 Recuse: 0
- **OTA Survey Results:** **Essential**

Nutrient vitamins and minerals – Allowed for fortification of organic foods in accordance with FDA requirements. §205.605(b)

- **NOSB Subcommittee Discussion:** Strong support for relisting. No new information to warrant removal.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0
- **OTA Survey Results:** **Essential**
- **OTA Position:** The Organic Trade Association supports the continued listing of nutrient vitamins and minerals on the National List at 205.605(b) (non-agricultural, synthetic), and we strongly support the review of nutrient vitamins and minerals by NOSB. The Organic Trade Association would like to see NOP complete the rulemaking it started in 2012, including all the nutrients petitioned and passed by NOSB, and publish an annotation that is transparent, certifiable and enforceable.

Peracetic acid – Allowed for use in wash and/or rinse water according to FDA limitations. Used as a sanitizers on food contact surfaces. §205.605(b) § Discussion Questions:

- **NOSB Subcommittee Discussion:** Strong support for relisting. Essential and safe.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 4 Abstain: 0 Absent: 3 Recuse: 0
- **OTA Survey Results:** **Essential**

Potassium citrate – Allowed as an ingredient or processing aid. Used as a chelating agent, buffering agent, nutrient supplement, and pH adjuster. §205.605(b)

- **NOSB Subcommittee Discussion:** No non-synthetic sources or alternatives. No new information in terms of harm to environmental or human health.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 4 Abstain: 0 Absent: 3 Recuse: 0
- **OTA Survey Results:** **Essential**

Potassium phosphate – Allowed as an ingredient or processing aid only in products labeled “made with organic (specific ingredients or food group(s)).” Used as a pH control in milk products, as a microbial nutrient (yeast food), and as a source of mineral potassium and/or phosphorus. §205.605(b)

- **NOSB Subcommittee Discussion:** No new information to warrant removal.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0
- **OTA Survey Results:** No responses were received.

Sodium acid pyrophosphate – Allowed as a leavening agent. §205.605(b)

- **NOSB Subcommittee Discussion:** Essential for production of organic foods requiring chemical leavening.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 4 Abstain: 1 Absent: 2 Recuse: 0
- **OTA Survey Results:** **Essential**

Sodium citrate – Allowed as an ingredient or processing aid. Used as an emulsifier in ice cream, cheese, and evaporated milk. Used as a buffer to control acidity and retain carbonation in beverages. §205.605(b)

- **NOSB Subcommittee Discussion:** No non-synthetic sources or alternatives. No new information in terms of harm to environmental or human health.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 4 Abstain: 3 Absent: 0 Recuse: 0
- **OTA Survey Results:** **Essential**

Tocopherols – Allowed as an ingredient or processing aid. Must be derived from vegetable oil when rosemary extracts are not a suitable alternative. Used as an antioxidant. §205.605(b)

- **NOSB Subcommittee Discussion:** Considered essential for food production. Support for relisting but some concern raised in public comment about its primary use as a preservative being inconsistent with organic principles.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0
- **OTA Survey Results:** **Essential**

Celery powder – Allowed as an ingredient or processing aid when organic forms are not commercially available. Used in a variety of processed meat products to provide “cured” meat attributes without using prohibited nitrites. §205.606(c)

- **NOSB Subcommittee Discussion:** Essential as curing agent for organic cured meats. More research is needed to produce a viable organic alternative.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0
- **OTA Survey Results:** **Essential**
- **OTA Position:** The Organic Trade Association supports the continued listing of celery powder on the National List due to the fact that it is an essential ingredient used in processed organic meat products, and an organic alternative is not commercially available. We are also pleased to announce that the Organic Trade Association, in collaboration with The Organic Center and the University of Wisconsin, was just awarded nearly \$2 million in research funds for the development of an organic alternative to conventional celery powder through the Organic Agriculture Research and Extension Initiative (OREI).

Fish oil – Allowed as an ingredient or processing aid when organic forms are not commercially available. Must be stabilized with organic ingredients or only with ingredients on the National List. Used to increase the content of omega-3 fatty acids in a variety of food products. §205.606(e)

- **NOSB Subcommittee Discussion:** Support for use as nutritional supplement. No new information to warrant removal. NOSB will address conservation concerns in a separate work agenda item.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0
- **OTA Survey Results:** **Essential**

Gelatin – Allowed as an ingredient or processing aid when organic forms are not commercially available. Used as a clarification or fining agent in teas and wine, as a stabilizer and thickener, and in capsules.

§205.606(g)

- **NOSB Subcommittee Discussion:** Organic forms and alternatives are not commercially available or have significant limitations. Detailed information about what the barriers are to organic gelatin development have not been specified.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0
- **OTA Survey Results:** **Essential**

Orange pulp, dried – Allowed as an ingredient or processing aid when organic forms are not commercially available. Used as a moisture retention agent and fat substitute. §205.606(n)

- **NOSB Subcommittee Discussion:** No indication that material is in use. No comments received from *manufacturers or certifiers that the material is used or needed. Not essential.*
- **NOSB Subcommittee Vote:** Motion to remove from National List — **Yes: 4** No: 1 Abstain: 0 Absent: 2 Recuse: 0
- **OTA Survey Results:** Producers of organic oranges responded to this survey. Year round, these producers generate organic wet orange pulp and peel as a byproduct that is then sold to the food processing industry to be dried or otherwise used.

Seaweed, Pacific Kombu – Allowed as an ingredient or processing aid when organic forms are not commercially available. Used as a thickening agent or as a base for broth. Provides a unique flavor profile.

§205.606(q)

- **NOSB Subcommittee Discussion:** No comments received from users of this material. NOSB will address conservation concerns in a separate work agenda item.
- **NOSB Subcommittee Vote:** Motion to remove from National List — **Yes: 1** No: 6 Abstain: 0 Absent: 0 Recuse: 0
- **OTA Survey Results:** No responses were received.

Seaweed, Wakame – Allowed as an ingredient or processing aid when organic forms are not commercially available. Used in soups and salads. Provides a unique flavor profile. §205.606(u)

- **NOSB Subcommittee Discussion:** In use by at least one operator. NOSB will address conservation concerns in a separate work agenda item.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0
- **OTA Survey Results:** No responses were received.



SPOTLIGHT -

NATIONAL LIST INNOVATION WORKING GROUP: CELERY POWDER

The Organic Trade Association, in collaboration with The Organic Center and the University of Wisconsin, was awarded nearly \$2 million in research funds for the development an organic alternative to conventional celery powder through USDA's Organic Agriculture Research and Extension Initiative (OREI). The announcement was made on October 3, 2019.

BACKGROUND

Celery powder has been in use for over a decade as a “curing” agent in certain processed meat products, and was included on the National List in 2007 as an allowed minor non-organic ingredient because an organic alternative was not available. Celery powder contains natural forms of nitrate that are converted to nitrite when added to meat, which, in turn, functions as a curing agent for products such as organic ham, hot dogs and bacon. Additionally, “pre-converted” forms are used where an incubation with a nitrate-reducing bacterium produces celery powders that are high in nitrite. The use of celery powder eliminates the need for conventional purified nitrate and nitrite curing ingredients. The essential function of nitrate/nitrite in processed meats is most importantly related to food safety with antimicrobial properties versus *Clostridium botulinum* and *Listeria monocytogenes* that are very important for protection of public health. Additionally, shelf life is improved.

The original petition for celery powder foresaw no difficulty in the future production of an organic version. To date, however, a viable, functional alternative with an adequate level of nitrate grown in a manner consistent with the organic standards and organic principles has not been achieved. Several technical and production issues have proven to be barriers to producing a celery crop using organic production methods that can deliver adequate uptake of nitrates for conversion to nitrites. For example, some of the alternative varieties that achieve the necessary nitrate levels impart too strong of a flavor in the meat products and would not be acceptable to consumers. Other factors include harvest and post-harvest conditions and the time and distance between harvest and processing, and how those variables impact nitrate level retention. The organic meat market also continues to be relatively small.

The National Organic Standards Board (NOSB) renewed the listing of celery powder on the National List during the 2012 Sunset Review due to the continued lack of an organic alternative. During the 2017 Sunset Review cycle, NOSB discussed removing its allowance, stating that such action would push the organic sector to develop an organic alternative. Organic producers and handlers explained that such a decision would be premature given the lack of an organic alternative, the time and resources needed to develop an organic alternative that would meet the functional requirements of a curing agent, and the commercial demand. Prematurely removing celery powder from the National List would make the production of organic bacon and other cured organic meats impossible, and this, in turn, would have a devastating impact on an already struggling organic livestock sector and its associated supply chain.

FORMING A WORKING GROUP TO DEVELOP AN ORGANIC ALTERNATIVE

In the fall 2015, the Organic Trade Association in collaboration with The Organic Center (TOC) convened the “National List Innovation Working Group” consisting of members interested in investing in applied research to identify alternatives to materials currently on the National List including organic, natural, or more compatible synthetics. The Working Group topics and participants vary, based on the needs and projects identified by the organic sector. Participants are investors in the development of alternatives, or by invitation of investors working in collaboration with public and private research institutions and extension personnel.

The first project (initiated by the Celery Powder Working Subgroup) was to find an organic alternative to non-organic celery powder. To begin to address the issues, the Working Group focused the first six months on establishing research partners, identifying funding opportunities, and working in collaboration with the University of Wisconsin on the submission of a proposal for an Organic Research and Extension Initiative (OREI) planning grant. The planning grant proposal, submitted in early March 2016 and awarded later that year, helped to develop the roadmap of integrated research and extension activities needed to adequately address and overcome production challenges. An additional proposal to Farmers Advocating for Organics (FAFO) was also awarded.

The money from the OREI planning grant was used to identify the needed partners, crops, data and research questions that, in turn, informed the full \$2 million OREI grant that was applied for on January 19, 2017, and again in 2018 and 2019. It was also used to fund the national stakeholder meeting held at the EcoFarm conference in, Asilomar, CA, in 2017. The FAFO grant money funded initial varietal testing in organic celery crops and broader testing of production-scale organic celery harvested in fall 2016. Unfortunately, while both OREI funding proposals in 2017 and 2018 were rated highly, both were not accepted, slowing research progress down in 2018.

Despite the setback, the efforts continued in full force, and **another \$2 million OREI grant was successfully submitted in April 2019 resulting in the nearly \$2 million award.**

GOING FORWARD: A MODEL THAT BENEFITS ALL OF AGRICULTURE

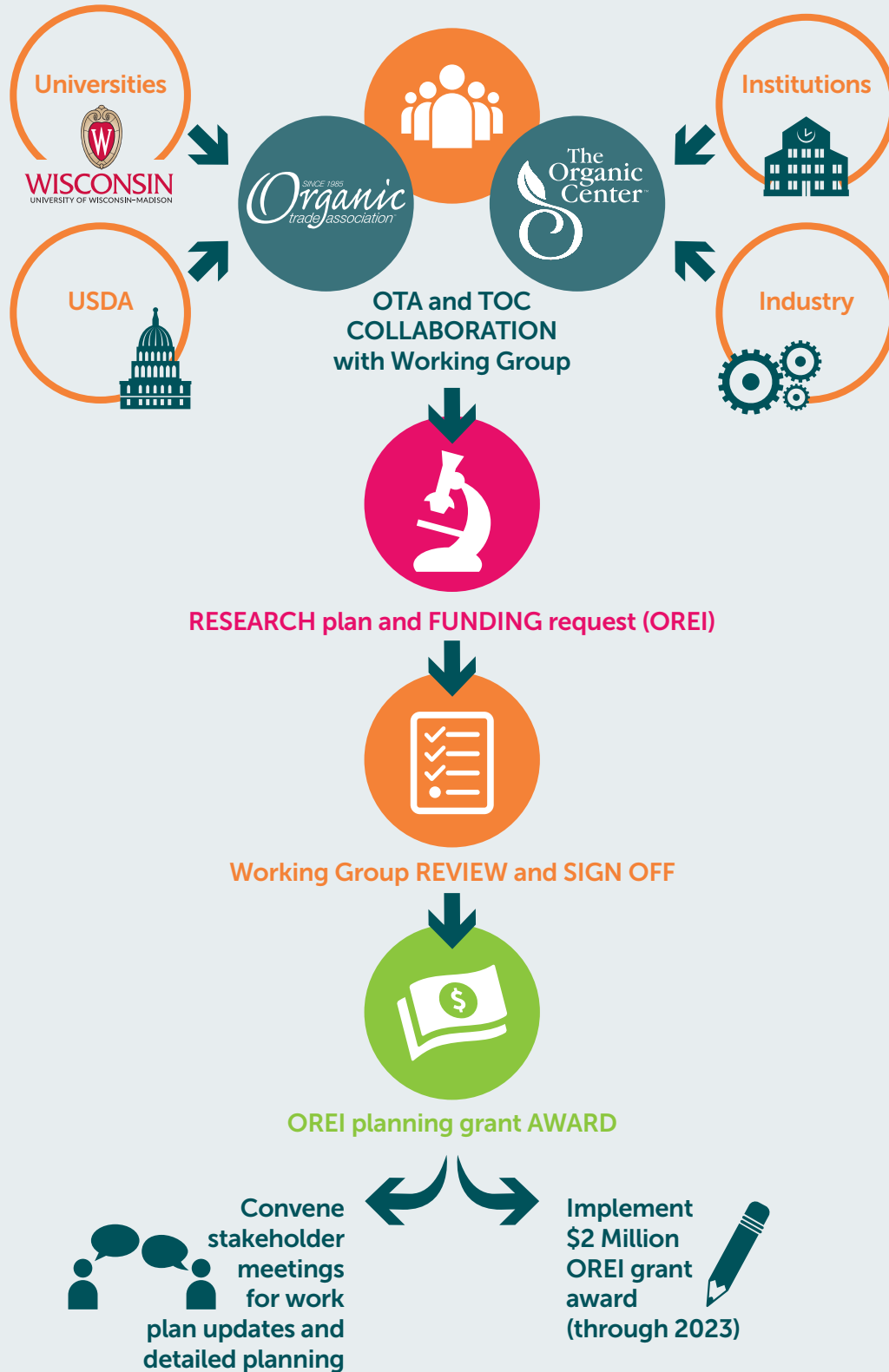
Despite the setback in funding, the efforts continue, not only for celery powder but for solutions that could potentially benefit all of agriculture. The working group research project sets out to identify potential varieties of organic crops that would meet the chemical specification needed for curing, while being easily incorporated into current crop rotation systems. It will also identify potential management protocols that need to be developed to achieve target nitrate levels in the curing crop to produce the required shelf life, prevent bacteria in the cured meat, and produce the desired flavor, color and texture in food. The project also aims to identify crops that could act as an incentive for expanding organic acreage, given the economic opportunity to partner with contractors that produce curing agents for organic processed meat products. Additionally, the project is investigating potential challenges and pitfalls associated with the production of a high nitrate crop, such as environmental concerns for run-off and excess nutrient leaching.

Identifying solutions for the organic processed meat industry’s need for a curing powder is extremely complex, and the timeline to develop an effective organic alternative does not happen overnight. It requires a very deliberate and well-researched road forward, it takes a multiregional, multi-stakeholder coordinated effort, it requires substantial funding, and it relies on consumer demand. Although the lack of funding has put the project behind schedule, we believe significant progress is being made, and that the commitment and organization of the Celery Powder Working Group and our research partners have presented a solid model on how to best carry out the process for developing alternatives to a National List material.

See Page 24 for A MODEL FOR DEVELOPING ALTERNATIVES.

Developing an ORGANIC ALTERNATIVE TO CELERY POWDER

AN ORGANIC TRADE ASSOCIATION WORKING GROUP PROGRESS UPDATE





SPOTLIGHT

ALERT, HISTORY IN THE MAKING!

A practical guide to complying with the new requirements for natural flavors

INTRODUCTION

The National Organic Program published a final rule that amends the National List of Allowed and Prohibited Substances (National List). The new ruling, which will be implemented December 27, 2019, requires the use of certified organic flavors whenever they are commercially available.

The listing of flavors will read as follows:

Flavors—non-synthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or non-synthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

This historical change is brought to you by the Organic Trade Association (OTA) as a result of a petition we submitted on November 6, 2014, to help grow the availability and use of organic flavors. In consideration of filing the petition, we recognized that the number of available certified organic flavors was not sufficient to meet the current needs of the organic marketplace. However, we also recognized that the growing organic flavor sector deserved more support than it was receiving. Currently, there is no requirement to use organic flavors; all use is voluntary despite the significant number of organic flavors available in the marketplace. The petition was a proactive step to push the needle in the direction of continuous improvement, and require the use of organic flavors when they are available in the quality, quantity and form needed.

The Organic Trade Association's position is that the organic flavor supply has grown to a size where it is no longer appropriate to allow the use of non-organic natural flavors when organic forms may be commercially available.

BACKGROUND

Natural flavors are currently on the National List of Allowed and Prohibited Substances, and allowed for use in NOP certified products labeled as "organic" and "made with," provided they are produced without synthetic solvents, synthetic carriers and artificial preservatives. As a general prohibition, they must also be produced without the use of genetic engineering and ionizing radiation. Natural flavors appear on the National List as a broad category listing, therefore many different types of natural forms are allowed. Examples include extracts, oleoresins, essential oils, compounded flavors, and distillates. See Page 45 for 'Type of Flavors.'

Flavors were not added to the National List as a result of a petition. Instead, they were included among natural substances initially placed on the list when NOP promulgated regulations pursuant to the Organic Foods Production Act of 1990. Since the first recommendation by the National Organic Standards Board (NOSB) to include the use of Natural Flavors in organic foods in 1995, there has been the expectation that over time, manufacturers would begin to produce certified organic flavors and efforts would be made to support the use and development of organic flavors. In fact, the 1995 NOSB Recommendation required certified operators to demonstrate efforts toward the ultimate production of an organic natural flavor. To a

large degree, the expectation has become a reality. Over a decade later, we have over 3,000 flavors available in organic form. Now it is time for the regulations to catch up with the marketplace and level the playing field by requiring everyone to use organic flavors when available.

On October 29, 2015, in response to the Organic Trade Association's petition and wide industry support, NOSB unanimously passed a recommendation to revise the annotation for flavors to require organic when **commercially available**. On December 27, 2018, after approving the NOSB recommendation and considering comments from the public during the proposed rule stage, NOP issued a final rule amending the National List. The final ruling on flavors will be implemented on **December 27, 2019**.

QUESTIONS AND ANSWERS

What are the new requirements for natural flavors allowed in organic products?

Natural flavors may be used in the 5% of an organic product provided the flavors are derived from non-synthetic sources only and produced without using synthetic solvents and carrier systems or any artificial preservative. Genetic engineering and ionizing radiation are prohibited as well. These requirements have not changed. The new requirement is that natural flavors may only be used when organic flavors are not commercially available.

How is commercial availability defined?

Commercial availability is defined as the ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan. (7 CFR 205.2) Price cannot be a consideration for determination of commercial availability.

Does the rule change apply to the "made with" label category?

No. Commercial availability only applies only to the 5% of certified organic (95%+) products (§ 205.301(b)). The "made with" labeling category allows for the use of up to 30% non-organic agricultural ingredients and/or non-agricultural ingredients listed on § 205.605 of the National List. Consistent with the organic regulations, the petition that OTA submitted was for certified organic products only. This includes organic products utilizing natural flavors as an ingredient, and/or organic flavors utilizing natural flavors as an ingredient.

Will I be out of compliance on 12/27/2019 if I am still using non-organic flavors?

No, you will not be out of compliance if you are using non-organic flavors on 12/27/2019. That is the date when search and documentation efforts begin; the process is on-going. Compliance will be met through documented activity to source and obtain organic flavors that are commercially available. Compliance will be evaluated on an on-going basis (continuous improvement) and determined through communication with the operation's certifier and the plan agreed to in the certified operation's Organic System Plan. The frequency and extent of the search and the specifications used to determine appropriate form, quality and quantity should all be detailed in the Organic Handling System Plan (See the Guidance on the next page).

I am a flavor house making certified organic flavors. Am I required to use organic flavor isolates?

Yes. It is understood that some compounded organic flavors may contain natural flavor isolates in the 5% allowed non-organic portion. This is possible because of the allowance of 'natural flavors' on the National List and the NOP organic product composition standards. However, the new requirement to use organic flavors when commercially available applies to all certified organic products, including flavors. **IMPORTANT!**

As a reminder, the term “organic” must not be used in a product name to modify a non-organic ingredient in the product (§ 205.300(a)). For example, a strawberry flavor may not be labeled as “Organic Strawberry Flavor” unless the strawberry flavor is “organic.” Flavors that meet the organic composition requirements (95%+ organic) but contain natural flavor isolates in the 5% must be labeled as “Organic Natural Flavor.”

What does the search process involve, and how can I meet the requirements of this new regulation?

First and foremost, don’t panic. The intent is continuous improvement and to increase the growth and use of organic flavors over time. The intent is not to hand down non-compliances to companies that are unable to secure organic flavors when they do not meet the specifications needed to make an awesome product that organic shoppers will buy and love. The intent is to: 1) start the process; 2) make a search and evaluation plan; and 3) work with your certifier on an annual basis.

Is there any guidance or commercial search criteria that can be used to help the process?

There is no formal guidance from the National Organic Program on commercial search and use of natural and organic flavors. However, the following developed by the Organic Trade Association reflects NOSB recommendations that were passed on commercial availability search for ingredients on § 205.605 and § 205.606, and related instruction from NOP on filing a petition. Additional resources on commercial availability are included below.

GUIDANCE ON DETERMINING COMMERCIAL AVAILABILITY OF ORGANIC FLAVORS

The aim of the following information is to help certified operators: 1) develop a sound and sensible organic flavor search plan that can be submitted to and agreed upon by the certifier; and 2) collect and maintain credible documentation to support the plan and search findings.

Commercial Availability is defined as the ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan (**7 CFR 205.2 – Terms Defined**).

The requirements of the Organic Handling System Plan, are described in § 205.201(a)(2) of the regulations:

§ 205.201(a) (2) “The producer or handler of a production or handling operation, except as exempt or excluded under § 205.101, intending to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food groups (s))” must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include:

(2) A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used, and documentation of commercial availability, as applicable:”

In addition to documentation of commercial availability, the Organic Handling System Plan also requires the following:

- A description of practices and procedures to be performed and maintained, including the frequency with which they will be performed;
- A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;
- A description of the recordkeeping system implemented to comply with organic requirements.

.....

The Organic Handling System Plan is the foundation and primary document that should be used to demonstrate compliance with the requirement to use organic flavors when they are commercially available.

.....

Role of the accredited certifying agency in determining commercial availability

An accredited certifier, in determining that a non-organic flavor is not commercially available in organic form, will:

- Evaluate the applicant or certified operator's Organic Handling System Plan and the operator's process for sourcing organic flavors, and determining whether they fulfill the required function. This includes a description of the frequency that the search is performed and research efforts to evaluate the quantity, quality and form of known organic sources.
- Evaluate the applicant or certified operator's Organic Handling System Plan and the operator's documented claims that an organic flavor is commercially available/unavailable in the form, quality, or quantity needed to fulfill the required function of the organic product.
- Validate that the applicant or certified operator has credible documentation that the flavor is not commercially available in an organic form by reviewing the list of known sources carrying organic flavors alongside documentation to support an unavailability claim.
- Require certified operators to update commercial availability information in each organic system plan update.

It is also recommended that certifiers maintain and submit to NOP an up-to-date listing of its certified organic operations and their certified organic flavors.

Role of the applicant or certified operator in demonstrating commercial availability

To adequately demonstrate that an organic flavor is not available, the following should be provided:

1. Complete or update the Organic Handling System Plan with detailed information on the process that will be used to conduct and document a commercial availability evaluation for organic flavors. Include the search and procurement methods used to identify organic sources that meet the quantity, quality and form requirements and the frequency of your search. Also describe the process or method used to determine whether the organic flavor fulfills the specification requirements of the organic product(s) the flavor is used in. Submit the plan to your certifier for approval, and then follow the plan.

2. Search efforts should be documented and include the identification of the organic flavor along with the date, source and contact information of the company contacted. A minimum of five sources that are known to offer organic flavors must be contacted. The number of companies contacted should be relative to the potential number of suppliers. Certifiers may ask that additional sources be contacted, depending on the availability of the flavor type and knowledge of other companies/sources that may carry the ingredient.
3. If the flavor is not available in organic form, please include a statement to this effect from the company contacted (letter, e-mail, phone log.). Alternatively, if search engines or databases are used, please describe the source, weblink, and any other helpful information such as a screenshot or search report.
4. If the flavor is available, but not in the quantity, quality or form needed, the following documentation may be submitted to support the non-availability claim:

Quantity – Report on the number of suppliers and amount produced. Specify the projected production and quantity of the flavor needed for a given amount of time and contrast that amount with the amount available. Describe other issues that may present a challenge to a consistent supply. A statement from the company contacted (or similar documentation) regarding the amount available must be submitted.

Quality – Specify how this determination was made, i.e. R & D testing, visual of the product upon arrival, microbial, organoleptic, etc. Clearly describe to your certifier why the quality of the flavor is not acceptable and how this conclusion was made. A statement or documentation from R & D supported by test results should be submitted if the ingredient was tested.

Form – A specification sheet (or similar document or method) for the desired flavor should be submitted along with a specification sheet (or similar document) of the flavor found. The inappropriateness of the form available should be clearly described with supporting proof.

Note: Price cannot be a consideration for determination of commercial availability.

5. Operators are required to at least update commercial availability information in each annual Organic Handling Plan Update.

TYPE OF FLAVOR OR 'FLAVOR NOMENCLATURE'

The search for organic flavors can be broken down and communicated to your certifier by 'type of flavor.' The general manufacturing process is implied by the nomenclature of the product, and helps determine the likelihood of an organic form due to the agricultural nature of the product and the complexity of processing.

Compounded Flavor: A mixture of ingredients such as extracts, essential oils and natural isolates. In most cases, it's usually dissolved in a solvent or it would be too concentrated.

Compounded WONF: Combination of a compounded flavor and a natural flavor WONF (with other natural flavor).

Distillate: A clear, flavorful liquid produced from fruits, herbs, roots, etc., by distillation; also the condensed product separated by distillation.

Extracts: Extracts are products that use solvents (typically alcohol or alcohol-water mixture) to pull out certain volatile and non-volatile fractions from raw materials such as spices and herbs, cocoa and vanilla, or flowers. Extracts found on the grocer's shelf, such as orange, almond, lemon, etc. are essential oils dissolved in an alcohol-water mixture.

Essential Oil: A volatile oil. An essential oil is what gives a botanical its aroma and can be the aromatic essence of a spice, flower, root, leaf or peel. It's made by steam distillation or cold pressing.

Essential Oil Isolate: Isolate of an essential oil – see above.

Isolate: A chemical or fraction obtained from a natural substance. For example, citral can be isolated from lemon oil or lemongrass.

Oleoresin: Solvent extracts of spices where the solvent has been completely removed. An oleoresin will contain the essential oil plus other important non-volatile components that characterize the flavor, color and other aspects of the starting raw material. For example, the oleoresin of pepper will contain its aroma as well as its taste sensations of heat and spice.

Single flavor chemical: A single molecule that provides flavor. These can be naturally or artificially derived, but they are specified to have a greater than 95% purity.

Add-Back Flavor: Adds back flavor lost during processing. For instance, orange juice can lose much of its flavor during the concentration process but flavorists can add orange oil during the formulation to increase the flavor. Add-back flavors imply that all ingredients of the flavors are derived from the named fruit.

Essence: Concentrated fragrance or flavorant. In some countries, essence is used to designate volatile oils, but in the U.S. this term is commonly applied to alcoholic solutions of volatile oils.

Natural Flavor WONF: A natural flavor that contains both a characterizing flavor from the named material and other natural flavor, which simulates, resembles or reinforces the characterizing flavor.

Single-fold Oil: The oil as it is produced from the plant (distillation or expression), without concentration.

HELPFUL RESOURCES AND REFERENCES

- National Organic Program Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>
- Find.Organic: <https://find.organic/>
- NOP 3011: National List Petition Guidelines
- NOSB Fall 2007 Recommendation: Guidance on the Establishment of Commercial Availability Criteria
- NOSB Fall 2016 Recommendation: Commercial Availability Criteria for National List Materials (unanimously passed)
- George A. Burdock. Fenaroli's Handbook of Flavor Ingredients, 5th ed. Washington D.C. CRC Press.
- Primo Bader and Steve Phelps. January-March 2007. The Flavor Factor: Exploring Today's Taste-Improving Technology. *Organic Processing Magazine*.

FATTY ALCOHOL — PETITION (PROPOSAL)

BACKGROUND

Fatty alcohol is petitioned for use as a sucker control on organic tobacco crops. The substance is produced from natural fats or petroleum sources, requiring chemical changes to produce the final product. Fatty alcohol is applied as a broadcast spray over top of tobacco plants in the early flower stage when suckers (auxiliary lateral buds) are tender, desiccating the sucker. Sucker control reduces drain on plant resources, and supports growth and yield of marketable tobacco leaves.

This is the second time that NOSB is reviewing this substance. The first petition was for a much broader use of the substance in tobacco and other crops, and did not specify the range of fatty alcohols. NOSB rejected (Fall 2017) the original petition, citing among other issues that the use of a synthetic growth regulator is not compatible with a system of sustainable and organic agriculture. The revised petition on the current meeting agenda is limited only to use on tobacco, and is limited only to the active ingredient C6, C8, C10, C12 naturally derived fatty alcohol.

NOSB SUBCOMMITTEE SUMMARY

The majority opinion of the subcommittee is to accept the petition and allow fatty alcohols for tobacco sucker control because of the limited scope of the petition and the essentiality of the substance for production of tobacco crops. Numerous public comments from tobacco growers indicate that this substance is essential for tobacco production because alternative substances and practices are not effective. Manual suckering exposes field workers to potential health issues such as tobacco poisoning from skin contact with tobacco leaves. Fatty alcohol is rapidly biodegradable and poses low concern for environmental contamination. The subcommittee proposal also includes a minority opinion that does not support the petition because labor savings and greater economic returns are insufficient criteria for allowing a synthetic material in organic production.

SUBCOMMITTEE VOTE: Motion to add fatty alcohol C6, C8, C10, C12 Naturally Derived Fatty Alcohol at §205.601 for sucker control on organic tobacco crops. — Yes: 4 No: 2 Abstain: 1 Absent: 1 Recuse: 0

ORGANIC TRADE ASSOCIATION'S POSITION

The Organic Trade Association has not taken a position on this proposal.

POTASSIUM HYPOCHLORITE – PETITION (PROPOSAL)

BACKGROUND

Potassium hypochlorite is petitioned for use as an irrigation water treatment under the same conditions as other chlorine materials on the National List: “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.” Potassium hypochlorite is produced by reacting chlorine with an aqueous solution of potassium hydroxide.

NOSB SUBCOMMITTEE SUMMARY

The subcommittee proposes to accept the petition for potassium hypochlorite because its chemistry and human and environmental risk are nearly identical to currently allowed chlorine materials sodium and calcium hypochlorite.

SUBCOMMITTEE VOTE: Motion to add potassium hypochlorite at §205.601(a)(2): Chlorine materials--For use in water for irrigation purposes, 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. — Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

ORGANIC TRADE ASSOCIATION’S POSITION

The Organic Trade Association has not taken a position on this proposal.

2021 SUNSET REVIEWS

BACKGROUND

At this meeting, NOSB will vote on whether to continue the allowance of several of the fertilizers, pest control products, livestock treatments, processing aids, and ingredients currently included on the National List of Allowed and Prohibited Substances to determine whether the substances should continue to be listed or should be removed from the list. These National List inputs will be reviewed and voted on by NOSB based on their Sunset timeline (five-year renewal date cycle), and may not be renewed if new information indicates these substances are incompatible with organic production, are not necessary, or are harmful to human health or the environment. The specific inputs included in this sunset cycle are listed below.

NOSB SUBCOMMITTEE SUMMARY & ORGANIC TRADE ASSOCIATION'S POSITION

The list below includes a description of material, highlights of the NOSB Crops Subcommittee discussion, and a summary of the Organic Trade Association Sunset Survey responses for the material.

Hydrogen peroxide – Allowed as an algicide, disinfectant, and sanitizer, including irrigation system cleaning systems. Also allowed for plant disease control. §205.601(a)(4); §205.601(i)(5)

- **NOSB Subcommittee Discussion:** Environmentally benign. Effective for disease control and as a cleaning agent. Essential tool for fire blight control.
- **NOSB Subcommittee Vote:** Motion to remove from National List— Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0
- **OTA Survey Results:** **Necessary**

Ammonium soaps – Allowed for use as a large animal repellant (e.g., deer), provided that there is no contact with soil or edible portion of crops. §205.601(d)

- **NOSB Subcommittee Discussion:** Low environmental toxicity. Non-synthetic alternatives have significant limitations.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0
- **OTA Survey Results:** No responses were received.

Horticultural oils (Narrow range oils) – Allowed as an insecticide and for plant disease control. Used as dormant, suffocating, and summer oils. §205.601(e)(7); §205.601(i)(7)

- **NOSB Subcommittee Discussion:** Important tool for fruit and vegetable growers. Non-synthetic alternatives have significant limitations.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0
- **OTA Survey Results:** **Necessary**

Pheromones – Allowed as insect management to confuse pests and prevent infestations. §205.601(f)

- **NOSB Subcommittee Discussion:** Non-toxic to humans and environment. Important tool for monitoring insect populations.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0
- **OTA Survey Results:** **Necessary**

Ferric phosphate – Allowed as slug or snail bait. §205.601(h)

- **NOSB Subcommittee Discussion:** Important pest management tool for fruit and vegetable growers. Ongoing research to understand the soil community response to ferric phosphate. Acknowledgement that efficacy is inextricably linked to formulations with a chelating agent.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 5 Abstain: 3 Absent: 0 Recuse: 0
- **OTA Survey Results:** No responses were received.

Potassium bicarbonate – Allowed for plant disease control. §205.601(i)(9)

- **NOSB Subcommittee Discussion:** Important tool for organic crop producers. Alternative materials and practices are insufficient.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0
- **OTA Survey Results:** No responses were received.

Magnesium sulfate – Allowed as a plant or soil amendment with a documented soil deficiency. §205.601(j)(6)

- **NOSB Subcommittee Discussion:** Non-toxic when applied as a foliar feed. Non-synthetic alternatives are not commercially available or have other limitations.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0
- **OTA Survey Results:** **Necessary**

Hydrogen chloride – Allowed for delinting cotton seed for planting. §205.601(n)

- **NOSB Subcommittee Discussion:** Essential for organic cotton productions. Significant environmental and health threats if substance is not handled properly. Safe and effective alternatives are not yet available.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0
- **OTA Survey Results:** **Necessary**

Ash from manure burning – PROHIBITED in crop production. §205.602(a)

- **NOSB Subcommittee Discussion:** Preference for manure to retain its full carbon and nutrient content when used as a fertility input on organic land.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0
- **OTA Survey Results:** No responses were received.

Sodium fluoaluminate – PROHIBITED in crop production. §205.602(g)

- **NOSB Subcommittee Discussion:** Toxicity associated with fluoride pollution.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0
- **OTA Survey Results:** No responses were received.

PAPER (PLANT POTS AND OTHER CROP PRODUCTION AIDS) PETITION (DISCUSSION)

BACKGROUND

Paper planting pots have been petitioned by Small Farm Works for inclusion on the National List. Paper pots and other growing containers are used as a vessel for growing transplants intended to be planted directly in the ground. Nitten paper chain systems, which are the subject of the petition, are used to facilitate transplanting closely spaced crops such as onions, salad greens, herbs, and others crops. In addition to paper, the products are formulated with several adhesives. Newspapers and other recycled papers are already allowed as synthetic substances for use as mulch and as a compost feedstock. Certifiers have historically extended the allowance for paper to its use in transplant pots, even though paper isn't specifically on the National List for this use. This petition was submitted for NOSB to specifically address the use of paper as a production aid for transplants intended to be planted into soil. At the fall 2018 meeting, NOSB presented a discussion document to solicit public comments on the necessity and environmental impact of the material and the availability of alternatives. At the spring 2019 meeting, NOSB presented a discussion document that expanded the scope of its review to include a variety of paper-based production aids including pots, seed tape, collars, and hot caps. Out of concern for the use of synthetic fibers in paper-based planting aids, NOSB requested a technical report to evaluate the types of synthetic fibers and the biodegradability of the synthetic fibers used in these types of products. The technical report clarified that synthetic fibers in paper pots and containers are also found in other paper materials currently allowed in organic production as mulches and compost feedstocks.

NOSB SUBCOMMITTEE SUMMARY

The subcommittee sees few differences between the current paper allowances and the petitioned paper pots and other paper-based planting aids, and has developed a listing and annotation for the possible allowance of paper pots and other production aids. Public comments are requested on the following discussion questions.

Discussion Questions:

1. Please comment on the following options under consideration by the subcommittee for listing at §205.601(o) as production aids:
 - a. "Virgin or recycled paper, without colored or glossy inks," or
 - b. "Virgin or recycled paper, without colored or glossy inks; any synthetic polymer fibers included must not exceed 15% of the paper and must be 100% bio-based with content determined using ASTM D6866 (incorporated by reference; see 205.3), and 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)"

2. Synthetic polymer content—
 - a. Should a maximum synthetic polymer content be stated explicitly? If so, what is the appropriate level?
 - b. What is the amount (or range) of synthetic polymer content in products currently available?
 - c. How would synthetic content be measured? How would a certifier or Material Review Organization verify content? For example, if a product included recycled paper as an ingredient, how would the synthetic polymer content be determined?
 - d. Is it possible to manufacture paper production aids that use only natural fiber sources and that meet the product specifications for their intended use?
3. Biodegradability—
 - a. Should a biodegradability standard be included for these products? If so, is this the appropriate biodegradability standard?
 - b. Does maximum synthetic polymer content need to be stated if there is a biodegradability requirement?
 - c. As the products biodegrade, what is the impact on the soil? Also, can fragments be consumed by wildlife or livestock before it is completely degraded?
4. Bio-based content—
 - a. Should a minimum bio-based content standard be included for these products?
 - b. Is 100% bio-based content achievable for these products? If not, what should be the minimum bio-based content requirement?
5. Is genetic engineering involved in the production of these products?
6. Does the annotation need to specify that added fungicides, insecticides, or other synthetic

SUBCOMMITTEE VOTE: Motion to accept the discussion document

— Yes: 6 No: 0 Abstain: 0 Absent: 2 Recuse: 0

ORGANIC TRADE ASSOCIATION'S POSITION

The Organic Trade Association continues to support the allowance of paper to be planted in the soil when used as a planting aid because paper is already allowed for equivalent uses (e.g., as mulch).

OTA continues to support the decision by NOSB to expand the scope of review to be inclusive of generic products that are paper-based and used as planting or seeding aids. We suggest that the appropriate scope of review is generic products that are paper-based and used as planting or seeding aids that are left to degrade in the soil. Other production aids that are not intended to degrade in the soil (which is a very large category of very diverse products) should be outside the scope of review.

In response to the discussion questions posed by the NOSB Crops Subcommittee, we question if commercially available forms of generic paper-based production aids (that are intended to be allowed under this listing) will actually comply with the restrictive annotation in Discussion Question 1b.

EXCLUDED METHODS TERMINOLOGY (PROPOSAL)

BACKGROUND

NOSB is addressing two items related to excluded methods: 1) induced mutagenesis, and 2) embryo transfer in livestock. These items represent a continuation of work and dialogue by NOSB over the past few years. On November 18, 2016, NOSB passed a recommendation on Excluded Methods Terminology that provided framework and criteria for determining a genetic manipulation as an excluded method and requested that NOP incorporate the information into a guidance document. This recommendation attempts to address the increased diversity in types of genetic manipulations performed on seed, livestock and other inputs used in agriculture. It is understood that genetic engineering is a rapidly expanding field in science at this time, and that NOSB and NOP will need to continually review new technologies to determine if they would or would not be acceptable in organic agriculture. Also, in November 2016, NOSB presented a discussion document with a running list of new technologies under review to determine if they are within the definition of excluded methods and thus prohibited. Several of the technologies in the document are identified as “to be determined,” with the understanding that NOSB will continue to address each method at future meetings.

NOSB SUBCOMMITTEE SUMMARY

The subcommittee has presented a proposal on two technologies that are currently on the “to be determined” list: 1) Induced mutagenesis, and 2) Embryo transfer in livestock.

Induced Mutagenesis: The subcommittee proposes that induced mutagenesis developed through in vitro nucleic acid techniques is consistent with the definition of excluded methods and should be identified as such in NOP Guidance. Other methods of induced mutagenesis need further discussion, so the subcommittee proposes that induced mutagenesis developed through exposure to UV light, chemicals, irradiation, or other stress-causing activities remain as “to be determined.”

Embryo Transfer in Livestock: The subcommittee proposes that embryo transfer (or embryo rescue) in livestock is not an excluded method and should be clarified as such in NOP Guidance. Use of hormones is not allowed in recipient animals.

SUBCOMMITTEE VOTE: Motion to accept the proposal on excluded methods determinations. —
Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

ORGANIC TRADE ASSOCIATION'S POSITION

The Organic Trade Association supports the recommendations that have been passed to date, including the clarification that gene editing techniques, such as CRISPR, are currently prohibited under the NOP regulations. The term 'bioengineering,' as defined by USDA, does not and should not affect the definition of "excluded methods" or any other definition under USDA's NOP. We maintain that gene editing and the other methods that are listed as 'excluded methods' in the terminology chart are inconsistent with our existing definition and therefore prohibited.

OTA supports updating the proposal's terminology chart to clarify that induced mutagenesis, developed via use of in vitro nucleic acid techniques, meets the definition of an excluded method. We also support the recommendation clarifying that embryo transfer in animals is NOT an 'excluded method.'

The Organic Trade Association recognizes that the definition of "excluded methods" was based on the efforts of NOSB in 1995, and several new technologies have emerged since that time. As a result, it is extremely helpful for organic stakeholders and NOP to have guidance with clear and up-to-date terminology to make concrete and consistent compliance determinations. We continue to be supportive of NOSB's work on a terminology chart that complements and provides additional detail to the existing regulatory definition of "excluded methods."

GENETIC INTEGRITY TRANSPARENCY OF SEED GROWN ON ORGANIC LAND (PROPOSAL)

BACKGROUND

Since 2012, NOSB has issued several discussion documents on the topic of “seed purity” (i.e., keeping seed stock used for organic production free from contamination by GMOs via a seed purity standard). Public commenters have expressed strong support for exploring the feasibility of a seed purity standard recognizing the importance of reducing inadvertent introduction of GMOs into crops through seeds. At the same time, there is concern that setting a standard without the proper infrastructure may penalize farmers for trespass of genetic contamination that is the fault of others. It could also ultimately narrow the availability of needed crops traits. Six years of discussion and public comment led to a conclusion that public data on seed contamination is needed to inform an effective and fair seed purity standard if one is to be established. NOSB continues to explore solutions to this complex problem.

NOSB SUBCOMMITTEE SUMMARY

The subcommittee proposes that NOP provide an “Instruction to Certifiers” that encourages certifiers and farmers to be proactive in obtaining information about GE contamination before planting seed that has a GE equivalent. There is no specific requirement, other than for certifiers to inform their clients about the option to request GE contamination test results from their seed and planting stock providers. The proposal does not set tolerance levels that could prohibit planting of seed that exceeds any specific tolerance. The goal is to aid producers in a goal of low-to-no detection of GE contamination of their organic crops (seed and planting stock) that have GE equivalents in the marketplace.

The proposed instruction also conveys that certifiers may choose to obtain testing information at the organic inspection. If presence of GE contamination is found on the finished crop by the certifier in their testing program or by a buyer of the finished crop, this seed GE contamination information will be useful in determining the cause of the GE contamination. Certifiers can also inform farmers who wish to test seed they grew or test seed or planting stock they purchased, that they are legally allowed to test for GE contamination, and a wide variety of laboratories around the U.S. and the world supply this testing service.

SUBCOMMITTEE VOTE: Motion to accept the “Genetic Integrity Transparency of Seed Grown on Organic Land Instructions to Certifiers” Proposal — Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

ORGANIC TRADE ASSOCIATION’S POSITION

The Organic Trade Association generally supports the intent behind the subcommittee’s proposal. However, we suggest that the proposal be revised to encourage producers to contact their suppliers “to obtain information regarding the levels of GE contamination” rather than “GE contamination test results.” We believe this will encourage a more realistic outcome consistent with what we believe seed suppliers are willing to provide. The proposed instruction also appears to apply to both organic and non-organic seed/planting stock. It is important to note that positive GE contamination data for organic seed obtained by the certifier could trigger an investigation on the seed itself (see NOP Policy Memo 11-13). GE contamination data for non-organic seed, however, would not trigger an investigation for the seed itself. This could potentially impose undue burden on organic seed growers and suppliers.

The Organic Trade Association strongly supports NOSB’s continued request for a NOP-funded task force to systematically collect data on GE contamination to better inform an appropriate solution. The Organic Trade Association continues to recommend that NOSB focus on a request to NOP for guidance on GMO testing for certifying agencies and industry. We believe this is the best next step to make gradual progress.

NOSB RESEARCH PRIORITIES (PROPOSAL)

BACKGROUND

Since adopting its Research Priorities Framework in 2012, NOSB has presented a 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 published each year prior to the fall meeting. The final priorities include feedback from organic stakeholders, which is publicly available through the Federal Register.

NOSB SUBCOMMITTEE SUMMARY

NOSB encourages integrated, whole farm research in the following areas:

Livestock

1. Evaluation of methionine in the context of a system approach in organic poultry production.
2. Prevention and management of parasites, examining breeds, geographical differences, alternative treatments, and pasture species.
3. Organic livestock breeding for animals 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.
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.

Food Handling and Processing

1. Comparison of alternatives to chlorine materials in processing: impact mitigation, best management practices, and potential for chlorine absorption by produce.
2. Production of celery for celery powder yielding nitrates sufficient for cured meat applications, and investigation of agriculturally derived alternatives.
3. Suitable alternatives to BPA (Bisphenol-A) for linings of cans used for various products.

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 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 the proposal on 2019 NOSB Research Priorities — Yes: 5 No: 0
Abstain: 0 Absent: 0 Recuse: 0

THE ORGANIC CENTER'S POSITION

The Organic Center supports the subcommittee's proposed 2019 Research Priorities. We're particularly pleased to see the inclusion of "Organic no-till practices for diverse climates, crops, and soil types," "Development of systems-based plant disease management," "Strategies for the prevention, management, and control of invasive insects," and "Production of celery for celery powder yielding nitrates sufficient for cured meat." The Organic Center is actively involved in conducting and communicating research on these issues, and we expect the prioritization of these topics by NOSB may help us secure further funding.

Based on feedback we've received during our own outreach efforts, we would also like to suggest that the areas of soil health, climate change, and pathogen protection be considered for inclusion in the 2019 Research Priorities.

MARINE MATERIALS IN ORGANIC CROP PRODUCTION (DISCUSSION)

BACKGROUND

Marine vegetation such as seaweeds are commonly used in the manufacture of crop production inputs such as fertilizers and soil conditioners. These marine materials are largely harvested from wild native ecosystems. During the 2015 Sunset Review of the §205.601(j) listing of aquatic plant extracts, concerns were raised about the increase in global harvesting of seaweeds and the accelerated potential for destruction of marine ecosystems. To more fully examine marine materials in organic production, a Technical Report was obtained in 2016. A discussion document posted for the fall 2016 NOSB meeting t posed questions about the naming conventions of marine plant/algae on the National List, the need to specify uses or harvesting guidelines of certain species, and whether further NOP guidance is needed. In spring 2017, NOSB proposed a motion to limit the §205.601(j) listing of aquatic plant extracts to only brown seaweeds. Public comments revealed that aquatic plant input products also use green and red algae, so the proposal was sent back to subcommittee to re-examine its approach to the issue. Another discussion document, posted for the fall 2018 meeting, explored a potential requirement for marine plants to be certified organic when used in crop inputs, and it initiated a robust response from public commenters. Although there was unanimous support throughout the comments that the issue of sustainability in marine plant harvesting should be addressed, there was not consensus that organic certification was necessarily the right solution based on the information available at the time. NOSB continues to seek an effective and realistic means of addressing this complicated issue of ensuring that marine algae harvesting maintains or improves the environment.

NOSB SUBCOMMITTEE SUMMARY

The discussion document on Marine Materials in Organic Crop Production was presented at the April 2019 NOSB meeting, and is being posted a second time for additional comment. It is identical to the April 2019 version with the exception of the addition of question #8.

The discussion document presents the approach of requiring organic certification of marine algae ingredient in crop inputs (proposed language changes in bold):

- §205.601 (j) As plant or soil amendments. (1) Aquatic plant extracts (other than hydrolyzed) – Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount use is limited to that amount necessary for extraction. **Marine algae ingredients must be certified organic.**
- §205.602 Non-synthetic substances prohibited for use in organic crop production. **Marine algae — unless certified organic.**

The discussion document summarizes and attempts to address the concerns raised at the last meeting about this approach, specifically regarding the authority of NOSB to require organic inputs, and the effectiveness of organic certification to meet sustainability goals. The document also summarizes a number of alternative approaches that were suggested in the last meeting. Those approaches include: limiting or prohibiting harvest of certain marine algae; exploring other existing third-party standards for sustainable harvesting; or adding annotations to material listings on the National List to require sustainable harvesting. Each of these approaches is met with its own set of questions and concerns that are outlined in the document.

Discussion Questions:

1. If you are not in support of requiring organic certification, what approach do you support? Please describe the method for defining, measuring, and most importantly, enforcing, that the harvest would not be destructive to the environment under an alternative approach.
2. Some existing wild harvest marine algae standards from other certifiers and third-party entities are listed in the Appendix. Please comment on strengths in these standards that could be adapted for NOP guidance. Please identify areas of weakness or areas that are not covered.
3. What existing certification or private standards to support marine algae harvest sustainability have not been included in this document or the Appendix that can help inform the NOSB's understanding of the current work being done?
4. How many crop input products approved for use in organic production currently contain certified organic marine algae ingredients?
5. Are there any crop input products utilizing or developing farmed marine algae?
6. Are there enough certifiers able to offer certification services to meet the needs of the crop fertilizer markets if organic certification were required? If organic certification were required of marine algae ingredients, what would be an appropriate phase-in time to allow markets to meet the demand?
7. NOSB hopes to convene an expert panel at the fall 2019 Board meeting to include a marine algae harvester for crop inputs, scientist, conservationist, and certifier, among others. What are some questions that could be posed to help identify the issues and solutions?
8. What are the standards for evaluating environmental harm? For example, what measures of community biodiversity and marine algae species characteristics (density, maximum height, girth, area) could be collected pre- and post-harvest? How soon must these variables return to baseline to avoid environmental harm?

SUBCOMMITTEE VOTE: Motion to accept this discussion document
— Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

ORGANIC TRADE ASSOCIATION'S POSITION

The Organic Trade Association continues to support the efforts of NOSB and the organic sector to move towards the allowance of only aquatic plants produced and harvested in a sustainable manner.

We still have questions about the extent of the problem that needs to be solved, and have identified a lack of technical information in the following key areas, 1) the effect seaweed harvesting has on the environment as documented by scientific evidence, and 2) the existing legal framework for seaweed harvesting in countries where most seaweed is harvested. To support NOSB's evaluation of these issues, we encourage subject-matter experts to share technical information to the Board through the public comment process. The Organic Trade Association's full written comments include lists of questions posed to the scientific community, and to seaweed harvesters and seaweed-based input suppliers.

We want to see continuous improvement in sustainable sourcing of inputs, but we must approach the issue carefully, using science-based information and thoughtful consideration of the global industry impacts of any new regulatory requirements, so that organic farmers continue to have reliable access to essential tools for production. In service of this goal, we identify in our full written comments several additional activities that NOSB can do to support continuous improvement in sustainable sourcing of inputs used in organic agriculture.



SPOTLIGHT:

EXPERT PANEL ON MARINE MATERIALS

At the fall 2019 NOSB Meeting, the Board will hear from an invited panel of experts on the topic of Marine Materials. The goal of the panel is to evaluate the environmental impacts of marine macro algae harvesting for crop fertility inputs and to explore possible means of mitigating harm. The information will support NOSB's efforts to address its work agenda item to seek an effective and realistic means of ensuring that marine algae harvested for use as a crop input substance is not harmful to the environment. Expert Panels such as this are one mechanism that NOSB can use to obtain technical information to support its evaluation of substance under the provisions of the Organic Foods Production Act.

The panel is composed of one harvester, one certifier, and two scientists:

- Dr. Raul Ugarte, *Acadian Seaplants Ltd.*
- Chris Grigsby, *Maine Organic Farmers and Gardeners Association (MOFGA) Certification Services*
- Dr. Allison Schmidt, *Dalhousie University*
- Dr. Nichole Price, *Bigelow Laboratory for Ocean Sciences*

WHAT ARE MARINE MATERIALS?

Marine materials refer to the broad group of marine plant and algae species that are harvested from aquatic environments and used as inputs in organic agriculture and food processing. In organic crop production, marine materials may include kelp-based fertilizers and soil conditioners. In organic livestock production, kelp may be used as feed additive for nutritional supplementation. In organic food processing and handling, various forms of marine materials and their derivatives are listed on the National List, such as agar, alginates, and kelp.



Hand Harvesting *Ascophyllum nodosum* in Nova Scotia — photo: Bill Wolf

HOW DID WE GET HERE?

- In 2015, during a [Sunset Review](#) of the §205.601(j) listing of aquatic plant extracts (allowed for use as plant fertilizers and soil amendments), concerns were raised about the about potential overharvesting of the seaweeds used in these input products. To more fully examine the use of marine plants and algae in organic production and handling, a [Technical Report](#) was obtained in 2016.
- In fall 2016, a [Discussion Document](#) was posted by NOSB that posed questions about the naming conventions of marine plants and algae on the National List, the need to specify uses or harvesting guidelines of certain species, and whether further NOP guidance is needed.
- In spring 2017, NOSB Crops Subcommittee presented a [Proposal](#) to limit the §205.601(j) listing of aquatic plant extracts to only brown seaweeds. Public comments revealed that aquatic plant input products also use green and red algae, so the proposal was sent back to subcommittee to re-examine its approach to the issues. [[Read OTA's Comments](#)]
- The NOSB Materials Subcommittee posted a [Discussion Document](#) for the fall 2018 meeting that explored a potential requirement for marine plants to be certified organic when used in crop inputs, and a number of alternative approaches such as: limiting or prohibiting harvest of certain marine algae; exploring other existing third-party standards for sustainable harvesting; or adding annotations to material listings on National List to require sustainable harvesting. [[Read OTA's Comments](#)]
- In spring 2019, NOSB presented another [Discussion Document](#) outlining requiring organic certification of marine algae ingredient in crop inputs to address the concerns raised at the previous meeting. The discussion document also puts forth additional discussion questions for stakeholder feedback. [[Read OTA's Comments](#)]
- In fall 2019, NOSB is presenting the same [Discussion Document](#) from spring 2019 with one additional discussion question. [[Read OTA's Comments](#)] See Page 59 for an overview of the fall 2019 discussion document.

ORGANIC TRADE ASSOCIATION MARINE MATERIALS TASK FORCE

Task forces make recommendations to the Organic Trade Association (OTA) on policy issues, association programs and special projects. OTA has many active task forces with dozens of members working on everything from commenting on FDA's Food Safety Rule revisions to analyzing Mexico's Operating Guidelines for Organic Agriculture.

To tackle the complex issue of sustainable sourcing of marine materials, OTA launched a Marine Materials Task Force this summer, following the last NOSB Meeting. OTA's Task Force provides a venue for consensus-building among those in the organic industry to identify the best solution for ensuring sustainable sourcing of seaweed-based crop inputs. The Task Force, comprised of member companies across the organic industry landscape, held multiple meetings over the course of the past few months to review the NOSB Meeting Materials and inform OTA's comments in response to NOSB Materials Subcommittee Discussion Document. The OTA Marine Materials Task Force plans to remain engaged in ongoing discussions on this complex and important topic.

POLICY AND PROCEDURES MANUAL REVISION (PROPOSAL)

BACKGROUND

The Policy and Procedures Manual (PPM) was established to assist NOSB in the implementation of its duties under the Organic Foods Production Act, and to establish operating procedures and policies for NOSB. The PPM was first adopted in October 2002. Since its adoption, the PPM has been revised 14 times with 11 revisions occurring from 2007-2011.

NOSB SUBCOMMITTEE SUMMARY

The subcommittee proposes the following changes:

Section/Page	Change
III. D. Page 8	Added to the NOSB Secretary's duties: To monitor and notify Subcommittee Chairs periodically of public comments posted in the open docket between the period when the meeting notice is posted in the Federal Register and when the proposals are posted (Pg. 8)
IV. F. 1 Page 20	Clarified language about when the new NOSB Chair takes office to match the language that is in VIII. F.
IV. G. 2 Page 22	Another type of discussion document: Petition material discussion document
IV. H. Page 23	Clarified the steps in the material review process for a new petition
IV. H. Page 24 Steps 2 & 3	Added clarifying language about how a Subcommittee determines sufficiency of a petition
IV. H. Pages 25 - 26, Steps 4 & 7	Added a process for a Subcommittee to develop a discussion document based on a petition
VIII. E. Page 34	Added an additional bullet point under the section about the policy for public communication between NOSB meetings for posting discussion documents and proposals between public meetings for review and public comment

SUBCOMMITTEE VOTE: Motion to accept the changes to the Policy & Procedures Manual (PPM)

—Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

ORGANIC TRADE ASSOCIATION'S POSITION

The Organic Trade Association supports all of the proposed changes to the NOSB Policy and Procedures Manual. The changes are easily understood and consistent with our understanding of existing practice or practices intended to be carried out. We have no concerns or questions.

The Organic Trade Association also strongly supports the PPM section on NOSB-NOP Collaboration starting on Page 8. Although not a part of the PPM topics on the table for discussion at this meeting, we continue to support that teamwork and collaboration between NOSB and the NOP, as well as others in the organic community, are needed to maintain, enhance and promote the integrity of organic principles and products.

Most importantly, as stated in the PPM: "The unique nature of the NOSB and its relationship with the NOP, as established through OFPA, requires that the volunteer Board, which regularly receives stakeholder input through public comment, must work collaboratively with the NOP. Similarly, the NOP, as required through OFPA, must consult and collaborate with the NOSB."

USE OF EXCLUDED METHODS VACCINES IN ORGANIC LIVESTOCK PRODUCTION (PROPOSAL)

BACKGROUND

Vaccines are permitted as a preventive health care material in organic livestock production. Uncertainty has existed about the status of vaccines made from excluded methods (i.e. genetic engineering) that are permitted, which has caused inconsistencies between certifiers in what vaccines are allowed to be used in organic livestock production. Although §205.105(e) requires excluded method vaccines to be reviewed and placed on the National List before use and there is a categorical listing for vaccines on the National List, there are not individual vaccine listings nor a specific references to those from excluded methods. This topic was discussed in depth by NOSB from 2009-2014, culminating in a unanimous recommendation from NOSB in fall 2014 that presented findings on manufacturing and availability of vaccines made with excluded methods, and requested that NOP review the information and provide guidance to the industry on these materials. NOP has not been able to act on this recommendation because of the following challenges: “having an updated definition of excluded methods that determines if new technologies were to be excluded methods for organic, having a clear understanding if there were non-excluded method vaccine equivalents to excluded method-derived vaccines, and how to provide for use of excluded method vaccines if there was an emergency when only an excluded method vaccine could address the problem in a timely way.” NOSB’s more recent work on excluded methods terminology will support the renewed focus of the Livestock Subcommittee’s work on vaccines. At the spring 2019 meeting, NOSB presented a discussion document with three options to clarifying the allowance of excluded methods vaccines in the regulations: 1) Follow the requirements of §205.105 (e) and start reviewing known excluded method vaccines for individual placement on the National List; 2) Allow all vaccines “as a class” without any review or consideration if they were produced through excluded methods; 3) Allow vaccines from excluded methods, but only if a vaccine is not “commercially available” that had not been produced from excluded methods to effectively treat that health issue. Most public commenters supported option 3. At the fall 2019 meeting, NOSB presents a proposal to implement that option.

NOSB SUBCOMMITTEE SUMMARY

The subcommittee proposes to amend NOP regulations so that vaccines from excluded methods may be used **only when** an equivalent vaccine not produced through excluded methods is not commercially available. This proposal implements the most popular of the three options presented for discussion at the meeting last spring. The subcommittee’s proposal includes information about how to determine commercial availability of a vaccine not produced through excluded method terminology.

SUBCOMMITTEE VOTE: Motion to change the USDA organic regulations at §205.105 (e). Addition to the current rule noted in bold.

(e) Excluded methods, except for vaccines: Provided, That **vaccines produced through excluded methods may be used when an equivalent vaccine not produced through excluded methods is not commercially available.** — Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

ORGANIC TRADE ASSOCIATION'S POSITION

The Organic Trade Association is committed and actively engaged in fighting the proliferation of GMOs to protect organic agriculture and trade, and preserve farmer and consumer choice. We do not in any way support the use of excluded methods in the production of organic seeds, crops, ingredients or other production methods. However, we do acknowledge that the regulations currently provide for one narrow exception to the prohibition on excluded methods—GMO vaccines—provided they are approved in accordance with §205.600(a).

The Organic Trade Association support NOSB's work towards a recommendation for vaccines that stands against the proliferation of GMOs in organic, while being practical in accepting the fact that some necessary vaccines are only available using excluded method technology.

We support the NOSB fall 2019 proposal in principle, based on several key principles that align with OTA's Position on GMO Vaccines. We believe the NOSB's fall 2019 proposal on Vaccines from Excluded Methods is effective to meet these key principles:

1. GMO vaccines are more narrowly restricted than what is being done under status quo.
2. Preference is given to non-GMO equivalent alternatives.
3. Organic producers have access to safe and effective vaccines to promote animal welfare.
4. Certification agencies reach consistent determination about which vaccines are allowed.

However, if NOSB passes this proposal, there are several outstanding issues that need to be addressed so that our identified key principles are upheld during rulemaking:

1. Confirm that NOSB has completed its review of GMO vaccines under the provisions of §205.600(a) to ensure compliance with the legal opinion of USDA's Office of General Counsel.
2. Ensure that the GMO vaccines are included in the Sunset Review of the listing of vaccines on the National List.
3. Protect organic producers from being mandated to use a GMO vaccine when a non-GMO version is commercially available.
4. Support certification agencies and certified operators with guidance on identifying vaccines from excluded methods and enforcing the commercial ability restriction.

2021 SUNSET REVIEWS

BACKGROUND

At this meeting, NOSB will vote on whether to continue the allowance of several of the fertilizers, pest control products, livestock treatments, processing aids, and ingredients currently included on the National List of Allowed and Prohibited Substances to determine whether the substances should continue to be listed or should be removed from the list. These National List inputs will be reviewed and voted on by NOSB based on their Sunset timeline (five-year renewal date cycle), and may not be renewed if new information indicates these substances are incompatible with organic production, are not necessary, or are harmful to human health or the environment. The specific inputs included in this sunset cycle are listed below.

NOSB SUBCOMMITTEE SUMMARY & ORGANIC TRADE ASSOCIATION'S POSITION

The list below includes a description of material, highlights of the NOSB Crops Subcommittee discussion, and a summary of the Organic Trade Association Sunset Survey responses for the material.

Atropine – Allowed as a medical treatment. Used as an antidote to organophosphate insecticide poisoning. §205.603(a)(4)

- **NOSB Subcommittee Discussion:** No effective alternatives. No opposition to relisting.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0
- **OTA Survey Results:** **Necessary**

Hydrogen Peroxide – Allowed as a disinfectant, sanitizer, and medical treatment. Used as a cleaning agent on contact surfaces, such as equipment, calf pails, bottles, and utensils. Also used to clean wounds and as a teat dip. §205.603(a)(15)

- **NOSB Subcommittee Discussion:** Important sanitation tool. Recommended for relisting.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0
- **OTA Survey Results:** **Necessary**

Iodine – Allowed as a disinfectant, sanitizer, and medical treatment, and as a topical treatment and external parasiticide. Used as a teat dip. §205.603(a)(16); §205.603(b)(3)

- **NOSB Subcommittee Discussion:** Widely used and important tool for livestock operators.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0
- **OTA Survey Results:** **Necessary**

Magnesium sulfate – Allowed as a medical treatment. Used to treat lactation tetany or grass tetany in ruminants. In swine, used to treat malignant hypothermia. Also used to treat inflammation and abscesses in livestock by soaking affected area in magnesium sulfate solution. §205.603(a)(19)

- **NOSB Subcommittee Discussion:** Important tool for livestock production. Satisfies OFPA.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0
- **OTA Survey Results:** **Necessary**

Fenbendazole – Allowed as a parasiticide for emergency treatment of dairy and breeder stock and for fiber bearing animals. §205.603(a)(23)(i)

- **NOSB Subcommittee Discussion:** Recommended for relisting. Essential for treatment of disease in animals.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0
- **OTA Survey Results:** **Necessary**

Moxidectin – Allowed as a parasiticide for emergency treatment of dairy and breeder stock and for fiber bearing animals. §205.603(a)(23)(ii)

- **NOSB Subcommittee Discussion:** Recommended for relisting. Essential for treatment of disease in animals.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0
- **OTA Survey Results:** **Necessary**

Peracetic acid – Allowed for sanitizing facility and processing equipment. §205.603(a)(25)

- **NOSB Subcommittee Discussion:** Recommended for relisting. Few effective alternatives.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0
- **OTA Survey Results:** **Necessary**

Xylazine – Allowed as a medical treatment. Used as a sedative, analgesic, and muscle relaxant. §205.603(a)(30)

- **NOSB Subcommittee Discussion:** No natural alternatives.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0
- **OTA Survey Results:** No responses were received.

Methionine – An essential amino acid allowed as a feed additive for poultry. §205.603(d)(1)

- **NOSB Subcommittee Discussion:** Continues to be essential. Supportive of continued efforts to identify and develop natural alternatives.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0
- **OTA Survey Results:** **Necessary**
- **OTA Position:** The Organic Trade Association supports the continued listing of methionine on the National List under its restrictive annotation. Although research and development of natural alternatives is progressing, the need for synthetic methionine remains necessary for organic poultry production, thereby satisfying the National List criteria. It is essential that viable alternatives be researched and trialed on commercial-scale flocks before prohibiting the use of this essential amino acid.

Trace minerals – Allowed as feed additives to satisfy livestock nutritional need. §205.603(d)(2)

- **NOSB Subcommittee Discussion:** Essential to livestock health and welfare.
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0
- **OTA Survey Results:** **Necessary**

Vitamins – Allowed as feed additives to satisfy livestock nutritional need. §205.603(d)(3)

- **NOSB Subcommittee Discussion:** Recommended for relisting. Are there sufficient year-round supplies of forages and livestock feedstocks available to naturally supply the B vitamins into the livestock rations, or should B vitamins be removed from §205.603?
- **NOSB Subcommittee Vote:** Motion to remove from National List — Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0
- **OTA Survey Results:** **Necessary**

FENBENDAZOLE – PETITION (DISCUSSION)

BACKGROUND

Fenbendazole is a parasiticide that has been petitioned for use in laying hens and replacement chickens intended to become laying hens. Birds that receive outdoor access and have contact with soil are more likely to come in contact with internal parasites. In poultry production, the substance is administered orally via drinking water and is effective in controlling internal parasites such as *A. galli* and *H. gallinarum*. If permitted in organic production, fenbendazole would only be allowed for emergency treatment when preventive management practices do not prevent infestation. Fenbendazole is currently allowed in organic production for emergency treatment for dairy and breeder stock and fiber-bearing animals under the restrictions at §205.603(a)(23).

NOSB SUBCOMMITTEE SUMMARY

The subcommittee is considering this petition and poses the questions listed below to the public for comment. The subcommittee does not intend to specify a withdrawal time for use on poultry because the FDA data shows that total residues of fenbendazole in eggs of treated chickens at zero-day withdrawal are well below the safe concentration of 2.4 ppm for residues in eggs.

Discussion Questions:

1. Is this material needed by organic poultry producers? If so, why?
2. Do currently allowed alternatives work to control internal parasites? And at what level of effectiveness?
3. What are some of the “emergency” events that would trigger use of this product? And how would producers determine those events?
4. Is there a concern with the 2.4 ppm residue of fenbendazole in eggs? Please submit information that supports this concern, or lack of concern.

SUBCOMMITTEE VOTE: Motion to accept the discussion document — Yes: 6 No: 0 Abstain: 0 Absent: 1
Recuse: 0

ORGANIC TRADE ASSOCIATION'S POSITION

At this point, the Organic Trade Association does not have concerns with the petitioned allowance of fenbendazole. Fenbendazole is already permitted under restricted conditions for other livestock species, hence it has already satisfied criteria for the National List in terms of not being harmful to the environment or human health, and being compatible with organic farming principles. The petitioned use would still be subject to the existing restrictions for fenbendazole, which limit its use only for emergency treatment when organic system plan-approved preventive management does not prevent infestation. Under these highly restricted conditions, poultry operation would still be required to establish preventive health care conditions as required by the NOP regulations and fundamental to organic production principles.

WHO ARE THE ORGANIC TRADE ASSOCIATION'S MEMBERS?

One of the Organic Trade Association's (OTA's) strongest assets as an organization is the diversity and breadth of its membership.

Unlike many trade associations, OTA is uniquely structured to include the full value chain for the organic industry, ensuring that all segments, from farm to marketplace, have a strong voice within the organization. In this way, it is possible to work together to catalyze solutions, form coalitions and collaborate, whether it be on issues before Congress and government agencies, or to strategize on strengthening the organic message and movement to the public.

OTA represents its members to government on sector needs, market development and promotion, and strong organic standards and regulations. Members also receive the latest information and quick answers on organic regulations and standards in the U.S. and around the world.

OTA's membership continues to grow, spurred by interest at all levels of the supply chain in the booming organic sector, and the need and desire to be a part of a network of engaged organic stakeholders. OTA now represents more than 9,500 businesses through direct membership and formal agreements with organic farmer-governed organizations that make up OTA's Farmers Advisory Council (FAC). These businesses cover every state in the union, from small organic producers to major growers, from local family-run organic operations to nationwide companies. All of OTA's direct members and FAC organizations are listed on [OTA.com](https://ota.com).

The Organic Trade Association's Board of Directors is democratically elected by the association's Trade members. Each Trade member company, regardless of size, has one vote. One of the Board seats is designated to a Farmer Board member.

HOW ARE POLICIES SET?

OTA Member Forums offer informal, ongoing conversation on issues of common interest, and help members network with peers, share their expertise, and discuss common challenges.

OTA Sector Councils offer a more formal avenue to build community among groups of members and to provide ongoing opportunities for networking, leadership development, and education. While Sector Councils do not act as policy-setting groups, they communicate sector issues, ideas, and concerns to OTA staff and Board.

OTA Task Forces, meanwhile, are time-bound, task-oriented, and outcome-focused groups charged with accomplishing a definite objective. Task forces can be convened by the Board, staff or members in order to recommend a course of action or accomplish a specific goal. Task forces provide transparent and inclusive opportunities for issue resolution and policy-setting, and are open to the membership at-large.

WHAT IS OTA'S COMMENT PROCESS?

The Organic Trade Association submits comments on behalf of its membership. Our positions and policies are primarily shaped through our task forces. In all cases, OTA's regulatory and legislative staff carry out an extensive process of membership engagement to capture how current issues and activities such as proposed rules or NOSB recommendations will impact certified farmers and handlers. Prior to submission of final comments, draft comments are distributed to membership at least a week in advance. Members have an opportunity to weigh in and shape any changes that may be needed prior to final submission. For a meaningful comment process under OTA's governance structure, a comment period needs at least 30 days.



Calling all stakeholders attending the
National Organic Standards Board Meeting!

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