NATIONAL ORGANIC STANDARDS BOARD

SPRING 2021 MEETING April 28–30 | Virtual



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ORGANIC TRADE ASSOCIATION RESOURCE BOOKLET



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Welcome to the spring 2021 National Organic Standards Board (NOSB) Meeting. The primary purpose of NOSB meetings is to provide an opportunity for organic stakeholders to give input on proposed NOSB recommendations and discussion items. The meetings also allow NOSB to receive updates from USDA's National Organic Program (NOP) on issues pertaining to organic agriculture. The meetings are open to the public.

QUICK LINKS TO KEY RESOURCES

- OTA's NOSB Meeting Resources Website helpful resources, summary of meeting packet; summaries and links to OTA's full written comments
- NOSB Meeting Webpage official government website for the NOSB meeting; instructions for joining virtual events; links to full official agenda and meeting packet
- OTA's Twitter Feed follow along for live reporting during the meeting

AT-A-GLANCE LIST OF TOPICS

PROPOSALS (vote)

- Paper-Based Planting Aids (Crops) proposal to allow with restrictions on biobased and cellulose content
- Biodegradable Biobased Mulch (Crops) proposal to allow biodegradable mulches that are not 100% biobased
- Ion Exchange Filtration (Handling) proposal on the use of resins, membranes, and recharge materials
- Human Capital: Strategy for Recruitment and Talent Management of Organic Inspectors and Reviewers evaluation of the causes and potential solutions for addressing the decline in qualified personnel

DISCUSSION (no vote)

- Ammonia Extract (Crops) discussion on a petition to prohibit nonsynthetic ammonia extract fertilizer
- Kasugamycin (Crops) discussion on a petition to allow kasugamycin (antibiotic) for control fire blight control
- **Zein (Handling)** discussion on a petition to allow zein (corn protein) as food coating on organic foods
- Fish Oil (Handling) options for restricting sources of fish oil to minimize environmental harm
- **Excluded Methods** identifying emerging technologies in the food sector and determining whether they will be considered excluded methods (thereby prohibited) in organic production and processing
- 2021 Research Priorities discussion on NOSB's annual list of research priorities for organic food and agriculture
- Human Capital: Supporting the Work of NOSB exploring opportunities to obtain outside assistance for NOSB, as appropriate, to help alleviate some of the workload
- **2023 Sunset Review (Crops, Livestock, Handling)** NOSB is will review over 30 inputs 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 in advance of its sunset date in 2023



AT-A-GLANCE SCHEDULE OF EVENTS & HOW TO JOIN

The public is welcome to observe the comment webinars and meeting. Registration is not required unless you wish to provide public comment. Instructions to join the webinars and meeting dates are provided below.

Public Comment Webinars

Day 1: Tuesday, April 20 (Noon – 5:00 PM ET) —	Click here to join	ì
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Day 2: Thursday April 22 (Noon – 5:00 PM ET) – Click here to join

Public Meeting

Day 1: Wednesday April 28 (Noon - 5:00 PM ET) - Click here to join

- Call to Order
- Agenda Overview
- Introductions
- NOSB report
- USDA-AMS-NOP report
- National Institute of Food and Agriculture (NIFA) update
- Livestock Subcommittee topics

Day 2: Thursday April 29 (Noon - 5:00 PM ET) - Click here to join

- Materials Subcommittee topics
- Compliance, Accreditation, & Certification Subcommittee topics
- Handling Subcommittee topics

Day 3: Friday April 30 (Noon - 5:00 PM ET) - Click here to join

- Crops Subcommittee topics
- Deferred votes
- Work agendas/Materials update
- Other business and closing remarks
- Adjourn

Click here to download the complete agenda.

THE NATIONAL ORGANIC STANDARDS BOARD

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

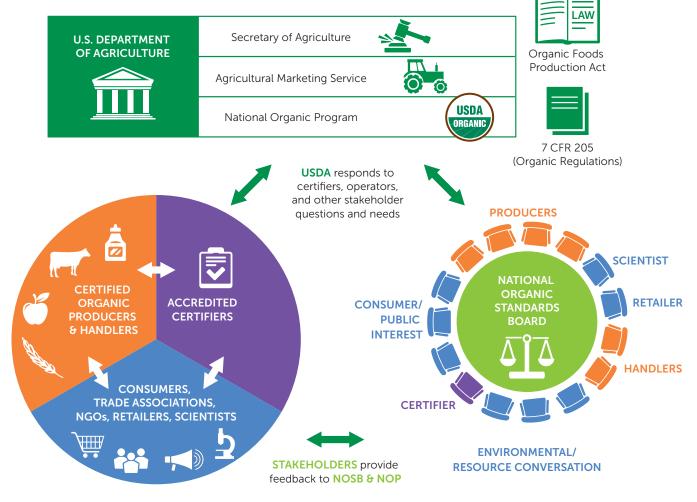
NOSB plays a critical role in the organic rulemaking process because it advises USDA on which production inputs should be allowed or prohibited in organic farming and processing. NOSB also makes recommendations on a wide variety of other standards issues, such as organic pet food standards, aquaculture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

The Organic Stakeholder Landscape







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.



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THE NATIONAL ORGANIC STANDARDS BOARD

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), Nate Powell-Palm (MT), Amy Bruch (NE), Logan Petrey (FL)

Handlers/Processors: Kim Huseman (CO), Jerry D'Amore (CA)

Retailer: Mindee Jeffery (CA)

Scientist: vacant

Consumer / Public Interest: Sue Baird (MO), Carolyn Dimitri (NY), Brian Caldwell (NY)

Environmentalists/Resource Conservationists: Asa Bradman (CA), Rick Greenwood (CA), Wood Turner (CA)

Accredited Certifying Agent: Kyla Smith (PA)

THE RESTRICTED ORGANIC TOOLBOX

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.

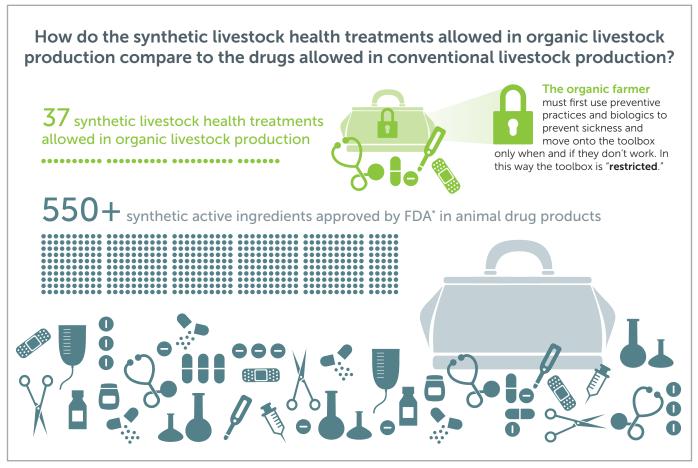


^{*}Ware, George W and Whitacre, David M. The Pesticide Book 6th Edition. 2004

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THE RESTRICTED ORGANIC TOOLBOX

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)

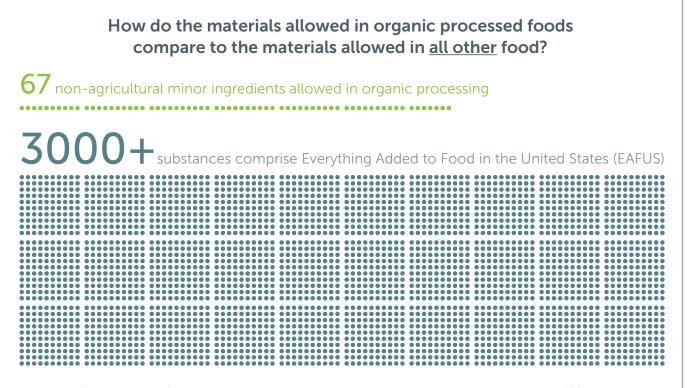
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Before organic farmers can use any of these substances, however, they must develop a pest and disease management plan that describes how they will first prevent and manage pests without the use of National List inputs.

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.

THE RESTRICTED ORGANIC TOOLBOX



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.

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.



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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 nontoxic 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.



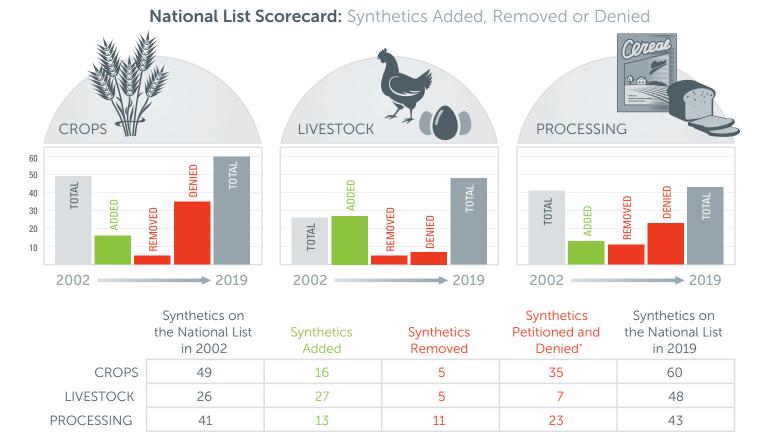
Removals: 17
Petitioned and denied: 59
Further restricted: 1

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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.



^{*} 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 handing 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 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.

NATIONAL LIST CRITERIA: INSIDE THE REVIEW PROCESS

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.

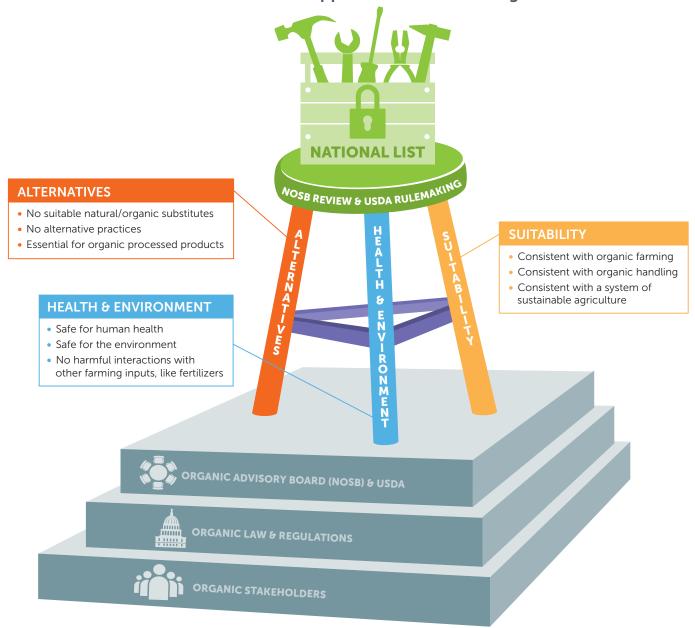
HUMAN HEALTH AND THE ENVIRONMENT

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

NATIONAL LIST CRITERIA: INSIDE THE REVIEW PROCESS

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))

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NATIONAL LIST CRITERIA: INSIDE THE REVIEW PROCESS

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.

DEVELOPING ORGANIC AND NATURAL ALTERNATIVES

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.

DEVELOPING ORGANIC AND 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.

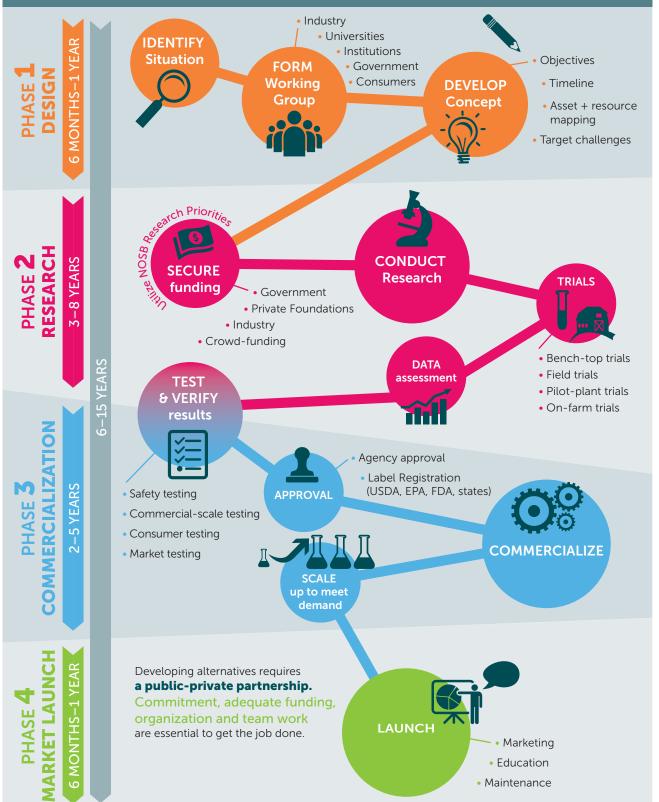
Market Launch: Lastly, there is a necessary a period of education and experience for growers and handlers to refine their use of a new material in the diverse settings and environments encountered in commercial settings. As in the case of organic tree fruit growers adopting new materials and practices 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



DEVELOPING ORGANIC AND NATURAL ALTERNATIVES

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.

SUNSET REVIEW

The National Organic Standards Board (NOSB) advises USDA on which production inputs should be included on the National List of Allowed and Prohibited Substances.

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 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.

<u>Human Capital: Strategy for Recruitment and Talent Management - Organic Inspectors and Reviewers (PROPOSAL)</u>

BACKGROUND: Human capital refers to the skills, knowledge, and experience held by an individual or population, and is generally considered one of the most important intangible assets that contribute value to an organization or community. NOP sent a memo to NOSB on July 31, 2020, requesting that the Board facilitate a public discussion related to Human Capital Strategy for Organic Inspectors and Reviewers. NOSB posted its first discussion document at the fall 2020 meeting to initiate discussion.

PROPOSAL: The Compliance, Accreditation & Certification Subcommittee is evaluating the causes and potential solutions for addressing the decline in qualified individuals who desire to be organic inspectors and certification reviewers. The Subcommittee's proposal includes aggregated responses to interview questions about specific challenges related to travel time, professionalism, compensation, continuing education, cost of insurance, and lack of consistency between expectations of certifiers.

Several proposed strategies are identified that could help alleviate the potential crisis of a shortage of organic inspectors and reviewers, such as:

- Develop working groups between organic industry leaders and organizations
- Collaborate with secondary education and other governmental entities to provide organic inspector training and apprenticeship programs
- Solicit funding from the federal Workforce Innovation and Opportunity Act (WIOA) to support inspector training
- Utilize virtual/web-based platforms for organic inspector trainings
- Support development and funding of one-on-one mentoring programs
- o Promote awareness of the value of experienced inspectors

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

- 1. What have you experienced or witnessed that contributes to the shortage of organic inspectors/reviewers?
- 2. What are some additional strategies that can be employed to increase the numbers of organic inspectors and reviewers?
- 3. Are there appropriate ways for the National Organic Program to assist with the financial burdens of?:
 - a. Initial cost of becoming a trained organic inspector.
 - b. Costs of continuing education for existing experienced inspectors, and
 - c. Compensation for organizations and/or experienced inspectors to provide qualified one-on-one mentorships to beginning inspector/reviewers.

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

Subcommittee Vote: Motion to adopt the proposal: 6 Yes, 0 No, 1 Absent

ORGANIC TRADE ASSOCIATION COMMENTS: OTA did not provide comments on this proposal.

Human Capital: Supporting the Work of the NOSB (DISCUSSION)

BACKGROUND: Human capital refers to the skills, knowledge, and experience held by an individual or population, and is generally considered one of the most important intangible assets that contributes value to an organization or community. NOP sent a memo to NOSB on July 31, 2020, requesting that the Board facilitate a public discussion related to Human Capital Strategy for Organic Inspectors and Reviewers. NOSB posted its first discussion document at the Fall 2020 meeting to initiate discussion.

DISCUSSION DOCUMENT: The Compliance, Accreditation & Certification Subcommittee is exploring opportunities to obtain outside assistance for Board work, as appropriate, to help alleviate some of the workload without compromising the integrity of the process or the independent nature of the production and deliberation of its proposals.

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

- 1. Please provide any general comments on the remark the following remark by a public commenter: "In addition to those fields noted in the memo, other expertise such as those in chemistry, ecology, biological sciences, plant pathology, and biological engineering would be particularly helpful, especially when considering many of the topics discussed and debated by the NOSB. We have long wondered what it would look like if each NOSB member had a research assistant (a co-op position for a graduate student, for example) to help conduct and provide literature reviews, write drafts, and otherwise support the work of NOSB members. What better way to expose young people to the organic community than through service to its leadership board!?"
- 2. Is the organic community comfortable with the Board getting support to "to help conduct and provide literature reviews, write drafts, and otherwise support the work of NOSB members"?
- 3. If so, what areas are appropriate for the Board to get support?
- 4. For which areas should the Board not use outside support?

Read the full discussion document in the NOSB Meeting Packet (p. 7-8)

Subcommittee Vote: Motion to adopt the discussion document: 5 Yes, 0 No, 1 Absent

ORGANIC TRADE ASSOCIATION COMMENT SUMMARY:

✓ OTA strongly supports providing NOSB with technical, legal and regulatory support to ensure NOSB proposals and discussion documents are clear, accurate and written in a way that stakeholders and NOP can understand, and NOP can easily act upon.

[Click here for full OTA Comments on Supporting NOSB]

Paper-Based Crop Planting Aids (PROPOSAL)

BACKGROUND: Paper planting pots have been <u>petitioned</u> for inclusion on the National List as an allowed input. Paper pots and other growing container and production aids are used to support seeding, growing and/or transplanting in the field and are intended to remain in the soil. NOP has authorized continued use of these materials while NOSB completes its deliberation.

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. Throughout the course of NOSB deliberation, the scope has expanded to include other paper-based planting aids such as seed tapes that are incorporated into the soil.

Several discussion document have previously been presented by the Crop Subcommittee in fall 2018, spring 2019, and fall 2019. A <u>Technical Report</u> was commissioned in 2019 to provide information about the range of synthetic fibers and adhesives used in these types of paper-based crop planting aids. The Board continues to collect and evaluate information to distinguish between synthetic paper fibers and synthetic fibers that are not strictly paper, also whether such fibers are biobased and/or biodegradable.

The first <u>proposal</u> was presented by the Subcommittee in spring 2020 for a new definition and listing to be added to the NOP regulations to allow the use of paper-based planting aids under certain conditions. That proposal did not pass, and a new <u>proposal</u> was presented in fall 2020 that also did not pass. The Subcommittee continues to work diligently to craft an annotation that captures the detailed composition metrics of paper-based planting aids that meet the needs of organic producers and product manufacturers, while complying with Organic Food Production Act criteria for the National List.

PROPOSAL: The Crop Subcommittee presents its third proposal that reflects the comments and suggestions received from the past two meetings with respect to nutrient and pesticide limitations, inclusion of biodegradable biobased mulch under this definition, composition of the non-cellulose portion of products, and methods of verifying biobased or cellulose-based content.

The Subcommittee is proposing a minimum requirement for cellulose-based fiber content (no less than 60%) and a minimum requirement for biobased content (no less than 80%). These limits prevent products from being made primarily from petroleum-based or non-biodegradable sources, while still allowing a minimal amount of synthetic fibers and adhesives needed for structure and functionality of products currently in the market. The Subcommittee also proposes restrictions on the types of materials allowed to make up the 40% of the product that is not cellulose based. The Board acknowledges that these specific percentages should be reviewed by future Boards and made more stringent as technology and materials change.

The Subcommittee's evaluation of environmental and human health impacts did not find evidence of harmful effects from the use of these paper-based planting aids. In term of necessity for production, the Subcommittee finds these materials to be critical for a segment of organic growers where mechanical or hand planting is not a suitable alternatives. The Subcommittee has thoughtfully customized a proposal that ensures the use of paper-based planting aids is compatible with a system of sustainable agriculture, and addresses the environmental concerns that might be associated with some types of paper.

The Subcommittee proposes to:

Add the following definition to §205.2 Terms Defined:

Paper-based crop planting aid. A material that is comprised of at least 60% cellulose-based fiber by weight, including, but not limited to, pots, seed tape, and collars that are placed in or on the soil and later incorporated into the soil, excluding biodegradable mulch film. Up to 40% of the ingredients can be non-synthetic, other permitted synthetic ingredients at §205.601(j), or synthetic strengthening fibers, adhesives, or resins. Contains no less than 80% biobased content as verified by a qualified third-party assessment (e.g. laboratory test using ASTM D6866 or composition review by qualified personnel). Added nutrients must comply with §205.105, 205.203, and 205.206.

And add the following listing to §205.601(p) Production Aids:

Paper-based crop planting aids as defined in 205.2. Virgin or recycled paper without glossy paper or colored inks.

Read the full proposal in the NOSB Meeting Packet (p. 11-16)

Subcommittee Vote: Motion to adopt the proposal: 6 Yes, 0 No, 1 Absent

ORGANIC TRADE ASSOCIATION COMMENT SUMMARY:

- ✓ OTA 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).
- ✓ We support the key tenants of the proposed definition and listing of paper-based crop planting aids, and commend NOSB's diligence to take in and respond to stakeholder suggestions for improvement.
- ✓ We identify a few non-substantive items for further clarification in the proposed definition and listing, and support NOSB in passing this proposal at this meeting.

[Click here for full OTA Comments on Paper-based Crop Planting Aids]

Biodegradable Biobased Mulch Film (PROPOSAL)

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

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

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

A <u>Technical Report</u> was commissioned in 2016 to evaluate long-term biodegradability of petroleum-derived biodegradable mulch films, and was inconclusive due to limited research available at the time. NOSB has continued to track new research by commissioning an expert panel at the spring 2016 NOSB Meeting. NOP also commissioned a <u>new report</u> from Michigan State University, which was made available in October 2019. A <u>discussion document</u> was presented at the spring 2020 meeting, and <u>reissued</u> in fall 2020, with questions for stakeholder feedback regarding a potential future annotation amendment that would allow biodegradable mulch films that are not 100% biobased. In the meantime, NOSB has renewed this listing at sunset review to allow time to identify a suitable solution.

PROPOSAL: The Crops Subcommittee has weighed the risks and benefits of using biodegradable mulch films as an alternative to plastic mulch and proposes an allowance for biodegradable biobased mulch film that that are not 100% biobased. The Subcommittee is proposing a minimum requirement of 80% biobased content for biodegradable mulch (BDM) films, which is the same minimum requirement being proposed for paper-based planting aids. The Subcommittee recognizes that this limit is aspirational in the sense that no commercially viable products current meet this criteria. Nevertheless, the Subcommittee sees this as a realistic goal, and also recommends that 100% be required if and when these materials become available.

The Subcommittee proposes to:

Revise the definition at §205.2 Terms Defined (bold text added):

Biodegradable biobased mulch film. A synthetic mulch film that meets the following criteria:

- (1) Meets the compostability specifications of one of the following standards: ASTM D6400, ASTM D6868, EN 13432, EN 14995, or ISO 17088 (all incorporated by reference; see §205.3);
- (2) Demonstrates at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, according to one of the following test methods: ISO 17556 or ASTM D5988 (both incorporated by reference; see §205.3); and
- (3) **Biodegradable plastic mulch films must be at least 80%** biobased with content determined using ASTM D6866 (incorporated by reference; see §205.3).

And revise the listing to §205.601(a)(2) Mulches (bold text added):

(iii) Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods. When 100% biobased biodegradable plastic films become available, producers are required to use 100% biobased content BDM plastic films.

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

Subcommittee Vote: Motion to adopt the proposal: 5 Yes, 1 No, 2 Absent

ORGANIC TRADE ASSOCIATION COMMENT SUMMARY:

- ✓ OTA supports NOSB's efforts to identify and advance regulatory solutions for allowing Biodegradable Biobased Mulch Film as an alternative to plastic mulch.
- ✓ We seek to better understand the information regarding the status of product development that has informed the Subcommittee's conclusion that 80% biobased content is a realistic goal for Biodegradable Biobased Mulch Film that would be allowed under this proposal.
- ✓ We recommend using consistent terminology in the proposal when referring to Biodegradable Biobased Mulch Films.
- ✓ We suggest alternative language to implement the concept of continuous improvement within the proposed annotation.

[Click here for full OTA Comments on Biodegradable Mulch]

Crops 2023 Sunset Review

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

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

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

ORGANIC TRADE ASSOCIATION COMMENTS: [Click here for full OTA Comments on Crop Sunset Materials]

DISCUSSION SUMMARIES: The Crops Subcommittee has provided discussion summaries for each substance undergoing sunset review and has indicated specific areas where additional information is requested from stakeholders. Read the full discussion in the NOSB Meeting Packet (p. 23-51)

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

- Allowed for use as an algicide and tadpole shrimp control in aquatic rice systems. One application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a time frame agreed upon by the producer and accredited certifying agent.
- The Subcommittee indicates that it may be time to reconsider copper sulfate as an algicide and means of controlling tadpole shrimp. It appears there is sufficient evidence to conclude that:
 - use of copper sulfate in rice fields is environmentally detrimental,
 - alternative seeding practices could eliminate the need for the chemical as both algae and tadpole shrimp cease to be problematic once seedlings are established, and
 - international standards do not allow for spraying of copper sulfate for organic rice production.
- Additional information requested by Subcommittee:
 - 1. What are the roadblocks to transitioning to a dry-seeding or transplanting of rice seedlings in US rice production?
 - 2. Are there viable practices that can be used to offset the toxic build-up of copper in the soil and water (i.e. crop rotation, phytoremediation with plants that draw copper from the soil)?

Oxone gas - §205.601(a)(5)

- Allowed for use as an irrigation system cleaner

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

- Allowed for use in control fire blight bacteria and for disinfecting equipment, seed, and asexually propagated planting material.
- Also allowed in hydrogen peroxide formulations at a concentration of no more that 6% as indicated on the pesticide product label.
- Additional information requested by Subcommittee: NOSB, through its various Subcommittees is
 engaging in a critical assessment of how it reviews the full suite of sanitizers either available in organic
 or petitioned for use in organic. As part of that assessment, the following draft framework has been
 suggested as a means of polling stakeholders to determine the appropriateness of certain materials in
 organic production:
 - 1. Base Process: How does the material fit into an adequate system of cleaning (contact time, scrubbing effort and force, water source, etc.), rinsing, and sometimes testing, as the essential first step in sanitation?
 - 2. Use: Is it a direct food contact material or a surface contact material?
 - 3. Need: Has the material met the need addressed by its original petition?
 - 4. Efficacy: How well does the material work for the specific need identified?
 - 5. Alternatives: Are existing alternatives adequate? Are there materials already on the list that can be employed in a new use, rather than adding or a new material or continuing to allow use of a less appropriate older material?
 - 6. Rotation: How does this material fit into rotations and/or the need for back up materials?
 - 7. Other Regulatory Reviews: How can we look to FDA and EPA to help us assess risk while, also evaluating against the OFPA criteria (particularly environmental fate and human contact impacts)?

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

- Allowed for use only in passive pheromone dispensers used for insect management, either to trap and monitor insect populations or to control a pest through pheromone mating disruption.
- EPA List 3 is outdated and no longer maintained by EPA. An alternative review system has not yet been implemented by NOP.
- Additional information requested by Subcommittee:
 - 1. Are there any new health or environmental concerns with the use of the List 3 inerts in passive pheromone dispensers?
 - 3. Are there any natural alternatives to the use of List 3 inerts in passive pheromone dispensers?
 - 4. What percent of ingredients in passive pheromones do List 3 inerts represent?
 - 5. Do the List 3 ingredients in the passive dispensers diffuse into the environment or do they remain in the dispensers?
- OTA COMMENT SUMMARY: [Click here for full OTA Comments on List 3 Inerts]
 - ✓ OTA supports renewal of the listing of EPA List 3 inert ingredients at §205.601 of the National List during this Sunset Review.

- ✓ OTA supports the unanimous 2020 NOSB Resolution calling for NOP action to resolve the longstanding discrepancy with respect to inerts on the National List.
- ✓ OTA's Inerts Task Force is committed to identifying and advancing viable alternative solutions for evaluating inert ingredients to ensure continued safety and availability of critical pest control tools for organic farmers.

Chlorine materials - §205.601(a)(2)

- Includes Calcium hypochlorite, Chlorine dioxide, Hypochlorous acid, Sodium hypochlorite
- Allowed for use as a sanitizer and disinfectant. For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.
- The Crops Subcommittee acknowledges that chlorine materials have been judged essential to ensure food safety and to comply with food-safety regulations under the Food Safety Modernization Act (FSMA) and generally support continued listing of chlorine materials. The Subcommittee also supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.
- Additional information requested by Subcommittee: NOSB, through its various Subcommittees, is
 engaging in a critical assessment of how it reviews the full suite of sanitizers either available in organic
 or petitioned for use in organic. As part of that assessment, the following draft framework has been
 suggested as a means of polling stakeholders to determine the appropriateness of certain materials in
 organic production:
 - 1. Base Process: How does the material fit into an adequate system of cleaning (contact time, scrubbing effort and force, water source, etc.), rinsing, and sometimes testing, as the essential first step in sanitation?
 - 2. Use: Is it a direct food contact material or a surface contact material? Do stakeholders see any distinction in the use of this material in this crop production context versus a food handling/processing context?
 - 3. Efficacy: How well does the material work for the specific need identified?
 - 4. Alternatives: Are existing alternatives adequate? Are there materials already on the list that can be employed in a new use, rather than adding or a new material or continuing to allow use of a less appropriate older material?
 - 6. Rotation: How does this material fit into rotations and/or the need for back up materials?
 - 7. Other Regulatory Reviews: How can we look to FDA and EPA to help us assess risk while also evaluating against the OFPA criteria (particularly environmental fate and human contact impacts)?

Magnesium oxide - §205.601(j)(5)

- Allowed for use only to control the viscosity of a clay suspension agent for humates in order to prevent crystallization of any fertilizer or micronutrient salts that may be in solution and prevent the plugging of spray nozzles during spray applications.
- Additional information requested by Subcommittee:
 - 1. Has magnesium oxide been used for the purposes of suspending humates in a clay solution as described in the original petition?

- 2. Are there any commercially available, non-synthetic alternatives that achieve the same purpose as magnesium oxide?
- 3. Is there still a need for liquid humates in organic agriculture?
- 4. Can non-synthetic acids be used in place of sulfuric acid in the manufacture of magnesium oxide?
- 5. Are there environmental or human health issues that should be noted in the decision to retain magnesium oxide on the National List?

Calcium chloride - §205.602

- Prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake such as bitter pit in apples, fruit cracking on developing figs, and blossom end rot on tomatoes.
- The restrictions on nonsynthetic calcium chloride produced through the brine process is for the purpose of preventing potential overuse of high solubility materials.
- Additional information requested by Subcommittee:
 - 1. On which crops and for what physiological disorders associated with calcium uptake is calcium chloride used by producers?
 - 2. The 2007 TAP states: "Since bitter pit of apples is a calcium deficit disorder, an alternate form of calcium, such as limestone, gypsum, or rock phosphate, could be used". Please comment.

Rotenone - §205.602

- Prohibited.
- Rotenone is a potent botanical pesticide that is prohibited in organic production due to adverse health effects.

Ammonia Extract (DISCUSSION)

BACKGROUND: Ammonia extract has been <u>petitioned</u> for inclusion on the National List as a <u>prohibited</u> nonsynthetic input in organic crop production. The petitioner identifies concerns that these types of ammonia fertilizers do not align with organic production principles, pose risks to the integrity of organic products, and increase the risk of fertilizer fraud. The petition also raises concerns about uncertainty and inconsistent determinations of material review organizations regarding the classification of ammonia extract technologies as nonsynthetic or synthetic.

A <u>discussion document</u> was presented in fall 2020 to solicit stakeholder input on a series of questions about the ability to distinguish synthetic ammonia sources from non-synthetic sources through testing, the impacts on soil health, and other questions about the classification and other issues related to ammonia extract. A third-party <u>Technical Report</u> was commissioned by NOSB and was publically released approximately one week after the spring 2021 NOSB meeting materials were posted.

DISCUSSION DOCUMENT: The Crops Subcommittee presents a second discussion document that builds on comments received from the last meeting on the topics of soil health and the potential for fraud. The Subcommittee indicates it received conflict data as to whether the use of ammonia extract promotes or degrades soil health.

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

- 1. Given the conflicting comments on the effects of ammonia on soil health, please provide further information that would help to resolve this conflict. Provide scientific citations so that the NOSB can have primary references as to the effect of ammonia extract on soil health.
- 2. Is there a range of concentrations in the soil solution in which ammonia is beneficial, while outside that range it is not?
- 3. Please provide additional information as to how the fraudulent use of synthetic ammonia could be prevented while at the same time allowing for the use of natural ammonia extract.
- 4. Should the use of natural ammonia extract be limited to a certain percent of nitrogen use in crops (similar to the Chilean nitrate restriction)?
- 5. If natural ammonia extract is limited to a certain percentage of nitrogen use, how can that amount be verified and separated from synthetic ammonia?
- 6. In mixed organic and conventional operations, how can the use of natural ammonia extract used in the organic crops be verified as opposed to synthetic ammonia used in the conventional crops?
- 7. Is there additional information about the effects of highly soluble organic fertilizers on soil health that the NOSB should be aware of?

Read the full discussion document in the NOSB Meeting Packet (p. 53-58)

Subcommittee Vote: Motion to adopt the discussion document: 6 Yes, 0 No, 2 Absent

ORGANIC TRADE ASSOCIATION COMMENT SUMMARY:

✓ OTA appreciates the petitioner giving NOSB the opportunity to weigh-in on the acceptability of novel ammonia extract substances in organic agriculture prior to wide proliferation of this emerging category of products. NOSB plays a critical role in evaluating inputs within the framework established in OFPA.

- ✓ The purpose of OTA's comments on this discussion document is to ensure that NOSB has complete technical information about products and manufacturing processes that may be implicated by the scope of the petition, and that NOSB's decision-making process is sound and in alignment with OFPA Criteria for the National List. We also provide information about the compatibility and necessity of the petitioned material to help inform NOSB's deliberation of the substance against OFPA Criteria. For comments on environmental impacts and soil health, please refer to The Organic Center.
- ✓ Our comments identify several significant concerns regarding the compatibility of purified natural ammonia with organic principles, including but not limited to: mimics conventional synthetic Nitrogen fertilizers, requires the removal of carbon value of organic waste, and may be out of step with international norms. NOSB must take these concerns into account as it evaluates the use of the substance against the OFPA Criteria for the National List.

[CLICK HERE FOR FULL COMMENTS FROM ORGANIC TRADE ASSOCIATION]
[CLICK HERE FOR FULL COMMENTS FROM THE ORGANIC CENTER]

Kasugamycin (DISCUSSION)

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

A third-party <u>Technical Report</u> was commissioned to support the NOSB review of this petitioned material. The Report identifies some level of resistance which is why EPA-registered labels require a resistance management plan and limits on frequency of applications.

DISCUSSION DOCUMENT: The Crops Subcommittee presents a discussion document to collect information from stakeholders on this petition. The Subcommittee recognizes that other antibiotics previously permitted in organic production have resulted in widespread resistance (e.g., streptomycin) and therefore were prohibited.

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

- 1. Is the use of kasugamycin necessary for the control of fire blight or are other integrated programs sufficient?
- 2. Would the use of kasugamycin decrease the need for other synthetic products used in organic agriculture such as coppers and lime sulfur?
- 3. Is the limitation to 4 applications (2 in California) sufficient to reduce or eliminate the chances for fire blight resistance?
- 4. If approved, should the use be annotated only for fire blight control in apples and pears?
- 5. Are there variable results of the efficacy of kasugamycin depending on region where it is used?

Read the full discussion document in the NOSB Meeting Packet (p. 59-60)

Subcommittee Vote: Motion to adopt the discussion document: 8 Yes, 0 No, 0 Absent

ORGANIC TRADE ASSOCIATION COMMENT SUMMARY: OTA did not provide comments on this document.

Ion Exchange Filtration (PROPOSAL)

BACKGROUND: Ion exchange filtration is a food processing technique used to facilitate removal of impurities from a liquid using a chemical exchange process. The process uses a chemically charged solution within an ion-exchange resin or membrane to selectively remove unwanted molecules from the liquid. Based on NOP policy information in 2002, 2008, and 2010, ion exchange filtration has been allowed for use in organic processing provided that recharge materials are on the National List. Last year, the topic of ion exchange reappeared on NOP's radar as a result of a conflicting materials review decision among certifiers.

NOP sent a <u>memo</u> to NOSB on August 27, 2019, requesting that NOSB provide information about the various ways ion exchange filtration is used by organic operations, the substances used in these processes, and potential alternatives to ion exchange technology. In 2020, a <u>Technical Report</u> was published and a <u>discussion document</u> was presented to seek information about the uses of ion exchange filtration in organic processing. Stakeholder comments indicated that there is widespread use of ion exchange filtration in organic processing, whether it be for removal of off-tastes, heavy metals, or clarification of the final product, and that alternatives to ion exchange filtration are not generally available.

The 2019 NOP Memo also asked NOSB to provide a recommendation on whether it is appropriate to include substances used in ion exchange filtration on the National List. A <u>proposal</u> was presented in fall 2020 that the recharge materials, but not the resins or membranes themselves, must be reviewed and included on the National List. The proposal nearly passed but was ultimately sent back to Subcommittee for further discussion about the potential for degradation of resins into food after repeat use.

PROPOSAL: The Handling Subcommittee presents an updated proposal to address NOP's question of whether it is appropriate to include substances used in ion exchange filtration on the National List.

The Subcommittee continues to support the longstanding policy that recharge materials need to be reviewed and included on the National List.

However, the Subcommittee is challenged to make a determination on whether the resins and membranes need to be on the National List. Based on past NOP guidance, substances that are classified by FDA as *secondary direct food additives* must be included on the National List in order to be used in organic processing, whereas substances classified as *food contact substance* can be used without reference to the National List unless explicitly prohibited. Stakeholder comments indicate that ion exchange resins appear to be classified by FDA as *both* secondary food additives and food contact substances. Legal expertise is needed to interpret FDA regulations defining secondary food additives and food contact substances, and how the FDA regulations legally relate to the Organic Foods Production Act. The Subcommittee states that these legal issues are beyond the capability of NOSB.

The Subcommittee's proposal also explores procedural issues regarding the allowance of ion exchange filtration without resins needing to be included on the National List. Requiring resins to be included on the National List could cause significant economic impact and disruption of current organic supply chains, and raises questions about how exactly these substances would appear on the National List (categorically, or each specific resin). However, not requiring listing could leave an unintentional loophole to the requirements of OFPA and could cause issues in the future with resins that would be less acceptable for use in organic production systems. The Subcommittee states that these technical and procedural issues are best left to legal interpretations and procedural interpretations that are beyond the capabilities of NOSB.

Read the full proposal in the NOSB Meeting Packet (p. 61-66)

Subcommittee Vote: Motion to adopt the proposal: 6 Yes, 0 No, 1 Absent

ORGANIC TRADE ASSOCIATION COMMENT SUMMARY:

- ✓ OTA supports the allowance of ion exchange filtration as an organic processing method.
- ✓ OTA supports the Handling Subcommittee's position that ion exchange recharge materials must be on the National List to be approved for use in organic processing.
- ✓ OTA understands NOSB's decision to defer back to NOP for clarification on the status of its Food Contact Substance Policy. If food contact substances, per NOP's 2002 policy, are outside of NOSB's scope of review, then ion exchange resins would not need to appear on the National List. Clarification and technical support from NOP on this question have always been needed.
- ✓ OTA supports the critical role of NOSB in this decision-making process, and above all, we support transparency and consistency. We respectfully urge NOP to conduct its outreach to the U.S. Food and Drug Administration, take into consideration all of the information NOSB has collected via public comments, and provide certifiers and industry with instruction or policy that is formalized in the NOP Handbook to ensure consistent regulatory decisions.

[CLICK HERE FOR FULL TEXT OF OTA'S COMMENTS]

Handling 2023 Sunset Review

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

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

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

ORGANIC TRADE ASSOCIATION COMMENTS: [Click here for full OTA Comments on Handling Sunset Materials]

DISCUSSION SUMMARIES: The Handling Subcommittee has provided discussion summaries for each substance undergoing sunset review and has indicated specific areas where additional information is requested from stakeholders. Read the full discussion in the NOSB Meeting Packet (p. 67-103)

Agar-Agar - §205.605(a)

- Allowed for use in food processing as a stabilizer, thickener, gelling agent, texturizer, moisturizer, emulsifier, flavor enhancer, and absorbent. Used in various foods including bakery products, confections, jellies and jams, dairy products, canned meat and fish products, and vegetarian meat substitutes.
- Agar-agar has the ability to withstand high temperatures and doesn't interfere with taste profiles.
- Additional information requested by Subcommittee:
 - 1. Have there been any new developments with natural alternatives to agar-agar?
 - 2. Are there sufficient quantities of agar-agar produced using non-synthetic extraction methods to exclude agar-agar produced using synthetic methods?

Animal enzymes – §205.605(a)

- Includes: Rennet—animals derived; Catalase—bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin
- Used as catalysts for biological processes that are useful in the processing of food products or ingredients, e.g. as a coagulant to curdle milk to be made into cheese or sour cream.
- Additional information requested by Subcommittee:

- 1. Since the last review, have organic animal enzymes become commercially available?
 - a. If so, is there sufficient supply that meets the needs of the organic industry?
 - b. If not, what are the barriers?
- 2. Are there ancillary substances used in animal enzymes that are not found on the chart below, or are there ancillary substances on the chart that you think should not be allowed? Please submit public comment explaining which substance and why.

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

Calcium sulfate - §205.605(a)

- Allowed for various uses in food processing such as: coagulate in tofu manufacturing (soft and silky tofu types), yeast food and dough conditioner, water conditioner, firming agent (in canned foods), jelling ingredient, and baking powder ingredient.

citrate.

- Mined sources only.
- Additional information requested by Subcommittee:
 - 1. Is there clear evidence of unacceptable environmental impacts from the mining of calcium sulfate?
 - 2. Is there clear evidence of unacceptable human health impacts from calcium sulfate mining?

Carrageenan - §205.605(a)

- Allowed for use in food processing as a gelling agent, emulsifier, and thickener. Used primarily in meat and dairy products, and also is a vegan alternative to animal-sources gelatin.
- Also known as Irish Moss. Sourced from seaweed (red algae).
- Additional information requested by Subcommittee:
 - 1. Should there be an effort to outline best management practices for seaweed farming and harvesting?
 - 2. Do seaweed farming practices for carrageenan production conflict with the proposed Marine Materials guidelines passed by the NOSB last year?
 - 3. Is carrageenan essential for production of organic products? Which products?

- 4. Are carrageen alternatives available to replace all current uses?
- 5. Would lack of carrageenan availability limit opportunities to produce vegan products?
- 6. Is there new information on the safety of carrageenan?

Glucono delta-lactone - §205.605(a)

- Allowed for use in food processing. Primarily used as a coagulant in the production of silken tofu. Also used as a curing or pickling agent, leavening agent, pH control agent and sequestrant.
- Production by the oxidation of D-glucose with bromine water is prohibited
- Additional information requested by Subcommittee:
 - 1. How widespread is the use of GDL in organic applications?
 - 2. Is there evidence that GDL being used in organic applications may derive from genetic modification of any kind?
 - 3. Have alternatives to GDL emerged in recent years that deliver the same product quality and functionality?
 - 4. Is the lack of International acceptance significant?
 - 5. How is organic silken tofu produced in the EU, Japan, etc. without the use of GDL?

Tartaric acid - §205.605(a)

- Allowed for various uses in food processing including as an acidulant, pH control agent, preservative, emulsifier, chelating agent, flavor enhancer and modifier, stabilizer, anti-caking agent, and firming agent. Used in the preparation of baked goods and confectionaries, dairy products, edible oils and fats, tinned fruits and vegetables, seafood products, meat and poultry products, juice beverages and soft drinks, sugar preserves, chewing gum, cocoa powder, and alcoholic drinks.
- Sourced from grape wine.
- Includes tartaric acid and its salts (i.e. potassium acid tartrate, sodium potassium tartrate acid)
- Additional information requested by Subcommittee:
 - 1. Is tartaric acid still an essential ingredient for organic processing?
 - 2. Are there any organic/natural alternatives for wine making?
 - 3. Is there a sufficient supply of organic grapes to make tartaric acid from organic grapes?
 - 4. Are there any ancillary substances that are associated with tartaric acid?

Cellulose - §205.605(b)

- Allowed for use in regenerative casings (peelable/non-edible hot dog and sausage casings).
- Powdered cellulose is allowed for use as an anti-caking agent (e.g. for use in shredded cheese) and filtering aid (e.g. for filtration of juices). Non-chlorine bleached only.
- Microcrystalline cellulose is prohibited.
- Additional information requested by Subcommittee:
 - 1. Is cellulose still essential to organic production?
 - 2. Are there ancillary substances in use that are not identified in the table in this document?
 - 3. Are there alternative sources of cellulose to those from virgin forests that might minimize concerns regarding impact on primary forests?

4. What percentage of cellulose in use is derived from grain and vegetable products vs. from wood/forestry?

Chlorine materials – §205.605(b)

- Includes: Calcium hypochlorite, Chlorine dioxide, Hypochlorous acid, Sodium hypochlorite
- Allowed for use in disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.
- The Handling Subcommittee acknowledges that chlorine materials have been judged essential to ensure food safety and to comply with food-safety regulations under the Food Safety Modernization Act (FSMA) and generally supports continued listing of chlorine materials. The Subcommittee also supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.
- Additional information requested by Subcommittee: NOSB, through its various subcommittees, is engaging in a critical assessment of how it reviews sanitizers either approved for organic or petitioned for use in organic. As part of that assessment, the questions below have been suggested as a framework to evaluate the appropriateness of sanitizers and disinfectants used in in organic production and handling. We invite members of the organic community to address these questions in light of the current sunset review of these chlorine materials -- calcium hypochlorite, sodium hypochlorite, chlorine dioxide, and hypochlorous acid:
 - 1. Are each of these chlorine materials essential for organic food production and handling?
 - 2. How well does each of these chlorine materials work for the specific need identified?
 - 3. Since each of these chlorine materials was last reviewed, have additional commercially available alternatives emerged that would negate the need for this compound in organic handling?
 - 4. How does each of these chlorine materials fit into an adequate system of cleaning (contact time, scrubbing effort and force, water source, etc.), rinsing, and sometimes testing, as the essential first step in sanitation?
 - 5. Are each of these chlorine materials a direct food contact material or a surface contact material? If it is a food contact material, how is it used in food processing and handling?
 - 6. How does each of these chlorine materials fit into rotations and/or the need for back up materials?
 - 7. How can we look to FDA and EPA to help us assess the risks of chlorine sanitizers while also evaluating against the OFPA criteria (particularly environmental fate and human health impacts)?

Potassium hydroxide - §205.605(b)

- Allowed for various uses in food processing including as a pH adjuster, cleaning agent, stabilizer, thickener, and poultry scald agent.
- Prohibited for use in lye peeling of fruits and vegetables.

- Additional information requested by Subcommittee:
 - 1. Is potassium hydroxide still critical for the lye peeling of peaches?
 - 2. Are there alternatives to potassium hydroxide for cleaning/sanitizing?
 - 3. For what other purposes is potassium hydroxide currently being used in organic processing?
 - 4. Are there any ancillary substances that are used with potassium hydroxide?

Potassium lactate - §205.605(b)

- Allowed for use as an antimicrobial agent and pH regulator only.
- Additional information requested by Subcommittee:
 - 1. What distinguishes potassium lactate from sodium lactate in terms of functionality? Is that difference important?

Silicon dioxide - §205.605(b)

- Allowed for use as a defoamer.
- Allowed for other uses when organic rice hulls are not commercially available in the appropriate quality, quantity, and form. Past stakeholder feedback indicated that organic rice hulls were not viable alternatives for use:
 - As an anticaking agent in organic powders, including organic cheese powders
 - In organic dry flavors in which rice hulls have not adequately or evenly disbursed flavor actives and have taken up moisture
 - As an anticaking agent at a recommended 2% application rate, when instead the rice hull rate has been 15-50%
 - As a flow agent for rice syrup solids
 - As a clarifier in the production of beer
- Additional information requested by Subcommittee:
 - 1. Are there organic alternatives to silicon dioxide that are more suitable to the uses described above, in which rice hulls are not viable?
 - 2. Is there reliable, consistent commercial availability of rice hulls for the applications in which it performs well?
 - 3. How prevalent is the use of silicon dioxide as a defoamer?
 - 4. How prevalent is the use of silicon dioxide for other allowed purposes, e.g. anticaking agent, flow agent, flavor disbursement?

Sodium lactate - §205.605(b)

- Allowed for use as an antimicrobial agent and pH regulator only.
- Additional information requested by Subcommittee:
 - 1. Why do JAS, IFOAM, and the Canadian standard prohibit the use of sodium lactate?

Zein (DISCUSSION)

BACKGROUND: Zein (corn protein) has been <u>petitioned</u> for allowance as a non-organic ingredient for use in organic food processing as a food coating. Zein is applied to foods as an alcohol solution; once the alcohol evaporates, the zein layer acts as protective moisture barrier. It is used as a confectioner's glaze or a coating on nuts and fruit, among other applications. Zein is derived from corn gluten meal. The petitioner states sourcing from certified organic corn gluten meal for the production of organic zein is not currently possible. A <u>technical report</u> was commissioned to support the NOSB review if this petitioned material.

DISCUSSION DOCUMENT: The Handling Subcommittee present a discussion document to summarize its review to date of the petitioned material. The Subcommittee highlights three main areas of focus regarding zein's suitability for inclusion on the National List:

- a) the environmental impacts of the corn wet-milling process used to create the corn gluten meal (sulfur dioxide released and reacts with air and water to form sulfuric acid and becomes one of the major contributors to acid rain)
- b) whether the zein product can be considered non-synthetic (NOSB has <u>previously evaluated</u> this question of whether the end products of the corn wet-milling process can be considered non-synthetic and precedent has been established to consider these end products as non-synthetics)
- o c) whether zein fills a unique functionality not already filled by currently allowed substances (beeswax, shellac, vegetable proteins, carnauba wax)

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

- 1. If zein is made from cornmeal that is wet-milled, how much (if any) sulfur residue is left in the final product?
- 2. What are the hurdles to achieving organic zein?
- 3. What sectors of the organic food market would benefit the most significantly from the addition of zein to the National List and how much will shelf-life be improved?
- 4. Do we need to revisit the classification as a non-synthetic, or is the established precedence sufficient rationale?

Read the full discussion document in the NOSB Meeting Packet (p. 105-108)

Subcommittee Vote: Motion to adopt the discussion document: 6 Yes, 0 No, 1 Absent

ORGANIC TRADE ASSOCIATION COMMENT SUMMARY:

- ✓ OTA is not taking a position on whether zein should be added to the National List for use in organic processing. Instead we are responding to the NOSB questions and providing additional insights on evaluation considerations and agricultural vs. non-agricultural determinations.
- ✓ OTA encourages NOSB to focus its energy on whether non-organic zein, as a food coating, is a necessary ingredient (or processing aid) in organic handling. Questions around its classification are important, particularly in deciding whether it would belong on § 205.605 or § 205.606 of the National List. However, classification questions could become a distraction to the first question to be asked − is the allowance of an additional non-organic food coating necessary or are there organic or natural alternatives?

✓ With respect to its classification, OTA encourages NOSB to first deliberate on whether Zein, a product derived from dent corn, is 'agricultural' or 'non-agricultural,' and to consider this question in the context of the existing regulatory definitions. To be allowed in products labeled as "organic," it must be on the National List, period. The first determination is whether the substance is agricultural or non-agricultural. The 'synthetic' or 'non-synthetic' determination is arguably less significant when considering the structure of the National List for Handling Materials and the requirements of § 205.605 vs. § 205.606.

[CLICK HERE FOR FULL TEXT OF OTA'S COMMENTS]

Fish Oil Annotation (DISCUSSION)

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

The Handling Subcommittee presented a <u>discussion document</u> in spring 2020 to explore new restrictions on fish oil that would prohibit the use of fish caught directly for the sole use of its oil, and prohibit fish oil from species and regions that are overfished or exploited.

DISCUSSION DOCUMENT: The Handling Subcommittee is presenting an updated discussion document with new information requesting additional stakeholder inputs on possible options. In response to previously submitted public comments and further discussions with scientists and groups involved in marine fishery ecology and policy, the Subcommittee developed three possible fish oil annotations and requests input from organic stakeholders on the merits and feasibility of each approach. Each option would be added to the existing listing for fish oil which reads §205.606(e) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8) - stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606.

- Option 1: Sourced from fishing industry by-product only and certified as sustainable by a thirdparty certifier.
- Option 2: Sourced from fishing industry by-product only and certified as sustainable against a third-party certification that is International Social and Environmental Accreditation and Labeling (ISEAL) Code Compliant or Global Seafood Sustainability Initiative (GSSI) recognized with full utilization of said scheme.
- Option 3: Sourced from fishing industry by-product only and has either a green or yellow Seafood Watch rating or is eco-certified to a standard recommended by Seafood Watch (https://www.seafoodwatch.org/).

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

- 1. Which is the best option to mitigate environmental concerns about the over-exploitation of fisheries used to produce fish oil sourced for organic products?
- 2. Are these requirements clear and enforceable?
- 3. What impacts would these requirements have on the availability of fish oil for organic products?

Read the full discussion document in the NOSB Meeting Packet (p. 109-114)

Subcommittee Vote: Motion to adopt the discussion document: 6 Yes, 0 No, 1 Absent

ORGANIC TRADE ASSOCIATION COMMENTS: OTA did not provide comments on this proposal.

Livestock 2023 Sunset Review

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

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

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

ORGANIC TRADE ASSOCIATION COMMENT SUMMARY: [Click here for full OTA Comments on Livestock Sunset Materials]

DISCUSSION SUMMARIES: The Livestock Subcommittee has provided discussion summaries for each substance undergoing sunset review and has indicated specific areas where additional information is requested from stakeholders. Read the full discussion in the NOSB Meeting Packet (p. 115-142)

Activated charcoal - §205.603(a)(6)

- Allowed only from vegetative sources and may be used as an antidote to poisons and other toxic substances and for removing various mycotoxins.
- Additional information requested by Subcommittee:
 - 1. Is activated charcoal essential to organic livestock health care and production?

Calcium borogluconate - §205.603(a)(7)

- Allowed only for treatment of milk fever in cattle, sheep, and goats.
- Additional information requested by Subcommittee:
 - 1. The National List references multiple substances for the treatment of ketosis and milk fever, including propylene glycol, calcium propionate, calcium borogluconate and electrolytes. Are they equally necessary and effective? Do organic producers have the correct tools for treatment of all stages of the development of these related conditions?
 - 2. Calcium borogluconate also appears on the National List under allowed electrolytes. Please describe the history and the importance of calcium borogluconate's consideration by organic systems as a stand-alone substance.

Calcium propionate - §205.603(a)(8)

- Allowed only for treatment of milk fever in cattle, sheep, and goats.
- Additional information requested by Subcommittee:
 - 1. Are there any new practices or non-synthetic materials that would make the use of calcium propionate unnecessary?
 - 2. Do our livestock stakeholders think the listing for calcium propionate is necessary at §205.603(a)(8) since electrolytes are listed as a group at §205.603(a)(11) *Electrolytes—without antibiotics*?

Chlorine materials – §205.603(a)(10)

- Includes: Calcium hypochlorite, Chlorine dioxide, Hypochlorous acid, Sodium hypochlorite
- Allowed for disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
- The Livestock Subcommittee acknowledges that chlorine materials are an essential part for maintaining hygiene in livestock facilities and generally supports continued listing of chlorine materials. The Subcommittee supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.
- Additional information requested by Subcommittee:
 - 1. Are there alternatives to chlorine materials that are less toxic sanitizer options in livestock operations?
 - 2. Should we be considering chlorine materials through a more holistic point of view and, as per the sanitizer panel during the Fall 2020 NOSB meeting, are there practices we should look to prior to using chlorine materials in livestock operations?
 - 3. Are there practices we should look to prior to using chlorine materials in livestock operations?
 - 4. Are there any new recommendations for how to rotate sanitizers to maintain maximum efficacy?

Kaolin pectin - §205.603(a)(17)

- Allowed for use as an adsorbent, antidiarrheal, and gut protectant.
- Additional information requested by Subcommittee:
 - 1. How widely used is kaolin pectin in organic livestock production?
 - 2. Are there any equally effective non-synthetic/natural substances available that serve the same functions as kaolin pectin?
 - 3. What problems/issues, if any, are there associated with the use of kaolin pectin in organic livestock production?
 - 4. Is there any concern that organic livestock producers may be using kaolin pectin on a routine, prophylactic basis, rather than solely to address livestock illness?

Mineral oil - §205.603(a)(20)

- Allowed for treatment of intestinal compaction. In organic livestock production, operators orally administer mineral oil to lubricate the intestinal tract and dislodge intestinal obstructions in cattle and other ruminants.
- Prohibited for use as a dust suppressant.
- Additional information requested by Subcommittee:
 - 1. Are there new studies that indicate that the use of mineral oil as a treatment of intestinal compaction is no longer necessary?
 - 2. Are there differences in interpretations by certifiers for allowed use of mineral oil as a treatment of intestinal compaction in livestock (7 CFR 205.603(a)(20))?
 - 3. If there are differences in interpretations amongst certifiers for the use of mineral oil as a treatment of intestinal compaction in livestock, what clarification or guidance could be provided that would eliminate the differences in interpretation?

Nutritive supplements - §205.603(a)(21)

- Includes injectable supplements of trace minerals, vitamins, and electrolytes per §205.603, with excipients per §205.603(f).
- Must be used in accordance with FDA and restricted to use by or on the order of a licensed veterinarian.
- Additional information requested by Subcommittee:
 - 1. Do advances in organic ration formulations change the need for injectable nutritive supplements?

Propylene glycol - §205.603(a)(27)

- Allowed for use only for treatment of ketosis in ruminants.
- Additional information requested by Subcommittee:
 - 1. When preventative measures do not work, are there natural/non-synthetic alternative treatments for ketosis in ruminants since approval of the petition? Are there any alternative synthetic treatments on the NL that make this listing redundant?
 - 2. Are there developments in manufacturing of propylene glycol that would require new evaluation of source materials?

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

- Allowed for use only as a disinfecting pre-milking and post-milking teat dip for the purpose of preventing mastitis.
- Additional information requested by Subcommittee:
 - 1. Are there preferred alternatives to acidified sodium chlorite for preventative care in dairy cows?
 - 2. Have there been changes in the availability of iodine that would reduce the need for acidified sodium chlorite?

Zinc sulfate - §205.603(b)(11)

- Allowed only for use in hoof and foot treatments for the control of foot rot in dairy cattle, sheep, and goats.
- The Livestock Subcommittee seeks public comments regarding the effectiveness of alternative methods
 for controlling foot rot, including management practices, and the use of hydrogen peroxide, peracetic
 acid or other materials. Further, the Subcommittee seeks feedback on whether the availability of zinc
 sulfate for use in organic livestock production would likely reduce the use of copper sulfate for
 treatment of foot rot.
- Additional information requested by Subcommittee:
 - 1. Has the use of zinc sulfate reduced the use of copper sulfate in treating foot disease in livestock?

Research Priorities 2021 (DISCUSSION)

BACKGROUND: Since adopting its Research Priorities Framework in 2012, NOSB has presented an annual list of research priorities for organic food and agriculture. The priorities are proposed by NOSB's Livestock, Crops, Handling, and Materials/GMO Subcommittees and are revisited and updated each year to ensure accurate reflection of existing need for new knowledge

DISCUSSION DOCUMENT: The Materials Subcommittee presents the following list of research priorities. The NOSB Meeting Packet (p. 143-154) contains full descriptions of each research priority.

Livestock

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

Crops

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

Food Handling & Processing

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

Coexistence with GE and Organic Crops

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

General

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

The Subcommittee seeks stakeholder comments in response to the following questions: During the Fall 2020 comment period, stakeholders identified several additional items for consideration as research priorities, on which, the Materials Subcommittee is seeking further input from the community. Should the following items be considered by the NOSB for inclusion in its proposal on 2021 research priorities?

- Research into the economics of organic livestock more broadly as producers continue to face difficult
 economic circumstances, including challenges with access to meat processing, varying price premiums,
 and high cost of feed
- Research into the effects of organic crop production on water
- Research into novel ammonia inputs, their field-level impact in organic systems, and their traceability and vulnerability to fraud
- Benefits and risks of livestock integration into crop rotations
- Nutritional value of organic animal products (such as dairy, meat, and eggs)
- Comparisons of pesticide, antibiotic, and synthetic growth hormone residues in organic and conventional products

Read the full discussion document in the NOSB Meeting Packet (p. 143-154)

Subcommittee Vote: Motion to adopt the discussion document: 6 Yes, 0 No, 0 Absent

THE ORGANIC CENTER COMMENTS: [CLICK HERE FOR FULL TEXT OF TOC'S COMMENTS]

Excluded Methods Determinations (DISCUSSION)

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

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

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

Subsequent recommendations identify specific technologies and whether they are prohibited under the existing regulatory definition of excluded methods. The 2016 recommendation identified these prohibited methods: Targeted genetic modification including CRISPR; Gene silencing; Accelerated plant breeding techniques; Synthetic biology; Cloned animals and offspring; Plastid Formation. And it also identified Marker assisted selection and Transduction as allowed. The 2017 recommendation identifies cisgenesis, intragenesis, and agroinfiltration as prohibited under the regulatory definition of excluded methods. The 2018 recommendation identifies embryo rescue in plants as not prohibited under the regulatory definition of excluded method. The Spring 2019 recommendation identifies transposons developed via use of in-vitro nucleic acid techniques as prohibited under the regulatory definition of excluded methods. This recommendation also clarifies definitions of cisgenesis and intragenesis. The Fall 2019 recommendation identified induced mutagenesis as prohibited under the regulatory definition of excluded methods, and allows embryo transfer in livestock (not prohibited under the regulatory definition of excluded methods). Other technologies remain as "to be determined" (TBD) for future consideration by NOSB.

DISCUSSION DOCUMENT: The Materials Subcommittee presents a discussion document that continues the work of identifying emerging technologies in the food sector and determining whether they will be considered excluded methods in the organic system.

The Subcommittee is seeking answers to the following questions to aid in creating guidance and/or regulation on excluded methods:

- 1. What new emerging methods in biotech should be added to the TBD list? Please also describe the primary purpose and how far from commercialization for use in food processing and/or agriculture the method is in its development.
- 2. Please prioritize the remaining TBD list methods according to the definitions, principles and criteria established in the 2016 Proposal (see Appendix A)
 - a. Would methods newly determined to be excluded by the NOSB/NOP be retroactive for commercial varieties already in the marketplace?
 - b. Should the NOSB grandfather in methods that have long been used in organic plant breeding (e.g., double haploids) and focus its energy entirely on new and emerging technologies?
 - c. How do we regulate technologies used to develop new seed varieties that companies are otherwise under no obligation to disclose?
- 3. Are unintentional excluded methods hiding in organic systems when the actual material produced and used has no trace of excluded method in the final organic product? Do we have the inspection, testing, and enforcement tools to keep prohibited methods out of the organic marketplace?
- 4. Given the lack of transparency around emerging technology entering food and agricultural systems, how can Organic producers, handlers, certifiers, and this Board, etc. stay educated on emerging methods and the potential for contamination?

Read the full discussion document in the NOSB Meeting Packet (p. 155-172)

Subcommittee Vote: Motion to adopt the discussion document: 6 Yes, 0 No, 0 Absent

ORGANIC TRADE ASSOCIATION COMMENT SUMMARY: [CLICK HERE FOR FULL TEXT OF OTA'S COMMENTS]

- ✓ OTA remains supportive of moving recommendations forward to NOP that will not only improve the practices used to keep GMOs out of organic seed, feed and crops, but will also clarify the standards and terminology used for making clear and consistent compliance determinations.
- ✓ OTA supports the recommendations that have been made to date, and this includes the clarification provided in the 2016 Recommendation that gene editing techniques, such as CRISPR, are currently prohibited under the NOP regulations per the existing definition of "excluded methods."
- Our priority, however, at this time is to ensure that the backlog of NOSB recommendations (including this one, strengthening organic seed usage and GMO contamination prevention) are address by USDA and implemented by a final rule or final guidance



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