September 30, 2024

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-24-0023

RE: Handling Subcommittee
Petitioned Material Discussion Document: Ethylene Annotation change

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Handling Subcommittee's Discussion Document on the proposed change to the Ethylene annotation. The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, material input providers, and others. OTA's mission is to grow and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA offers the following input on the questions from the subcommittee:

1. Should HS consider this substance any differently than it does for ripening tropical fruit because in the petitioned use it would be inhibiting growth rather than encouraging it?

> The subcommittee should apply the criteria outlined in 7 CFR § 205.600. None of these criteria differentiate between inhibiting or encouraging growth as allowable activities for substances. Several physical processes, such as temperature control, are already permitted in organic processing to both inhibit and encourage growth. Since this is not part of the regulatory criteria, it should not influence the NOSB's deliberations. The more relevant criterion is § 205.600(b), which states that the substance must be "essential for the handling of organically produced agricultural products."
>
> OTA did not have extensive time to consult with its membership, but in our limited feedback we heard differing opinions on expanding the scope of ethylene usages. It could be beneficial for extending storage life and reducing waste in organic potatoes and onions however the benefit needs to be weighted against consumer expectations in the label. We have also heard from producers of onions that temporal controls have proven sufficient for their needs and do not see the expansion of ethylene's use as essential.

2. How should HS consider petitioned synthetic substances which may pose less of a human health concern than natural alternatives?

> In evaluating a synthetic substance, under § 205.600(b)(1), the NOSB must evaluate alternative organic and natural substances, and under § 205.600(b)(3), the NOSB evaluates whether synthetic substances have adverse effects on human health. Additionally, § 205.600(a) references the

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Organic Foods Production Act (OFPA), which includes the potential prohibition of a natural substance if it is "harmful to human health" (§ 6517 National List(c)(2)(A)(i)). While OFPA and the NOP regulations consider both natural and synthetic substances in terms of harm, they do not evaluate relative harm between different types of substances. However, human health impacts are clearly a priority, so the NOSB should weigh the relative harm of using a synthetic material versus the benefits of reducing harm to farm workers. OTA believes that minimizing harm to workers should take precedence over a strict preference for natural substances, in line with organic principles protecting farm and food worker safety (§ 6517 National List(c)(2)(A)(iii)). If a synthetic substance is essential for handling and is safer than a natural alternative, OFPA and § 205.600(b) could support its listing.

For this specific petition, we have heard concerns from some producers about the flammability of ethylene and its potential risks to workers. Similarly, while clove oil is natural, there are concerns about its health risks and effectiveness.

3. If the HS recommends an annotation change to ethylene to permit its use as a sprout inhibitor, should HS consider any additional revisions to the annotation related to ripening of tropical fruit or degreening citrus for these allowed uses to be more clear?

OTA does not have further input on this question.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

Scott Rice
Sr. Director, Regulatory Affairs
Organic Trade Association

cc: Tom Chapman
Co-CEO
Organic Trade Association

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September 30, 2024

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-24-0023

RE: Compliance, Accreditation, and Certification Subcommittee
Discussion Document: Risk-based Certification Discussion Document

Dear Ms. Arsenault:

Thank you for this opportunity to provide feedback to the Compliance, Accreditation, and Certification Subcommittee on its Risk-based Certification Discussion Document Discussion Document. The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, material input providers, and others. OTA's mission is to grow and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA appreciates the significant and detailed work the Subcommittee has put into its discussion document. All successful risk management approaches require leadership commitment and prioritization. The NOSB and the NOP's focus on this area demonstrates such leadership. We hope the NOSB considers making leadership in risk management a continuous and dynamic task, much like its ongoing leadership in setting research priorities for the organic sector. As a collective set of stakeholders representing diverse interests in organic integrity, the NOSB is uniquely positioned to continuously address and advise the sector on risk factors that should be integrated into oversight activities.

We offer the following feedback on the questions posed by the Subcommittee:

A note on our comments: While the document addresses risk from the perspectives of both certified entities and certifiers, it primarily focuses on the adoption of risk-based oversight by certifiers and reviewing the one-size-fits-all approach to certification. Therefore, our comments are framed with this focus in mind.

1. How does your organization define risk?

We define risk in terms of potential threats to organic integrity and adherence to organic standards. This includes evaluating both the likelihood of non-compliance and its potential impact on the certification process, consumers, and the broader organic ecosystem.

a. Would it be valuable for the definitions listed above (Risk-based oversight, Risk management, Risk, Vulnerability) to be included at § 205.2 Terms Defined?

Subjectivity and communication challenges are common issues in risk management. Alignment of definitions can help mitigate these challenges. We do not have a strong position on whether adding these

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terms to § 205.2 is necessary, but we do believe that having ACA and NOP use common definitions is critical. Since NOP provides oversight of certifiers through accreditation audits and reviews of risk-based procedures in § 205.504(b)(7), NOP could drive alignment via the accreditation process without requiring regulatory changes.

b. Are there other definitions that would be beneficial to include at § 205.2 Terms Defined? Should all certifiers use the same risk criteria to evaluate operations?

It will be important to have key terms in risk frameworks, criteria and measurements defined. However, risk criteria will evolve as risk profiles change, and regulatory definitions might not be flexible enough for this purpose. Definitions like "impact" (magnitude) or "likelihood" should align with common risk management standards, such as ISO 31000.

Certifiers must align on risk criteria, as misalignment could create risks in itself. Consistent criteria will also enhance NOP's oversight effectiveness during accreditation audits. That said, risk criteria must remain dynamic and responsive to emerging data, changing environments, and evolving risks. An over-reliance on historical data can create biases and gaps. It's important that criteria are not determined solely by certifiers; the day-to-day experience of certified entities as well as current competitive pressures should also inform these criteria to ensure comprehensiveness.

We believe that codifying risk criteria in regulations may be impractical due to the time and resources required for revisions. Instead, this should be an ongoing, continuous process. The NOSB could serve a role similar to its work with research priorities, regularly reviewing and advising on risk criteria.

2. What resources are available that could help organizations become more proficient at risk-based oversight?

General risk management training, such as ISO 31000, is valuable, but there will also be a need for organic-specific risk management training once frameworks and criteria are determined. OTA maintains the Organic Fraud Prevention Guide, which helps certified entities (farms and businesses) assess risk in their operations and supply chains. Similar resources should be developed for certifiers to apply risk criteria effectively.

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

A poorly executed risk management approach could be worse than having none at all. Ensuring alignment between the NOP and certifiers is paramount to prevent gaps that bad actors could exploit. Another risk is over-reliance on historical data, which may cause emerging risks to be overlooked. Finally, ensuring the risk criteria are properly prioritized is also important as resources are limited. If appropriate focus is not applied then again risk management will fail as resources are spread too thin to be effective. Lessons from food safety oversight, which has applied risk management approaches for some time, could be adapted to the organic context.

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

The one-size-fits-all approach to certification should be reviewed to ensure it provides value. If it doesn't, it should be evaluated for what barriers to entry or added costs it creates. Such inefficiencies make organic

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production less profitable or products more expensive. While changes to the Organic Foods Production Act (OFPA) would be beyond NOSB's purview, an exploration of the costs and benefits of various approaches, even in area's outside of NOSB's scope could help to inform improvements in public policy.

We believe that as organic grows, both small producers and large-scale operations are disproportionately impacted by the current one-size-fits-all approach. Small producers may have the same 'likelihood' of a given risk yet will pose a lower overall risk to the market due to their size (impact). Similarly, national retail distributors, who primarily act as conduits between brands, may have high transaction volumes (high impact) but lower financial incentives for fraud and therefore a low likelihood. Lastly an operation that has been stable and compliant for years may have both a low likelihood and impact and therefore low risk overall. For all three types of operations, revisiting the Organic System Plan (OSP) to assess whether all areas yield meaningful value for organic integrity and take steps to remove the inefficient areas could help reduce the certification burden and cost of organic products.

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

We recommend that the NOSB look to take a role in continually evaluating risk criteria from the broader organic community on an ongoing basis. While these criteria may not change frequently, regular reviews are necessary to identify emerging risks or shifting priorities. The NOSB could also help identify data sources and performance indicators for these risks, ensuring the organic sector remains proactive in managing risk.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

Scott Rice
Sr. Director, Regulatory Affairs
Organic Trade Association

cc: Tom Chapman
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Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-24-0023

RE: Compliance, Accreditation, and Certification Subcommittee
Discussion Document: Residue Testing for a Global Supply Chain

Dear Ms. Arsenault:

Thank you for this opportunity to provide feedback to the Compliance, Accreditation, and Certification Subcommittee on its Residue Testing for a Global Supply Chain Discussion Document. The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, material input providers, and others. OTA's mission is to grow and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA appreciates the significant and detailed work the Subcommittee has put into its suggested updates to the various residue related guidance and instruction documents contained in the NOP Program Handbook. OTA recognizes the necessity of these updates to be responsive to the evolving and expanding focus of testing initiatives, as well as the technologies involved, in the interest of maintaining organic integrity and deterring fraud. We also point to the importance of consistency across all these efforts in ensuring certifiers and inspectors have the resources needed, and that oversight is fair and sound.

Below we answer some of the questions posed, as well as offer some overall feedback and thoughts.

Risk Assessment
We recognize the Board's work on risk assessment and the discussion document included in the materials for the Fall meeting focused on this topic. We also acknowledge the suggestion in this residue document of incorporating a risk-based decision tree in new guidance as a tool for when and where to sample, and encourage the Board to link these two focus areas closely. Doing so will help certifiers, inspectors, and the trade make the best and most informed decisions—and have the greatest impact on organic integrity—when choosing where to focus finite time and financial resources.

Role of the Organic Trade
This detailed collection of recommended updates will be critical in equipping certifiers and inspectors with the tools they need to continue their essential role in ensuring compliance. **We also point to the vital role the organic trade has in these efforts as well.** OTA has developed an extensive Organic Fraud Prevention Guide, part of which focuses on establishing a testing program. Internal testing programs are critical tools that can be used to verify there was no intentional application of prohibited substances, to measure the effectiveness of contamination and commingling prevention measures, as well as to deter fraudulent activity of suppliers. While an internal testing program cannot replace the role of the third-party certifier in oversight activities, it is an important complementary safeguard in ensuring organic

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integrity. Our Organic Fraud Prevention Guide references the NOP Handbook documents and we encourage the Board and NOP to keep the trade in mind as an audience and user of these documents as they move forward in their work.

Training

With the level of detail and complexity these suggested updates present, it is imperative that investment in training of certifiers and inspectors meet the increasing demands for expertise in this field. The Organic Integrity Learning Center has proven an essential part of meeting training needs and we encourage NOP continue to populate it with resources. We also encourage the continued partnership between the NOP, the Accredited Certifiers Association, and the International Organic Inspectors Association in ensuring the certification and inspector community has the training it needs.

Guidance Document Questions

1. NOP 2610

    b. To increase bandwidth, should certifiers outsource sampling to a third party?

    We do not support certifiers outsourcing sampling to a third party. As an integral part of certifier responsibility, we foresee doing so poses the risk of losing control, consistency, and integrity in certification oversight.

4. NOP 2613

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

    Regardless of sampling methodology, results from third-party operations should not be accepted as a basis for compliance action or as evidence that no compliance action should be taken. Depending on the circumstance, such results can be used to assess risk or direct further sampling and testing done under the authority and supervision of the certifier.

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

    Sampling best practice should be to sample single ingredients. While presence of a prohibited substance may suggest the failure of an operation's organic system plan, sampling a multi-ingredient product prevents accurate and effective follow-up when it is not known which of the ingredients has tested positive for a prohibited substance. In cases when the individual ingredients in the product, or the separate lots of a mixed lot are still available, testing of these may be helpful in directing compliance action and/or addressing the organic system plan failure.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

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September 30, 2024

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-24-0023

RE: Materials Subcommittee
Proposal: Inert Ingredients in Organic Pesticide Products

Dear Ms. Arsenault:

Thank you for this opportunity to provide feedback to the Materials Subcommittee on its proposal regarding Inert Ingredients in Organic Pesticide Products. The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, material input providers, and others. OTA's mission is to grow and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA appreciates the Subcommittee's significant work on this topic and has previously submitted extensive comments on the Board's efforts to move beyond the current reliance on the outdated regulatory references to EPA List 3 and List 4 inerts. In consideration of this proposal, OTA convened its Inerts Task Force, made up of end-users of pest control products, manufacturers and formulators of pest control products, and persons with expertise on the composition and/or regulatory framework regarding pest control products used in organic production. OTA and members of the Task Force see a path forward via either of the two options presented, with a preference for pursuing Option 2. We support putting these two options forward for potential rulemaking and do not believe there is need to return the proposal to subcommittee.

However, we have some concern with the lack of detail on the process by which substances are initially reviewed by the NOSB and placed on the National List as required by the Organic Foods Production Act (OFPA). In Option 2, the Subcommittee proposes to allow substances defined and allowed by EPA as "inert ingredients" (40 CFR 152.3 & 7 CFR 205.2) with restrictions, only allowing those inerts which are allowed in formulations that are exempt from the requirement of tolerance. The subcommittee proposes to further restrict these substances with an "exceptions" list, beginning with alkylphenol ethoxylate and per- and polyfluoroalkyl substances. We understand that this exceptions list would be further added to if, at sunset review or in response to a petition, substances exempt from the requirement of tolerance are found not to align with OFPA criteria. While this appears to be a practical way forward and offers a recommendation for a regulatory amendment, it is unclear how the Board would provide an *initial* review of these substances as required by OFPA.

We appreciate this is the first step in the regulatory process and are confident that in working together, the NOP and NOSB can lay a foundation to replacing the outdated regulatory references. Just as the Subcommittee has committed to laying out an inerts sunset "roadmap" regardless of which option is adopted, it would be helpful if in moving forward the Subcommittee and Board also committed to further

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elaborating on the transition process and how the Board will initially review substances and add them to the National List. Perhaps this process of initial review can be conducted in parallel to rulemaking. However the Board and NOP determines the most appropriate and workable way forward, it will be critical this process remain in alignment with OFPA requirements as well as remain transparent to the community to provide confidence to manufacturers and end users that substances the industry has relied upon remain available.

We are encouraged that with whatever option the NOP and Board proceed, moving beyond the EPA List 3 and List 4 references will allow for the review of further substances that align with organic principles and spur greater opportunity for innovation in the development of tools for organic producers. On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

Scott Rice
Regulatory Director
Organic Trade Association

cc: Tom Chapman
Co-CEO
Organic Trade Association

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September 30, 2024

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-24-0023

RE: Materials Subcommittee
Discussion Document: Induced Mutagenesis

Dear Ms. Arsenault:

Thank you for this opportunity to provide feedback to the Materials Subcommittee on its Induced Mutagenesis (IM) Discussion Document. The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, material input providers, and others. OTA's mission is to grow and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Upon consideration of the Technical Review (TR) for IM, the Subcommittee offers pros and cons regarding the acceptability of IM in organic production and asks several questions of stakeholders. We offer our responses to these questions and thoughts on the use of IM in organic production.

1. Should induced mutagenesis be classed as an excluded method? On what basis?

   IM is a breeding technique that has been in use for over 100 years. It attempts to derive new and useful genetic variation by accelerating processes that occur in nature from chemical or radiation-based events and does not make use of gene editing techniques used in biotechnology. All plant breeding is an attempt by humans to amplify and accelerate natural systems, including basic cross-breeding and selection in which breeders speed up the process of natural selection that would occur in wild plant species. Mutagenesis is no different.

   In the discussion document, the Subcommittee argues that IM should be excluded because it fails two of the three criteria for excluded methods:
   2. Use means that are not possible under natural conditions or process
   3. Use means that are not considered compatible with organic production

   The discussion goes on to suggest because some forms of mutagenesis use chemicals that would not impact a plant in nature, it should be excluded. And that the chemicals used are not compatible with organic production. We will address the second point first.

   On the point of synthetic chemicals being incompatible with organic production, we agree with the existing framework of the organic regulations that limit their use in organic agriculture but not in inputs in the pre-production phase. The exclusion does not reach back into the history of breeding lines, or the history of the biotic or abiotic inputs that are used in a production system. For example, the regulations do not address hybrid non-treated conventional seed, even though

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chemicals used to produce the inbred lines and the seed itself are highly dependent on chemicals banned in conventional and organic food production (but allowed in non-food crops like seed). The exclusion of certain synthetic chemicals in organic pertains directly to the production of a certified organic product. In this regard, inducing mutagenesis is no less organic in production than a conventional cow eating conventional feed and producing manure to be later used in fertilizer for organic farms in organic production. It is a pre-production phase. Both the composted fertilizer and the commercial seed are biotic inputs into a system.

Regarding natural conditions or process, as the TR points out, mutagenesis does indeed occur in nature. Focusing and amplifying the process is what plant breeding does. Nature, without humans, would never create large populations of highly inbred parents in isolation and then cross them in isolation with another highly inbred parent population. You might have inbreeding and you might have hybridization, but you would never have the amplification and scale in nature. And yet we allow hybrid seed production because we recognize that the domestication of crops requires such human intervention. IM is analogous. It is indeed "unnatural" in the sense of the how we as humans intervene, but it is not transgenic, and it is not higher risk than natural crosses. For reference, natural crosses of squash with bitter gourds have hospitalized people in the US and across the globe on a regular basis. There is no record of a variety produced with mutagenesis doing the same.

Lastly, we point to NOP Policy Memo 13-1 *Cell Fusion Techniques Used in Seed Production*. While the focus of this memo addresses several approaches of cell fusion and makes a determination on which of these are allowed in organic production, there is also a clarification statement within which explicitly states "Mutagenesis (treatment of plants with radiation or chemicals to induce random mutation) is considered part of traditional breeding programs." We support revisiting and reevaluating positions when new information merits, however we also believe it is important to note when NOP Handbook documents provide existing guidance and consistency on this topic.

2. If IM is determined to be an excluded method, how should varieties produced using it be handled?
    a. Should all varieties with IM heritage be disallowed for organic production? How would this be managed?
    b. Should varieties with IM background currently in use be allowed, and IM be prohibited from use in plant breeding going forward?

As noted, we do not believe IM to be an excluded method. Should the Board feel differently, we would foresee screening and restricting seeds produced as a result of IM to be a challenging path forward, no matter if this restriction were made to existing or yet to be released varieties. Such a process would place a heavy burden on both producers and certifiers to follow due diligence in making these determinations, especially given this information may be difficult or impossible to obtain from the seed provider or distributor, be they organic or conventional. The challenge of such a process is further highlighted by the questions raised in the text of the IM discussion document.

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3. Should varieties with IM be allowed, perhaps on the basis that IM is compatible with organic production because subsequent backcrossing sufficiently reduces any negative features it may introduce?

   Per NOP Policy Memo 13-1, IM is allowed and defined as traditional plant breeding. We believe IM should continue to be allowed and do not see the need for a distinction on risks in commercial varieties that would differ from risks incurred in variety development in other forms of traditional breeding.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

Scott Rice
Sr. Director, Regulatory Affairs
Organic Trade Association

cc: Tom Chapman
Co-CEO
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September 30, 2024

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-24-0023

RE: Crops Subcommittee
Proposal: Compost

Dear Ms. Arsenault:

Thank you for this opportunity to provide feedback to the Crops Subcommittee on its Compost proposal. The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, material input providers, and others. OTA's mission is to grow and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA **supports the Subcommittee's proposal to amend the practice standard**, removing the C:N ratio requirements and amending the language regarding time and temperature requirements. These appear to be widely supported. **OTA currently does not have a position on how the Subcommittee approaches the inclusion or exclusion of synthetic feedstocks in compost** and encourages the Board and organic community to think about how we can collectively move forward in a wider context.

As we find in many of our deliberations, we are challenged to address larger issues of sustainability when we constrict our conversations into silos. If we wish organic to be relevant in wider sustainability discussions, including those addressing environmental and human health challenges, we must look holistically at how we can do better. In this same agenda, the Board is proposing the top research priority for crops is "the extent and impact of plastic use in organic crop production, and how organic producers can lead in reducing it and aligning with consumer concerns." Organic—and conventional—production relies on tremendous amounts of nonbiodegradable, unrecyclable plastics. Organic has indicated a desire to move beyond this reliance by placing in the regulation an allowance for biodegradable biobased mulch, referencing some of the same or similar ASTM standards for degradability as proposed by a petition to USDA.

Yet to date, no commercially available mulches exist that meet this definition, and we see continued use of nonbiodegradable plastic mulches. While these are required to be removed from the field at the end of the growing or harvest season before they can degrade, weather, exposure and the practicalities of farm machinery and movement in the field see some of this degrade before it can be removed. While we may be uncomfortable with some biodegradable synthetics, we must ask to what degree are we comfortable with the continued use of nonbiodegradable plastics and synthetic microplastics that don't break down at all. Perfect solutions are rare, and tradeoff decisions must be made in the context of real-world challenges, not theoretical protocols. Synthetic contamination of farms can occur through various practical avenues, such as poorly maintained equipment, inadvertent water contamination, or inadvertent litter. Even with current composting standards, the physical removal of plastics from waste streams is unlikely to be

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completely effective. We encourage the board to challenge itself to explore the relative sustainability of real world tradeoffs and the collective impact of not engaging in the efforts to reduce the reliance on plastics.

OTA appreciates the Board has committed to taking a deeper look at resin formulated and fiber-based products and encourages the Board to address biodegradable synthetics in compost with mindfulness to the need to address the use of these or similar substances in biodegradable biobased mulch.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

Scott Rice
Sr. Director, Regulatory Affairs
Organic Trade Association

cc: Tom Chapman
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September 30, 2024

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-24-0023

RE: Livestock Subcommittee
Petitioned Material Proposal: Meloxicam

Dear Ms. Arsenault:

Thank you for this opportunity to provide feedback to the Livestock Subcommittee on its petitioned material proposal to add meloxicam to the National List of synthetic substances allowed for use in organic livestock production at 7 CFR § 205.603. The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, material input providers, and others. OTA's mission is to grow and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

On behalf of our members in the livestock sector, **OTA supports the addition of meloxicam to the National List**. Meloxicam offers an additional and needed treatment for pain management in organic livestock production systems and offers a longer therapeutic effect than existing allowed treatments on the National List. With the addition of meloxicam, organic livestock producers will have access to a treatment that is widely accepted in the organic standards of our trading partners and by animal welfare oversight programs. Further, according to OTA's 2024 consumer survey, 54% of consumers believe organic certification is better for animal welfare, and 45% are willing to pay a premium for organic products that protect animal health and welfare. Organic standards must safeguard the brand equity of the USDA organic seal. Therefore, the Board must ensure that any restrictions on synthetic pain relief substances do not conflict with consumers' expectations around the organic seal and animal welfare. The ability to treat animals with meloxicam will ensure organic livestock management continues to meet consumer expectations regarding animal welfare.

With this support, OTA offers three points of feedback in the review of this petition, one regarding the annotation included in the motion to list, one to bring consistency to National List listings, and one regarding the lack of a Technical Review.

1. Annotation: The listing motion includes the following annotation:
   i) Use by or on the lawful written order of a licensed veterinarian; and
   ii) A meat withdrawal period of at least two-times that required by the FDA

   The petition addresses use beyond only meat animals and notes withdrawal times for meat and milk animals. As the intended use for meloxicam is for both classes of animals, an annotation that mirrors existing listings for pain substances would be preferable. Additionally, the use of

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Meloxicam is authorized under AMDUCA which does not prescribe a specific withdrawal time in duration. Finally, this listing is inconsistent with how other substances and withdrawal times are listed on the National List and could create undue confusion for certifiers, vets, and producers. Of the 9 listings on § 205.603 with withdrawal time annotations, 8 list the withdrawal times in days (See attached appendix). While removing the word "meat" alone would be consistent with the Flunixin annotation, the suggested minor revision below would bring the wording in line with the other 8 listings with withdrawal periods. We suggest this minor revision [1]is within the intent of the original wording and therefore should be accomplishable in the meeting and is not substantive enough to hold progress on this petition.

Revise annotation to; suggested change in *italics*:

(i) Use by or on the lawful written order of a licensed veterinarian *and in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations*; and

(ii) A ~~meat~~ withdrawal period of at least ~~two times that required by the FDA~~ *42 days after administering to livestock intended for slaughter; and a milk discard period of at least 10 days after administering to dairy animals.*

2. The board may want to consider amending the annotation of Flunixin in a separate proposal in the future to bring consistency to withdrawal listings on § 205.603.
3. Technical Review: The Board's proposal notes (1) board expertise, (2) thoroughness of the petition, (3) lack of a conflict of interest between petitioners and the substance, and (4) unmet acute animal welfare needs as reasons for moving forward at this meeting. OTA concurs with this logic noting the petition and review was substantive and complete. However, over time the board expertise may change, and OTA believes in the strength of the Technical Review (TR) process in which an independent third-party expert evaluates a substance. Contracting a TR for the benefit of the NOSB has become standard practice with most petitioned substances and many materials under sunset review. While we agree with the board urgency to address animal welfare concerns now by moving forward with this petition, we also recommend the Board pursue a TR on meloxicam after recommending its listing to ensure future boards have access to sufficient expert analysis on the substance.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

[1] https://dairy.extension.wisc.edu/articles/nsaid-use-aro
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10144785/
https://www.dairyherd.com/news/meloxicam-pain-relief-cows-and-calves
https://aabp.org/committees/resources/Pain_Brochure_8-15.pdf
http://www.farad.org/publications/digests/032008ExtralabelNonsteroidal_anti-inflammatory.pdf
https://ec.europa.eu/health/documents/community-register/2018/20180319140321/anx_140321_en.pdf
https://extension.usu.edu/dairy/files/UtahStateDairyVetNewsletterMar2015.pdf

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Respectfully submitted,

Scott Rice
Sr. Director, Regulatory Affairs
Organic Trade Association

cc: Tom Chapman
Co-CEO
Organic Trade Association

Appendix on 205.603 and withdrawal annotations

5 of 9 substances have annotations that reference AMDUCA and 21 CFR part 530
8 of 9 substanves have annotations that reference withdrawal times in days.
1 of 9 substances have an annotation that references withdrawal times in two-times FDA.

§ 205.603 Synthetic substances allowed for use in organic livestock production.
In accordance with restrictions specified in this section the following synthetic substances may be used in organic livestock production:

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(3) Atropine (CAS #-51-55-8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian; and
(ii) A meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals.

(5) Butorphanol (CAS #-42408-82-2)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian; and
(ii) A meat withdrawal period of at least 42 days after administering to livestock intended for slaughter; and a milk discard period of at least 8 days after administering to dairy animals.

(12) Flunixin (CAS #-38677-85-9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA.

(18) Magnesium hydroxide (CAS #-1309-42-8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires use by or on the lawful written order of a licensed veterinarian.

(23) Parasiticides—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

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Allowed for fiber bearing animals when used a minimum of 36 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.

(i) Fenbendazole (CAS #43210-67-9)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

(ii) Moxidectin (CAS #113507-06-5)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

(29) Tolazoline (CAS #59-98-3)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian;

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

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

(30) Xylazine (CAS #7361-61-7)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian; and,

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

(b) As topical treatment, external parasiticide or local anesthetic as applicable.

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

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September 30, 2024

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-24-0023

RE: Livestock Subcommittee
Proposal: Methionine Annotation change

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Livestock Subcommittee's Proposal to change the DL-Methionine annotation for use in Organic Livestock Production. The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, material input providers, and others. OTA's mission is to grow and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

On behalf of our members in the livestock sector, OTA supports the proposed revision to remove the restrictive methionine annotation. While OTA and its members have found the current process manageable and did not request the NOSB take up this initiative, we acknowledge that the current restrictive annotation presents tradeoffs that the NOSB has carefully considered. Despite investments in research and development, no viable natural alternative to synthetic methionine has been identified, and its inclusion remains critical for organic poultry production.

Maintaining the restrictive annotation brings hidden costs for producers, inspectors, and certifiers who must manage feeding ratios, maintain and audit documentation, and address noncompliance. These costs, in both time and money, are either passed on to the consumer or borne by the producer. For producers, this makes organic farming less financially viable, and for consumers, it raises the price of organic poultry products, thereby limiting access to a larger portion of the U.S. population and limiting the expansion of organic poultry production. Furthermore, the time and resources currently spent by certifiers on enforcing methionine restrictions could be reallocated to reducing certification costs or enhancing due diligence in other areas, such as preventing feedstock fraud, an activity that would bring benefit to both producers and consumers.

Methionine has long been approved on the USDA's National List, and OTA is unaware of any consumer research indicating concerns over the level of use of essential feed additives that are synthetic. Additionally, restricting methionine could create challenges in meeting consumer expectations around animal welfare. According to OTA's 2024 consumer survey, 54% of consumers believe organic certification is better for animal welfare, and 45% are willing to pay a premium for organic products that protect animal health and welfare. Organic standards must safeguard the brand equity of the USDA organic seal and therefore the board must ensure that any restrictions on essential feed inputs that are synthetic do not conflict with consumers' expectations around the organic seal and animal welfare.

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On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

Scott Rice
Sr. Director, Regulatory Affairs
Organic Trade Association

cc: Tom Chapman
Co-CEO
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September 30, 2024

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-24-0023

RE: Compliance, Accreditation, and Certification Subcommittee
Discussion Document: Consistency in Organic Seed Use

Dear Ms. Arsenault:

Thank you for this opportunity to provide feedback to the Compliance, Accreditation, and Certification Subcommittee on its Organic Seed Use Discussion Document. The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, material input providers, and others. OTA's mission is to grow and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA appreciates the thoughtful discussion around this topic. To help answer the questions posed by the Subcommittee, OTA convened an Organic Seed Task Force composed of members from the seed trade, organic producers, certifiers, and others deeply engaged in this topic. Based on the expertise and feedback from this group, we answer the questions posted in the discussion document.

Beyond our response to this and any future organic seed-related discussion documents put forth by the Board, OTA and our Organic Seed Task Force are committed to remaining engaged on this topic. We envision and intend to work toward a clear, achievable process for moving our industry progressively forward in the production and planting of more organic seed. Success will be realized when we have a predictable approach to organic seed that sends clear signals to the seed industry as to the market needs and opportunities. Compliance with organic seed use requirements will necessitate a simpler approach for farmers, especially highly diversified farms, when documenting compliance. As well, success will be impingent on clear guidance for certifiers on how to assess compliance priorities based on risk, e.g., the highest acreage crops for a farmer should show a higher level of improvement. Progress, clarity, and consistency will take time to develop and require ongoing collaboration across the industry. We look forward to updating the NOSB as our work proceeds.

1. Is there still support for the 2018 and 2019 recommendations?

   2018 Recommendation
   We believe NOP should advance the portion of the 2018 recommendation updating the regulation. OTA continues to strongly support an amendment to the organic regulations at § 205.204 to require improvement in sourcing and usage of organic seed (continuous improvement) and we support the adjusted regulatory language included in the fall 2018 proposal.

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The intent of the allowance in 7 CFR § 205.204(a) to use non-organic untreated seed under certain conditions was to provide a transition time for the industry while the production of organic seed and planting stock caught up to its demand. Although tremendous strides have been made in the past decade to increase the availability of organic seed and planting stock, improvements in the private and public sector are both needed. The private sector has continued to work to increase both the production and use of organic seed to meet the diverse and regional demands of organic production, and more educational resources and tools exist to support the sourcing and planting of organic seed.

Unfortunately, however, in part due to a poor regulatory framework, growth in organic seed production has become stagnant. Commercial availability is applied inconsistently, and the level at which certifiers monitor and enforce the use of organic seeds and planting stock varies significantly. This greatly hinders efforts. To help remedy the situation and match the efforts made by industry, it is time that NOP's regulations are amended and guidance on sourcing organic seed and planting stock is updated.

2019 Recommendation

OTA largely supported the recommendations in both the 2018 and 2019 proposals outlining updates to NOP Guidance 5029, but had specific comments for changing and clarifying these proposals:

- We requested specific language that any conventional replacement variety be documented as being produced without the use of excluded methods. This language was included in the 2019 proposal.
- We requested removal of language addressing contamination and commingling with seeds derived from excluded methods, and instead make a simple reference to NOSB recommendations and existing guidance on the topic. This was addressed when seed purity considerations were moved to a separate document.
- The recommended Guidance language in both recommendations referenced 3, not 5, as the number of sources that must be referenced, but that the exact number is less important than describing criteria and conditions that should determine the number as it relates to the potential number of suppliers offering the organic equivalent variety. We noted the search and procurement methods for sourcing organic seed and planting stock provided in 4.2.1((b)(1)(i-vii) are very valuable, and we do not take issue with this final approach.

We refer to our previous comments on both the 2018 and 2019 recommendations, included here as attachments.

2. How burdensome is it for producers to demonstrate compliance with the commercial availability requirement for seed?

Our discussions with producers, certifiers, and seed companies would suggest that the ease or burden of this is dependent on how many crops and varieties of crops a producer utilizes. For example, a producer doing a corn/bean/cover crop rotation does not have a highly burdensome process for demonstration, although the certifier's ability to assess the validity of compliance may still be challenging. Whereas a specialty crop producer for fresh market vegetables who grows dozens of crops and potentially over a hundred varieties, would have a very difficult and burdensome process. We believe future solutions need to look at simplifying this process, and that

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there should be an exploration of a focus on the top crops with more rigorous demonstration and efforts at continuous improvement on those, either determined by percentage of acreage or a tiered approach.

3. In general, how available is organic seed, and is untreated seed significantly easier to find than organic seed?

   This is entirely crop and market segment dependent. Generally, there are many types and traits of crops with correct market fit and organic seed production. Availability of certain crops like soybean and cabbage will be sufficient; in others like premium alfalfa seed and carrots it is not sufficient. Particularly in crops where market signals around organic seed interest remains weak, breeding and production companies will need data and time to invest in and allocate seed production capacity. An exercise in identifying accurate acreage and clarifying market uses must be executed to scale seed production effectively. Building up sufficient seed supply takes planning and time.

   We prefer to refer to non-organic seed that is used by organic growers as conventional untreated seed. This is because there are seed treatments that are allowed in organic production, and using the term "untreated" does not identify how the seed itself was grown. Conventional untreated seed is much more broadly available because it has been servicing both the conventional and organic markets, is available from most seed suppliers, and remains the 'norm' of seed used. The majority of seed suppliers carry conventional untreated seed; some suppliers carry conventional untreated and organic seed; few suppliers carry only organic seed.

4. Are there some crops for which organic seed is available? Are there any crops for which lack of organic seed supply is notable?

   The answer to both questions is yes though this provides a narrow perspective on the state of the organic seed market. An analysis on crop markets, value, acreages, and subsequent variety fit and seed availability should be executed to flesh out a fully informed response. For example, field crop data like acreages, planting windows, density, and market specs are well known and fairly straightforward so it is easier to give full-stop answers of 'yes' or 'no' on organic seed availability.

   On the other hand, in vegetables there is a matrix of factors to run through including but not limited to nationwide planting demands, 365 seasonality of market demands, vast planting density differences by region and end product, and huge quantity differences between direct and wholesale operations. We highlight examples of the complexity through these examples:

   a. Soybean Seed
      There is inadequate availability of organic seed at this time, although seed companies can and would rise to meet increased demand for organic seed if the seed guidance were strengthened. The reasons for incomplete availability of organic soybean seed are primarily economic. There is no shortage of highly competitive germplasm that can be produced organically. Seed companies are reluctant to commit to large inventories of organic soybean seed which may not sell. In addition, many organic farmers save and replant soybean seed.
      Conclusion: Achievable with notice

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b. Alfalfa Seed
There is an inadequate supply of premium organic alfalfa seed to meet demand. There are technical and economic challenges to organic alfalfa seed production which are difficult to solve, in spite of efforts spanning 20 years. Restricting organic farmers to use only organic alfalfa seed is not currently feasible.
Conclusion: Difficult to Achieve

c. Cabbage Seed
Cabbage is grown in all four quadrants of the U.S. with uses covering fresh market, shipping, processing, and storage industries. Each growing region has differing fungal and bacterial pathogens and each industry requires widely different variety specifications. There could be an adequate supply of organic cabbage seed to meet demand. The quality and diversity of available genetics and consistency of organic seed supply in a fixed acreage market with relatively limited variables in density, planting slot, and growing region would make it possible to scale seed supply to sufficiently cover a majority of growers, markets, and slots.
Conclusion: Achievable with notice

d. Carrot Seed
Carrot is grown in all four quadrants of the U.S., requires year-round production, and with uses covering fresh market (baby, bunching) and processing (cut and peel, cello pack). Each growing region has differing fungal and bacterial pathogens, and each industry requires widely different variety specifications.
There is an inadequate supply of organic carrot seed to meet demand. While there are significant genetics to cover certain markets such as early spring planting slots, fresh market use, or Northeastern production, other segments of the market lack appropriate genetics. Additionally, there are technical and economic challenges to organic carrot seed production which are difficult to solve, due to significant Lygus pest pressure and scalability of reliable quality production isolations.
Conclusion: Difficult to Achieve

5. Is current organic seed research meeting industry needs? Which crops/varieties are the most promising avenues for organic seed research?

No, there is not sufficient research to meet the demands of the organic seed sector. Following are some areas where research is needed.

- Organic seed production is often significantly more challenging than conventional seed production, in part due to the length of time the crop needs to be in the ground. Any research into how to better produce organic seed would be valuable.
- In order to properly invest in seed markets including variety development, seed production, and marketing activities, increased reporting is needed on organic acreage by market use, region, and density.
- A better understanding of economic factors such as seed industry consolidation and identifying gaps and opportunities in underserved seed markets would be very helpful.
- Development and production of orphan crops and cover crops that are adapted for organic systems.

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- Research into scalable technologies to achieve quality, disease-free, high-germ, and uniform organic seed to further seed production capacity at the regional level.

6. How can the NOP address the handler role in seed choice, beyond the updates to Guidance 5029 that the NOSB previously recommended? Should the regulations be amended to apply the commercial availability requirements in 7 CFR § 205.204 to handling operations? Should handler Organic System Plans address seed choice? If so, how?

   Shifting the commercial availability requirement to the handler isn't going to solve the issue of increasing organic seed use. We believe the regulations are sufficient as written in placing responsibility for sourcing organic seed and meeting commercial availability requirements on the producer. In instances when a handler supplies seed to a producer, the existing expectation is that the producer will obtain sourcing documentation from them. Requiring the handler to provide this directly to a certifier does not address the underlying challenges we are seeking to solve.

   To get to the root issue of this issue, we must address expectations and oversight in meeting the commercial availability criteria. We must be clear in what is meant by continuous improvement, both for the producer and for the certifier. We offer some reflection on this in our responses to other questions.

7. What additional information do certifiers and inspectors need to effectively enforce the commercial availability requirement (i.e. how would a certifier or inspector know that an organic option is available and must be used)?

   In previous comments on this topic, OTA has emphasized that perhaps the most important tool that can help certified producers, handlers and certifying agents in their efforts to source and evaluate the availability of organic seed and planting stock is a searchable national database of available organic varieties. Attempts to date at establishing a centralized seed database have been inadequate. Renewed discussions need to occur, including the potential for USDA to fund a third-party database that could manage real time data of organic seed inventories. Should a centralized database be realized, it would be extremely helpful for NOP to engage and further serve the organic community by advocating for participation and use of such a database through its marketing materials, certifier trainings and communication channels. Further, NOP could, include an explicit reference in the seed guidance for certifiers, inspectors, and producers to use this database as a seed-sourcing tool. To alleviate concerns of promoting one service over another and to further assist searching efforts, NOP could also include reference to other seed resources. Referencing these tools in AMS marketing materials, guidance and certifier trainings would increase their visibility to certifiers and producers and encourage their use to spur further engagement and investment.

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In addition to referencing existing search tools, we are very interested in the option of having certifiers provide organic seed availability of their certified clients to NOP, in such a way as to include this information in a separate field in the NOP Organic Integrity Database. Operators could then search that field for a specific variety of organic seed, and all certified operations who carry that seed would then be found. If this is feasible, we believe NOP should make such reporting a requirement.

8. How could the NOP (or other entity) make information about commercial availability available publicly? What additional factors could be used to determine that a seed must be used? How could the EU's seed expert panel model inform the U.S. approach?

   See our response above regarding making information about commercial availability available and consistent. In addition to this, it is important to highlight the challenging role certifiers play. Certifiers have the important job of communicating organic seed requirements to organic producers and handlers, granting approval for the use of non-organic seed due to the commercial unavailability of organic seed, issuing non-compliances when adequate searches are not conducted, and reinforcing the need for continuous improvement as appropriate. This job comes with great challenges given the time, resources and complexity involved in verifying a claim that a particular seed variety is "commercially unavailable."

   Consistent implementation of the organic seed requirements and NOP guidance will significantly be improved through training for certifiers and inspectors. OTA appreciates NOSB's willingness to work with ACAs, IOIA and other stakeholders on developing the requirements that should be met as part of a comprehensive training on organic seed use and determination of commercial availability.

9. Who could/should build/maintain a U.S. commercial availability database for seed? What attributes should be listed/made available?

   The Organic Integrity Database has become a widely recognized and broadly used reference in organic certification, by both the certifiers and the trade. As noted above, if it is feasible to include seed availability as a separate field, we would strongly support this.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

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Scott Rice
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Organic Trade Association

cc: Tom Chapman
Co-CEO
Organic Trade Association

Attachments: OTA Comments re: 2018 Strengthening Organic Seed Guidance Proposal
OTA Comments re: 2019 Strengthening Organic Seed and Planting Stock Guidance Proposal

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OTA Comments re: 2018 Strengthening Organic Seed Guidance Proposal

October 4, 2018

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2642-So., Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-18-0029

RE: Crops Subcommittee – Strengthening the Organic Seed Guidance (Proposal)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Crops Subcommittee's Proposal on Strengthening the Organic Seed Guidance. The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Seed is the fundamental starting point for transforming agriculture through nutritious ecologically grown food, feed and fiber, especially when coupled with the principles behind organic production of building healthy soils, using non-toxic inputs, and stewarding natural resources and the environment. As the foundation for organic farming systems, seed deserves continuous attention, from protecting its genetic resources, to preventing contamination, to building a strong organic seed sector that can supply the needs of a diverse and resilient agriculture.

OTA is committed to the development of the organic seed and planting stock industry, and we agree that NOP regulations need to be amended to require demonstrable improvement over time. We also agree that NOP's existing Organic Seed, Annual Seedlings and Planting Stock Guidance (NOP 5029) needs to be revised to support this rule change and reflect the current state of the organic seed industry. Increasing support for organic seed lines through a stronger seed requirement is not only fundamental to improving organic farm systems, it is essential to further reducing unintended GMO presence and limiting the extent to which seeds outside of NOP purview are used and for ensuring the consistent application and enforcement of organic seed requirements.

Summary of OTA's Position
OTA continues to strongly support an amendment to the organic regulations at § 205.204 to require improvement in sourcing and usage of organic seed (continuous improvement) and we support the adjusted language included in the fall 2018 proposal. As a stand-alone motion, we urge NOSB to **pass this section of the proposal** at this meeting.

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The proposal to **revise NOP guidance is close** but needs additional work. OTA thanks the Crops Subcommittee for considering most of the public comments received prior to the fall 2017 meeting and for making many changes accordingly. Although we support most of the proposal, there are a few new additions and an omission we are concerned about. We continue to urge NOSB to clearly state in guidance that conventional untreated seed must be produced without the use of excluded methods. At the same time, we also urge NOSB to leave seed purity considerations out of this document. It muddies the water, introduces a separate proposal that is complex and under construction and may slow up--if not hold back--this proposal from making it through the rulemaking process. We recommend articulating that non-organic seed must not be genetically modified, and referencing the required contamination prevention measures in the organic regulations and associated NOP guidance. This would be a significant improvement to existing seed/planting stock guidance and it will avoid introducing concepts that stakeholders are still working through.

At-a-glance

OTA **disagrees** with the omission of the following language (in bold italics) from the proposal:

- § 4.1.2 Certified operations may use non-organic seed and planting stock only if equivalent organically produced varieties of organic seeds and planting stock are not commercially available, ***and the conventional replacement variety can be documented as being produced without the use of excluded methods[1].***

Although we are in complete support of all efforts to prevent GMO contamination and maintain genetic integrity of seed, we have concerns about including the following sections as stand-alone statements, out of context from their associated guidance:

- § 4.1.2 When there is a risk of excluded-method contamination in seed production, the certified operation may ask the seed supplier for a non-GMO level of purity assurance, and communicate this information to their organic certification agency.
- § 4.1.3 d. Contamination from GMO Consideration: non-organic seed can be used if there is no organic seed available of equivalent variety with the desired level of purity from GMO contamination.

We do not agree with the inclusion of the new language to the fall 2018 proposal:

- § 4.1.2(c) Horticultural crops, which may have specific flavor profiles, size, color or other characteristics, can also be shown to not have an equivalent organic variety through descriptions provided in seed/planting stock catalogs or websites.

Finally, as communicated in our fall 2017 comments, we continue to emphasize that guidance stipulating an **exact number** of sources that should be contacted is less important than describing the criteria or conditions that should help determine the number as it relates to the potential number of suppliers offering the desired organic equivalent variety, AND it must include the dates of organic seed sourcing:

[1] Excluded Methods (genetic engineering), as defined in 7 CFR 205.2 of USDA's organic regulations

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- Minimum of five sources should be contacted;
- These sources must be companies that offer organic seed and planting stock;
- The number of seed or planting stock sources contacted should be relative to the number of companies potentially supplying the organic equivalent variety being procured and to the quantity (commercial vs. backyard) of seed needed;
- Documentation regarding source searching should be maintained as part of record keeping, and should include the dates of organic seed sourcing attempts. Sourcing dates should be verified to confirm the grower attempted sourcing efforts in sufficient time to actually be possible (e.g. 3-6 months for off-the shelf quantities and 12-18 months for large quantities of high-density crops such as baby leaf lettuce, spinach, arugula, kale).

We offer the following more detailed comments:

The intent of the allowance in 7 CFR § 205.204(a) to use non-organic untreated seed under certain conditions was to provide a transition time for the industry while the production of organic seed and planting stock caught up to its demand. Although tremendous strides have been made in the past decade to increase the availability of organic seed and planting stock, improvements in the private and public sector are both needed. The private sector is continuing to work to increase both the production and use of organic seed to meet the diverse and regional demands of organic production, the number of companies supplying organic seed has grown tenfold, and more educational resources and tools exist to support the sourcing and planting of organic seed. Unfortunately, however, in part due to a poor regulatory framework, the existing USDA-NOP seed guidance as written does not reflect the progress that has been made in the organic seed sector since the regulations and the 2005 and 2008 NOSB recommendations were written. Commercial availability is applied inconsistently, and the level at which certifiers monitor and enforce the use of organic seeds and planting stock varies significantly. This greatly hinders efforts.

To help remedy the situation and match the efforts made by industry, it is time that NOP's regulations are amended, and guidance on sourcing organic seed and planting stock is updated. Below we have included a chart with the language proposed in the fall 2017 recommendation and the language included in the revised proposal for this fall 2018 meeting. Following each section are our comments.

**NOTE:* *The language we have included under the column for "Fall 2018 proposal" is taken from the "Crops Subcommittee Proposal" starting on page 196 of the proposal. The language in the proposal is not always consistent with the language suggested in the discussion portion of the document.*

NOP regulation

Fall 2017 proposal	**Fall 2018 proposal**
205.204(a)(1) – ADD: (i) Improvement in sourcing and use of organic seed must be demonstrated every year until full compliance with (a) is achieved.	**205.204(a)(1) – ADD:** (i) Improvement in searching, sourcing and use of organic seed/planting stock must be demonstrated every year with the goal of achieving full compliance in the use of only organic seed/planting stock

OTA Comments: OTA has consistently supported the need to stress the goal of continuous improvement in guidance to improve ongoing efforts to use organic seed and planting stock. We acknowledge, however, that the organic regulations do not explicitly require "improvement." This is problematic

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because the intent of the allowance in 7 CFR § 205.204(a) to use non-organic seed under certain conditions was to provide a transition time for the industry while the production of organic seed and planting stock caught up to its demand. However, 16 years later, the increased use of organic seed and planting stock has been less than robust. Commercial availability has been applied inconsistently since the implementation of the rule, and the level at which certifiers monitor and enforce the use of organic seeds and planting stock varies significantly.

A change to the regulation is a top priority because it signals to the broader organic sector that organic seed is important to organic integrity, and that further investments in organic seed will have a positive ripple effect that leads to more high-quality seed options well suited to organic systems. It's important to note that the revised language will not force farmers to use organic seed that isn't a good fit for their production system and markets. The recommendation simply requires organic operations to take extra measures to demonstrate improvement (searching, sourcing and use) over the years. If a particular variety or type of seed is not available in organic form, an organic operator would not be penalized.

OTA urges NOSB to make a motion and vote to pass the proposed regulatory change separate from the proposal on guidance. We believe the intent of "continuous improvement in use of organic seed" will be adequately expressed to NOP for the purpose of rulemaking, and it is no longer productive to wordsmith the exact proposed language that may appear in the regulation.

NOP Guidance 5029

Fall 2017 proposal	**Fall 2018 proposal**
5029 – 4. Policy: Producers must prevent and avoid contamination from excluded methods in seed of at-risk crops (corn, soybeans, canola, alfalfa, beets, chard, cotton, rice, and summer squash).	**REMOVED**

OTA Comments: Consistent with our fall 2017 comments, we agree with the removal of this recommendation.

NOP Guidance 5029

Fall 2017 proposal	**Fall 2018 proposal**
§ 4.1.2 Certified operations may use non-organic seed and planting stock only if equivalent organically produced varieties of organic seeds and planting stock are not commercially available, **and the conventional replacement variety can be documented as being produced without the use of excluded methods[2].**	§ 4.1.2 Certified operations may use non-organic seed and planting stock only if equivalent organically produced varieties of organic seeds and planting stock are not commercially available. **When there is a risk of excluded-method contamination in seed production, the certified operation may ask the seed supplier for a non-GMO level of**

[2] As defined in 7 CFR 205.2 of USDA's organic regulations - *Excluded methods.* 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

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	purity assurance, and communicate this information to their organic certification agency.

OTA Comments: We disagree with the removal of the language from the fall 2017 proposal. OTA requested this change in our comments on NOP's draft guidance in 2011 and in all of our comments to NOSB on this proposal. NOP 5029 should be amended to reiterate the already existing prohibition on excluded methods because the regulations do not explicitly state that non-organic seed must be non-GMO. Although certification agencies may be clear on this point (and that is good), industry and consumers are not, and it is very helpful to have a formal NOP document to point to. We frequently receive questions and hear from operators pointing to the lack of any specific GE reference to seed in the regulations as well as in the guidance. OTA explicitly requested this language be included because of the lack of clarity we continue to see in organic trade and media channels.

We also do not agree with the replacement language included in the fall 2018 proposal. As we have previously stated, any further language or guidance on protecting or preventing seed from contact with GMOs should simply reference NOSB's recommendation on "Prevention Strategy Guidance for Excluded Methods," NOP's existing guidance on Commingling and Contamination Prevention (NOP 5025), and NOP's Policy on Genetically Modified Organisms (PM 11-13). Trying to include only parts of other guidance under construction may create confusion and hold up rulemaking. We also believe it is premature to make any reference to seed purity in this proposal. From a strategic standpoint, it may hinder the passage of a proposal intended to help increase the usage of organic seed. We are in strong support of all efforts to address the challenges related to GMO seed contamination and genetic seed integrity, but we think it is wise to separate out the topics according to feasibility and push through the low hanging fruit rather than trying to incorporate and solve everything in one document.

NOP Guidance 5029

§ 4.1.2(c) **On-farm variety trials of organic seed may be used by producers to evaluate and document equivalency and quality of varieties that are available. Trials are encouraged and records of results should be kept to show inspectors, but the trials are not mandatory**.	**§ 4.1.2(c) On-farm variety trials of organic seed/planting stock may be used by producers to evaluate and document organic variety/cultivar equivalency to the non-organic item in use. Horticultural crops, which may have specific flavor profiles, size, color or other characteristics, can also be shown to not have an equivalent organic variety through descriptions provided in seed/planting stock catalogs or websites.**

OTA Comments: We agree with the removal of this sentence: "Trials are encouraged and records of results should be kept to show inspectors, but the trials are not mandatory." Adding "but they are not mandatory" in effect discourages a practice (increased organic seed usage) that guidance should be encouraging. At the same time, we are uncertain why the new sentence regarding horticultural crops appeared in this proposal. OTA encourages its removal or at very least a revision. The ultimate flaw with the guidance is that it does not account for various grower types (small, medium, large and crop

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.

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type) and how they acquire seed. Large-scale growers typically do not consult seed catalogs for the characteristics described, especially flavor profiles. In the case of horticultural crops, they have a multitude of sales representatives from seed breeder and distributor companies who service them by putting in trials, taking contracts (either by reserving seed and/or doing contract productions for them), and delivering the seed of the varieties selected from their on-farm trials to them in a timely manner. The data included in seed catalogs will likely not be appropriate because it is generic information that is typically not reflective of subjective traits like 'flavor.' Accordingly, it may not be relevant to the exact bioregion, market and slot in which the grower sourcing seed is growing.

NOP Guidance 5029

Not included, new language was added as "an improvement."	**§ 4.1.2(d) Documentation of these trials must be available at the annual inspection. This documentation should include which seed characteristics are desired, and be based upon the varietal benefits of the current non-organic seed/planting stock in use. The varietal characteristics discovered during the on-farm trail, of both the non-organic seed/planting stock and the organic seed/planting stock trialed, can be tracked in a simple table or spreadsheet detailing the specific characteristics sought, and whether or not the various varieties grown contained those characteristics.**

OTA Comments: OTA supports the intent behind this new language. Reporting trial performance, when performed, should be feasible considering of all the trialing that is occurring on professional farms/greenhouses. For example, in the Salinas Valley area, there are over 35 companies putting in over 100 trials per large-scale grower. These trial results are detailed, and can be readily transferred to an inspector during the certification process.

NOP Guidance 5029

4.1.3 The following considerations could be acceptable to justify use of non-organic seeds..... **d. Contamination from GMO consideration: non-organic seed can be used if organic seed cannot be sourced because of GMO contamination.**	**§4.1.3 d. Contamination from GMO Consideration: non-organic seed can be used if there is no organic seed available of equivalent variety with the desired level of purity from GMO contamination.**

OTA Comments: We continue to be concerned about formalizing such justification in NOP Guidance. The comments OTA submitted in fall 2017 represented many stakeholders including organic seed producers, certifiers and organic seed advocacy organizations. As we stated in those comments, the use of excluded methods (GMOs) is prohibited in organic production, and handling and organic agricultural products should have minimal if any GMO contamination. A proposal for guidance that formally recognizes contaminated organic seed (at some level above desired purity) as an acceptable reason to use non-organic seed contradicts basic production principles, disincentives the requirement to produce and use organic (non-GMO) seed, and it does not acknowledge certifying agents' roles in determining whether GMO contaminated seed is non-compliant or a result of unavoidable contact. **The revised language only makes it more problematic because of the reference to "desired level of purity."** This

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will be very hard for producers and handlers to understand and verify. Without the establishment of a seed purity standard, it makes an already challenging compliance determination even harder. We do not believe this proposed language is needed nor helpful in this guidance, and we strongly urge the subcommittee to remove it.

NOP Guidance 5029

§ 4.2.1 b 1. Evidence of efforts made to source organic seed, including *i.* Documentation of contact with three or more seed or planting stock sources to ascertain the availability of equivalent organic seed or planting stock. **Five sources must be contacted for seed of at-risk crops.** **ii.** Sources should include companies that offer organic seeds and planting stock. **Such sources should provide evidence of their organic certification (if relevant), ability to source organic seed, and specific varieties sourced every year.** **iii. Failure to demonstrate improvement in sourcing organic seed over time may result in additional seed sources being required or additional steps taken to procure organic seed.** **3. If seed sourcing is carried out or mandated by the buyer of a contracted crop, the producer must keep records of the buyer's documentation on attempting to source organic seed as part of the producer's own Organic System Plan. Such documentation must be comparable to that required of a producer who sources their own seed.**	**§ 4.2.1 b** 1. Evidence of efforts made to source **organic seed/planting stock**, including **i. At least five documented sources must be contacted for seed/planting stock of all crops when this number of sources is available for an equivalent variety or cultivar.** **ii. Sources must include companies that offer organic seeds and planting stock.** **iii. Failure to demonstrate improvement in sourcing organic seed/planting stock over time may result in additional seed sources being required or additional steps taken to procure organic seed/planting stock, by the organic certifier.** **3. If seed/planting stock is sourced or mandated by the buyer of a contracted crop, the producer must obtain sourcing information and documentation from the contracted buyer. The buyer's attempts to source organic seed/planting stock then becomes part of the producer's Organic System Plan. Such documentation must be comparable to that required of the producer who sources their own seed/planting stock.**

OTA Comments: OTA supports the change specifying a ***minimum*** of five sources should be contacted. However, we continue to stress that guidance stipulating an **exact number** of sources that should be contacted is less important than describing the criteria or conditions that should help determine the number as it relates to the potential number of suppliers offering the desired organic equivalent variety. For this reason, we support the criteria added to this proposal with the understanding that a **minimum of five sources must be contacted AND they must be companies that offer organic seed**. **Additionally, if only three companies with organic seed or planting stock exist, a certified operator should not be penalized for not contacting FIVE.**

In our fall 2017 we suggested the following language:

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- Minimum of five sources
- These sources must be companies that offer organic seed and planting stock.
- The number of seed or planting stock sources contacted should be relative to the number of companies potentially supplying the organic equivalent variety being procured and to the quantity (commercial vs. backyard) of seed needed.

In addition to this suggested sourcing criteria, we also emphasize the need for the guidance to address the dates of organic sourcing attempts. It is important that growers report the date of the inquiry they made to a seed supplier by variety/quantity and the response of the company on the data of inquiry. In our fall comments, we requested that the following criteria also be included in the proposal. As it relates to "evidence of efforts made to source organic seed/planting stock," we urge NOSB to reconsider adding the following language to the proposal:
Certified operations should contact seed or planting stock sources to ascertain the availability of organic seed or planting stock for all crops grown.

- Documentation regarding this search should be maintained as part of record keeping, and should include the dates of organic seed sourcing attempts. Sourcing dates should be verified to confirm the grower attempted sourcing efforts in sufficient time to actually be possible (e.g. 3-6 months for off-the shelf quantities and 12-18 months for large quantities of high-density crops such as baby leaf lettuce, spinach, arugula, kale).

With respect to the role of the buyer/handler sourcing seed (**§ 4.2.1 (b)(3))**, we support the changes made. Buyers are often certified handlers who contract with producers to grow certain varieties often not available as certified organic. If a certified handler (buyer) mandates a particular variety to be planted ***and the buyer/handler is responsible for sourcing the seed***, the certified handler should be held responsible for determining if the variety is commercially available as organic, and this information should be included in the producer's Organic System Plan. Specifically stating that the buyer's attempt to source organic seed must become part of the Organic Systems Plan is critical, and will support growers in their ability to collect this information. We want to acknowledge that with the proposed revision to the regulation (requiring continuous improvement), the buyer would also need to demonstrate and document (for the organic producer) improvement in searching, sourcing and use of organic seed/planting stock every year with the goal of achieving full compliance in the use of only organic seed/planting stock.

NOP Guidance 5029

4.4.4 Certifying agents should review an operation's progress in obtaining organic seeds, planting stock and transplants by comparing current source information to previous years **a. If sufficient progress is not demonstrated, a certifying agent may ask for a corrective action plan and require additional seed sources be researched, encourage variety trials, or require additional steps to procure organic seed**. **b. Non-compliances should be issued for repeated lack of progress in sourcing organic seed over time**.	4.4.4 Certifying agents should review an operation's progress in obtaining organic seeds, planting stock and transplants by comparing current source information to previous years **a. If sufficient progress is not demonstrated, a certifying agent may ask for a corrective action plan and require additional seed sources be researched, encourage variety trials, or require additional steps to procure organic seed**. **b. Non-compliances should be issued for repeated lack of progress in sourcing and using commercially available organic**

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	seed/planting stock over time. Judgment of a non-compliance can include, but is not limited to, the certifier's communication detailing commercially availability organic seed/planting stock and continued nonuse by the farmer, the producer's lack of on-farm seed trials for judging equivalency between non-organic seed and organic seed, and organic seed searches that do not include suppliers who carry organic seed.

OTA Comments: OTA supports the continued inclusion of 4.4.4 (a) and we do not take issue with the new language added in 4.4.4(b).

NOP Guidance 5029

4.4.5 Certifying agents should review the prevention measures taken to avoid contamination for seed of at-risk crops.	**4.4.5 Certifying agents should review the prevention measures taken to avoid contamination for seed of crops at-risk of GMO contamination.**

OTA Comments: OTA agrees with continuing to include this recommendation as slightly revised.

OTHER TOPICS

Organic Seed Finder

OTA thanks the Subcommittee for providing its thoughts and suggestions on this topic. OTA again emphasizes that perhaps the most important tool that can help certified producers, handlers and certifying agents in their efforts to source and evaluate the availability of organic seed and planting stock is a searchable national database of available organic varieties. We continue to support the use the Organic Seed Finder (www.organicseedfinder.org) as a primary resource for national organic seed availability data. As we have expressed in previous comments, it would be extremely helpful if NOP would engage and further serve the organic community by advocating for the participation and use of the Organic Seed Finder through its marketing materials, certifier trainings and communication channels, and by including an explicit reference in the seed guidance for certifiers, inspectors, and producers to use this database as a seed-sourcing tool. To alleviate concerns of promoting one service over another and to further assist searching efforts, NOP could also include reference to other helpful seed resources such as Pick A Carrot (https://www.pickacarrot.com/), ATTRA Directory of Organic Seed Suppliers (https://attra.ncat.org/attra-pub/organic_seed/) and SeedWise (https://www.seedwise.com/). Referencing these tools in AMS marketing materials, guidance and certifier trainings would increase their visibility to certifiers and producers, and encourage their use to spur further engagement and investment.

In addition to referencing existing search tools, we are very interested in the option of having certifiers provide organic seed availability of their certified clients to NOP, in such a way as to include this information in a separate field in the NOP Organic Integrity Database. Operators could then search that field for a specific variety of organic seed, and all certified operations who carry that seed would then be

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found. If this is feasible, we believe NOP should make such reporting a requirement.

Accredited Organic Certifier and Organic Inspector Training
As stated in our fall 2017 comments, certifiers have the important job of communicating organic seed requirements to organic producers and handlers, granting approval for the use of non-organic seed due to the commercial unavailability of organic seed, issuing non-compliances when adequate searches are not conducted, and reinforcing the need for continuous improvement as appropriate. This job comes with great challenges given the time, resources and complexity involved in verifying a claim that a particular seed variety is "commercially unavailable."

Consistent implementation of the organic seed requirements and NOP guidance will significantly be improved through trainings for certifiers and inspectors. OTA's appreciates NOSB's willingness to work with ACAs, IOIA and other stakeholders on developing the requirements that should be met as part of a comprehensive training on organic seed use and determination of commercial availability.

Conclusion
OTA strongly supports an amendment to the NOP regulations to require demonstrable improvement over time, and we urge NOSB to pass this part of the proposal at this meeting. We also strongly support the need to revise NOP's Organic Seed, Annual Seedlings and Planting Stock Guidance (NOP 5029) to not only support this rule change but to reflect the current state of the organic seed industry. We recommend additional work on the proposed revisions to guidance.

OTA is committed to and strongly supports the further development of the organic seed and planting stock industry. We also are committed to finding solutions to meet this objective. The goal of our efforts should be to promote the continued growth and improvement in organic seed and planting stock production, and subsequent usage by organic growers without hurting or putting undue burdens on growers. The intent is not to have non-compliances handed down to farmers trying to comply with the seed and planting stock commercial availability section of the Rule. Instead, the intent is to maintain NOP guidance that will help ensure the consistent application and enforcement of organic seed requirements, which, in turn, will promote the breeding, development and production of a greater diversity of varieties well suited for organic production systems.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your continuing work in this important area.

Respectfully submitted,

Gwendolyn V. Wyard

Gwendolyn Wyard
Vice President, Regulatory and Technical Affairs
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO

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OTA Comments re: 2019 Strengthening Organic Seed and Planting Stock Guidance Proposal

April 4, 2019

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2642-So., Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-18-0071

RE: Crops Subcommittee – Strengthening Organic Seed and Planting Stock Guidance (Proposal)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Crops Subcommittee's Proposal on Strengthening the Organic Seed Guidance.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Seed is the fundamental starting point for transforming agriculture through nutritious ecologically grown food, feed and fiber, especially when coupled with the principles behind organic production of building healthy soils, using non-toxic inputs, and stewarding natural resources and the environment. As the foundation for organic farming systems, seed deserves continuous attention, from protecting its genetic resources, to preventing contamination, to building a strong organic seed sector that can supply the needs of a diverse and resilient agriculture.

OTA is committed to the development of the organic seed and planting stock industry, and we are delighted that NOSB passed a recommendation at the fall 2018 meeting to be amend the organic regulations at § 205.204 to require demonstrable improvement of organic seed usage over time. We also agree that NOP's existing Organic Seed, Annual Seedlings and Planting Stock Guidance (NOP 5029) needs to be revised to support this rule change and reflect the current state of the organic seed industry. Increasing support for organic seed lines through a stronger seed requirement is not only fundamental to improving organic farm systems, it is essential to further reducing unintended GMO presence and limiting the extent to which seeds outside of NOP purview are used, and for ensuring the consistent application and enforcement of organic seed requirements.

The Organic Trade Association largely supports the Subcommittee's proposal and we encourage the full Board to pass it at this meeting.

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With a couple of concerns noted below, we thank the subcommittee for making the following changes from the fall 2018 version:

- The guidance now states that conventional untreated seed must be produced without the use of excluded methods[3]. The Organic Trade Association strongly agrees; it is important that this requirement is explicitly stated in Guidance.

- Seed purity considerations are dealt with in a separate document. This should allow for this proposal to move forward as work on seed purity continues.

- The following language was removed from **4.1.2(c):** *Horticultural crops, which may have specific flavor profiles, size, color or other characteristics, can also be shown to not have an equivalent organic variety through descriptions provided in seed/planting stock catalogs or websites.* We agree with the removal of this language; however, we remain disappointed about the reference to seed catalogs without a qualifier. The guidance continues to not account for various grower types (small, medium, large and crop type) and how they acquire seed. As we stated in our previous comments, large-scale growers typically do not consult seed catalogs for the characteristics described, especially flavor profiles. In the case of horticultural crops, they have a multitude of sales representatives from seed breeder and distributor companies who service them by putting in trials, taking contracts (either by reserving seed and/or doing contract productions for them), and delivering the seed of the varieties selected from their on-farm trials to them in a timely manner. The data included in seed catalogs will likely not be appropriate because it is generic information that is typically not reflective of subjective traits like 'flavor.' Accordingly, it may not be relevant to the exact bioregion, market and slot in which the grower sourcing seed is growing.

- The proposal retains "three" as the minimum number of seed sources that should be contacted instead of our recommended "five." The Organic Trade Association would have liked to see the number increase to "five." However, the **exact number** of sources that should be contacted is less important than describing the criteria or conditions that should help determine the number as it relates to the potential number of suppliers offering the desired organic equivalent variety. The search and procurement methods for sourcing organic seed and planting stock provided in 4.2.1((b)(1)(i-vii) are very valuable, and we do not take issue with this final approach.

Additionally, the Organic Trade Association supports:

- **The final language included in 4.1.2(d):** Documentation of on-farm trials or seed characteristic searches can be provided at the annual inspection. This documentation can

[3] As defined in 7 CFR 205.2 of USDA's organic regulations - *Excluded methods.* 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.

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include which seed characteristics are desired, and be based upon the varietal benefits of the current non-organic seed/planting stock in use. The varietal characteristics discovered during the on-farm trail, of both the non-organic seed/planting stock and the organic seed/planting stock trialed, can be tracked in a simple table or spreadsheet detailing the specific characteristics sought, and whether or not the various varieties grown contained those characteristics.

- **The guidance explaining the role and requirements of seed/planting stock that is sourced or mandated by the buyer of a contracted organic crop (4.2.1(b)(3).** If seed/planting stock is sourced or mandated by the buyer or handler of a contracted organic crop, the producer must obtain sourcing information and documentation from the contracted buyer/handler. The buyer's attempts to source organic seed/planting stock then becomes part of the producer's Organic System Plan.

- **The guidance on the information certifiers should review to evaluate progress in obtaining organic seeds, planting stock and transplants (4.4.4)**. We appreciate the guidance provided on requesting corrective action plans and acting on repeated lack of progress. This of course all needs to be carried out in a sound and sensible manner by certifiers working closely with their certified operators.

- **The use of an organic seed/planting database.** OTA again emphasizes that perhaps the most important tool that can help certified producers, handlers and certifying agents in their efforts to source and evaluate the availability of organic seed and planting stock is a searchable national database of available organic varieties. We continue to support the use the Organic Seed Finder as a primary resource for national organic seed availability data. We are also very interested in the option of having certifiers provide organic seed availability of their certified clients to NOP, in such a way as to include this information in a separate field in the NOP Organic Integrity Database. Operators could then search that field for a specific variety of organic seed, and all certified operations who carry that seed would then be found. If this is feasible, we believe NOP should make such reporting a requirement.

- **Support for Organic Certifier and Inspector Trainings.** Certifiers have the important job of communicating organic seed requirements to organic producers and handlers, granting approval for the use of non-organic seed due to the commercial unavailability of organic seed, issuing non-compliances when adequate searches are not conducted, and reinforcing the need for continuous improvement as appropriate. This job comes with great challenges given the time, resources and complexity involved in verifying a claim that a particular seed variety is "commercially unavailable." Consistent implementation of the organic seed requirements and NOP guidance will significantly be improved through trainings for certifiers and inspectors as well as through best practices. OTA's appreciates NOSB's continued support in this area.

Conclusion

The Organic Trade Association strongly supports the further development of the organic seed and planting stock industry, and we are committed to finding solutions to meet this objective. The goal of our efforts should be to promote the continued growth and improvement in organic seed and planting stock production, and subsequent usage by organic growers without hurting or putting undue burdens on growers. The intent is not to have non-compliances handed down to farmers trying to comply with the

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seed and planting stock commercial availability section of the Rule. Instead, the intent is to have an organic regulation that explicitly supports continuous improvement and NOP guidance that will help ensure the consistent application and enforcement of organic seed requirements. This in turn will promote the breeding, development and production of a greater diversity of varieties well suited for organic production systems.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your continuing work in this important area.

Respectfully submitted,

Gwendolyn Wyard
Vice President, Regulatory and Technical Affairs
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
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September 30, 2024

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-24-0023

RE: Celery Powder—Handling Subcommittee 2026 Sunset Reviews

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the 2026 Sunset Review of celery powder listed on 205.606 of the National List (7 CFR § 205.606 - non-organically produced agricultural products allowed as ingredients in or on process products labeled as organic).

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, brands, retailers, and others. OTA's mission is to grow and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

The Organic Trade Association supports the continued listing of celery powder on the National List due to the fact that it remains an essential ingredient used in processed organic meat products. Since the last sunset review, much work has been done to develop organic sources of celery or alternative vegetable powder. However, at this time an organic alternative is not yet commercially available. Celery powder has been in use for over a decade as a “curing” agent in certain processed meat products as an alternative to sodium and potassium nitrate and nitrite. Since 2007, conventionally grown celery powder has been allowed for use in certified organic meat products. Since 2010, the organic sausage/deli category has grown at a compound annual growth rate (CAGR) of 29.8% to an estimated $198 million in 2022. Despite this growth, the organic meat category as a whole still only represents .8% of all retail meat sales in the US and represents the least penetrated organic food category (by comparison, total food is 4.3% of the total US retail food market). As the demand for organic processed meats increases, the organic industry wants to replace the use of conventional celery powder with an organic alternative.

Work continues to build an adequate and stable supply of organic celery powder for the organic cured meat industry. Our sister organic research organization, The Organic Center, is engaged in an ongoing joint project with the University of Wisconsin-Madison and the University of Florida entitled Organic Alternatives to Conventional Celery Powder. Funded by a USDA Organic Research and Extension Initiative Grant, the project aimed to address this critical issue with four objectives:

1. Assessment of nitrogen (N) fertility, genetics, and environment on nitrate levels in organic celery, chard, and beets
2. Sensory and quality evaluation of cured meat products using organic vegetable powder
3. Economic and market assessment of organic celery powder and cured meat products
4. Extension of results.

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The long-term goal of the project aims to enhance the capacity of farmers and processors to profitably produce high quality organic processed meat products, while providing economic, agronomic, and environmental benefits to organic crop rotations. While ideally we would have seen further progress on the great work already accomplished, the COVID pandemic set back this and many research projects, losing vital field seasons and research hours. With the pandemic largely behind us, we look forward to this work continuing in earnest.

The research conducted by the University of Wisconsin-Madison and the University of Florida has demonstrated that celery and Swiss chard with adequate levels of tissue nitrate can be produced, using rates of nitrogen fertilizer greater than rates used for standard production of table celery. Higher rates of nitrogen fertilizer, to our knowledge, is also used to produce conventional curing powders. However, these higher rates can likely be managed through cover cropping in ways that minimize negative environmental impacts, although more research is required to confirm best management practices depending on soil type, crop rotation, and environment. While research in two major production regions has generated recommendations for appropriate nitrogen fertility in these environments, more data is needed from working farms to validate these results across more harvest conditions as well.

While organic sources of curing powders are now available, concerns remain with respect to the feasibility of these sources meeting the needs of the entire organic meat processing industry. These concerns include the availability and consistency of supply, as well as understanding the season-to-season variability between sources, for which we need further research. Current research has also investigated the impact of organic curing powders on processed organic meat quality and food safety. Work at UW-Madison demonstrated that organic sources of curing powders produce equivalent food safety and quality parameters as compared to conventional sources. However, more work is needed in partnership with industry to optimize formulas to account for the novel organic curing powder sources.

To further scale up supply, more research is also required to understand how to optimize the fermentation of the organic juices to produce the nitrate used in curing powders. New technologies are being explored to produce the high-quality, consistent product required by industry using organically-allowed practices. In addition to fermentation research, scaling up supply also requires a continued assessment of transportation and processor/handler logistics to ensure consistent product quality. Finally, concurrent with—or in addition to—ramping up supply, processors of cured meat products will require time to trial alternatives to ensure products meet the taste and consistency consumers expect.

Results of OTA Outreach

In addition to the research noted, OTA used our online sunset surveys (see Appendix A) to solicit feedback from certified operations to determine the continued need for celery powder, as well as to address specific questions posed by the Board. OTA posted online sunset surveys for each input under review as part of the 2026 Sunset Review cycle. These surveys are open to any NOP certified organic operation and include questions addressing the necessity of each input, as well as any questions posed by the Board. The names of the companies submitting the information remain confidential and are not disclosed to OTA unless there is interest in providing contact details for follow-up information.

Below is a summary of the feedback OTA has received celery powder during this sunset cycle.

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Substance	Summary of Responses
Celery powder	Responses received from certified organic producers and processors of cured meat products **Use** - In a variety of processed meat products that carry the "uncured" label, as required by USDA-FSIS. This includes hot dogs (beef and turkey), meat sticks, summer sausage logs, deli ham, summer sausage, pepperoni, pork bacon and half hams. Celery powder provides additional attributes to curing, including maintaining a pink color, flavor, and stability of the finished product. **Have you tried alternative substances or management practices?** - See other comments **How necessary is this substance to your operation?** - Essential **NOSB questions to stakeholders** **1. Is there stakeholder concern about ongoing non-specified ancillary substances used in this material?** - We are unaware of ancillary substances in celery powder. **2. Is organic supply commercially available for this material? What are the barriers to organic production?** - Wenda Ingredients (Suzhou China) offers NOP certified organic celery powder and organic celery juice powder. The celery is grown in Chile then shipped to China for production. When referencing 606, we also noticed they offer organic beet powder and organic beet juice powder. **3. Is the organic version of the same caliber as the nonorganic?** - Prosur in Spain (Prosur - Get it Natural) offers EU organic plant-based curing agents. This product works best with poultry and ham. Since less effective with other pork products, its use would be limited in our business.

As evidenced by the results of the work to date, the Organic Trade Association, The Organic Center, our research partners, and cured meat processors are committed to help the industry innovate and proactively take steps to transition to an organic form of celery or vegetable powder. However further work and investment is necessary to scale up production, diversify raw and processed suppliers, and ensure there is product consistency before removing celery powder from § 205.606 of the National List.

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

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Scott Rice
Sr. Director, Regulatory Affairs
Organic Trade Association

cc: Tom Chapman, co-CEO
Organic Trade Association

Appendix A – OTA Sunset Survey on Celery Powder

- What products do you use this on?
- Have you tried using any alternative substances (e.g., other substances that are on the National List and/or other natural substances) or management practices?
- How necessary is this substance to your operation:
    - Not Necessary
    - Somewhat necessary
    - Essential
- Optional: Please provide any additional context and/or contact information so we can follow up with any questions.

NOSB Questions to Stakeholders

1. Is there stakeholder concern about ongoing non-specified ancillary substances used in this material?
2. Is organic supply commercially available for this material? What are the barriers to organic production?
3. Is the organic version of the same caliber as the nonorganic?

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