NATIONAL ORGANIC COALITION



April 4, 2019

National Organic Standards Board
USDA – AMS
1400 Independence Ave, SW
Washington, DC 20250

**RE: AMS-NOP-18-0071**

## Comments to the National Organic Standards Board

April 2019
Seattle, WA

National Organic Standards Board:

The National Organic Coalition (NOC) is a national alliance of organizations working to provide a "Washington voice" for farmers, ranchers, environmentalists, consumers and industry members involved in organic agriculture. NOC seeks to advance organic food and agriculture and ensure a united voice for organic integrity, which means strong, enforceable, and continuously improved standards to maximize the multiple health, environmental, and economic benefits that organic agriculture provides. The coalition works to assure that policies are fair, equitable, and encourage diversity of participation and access.

NATIONAL ORGANIC COALITION

## Contents

## OVERSIGHT & ENFORCEMENT

The lack of consistent enforcement and clear standards in multiple sectors of the organic industry is harming U.S. farmers and putting some organic farms out of business. The purpose of the organic law and the regulations is to ensure clear and consistent standards and a level playing field. Organic operations expect fairness, and consumers expect integrity. The USDA is failing to deliver on this promise.

The National Organic Coalition appreciates the work of the NOSB, the USDA National Organic Program, certifying organizations, industry participants, and many other organic stakeholders to address organic import fraud. We are pleased that the 2018 Farm Bill bolsters the USDA's authority, resources, and responsibilities with the goal of stopping the flow of fraudulent organic products into the United States. We expect the USDA to move forward swiftly to implement these Farm Bill provisions. NOC looks forward to partnering with the NOSB and USDA in that process.

Concurrently with this, the USDA must enforce the pasture rule and finalize the 2015 regulation to clarify the rules pertaining to the transition of conventional dairy livestock into organic production ('Origin of Livestock'). In 2013, the USDA Office of Inspector General highlighted this lack of consistency in the interpretation of Origin of Livestock rules by certifiers in its report[1] on organic milk operations. Yet, six years later we are still waiting for USDA to restore fairness. Organic dairy producers who abide by the letter and spirit of the regulations are paying the price. In some cases, they are no longer in operation due, in part, to unfair competition from operations making use of loopholes.

Against the will of the organic community, USDA has refused to enforce true outdoor access for organic poultry. As a result, consumers are seeking out other labels, such as "pastured." In addition, USDA is inadequately enforcing biodiversity and soil health provisions within the organic standards. NOC is dismayed that entire systems of production are being certified in the absence of clear standards to govern their compliance with the organic law. NOC is deeply concerned about the continued certification of hydroponic and container production systems in the absence of standards.

These enforcement challenges demand regulatory action. Participation in the organic program is voluntary and new regulations apply only to those farmers who have opted into organic production. NOC urges this administration to protect organic farmers and the industry by moving forward in 2019 to issue a proposed rule on enforcement for organic imports and to finalize the 2015 proposed rule on Origin of Livestock. NOC is urging a moratorium on all new certifications of operations for which there are no clear standards, including hydroponic and container production operations.

We are calling on the organic community to seek unity in our efforts to respond to this crisis of confidence in the organic program from both farmers and consumers.

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[1] USDA Office of Inspector General (2013). *Agricultural Marketing Service National Organic Program – Organic Milk Operations, Audit Report 01601-0002-32*. Retrieved from USDA website: https://www.usda.gov/oig/webdocs/01601-0002-32.pdf

## PEER REVIEW

NOC urges the NOSB to call on the USDA National Organic Program to make public the results of the 2018 peer review audit, which contains information about the NOP's oversight and accreditation process for certifiers. Based on the information shared by the NOP at the St. Paul NOSB meeting, we understand that:

- The NOP does not have a sufficient number of auditors to oversee accreditation functions.
- Certifier satellite offices are not audited frequently enough.
- Procedures for residue sampling are not clearly understood or followed by international certifiers and satellite offices.
- NOP has insufficient personnel to handle complaints and enforcement actions.

These are just a few of the serious problems identified by the peer review audit, but a complete understanding is not possible without access to the full report. According to a 2014 Memorandum to the NOSB[2] pertaining to peer review audits, the NOP procedure is to post a copy of the peer review panel report and the NOP response on the NOP website. This step is essential to ensure full transparency and full information regarding the outcome of the 2018 peer review audit of the NOP's accreditation functions.

NOC believes the NOP exerts too much control over several aspects of the peer review audit process. For example, by appointing members of the panel, controlling which files will be reviewed, and determining what questions the panel can consider.

For truly independent and effective oversight, members of the peer review panel must have demonstrated knowledge of organic certification and accreditation and should use a risk-based focus of review (for example, by examining NOP accreditation of international certifiers and satellite offices for high-risk regions).

A current area of risk is the proliferation of certified hydroponic and container production operations. NOC calls on the NOSB to request that the 2019 peer review audit examine the accreditation process for certifying agencies that certify operations in the absence of clear standards, including hydroponic and container operations.

[2] McEvoy, M. (November 19, 2014). *National Organic Program Accreditation Peer Review Process* [Memorandum]. Washington, DC: U.S. Department of Agriculture. Retrieved from: https://www.ams.usda.gov/sites/default/files/media/NOSB%20Memo%20NOP%20Accreditation%20Peer%20Review%20Process.pdf

For the peer review audit process to be effective, the peer review entity must have the ability to track the NOP's corrective actions and compliance with issues that have arisen in previous peer review audits. The NOP's compliance with recommendations from the 2016, 2017, and 2018[3] peer review audits should be considered as a part of the 2019 peer review audit. The peer review panel membership should be determined by an outside entity, which might include members of the NOSB, and it should have the authority to request any files and look at any certifiers that it judges to be appropriate.

## LIMITED COMMENT PERIOD

NOC would like to reiterate our concerns and echo those voiced by many others in the organic community regarding the unsatisfactory limited comment period, given the breadth and depth of the materials published. This is a recurring problem and continues to be cause for concern. We appreciate the hard work the Board members have put in to prepare the materials, and we want to give each comment the attention needed to provide thorough and valuable feedback. To do anything less would be disrespectful of the Board's time and efforts, as well as the process as a whole. This process depends on a high level of stakeholder engagement and expertise. The limited comment period detracts from the quality and thoroughness of stakeholder input.

## POLICY DEVELOPMENT SUBCOMMITTEE (PDS)

### Transparency, Open Docket, & Subcommittee Notes

NOC would like to thank the NOSB and NOP for the expanded use of the open docket as a means of communication between the Fall 2018 and Spring 2019 meeting, and would like to encourage the continuation and expansion of this practice. We have heard many times over that the NOSB members are in favor of publishing discussion documents and proposals as available. We understand that documents require final approval before publication, and we encourage the NOP to work expeditiously to structure the approval process to make NOSB materials available earlier in the process when possible.

In addition, we encourage further implementation of the open docket in a way that encourages the NOSB members and subcommittees to solicit information on specific issues from the public between official comment periods. We feel it would be most appropriate for organic stakeholders to be made aware of these publications to the open docket via an Organic Insider email alert.

We would also like to thank the NOP for reinstating the publication of the subcommittee notes. In the absence of published materials, or materials that continue to be published later than anticipated, the subcommittee notes provide the only information available regarding upcoming discussion documents

[3] Peer review audits are posted online to the USDA website here: https://www.ams.usda.gov/reports/2016-peer-review-ams-national-organic-program

and proposals, as well as sunset materials. As noted in our fall 2018 comments, this is not only a matter of transparency, but a matter of law. The General Records Schedule 6.2[4] "covers Federal records created or received by Federal advisory committees and their subgroups pursuant to the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended) and records related to the management of these committees by their sponsoring agencies or departments." These requirements mean that records of subcommittees of FACA committees must be maintained "permanently" and be made available to the public. This includes meeting minutes.

# MATERIALS SUBCOMMITTEE (MS)

## Proposals

### Excluded methods determinations

NOC appreciates the subcommittee's effort to clarify transposons as part of the excluded methods list and discussion, as well as the definitions for cisgenesis and intragenesis. We hope that future proposals and discussion documents on this topic include the excluded methods definition under 7 CFR 205.2 to provide relevant context for the organic community in addition to a clear statement with citations justifying the subcommittee's decision to move a method to the excluded category.

NOC supports and is in full agreement with the comments submitted to the Board from the Organic Seed Alliance.

**We support the general approach of this proposal but recommend clarifying that transposons are not a method. We offer the following clarifications in response to the proposal at hand:**

**Transposons**

Transposons are naturally occurring DNA sequences that are activated by stress on a genome. They are an evolutionary mechanism that, when activated under stress, create diversity in a species to allow quicker and better adaptation to that stress. The plant breeding community is still learning how transposons work and ways to activate and direct them in noninvasive ways.

**We recommend that transposons not be listed in a table of excluded methods since they are technically not a method. Instead, the subcommittee should focus only on the methods for activating or directing transposons in ways that do not occur in nature. Transposons should then be referenced as part of the descriptions for these methods and/or in the notes section.**

Transposons can be separated into three categories:

[4] https://www.archives.gov/records-mgmt/grs/grs06-2.pdf. The PPM, page 12, requires, "Records of the NOSB shall be defined and handled in accordance with General Records Schedule 6.2 or other approved agency records disposition schedule."

1. Activation of transposons under natural physical stress conditions (e.g., drought or heat). Because these activities are naturally occurring, and activate naturally occurring transposons, there is no need to list this in the table of methods.

2. Transposons activated or directed through in vitro techniques should be excluded because this method fits the definition of "modern biotechnology," as defined in the 2018 fall proposal on the same subject.

3. Transposons activated under chemical and radiation stress warrants further evaluation as part of the "induced mutagenesis" discussion document on this meeting's agenda, since allowing or disallowing chemical/radiation-induced mutations affects both the determination for induced mutagenesis and the activation of transposons under these types of stress.

**Definition for cisgenesis and intragenesis**
We support updating the definitions to the excluded methods terminology chart for cisgenesis and intragenesis with those provided in the proposal:

Cisgenesis: The gene modification of a recipient plant with a natural gene from a crossable sexually compatible-plant. The introduced gene includes its introns and is flanked by its native promoter and terminator in the normal-sense orientation.

Intragenesis: The full or partial coding of DNA sequences of genes originating from the sexually compatible gene pool of the recipient plant and arranged in sense or antisense orientation. In addition, the promoter, spacer, and terminator may originate from a sexually compatible gene pool of the recipient plant.

NOC is very supportive of clarifying the terminology used for making determinations regarding which methods are excluded in organic production systems. We appreciate that this topic remains a priority for the Materials/GMO Subcommittee. This work will provide more clarity to the organic farming and research communities, as well as the organic seed trade.

## Discussion Documents

### Induced mutagenesis

NOC appreciates the subcommittee's effort to clarify which plant breeding methods should be excluded from organic production. The methods at issue in this discussion document are those that induce mutations in plants, including heat, UV light, chemicals, irradiation, and x-rays. Tackling the various methods used to induce mutagenesis is terribly difficult because the organic community doesn't readily know the following:

- How frequently these various methods are used in plant breeding programs;

- The extent to which organic growers rely on varieties developed with these methods;

- How difficult it would be to create a system for tracing these methods to finished varieties in the marketplace; and

- What ramifications there would be on variety options available to organic growers should induced mutagenesis be wholly excluded.

The answers to these questions are important from an enforcement standpoint since the Crops Subcommittee's proposal, "Strengthening the Organic Seed Guidance April 2019," at **4.1.2** recommends that "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."** Seed companies would be greatly challenged to provide, and at times would be unable to provide, this documentation for some methods that have been determined, or may soon be determined, as excluded, including those developed through induced mutagenesis.

Given the limited comment period, were we unable to give this important topic the attention it deserves. We look forward to providing more detailed comments in the future.

## Embryo transfer in livestock

NOC has many concerns regarding embryo transfer in livestock. One of our main concerns is reduced genetic variability: The relatively small gene pool sourced from the donor cows may have a negative impact in the future, especially in reference to rare breeds. Genetic homogeneity is far worse in animals than in plants.

Given the limited comment period, were we unable to give this important topic the attention it deserves. We look forward to providing more detailed comments in the future.

## Assessing cleaning and sanitation materials used in organic crop, livestock and handling

NOC is pleased to see the discussion document outlining plans for a comprehensive review of sanitizers, disinfectants, and cleaners. We agree this will be an important tool to evaluate essentiality, consider the availability of either approved synthetic or natural alternatives to the current or proposed National List (NL) materials, and evaluate materials under the OFPA and NOP regulatory criteria for inclusion on the NL.

The discussion document notes, "there is universal support among NOSB members to provide materials to organic producers in order to meet food safety requirements," and that "this review could help identify materials needed to fill potential gaps in organic crop production, livestock health, and food safety."[5] NOC supports the intentions stated, but notes there are key steps missed in order to accomplish these goals.

[5] https://www.ams.usda.gov/sites/default/files/media/NOSBProposalsAllApril2019.pdf, p 37.

While the discussion document goes on to talk about how "the NOSB has requested a technical review to provide information on the essentiality and appropriateness for these types of materials ***in a variety of situations***,"[6] (emphasis added) the specifics outlined under what has been requested from the technical review never mention identifying the "variety of situations" for which sanitizers, disinfectants, and cleaners are used or required by law in organic production. It would seem impossible to evaluate for essentiality when need is not defined.

Further, after identifying the "variety of situations" for which sanitizers, disinfectants, and cleaners are needed or required in organic production, it would seem prudent that we then identify which NL materials are currently available to meet those needs and regulatory requirements. Without these two steps, how do we begin to identify "potential gaps in organic crop production, livestock health, and food safety" for which new sanitizers, disinfectants, or cleaners may be needed?

We agree with the Accredited Certifiers Association's (ACA) comments that "it is crucial that any criteria and questions developed be based on statutory requirements," and echo their "request that the information and evaluation criteria developed be linked to specific criteria listed in the Organic Foods Production Act (OFPA) (7 USC 6517 and 6518)." And further note that the ACA comments raise good points, including the request for greater guidance for certifiers to ensure consistent application of standards that creates a level playing field for all organic operations.

For additional considerations when conducting a comprehensive review of sanitizers, disinfectants, and cleaners, we point to Beyond Pesticide's more detailed comments. We would like to emphasize their recommendation on evaluation criteria that "resistance is an issue not only with target organisms, but also with other organisms that may be exposed to the material through use or in effluent, so one additional criterion should be **'Is this material used to treat for human disease prevention?'"**

The Materials Subcommittee has outlined many of the issues we believe should be addressed in a comprehensive review of sanitizers, disinfectants, and cleaners, but we believe this issue must be addressed within a framework that first identifies the needs and regulatory requirements for cleaning and sanitizing materials in organic production and handling. We encourage the Materials Subcommittee to closely review these comments, as well as those submitted by Beyond Pesticides and the Accredited Certifiers Association, when preparing the fall proposal.

## Genetic integrity transparency of seed grown on organic land

NOC appreciates the opportunity to comment on this discussion document and the NOSB's work to assess the difficult issue of contamination. The issue is complex, as evidenced by previous discussion documents and public comments, and deserves much consideration. We will attempt to clearly state our suggestions to make the document stronger, as well as our concerns.

[6] https://www.ams.usda.gov/sites/default/files/media/NOSBProposalsAllApril2019.pdf, p 37.

NOC continues to be supportive of this effort and also feels compelled to express significant concerns with the proposal.

This proposal would benefit from a clearly stated goal and purpose for the pilot project. Reading through the proposal, one might surmise the goal could be to identify tolerance levels of genetic contamination in seed, create transparency around GE contamination levels of seed without identifying tolerance levels, or address "the issue of clarity around genetic purity of the seed,"[7] which is a vague statement. The end goal is also unclear – is it regulatory change, a guidance document, or both?

We share the concerns outlined in the letter of January 2, 2019, signed by our members Organic Seed Alliance (OSA) and Rural Advancement Foundation International (RAFI), [included in full as Appendix B] that achieving more transparency in the seed market should not burden farmers. We understand that the proposal aims to provide operators with increased transparency regarding the levels of contamination they are starting with, by virtue of the seeds they plant. But we are concerned that there is an unfair burden placed on organic farmers who source non-organic field corn seed and are required to navigate the testing and reporting process of detection levels. While this may incentivize sourcing organic seed, this requirement also means that some organic field corn growers will have to navigate the complexity of taking appropriate samples, where to send them for testing, and then cover the cost of that testing. For some growers, this additional cost of time and money may be unacceptable.

We are deeply concerned about the unintended consequences for farmers that this approach may have. As stated in the January 2, 2019 letter:

> *This proposal forces farmers into the impossible position of deciding whether to knowingly plant seed with detectable levels of GE traits or scrambling to find an alternative, which would increase operating costs, effectively penalize them for the presence of GE traits in the seed they source, and complicate issues of liability for them and the seed companies they source from. This pilot project could set the unintended precedent of farmers assuming liability for detectible levels that are out of their control.*

Our concern of unintended consequences includes fewer organic field corn varieties available to growers, given that some organic field corn companies view this approach as putting them at a disadvantage. Similarly, while the proposal may aim to incentivize organic seed sourcing, there is concern that it may have the opposite effect. Organic field corn growers already face limited options.

We feel that the responsibility for data collection and reporting should not be placed on certifiers. We recognize this approach is in response to the absence of a USDA task force, which many of us have called for, and which would be better suited to carry out much needed data collection to inform policy. A USDA task force remains the best approach to collecting reliable data in a way that does not place this burden on organic farmers and the certification and enforcement system.

[7] NOSB April 2019 proposals and discussion documents, p. 36, Retrieved from https://www.ams.usda.gov/sites/default/files/media/NOSBProposalsAllApril2019.pdf, p 36

The need to collect more data has been an overarching theme, and one that USDA has failed to address. OSA has committed to conducting a seed company survey this spring of seed companies supplying organic and conventional, untreated field corn seed to organic growers. We ask for your support of their efforts, and that the Board use this information to inform next steps.

### Marine materials

NOC greatly appreciates the continued hard work on this complicated issue. The organic regulations require that organic production utilize "practices that foster cycling of resources, promote ecological balance, and conserve biodiversity."[8] Consumers who choose organic foods expect this to be true from farm to fork, including the inputs used by organic farmers.

Ensuring that marine plants and algae used in organic farm products are sourced in a manner that fosters resource cycling, promotes ecological balance, and conserves biodiversity is complicated, especially given the complex nature of marine ecosystems. Nevertheless, this endeavor is critical to organic integrity. Structures must be developed that ensure production of organic food is not indirectly contributing to the destruction of ocean habitats or depletion of marine resources.

**NOC is becoming increasingly convinced that the organic community is ill-equipped to tackle this issue, and strongly advocates for creating an independent panel of marine scientists not connected with industry to come up with precautionary standards in the absence of perfect knowledge about these species and the impact of harvesting them.** Within the organic industry, there are many experts on terrestrial ecosystems, who have a passion for the work they do. We must seek experts in marine ecosystems with that same passion to guide our efforts. Dr. Robin Hadlock Seeley has assured us that she would be more than willing to work further toward this goal, including suggestions of scientists to form the panel.

Given the limited comment period, were we unable to give this important topic the attention it deserves. We look forward to engaging further in the future.

## Compliance, Accreditation, Certification Subcommittee (CACS)

### Oversight improvements to deter fraud

NOC appreciates the thoroughness on the part of the NOSB and NOP in gathering feedback from organic stakeholders on fraud. The NOP has received direction from both the 2017 Office of Inspector General

[8] 7 C.F.R. §205.2.

report[9], as well as from Congress in the 2018 Farm Bill[10]. Organic stakeholders have weighed in on multiple occasions in multiple ways. While there is much data and feedback to be collected, now is the time for action.

Fraud – both within and outside of the United States – cannot be tolerated within the organic system. ***All* fraud impacts all players in the trade.** NOC's comments will focus on the need for improved effectiveness of controls throughout the organic supply chain – both at home and abroad.

**Discussion Questions**

1. **Are there additional activities missing from the list above that would result in better oversight and enforcement of the organic regulations?**

**For international operations:**

- Examine the limitations of the NOP's authority over uncertified entities engaging in fraudulent activity, as well as for operations that have surrendered their certificates. NOC believes that there may be additional measures that need to be taken beyond the provisions in the 2018 Farm Bill or Enforcement Rulemaking to address challenges related to uncertified operations that are committing fraud because it is very difficult for the NOP to take enforcement actions or collect civil penalties for these operations, particularly from foreign operations. In addition, the civil penalties levied by NOP may not be large enough to serve as a deterrent. NOC is interested in exploring whether greater transparency and information about operations that have surrendered certificates can facilitate the detection of fraud.

- Identify other industries/products that have a longer history of dealing with fraud and learn from the measures they took and their outcomes.

- Identify whether the fraudulent imported grain is being insured as organic and use insurance information to flag potentially fraudulent organic imports.

**Strengthen enforcement in the livestock sector for domestic operations:**

- Implement Origin of Livestock Rulemaking – With broad support from the organic community and a fall 2018 unanimous resolution from the NOSB[11], now is the time to close the loophole

[9] "National Organic Program International Trade Arrangements and Agreements," Retrieved from https://www.usda.gov/oig/webdocs/01601-0001-21.pdf.
[10] 2018 Farm Bill, Sec. 10104, Organic Certification, beginning p. 410, Retrieved from https://www.congress.gov/115/bills/hr2/BILLS-115hr2enr.pdf.
[11] National Organic Standards Board Fall 2018 transcript, p. 1308, Retrieved from https://www.ams.usda.gov/sites/default/files/media/TranscriptsOct2018NOSBMeeting.pdf.

that would clarify requirements for the transition of dairy cows into organic and ensure consistent enforcement of the standards.

- Provide full transparency and follow-up on the Dairy Compliance Project. It is imperative that bad actors in the dairy sector and their certifying agents are bought into compliance or are excluded from the program.

- Implement Organic Livestock & Poultry Practices rulemaking for greater consistency in organic livestock standards and a level playing field.

**3. Please provide your thoughts on how these items should be prioritized. E.g. by importance? By ease of implementation?**

These items should be prioritized in a manner that makes the most impact in the least amount of time. We in no way suggest the following is an exhaustive list of what needs to be done. We do feel it is where efforts should begin.

1. **ELIMINATE THE EXCLUSION FROM CERTIFICATION FOR UNCERTIFIED ENTITIES:** NOC feels strongly that eliminating the exclusion from certification for uncertified entities is the single most important action that can be taken to increase the integrity in the global organic control systems. We are aware that others have submitted detailed comments on exactly who should and should not be required to be certified. In addition, Congress was very clear on this topic in the 2018 Farm Bill[12] enacted December 20, 2018:

   *SEC. 10104. ORGANIC CERTIFICATION. (a) EXCLUSIONS FROM CERTIFICATION.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue regulations to limit the type of organic operations that are excluded from certification under section 205.101 of title 7, Code of Federal Regulations, and from certification under any other related sections under part 205 of title 7, Code of Federal Regulations.*

2. **ORGANIC INTEGRITY DATABASE:** NOC is deeply concerned about significant gaps in data collection, especially for organic acreage data. These gaps greatly impede the organic community's ability to deter fraud, especially through the use of mass balance audits.

   a. The NOP should move forward in making product and acreage reporting mandatory for certifiers.
      i. A sound and sensible approach should be used to ensure that for certifiers working with small, diversified producers, data can be captured in a reasonable way. AMS must establish meaningful crop categories, ideally ones that are

[12] 2018 Farm Bill, Sec. 10104, Organic Certification, beginning p. 410, Retrieved from https://www.congress.gov/115/bills/hr2/BILLS-115hr2enr.pdf.


harmonized with the NASS codes used in the 2014 and 2015 Organic Certifiers Surveys that NASS conducted.

ii. Accredited Certifying Agents (ACAs) must be required to report aggregated production area certified by crop and location at least on an annual basis to the Organic Integrity Database (OID), and required to update the OID within 72 hours when an operation surrenders its certificate, or its certificate is suspended or revoked.

b. AMS must improve the user interface for the OID so users, including researchers, can gain access to meaningful data that can be segregated in different ways. This function is essential to keep this information publicly accessible and to provide researchers with the necessary tools to conduct research on organic production and marketing trends.

c. AMS must hire qualified statisticians to maintain and analyze the data from the OID. These statisticians will be able to assist in efforts to detect fraud. Ideally, AMS should produce publicly available reports to provide the public with much needed information related to organic production and marketing trends.

3. **NOP ACCREDITATION SYSTEM:** NOC is equally concerned about the functioning of the NOP's accreditation process and the lack of enforced consistency from one certifier to another.

a. Consistent, transparent NOP peer review audits are a must. See our more detailed comments in this document on this subject. The results of the 2018 NOP peer review audit must be released.

b. Improve qualifications and training of NOP auditors to monitor, detect, and address fraud. Establish minimum requirements for qualifications and initial and continuing training.

c. Increase oversight of certifiers, including satellite offices domestically, as well as in foreign countries, which should be required to be audited on an annual basis. Develop more robust auditing of ACAs with increased attention on whether a certifier's process and qualifications are sufficient to verify compliance and detect fraud.

d. Strengthen requirements for certifier attendance at NOP trainings, and verify during accreditation audits that appropriate staff have been advised of the information obtained at those trainings.

e. Provide guidance and training to certifiers to develop a stronger system of collaboration, consistency, and transparency when investigating fraud.

f. Clearly outline each fraud detection project. For example, identify the number of staff that will be dedicated to priority area, such as the number of staff that will be dedicated to track import shipments, the percentage of ships tracked, the methodology for risk assessment, and the tools used. Have the project manager of each area provide an update to NOSB and organic stakeholders via a report to be published with the spring and fall NOSB materials. This provides an opportunity for transparency, and also allows organic stakeholders to comment, sharing tools they are aware of that may aid the NOP in their efforts in an ongoing basis.

4. **RISK-BASED SYSTEM:** A risk-based system of cross checks led by the NOP in communication with certifiers would be an excellent tool to detect and deter fraud.

    a. NOP should implement a policy to conduct an automatic investigation whenever there is a surge in imports for a specific product to determine if fraudulent activity is contributing to that increase.

    b. NOP should implement a policy that triggers an immediate USDA audit of any international organic certifier whose accreditation has been revoked by a nation with which the U.S. has an organic equivalency agreement.

    c. NOP should continue to work to leverage the resources of other federal agencies to include them in the effort to deter fraud in organic supply chains.

    d. NOP should fully explore the authorities provided in the 2018 Farm Bill, such as electronic certificates, and implement these as soon as possible.

5. **COMPLAINT & ALERT SYSTEM:**

    a. Create a risk assessment process for prioritizing complaints.

    b. Improve the timing and communication around NOP's complaint system.

    c. Develop a public alert system that identifies products or regions where heightened vigilance is needed.

6. **STOP SALE AUTHORITY:** Work with Congress to explore stop sale authority.

7. **GROWER GROUPS:** Conduct rulemaking to ensure consistent oversight and enforcement of group operations.

8. **INFORMATION SHARING ACROSS CERTIFIERS**: Require that information about operations is communicated across certifiers so operations are not able to switch certifiers in an effort to evade detection of fraudulent activity.

## Energy systems infrastructure on organic farms

The development of oil, gas, and other energy infrastructure, including fracking, affects everyone, but it has particularly severe impacts on organic farms in the path of its development. While we realize that the NOSB and NOP cannot change the energy industries, there is a need for action to protect organic farmers and consumers. The NOSB must provide the NOP with clear and consistent guidance for energy companies, certifiers, and farmers on how to "coexist" and still protect organic integrity of land and food. Therefore, we support the NOSB's proposal to put "energy infrastructure impacts" on the work agenda of the CACS.

The goal of this project is to develop guidance for certifiers addressing energy infrastructure, such as pipelines, fracking, utilities, etc., to protect integrity of organic land. We believe that the location of the Fall 2019 meeting in Pittsburgh, a place that has been severely affected by such development, provides an opportunity to bring together experts and affected organic growers to discuss possible ways to avoid and mitigate impacts on organic farmers and protect the integrity of organic land. We suggest that a panel discussion at the Pittsburgh meeting could inform a discussion document concerning future NOSB actions.

Such a panel should include certifiers and/or inspectors who have dealt with the mitigation of impacts of oil and gas infrastructure development, such as Doug Raubenolt, IOIA-trained, experienced organic inspector, and former organic producer, who has worked through OEFFA's Organic Agriculture Impact Mitigation Plan on several organic farms; researchers who have studied the impacts of oil and gas infrastructure development on food, such as Ted Auch, Susan Nagel[13] on health effects[14], Marsha Haley[15] on safe setback distances[16], Michelle Bamberger[17] on livestock exposure[18], and Seth Shonkoff[19] on irrigation[20]. Panelists should address questions such as:

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[13] Biography retrieved from https://medicine.missouri.edu/faculty/susan-nagel-phd

[14] Nagel, Susan (Contributor). *What is the latest science on fracking and hormone disruption?* [audio podcast]. Retrieved from https://endocrinedisruption.org/assets/media/documents/Nagel%20podcast%20complete%203-8-18.mp3

[15] Biography retrieved from http://radiationoncology.pitt.edu/people/marsha-haley-md

[16] Haley, Marsha (Contributor). *How can we set safe setback distances?* [audio podcast]. Retrieved from https://endocrinedisruption.org/assets/media/documents/Haley%20podcast%20-%20complete.mp3

[17] Biography retrieved from http://www.vetbehaviorconsults.com/doctor.html

[18] Bamberger, Michelle (Contributor). *Is our food at risk? Livestock Exposure* [audio podcast]. Retrieved from https://endocrinedisruption.org/assets/media/documents/Bamberger%20podcast%205-31-17.mp3

[19] Biography retrieved from https://www.psehealthyenergy.org/about/staff/seth-shonkoff/

[20] Shonkoff, Seth (Contributor). Is our food at risk? Crop Irrigation [audio podcast]. Retrieved from https://endocrinedisruption.org/assets/media/documents/Shonkoff%20Podcast%20-%20complete%20-%20with%20final%20edits-2.mp3


- What are some examples of the impacts felt by organic farmers?
- How have certifiers been addressing pipelines and other energy infrastructure construction on organic farms?
- What kinds of mitigation plans have been used, or could be used?

The panel could provide rich information to lay groundwork for the board's unpacking of this issue and the development of a discussion document which could then lead to guidance or instruction to certifiers.

# LIVESTOCK SUBCOMMITTEE (LS)

## Petition

### Oxalic Acid 205.603

NOP must adopt apiculture rules, which would provide a framework for making decisions about materials used in organic beekeeping. The NOSB has made such a recommendation in the past, which the NOP has ignored. We feel strongly that the NOSB and organic stakeholders must hold fast to our assertion that there must be standards for a production system before we add materials to the National List for use in those systems. Until such standards are developed, we have a difficult time commenting on materials for use in organic apiculture.

## Discussion Document

### Use of Excluded Methods Vaccines in Organic Livestock Production

We favor a policy of allowing vaccines made by excluded methods only when:

1. There are no commercially available vaccines that are not produced through excluded methods to prevent that specific animal disease or health problem; and
2. the specific health problem poses an emergency.

We suggest an approach to defining "emergency" in this situation that is parallel to that used for defining emergency use of parasiticides.

Regardless of the approach taken, it will need to be informed by a list of available vaccines. It appears that such a list is available through APHIS.[21] The Accredited Certifiers Association has commented:

> *We have heard it suggested that the six-digit codes assigned to the product listings can provide clarity as to whether vaccines are produced with excluded methods. However, we were recently*

[21] Veterinary Biological Products, Licensees and Permittees (January 31, 2019). *USDA APHIS*. Retrieved from https://www.aphis.usda.gov/animal_health/vet_biologics/publications/CurrentProdCodeBook.pdf.


*advised by USDA-APHIS that relying on the coded information would lead to incorrect characterizations.*

While it may be the case that relying on the currently coded information would lead to incorrect characterizations, it would appear to us that this provides a starting point. The roadblock had previously been that no list of available vaccines existed. It would appear that this major hurdle has been overcome. NOC supports the third regulatory solution put forward by the NOSB in the discussion document and we would suggest using the coded list of animal vaccines from APHIS as a building block to produce the information necessary to make option 3 viable.

## Sunset

### (Parasiticide) Fenbendazole 205.603(a)

### (Parasiticide) Moxidectin 205.603(a)

NOC supports the relisting of both fenbendazole and moxidectin, and feels strongly that now that there is a greatly reduced withholding time for these materials, it is imperative that the Spring 2018 NOSB recommendation passed by unanimous vote be added to the rule, as follows:

**Spring 2018 NOSB Vote: unanimous decision**
**Motion to add the following at § 205.2 Definitions**
Emergency (treatment for parasite control in breeding, dairy and fiber bearing animals). An urgent, non-routine situation in which the organic system plan's preventive measures and veterinary biologics are proven, by laboratory analysis or visual inspection, to be inadequate to prevent life-threatening illness or to alleviate pain and suffering.

Add to § 205.238 (b)

(4) Organic breeding, dairy and fiber bearing animals when meeting the following conditions:

(i) Organic livestock has been managed according to 238(b) and 238(c)(2), 238(c)(4), and 603(a)(23) and only in the event of an emergency where management strategies have been proven insufficient to prevent or control parasites within the accepted threshold for specific parasites, age and species of the animal. These management strategies include but are not limited to, forage height and plant diversity to maintain parasite levels below treatment thresholds and monitoring with documentation of parasites through use of methods such as fecal monitoring and FAMACHA (FAffa Malan Chart—used for tracking anemia in goats and sheep).

(ii) The organic system plan is changed to prevent a similar livestock emergency in individual animals or the whole herd/flock in future years.

**Subcommittee question**

1) Do livestock producers still have a necessity for the usage of fenbendazole for emergency treatment of parasites when good pasture management techniques are being used?

> Both moxidectin and fenbendazole are needed as they are used alternately over time. Used in this fashion will help to reduce the probability of parasites developing resistance to the materials. Even with good pasture management and nutritional status, weather and other environmental factors can cause the animals to become infected with parasites.

### Atropine 205.603(a)

NOC supports the relisting of atropine due to its essentiality as an antidote for organophosphate poisoning and usefulness as an antispasmodic. The TR describes it as a benign treatment without a holistic or natural alternative. The withdrawal periods of 56 days and 12 days are twice the listed FARAD Withdrawal Interval (WDI).

### Hydrogen peroxide 205.603(a)

Hydrogen peroxide is relatively nontoxic in low concentrations, though it is a powerful oxidizer and may damage soil biota. Repeated exposure to vapor is harmful. It breaks down quickly to oxygen and water, and therefore does not have a residual effect.

NOC supports relisting of hydrogen peroxide as a safer alternative to other more toxic sanitizers.

### Iodine 205.603(a)(14) & 205.603(b)(2)

Most processors are already requiring iodophors without NPEs. NOC supports Beyond Pesticide's recommendation for an annotation change for iodine. Although the option for the NOSB to add annotations at sunset was unilaterally removed by the NOP, we believe this is an example of where it is important to add an annotation to prohibit the use of nonylphenol ethoxylates (NPE) forms of iodophors in organic production; NPEs are suspected endocrine disruptors and proven aquatic toxins.

The iodine listings should not permit iodophors containing alkylphenols or alkylphenol ethoxylates. (APs and APEs are the general classes that include NPs and NPEs.) They should be annotated "without alkylphenols or alkylphenol ethoxylates."

In answer to subcommittee questions:

1. **Can iodophor forms of iodine be produced using fewer toxic surfactants than nonphenol polyethylene glycol ether (NPE) and similar NPEs? If so, what might be substituted?**

   Yes. Organic alternatives include ethanol or essential oils for some uses. Other natural alternatives identified by the TR include udder washes containing essential oils, vinegar, natural acids, nisin for teat dips, and natural ethanol. Other substitutes include chlorhexidine, alcohols, hydrogen peroxide, essential oils, and other chlorine materials. EPA has approved the following

for use in Design for the Environment disinfectant products: citric acid, hydrogen peroxide, l-lactic acid, ethanol, and isopropanol.

2. **If the use of NPE surfactants was prohibited in teat dips for use in organic livestock production how would this impact the organic industry?**

   Most processors are already requiring iodophors without NPEs, without significant negative impact to the organic industry.

3. **Are there equally effective alternatives to iodophor based teat dips for commercial use in organic livestock production?**

   We encourage the subcommittee to look at the formulations of iodophors that are currently being manufactured without the use of NPEs. There are many commercially available non-NPE iodine-based disinfectants and teat dips that are currently being used in organic production.

### Magnesium sulfate 205.603(a)

Magnesium sulfate is essential for organic livestock production. It is used when grass tetany and organophosphate poisoning occur. Both are acute situations and an effective immediate treatment is necessary. NOC supports relisting magnesium sulfate.

### Peracetic acid 205.603(a)

Peracetic acid is a stronger oxidizer than chlorine dioxide and sodium hypochlorite, but weaker than ozone. It is more persistent and has higher residual activity than chlorine-based disinfectants, but its degradation products are less hazardous. It does not harm aquatic life or form carcinogenic and mutagenic compounds in breaking down like chlorine.

NOC supports the relisting of peracetic acid and maintains it is necessary for organic livestock production. It is useful as a replacement for chlorine compounds with a wider range of usefulness and innocuous degradation products.

### Xylazine 205.603(a)

NOC supports the relisting of xylazine. Tolazoline and xylazine are always used together, and therefore should be reviewed and considered for sunset together.

Xylazine should be relisted for the rare cases in which they are needed, such as surgery and humane dehorning. Dehorning is done on all dairy animals that are not genetically polled. While more polled genetics are becoming available in most breeds, and many farmers are moving in that direction, it is not feasible for all herds depending on what the needs for genetic improvements may be. There are other natural alternatives that exist that can be used in minor circumstances but are not as effective for pain relief or humane treatment.

The NOSB should examine the allowance of off-label uses of veterinary medicines and the question of how organic integrity can be protected, given that the FDA system for approving these does not require testing to enter the marketplace. We point to the more detailed comments of Beyond Pesticides in this area.

## Methionine 205.603(d)

**Spring 2019 NOSB Questions Posed:**

1. **What types of ingredients have been tested in feed ration trials with the goal of developing acceptable sources of natural methionine, and what were the results?**

   Crab and fish meal can be used to supplement for methionine, but most egg producers want to say their layers are fed a vegetarian diet. Sesame meal can also be used but it is still not available in large enough quantities to supply the egg industry.

2. **Are there new options being trialed to find natural and/or organic agricultural sources of methionine that meet the needs of organic poultry?**

   Study published December 2018, "Sustainable Fish and Invertebrate Meals for Methionine and Protein Feeds in Organic Poultry Production,"[22] investigated other supplements for methionine in poultry feed. The paper mentions a study at Department of Poultry Science, University of Arkansas, Fayetteville, done in 2017, evaluating feeding Asian carp, an invasive fish species. If processed and dried without a synthetic preservative, this would be allowed in organic production.

   The paper also reports on studies evaluating the potential of using various insects as a feed supplement. The insects have an even higher level of methionine. Issues around creating meal that is feed grade and organically certifiable would need to be addressed before the insect meal will be available.

   Inspect meal has been proposed to be included in The Association of American Feed Control Officials (AAFCO) as a poultry feed ingredient. This may be one possible future avenue to eliminate methionine supplementation. Black soldier fly larvae has been given FDA recommendation.[23]

[22] "Sustainable Fish and Invertebrate Meals for Methionine and Protein Feeds in Organic Poultry Production," A. C. Fanatico, K. Arsi, I. Upadhyaya, J. Morales Ramos, D. Donoghue, A. M. Donoghue, *The Journal of Applied Poultry Research,* Volume 27, Issue 4, December 2018, Pages 437-448, https://doi.org/10.3382/japr/pfy037.

[23] Black soldier fly larvae earns FDA recommendation (September 11, 2018). *Morning Ag Clips.* Retrieved from https://www.morningagclips.com/black-soldier-fly-larvae-earns-fda-recommendation/.

3. **Has there been any research to determine if pastured poultry that has access to growing vegetation, have less of a need for synthetic methionine than poultry that does not have access to living plants, bugs and biologically active soils?**

   A recent study, "Alternative feeding strategies and genetics for providing adequate methionine in organic poultry diets with limited use of synthetic amino acids,"[24] found little positive effect from either genetics, reducing feed consumption, or pasture consumption for reducing the need for methionine supplementation without reducing the health of the birds and or egg and meat production.

From the very beginning, the NOSB has stressed the importance of phasing out the use of synthetic methionine in organic poultry production. This was accomplished for years with expiration dates and step-down allowed rates. At the Spring 2015 meeting, the NOSB also voted unanimously to adopt the following resolution, which was understood to keep the methionine issue on the LS work agenda:

> *The National Organic Standards Board is committed to the phase-out of synthetic methionine for organic poultry production, and encourages aggressive industry and independent research on natural alternative sources of methionine, breeding poultry that perform well on less methionine, and management practices for improved poultry animal welfare.*

The NOSB must address the need for synthetic methionine in the context of an organic system of production. In its examination of the role of synthetic methionine in an organic poultry production system, the following questions must be addressed:

1. How do methionine requirements vary with species and with breeds within species?

2. How much methionine is provided by pasture under optimum conditions?

3. Can poultry pasture be improved to provide more sources of methionine (e.g., more insects)?

4. Can natural sources of methionine be combined to provide methionine that is missing from pasture?

5. Are there particular conditions –e.g., seasons or temperature ranges— under which poultry pasture cannot be sufficiently improved and natural sources of methionine are inadequate to produce specific breeds/species?

These questions are pertinent to the question of whether organic systems require synthetic methionine, that is, whether it is "necessary to the production or handling of the agricultural product because of the

[24] H.K. BURLEY, P.H. PATTERSON and K.E. ANDERSON, (Burley & Patterson – Department of Animal Science, The Pennsylvania State University, University Park, PA, USA; Anderson – Prestage Department of Poultry Science, North Carolina State University, Raleigh, NC, USA), World's Poultry Science Journal, Vol. 72, March 2016.

unavailability of wholly natural substitute products." If poultry producers can choose breeds, pasture systems, and natural sources of methionine that can provide for the needs of the birds, then there is no need for synthetic methionine. If an organic management system can provide for the needs of the birds without adding synthetic methionine when temperatures are suitable for the birds to be on pasture, then an annotation can limit the use to those situations when pasture is not possible. Thus, questions surrounding the use of synthetic methionine are tightly linked to other issues of animal welfare that USDA has refused to address in regulations.

### Trace minerals 205.603(d)

Organic production should not be dependent on synthetic nutrients. While we realize that the variability in forage and feeds may occasionally lead to a need for supplementation, the existing annotation is not restrictive enough to prevent reliance on synthetic materials. Therefore, we recommend adding the annotation, "when forage and available natural feeds are poor quality."

### Vitamins 205.603(d)

Synthetic inputs may be needed to respond to unusual conditions or fine tune the system, but in organic production, they cannot be routine. The blanket listing of all synthetic vitamins is not justified. The 1995 NOSB recommendation on vitamins saw a limited use of synthetic vitamins, to be reviewed within two years. Livestock producers were "to decrease or eliminate use of feed additives when possible."

NOC supports a listing for vitamins that is limited to vitamins A, C, and D because the need for synthetic forms of others is not supported by the 2015 Technical Review of Vitamins for Livestock.[25] The listing should read:

205.603(d) As feed additives
(3) Vitamins A, C, and D, used for enrichment or fortification when forage is not available and available natural feeds are of poor quality.

## HANDLING SUBCOMMITTEE (HS)

## Petitions

### Silver dihydrogen citrate 205.605(b)

NOC supports the handling subcommittee's vote to reject the proposal to add silver dihydrogen citrate at 205.605(b). Our opposition to adding this material to the National List is detailed in our comments from fall 2018, included here as Appendix A. Silver dihydrogen citrate poses health and environmental risks –particularly the risk of increasing resistance to antibiotics and silver-based medications. The petition for SDC must be denied to protect the effectiveness of remaining antimicrobial medications.

[25] 2015 Technical Review of Vitamins for Livestock, lines 1142-1201.

## Pullulan 205.605(a)

The petition for pullulan raises several concerns.

NOC appreciates the petitioner's statement that the purpose of the petition is two-fold: to protect the continued production and availability of USDA-NOP certified dietary supplements and **to support the commercial development of certified organic pullulan** [emphasis added].[26] In addition, "according to the petition, Capsugel is the owner of U.S. patents covering pullulan capsules, and they are **in the process of developing organic pullulan** [emphasis added]."[27] While the assurance that the only manufacturer of pullulan is "in the process of developing organic pullulan" is a step in the right direction, we are left wondering why they have not done so before now. As noted in the subcommittee's materials, Capsugel originally petitioned to add pullulan to §205.605 in 2004, with no NOSB recommendation made at that time.[28] It would appear that Capsugel has had fifteen years to develop organic pullulan.

Pullulan is created by vat fermentation, and is another example of the need for NOSB guidance on the classification and listing of products from fermentation. We refer you to our full comment on "clarify products of fermentation."

While the petition requests the listing of pullulan for the specific use in tablets and capsules for dietary supplement, pullulan is also used for many other purposes, such as films to extend the shelf life of various foods. The motion proposing listing of pullulan should specify its use in dietary supplement tablets and capsules.

## Collagen gel (casing)

NOC shares many of the same concerns as our member organization, Beyond Pesticides, when it comes to collagen gel casings.

As noted in our spring 2015 and fall 2018 comments, now that any agricultural commodity can be produced organically, listing on §606 only stifles organic production of new organic substances and promotes chemical-intensive production. This is especially true of collagen gel casings. In the time that it takes to add a new regulation, petitioners could overcome obstacles to supplying the organic product.

Collagen gel is made from the skis of cows, pigs, chickens and/or turkeys. All of these are produced organically. In discussing the usual casings (made from intestines), there is an issue with chicken/turkey sausage, since casings are not made from their intestines. However, collagen is made from them, so the issue of having enough collagen from organic animals should not be an issue.

[26]NOSB April 2019 proposals and discussion documents, p. 99. Retrieved from https://www.ams.usda.gov/sites/default/files/media/NOSBProposalsAllApril2019.pdf, p 99.
[27] *ibid.*
[28] *ibid.*


There appears to be a practical issue of isolating organic intestines to use for organic collagen gel. Instead of petitioning for the use of casings made from meat contaminated with pesticide and antibiotic residues, those who wish to use collagen gel casings for organic sausage should devote their efforts to eliminating those practical obstacles.

Listing collagen gel casings on §606 would promote chemical-intensive production, and using them in organic would contaminate organic production. Non-organic collagen gel comes from animals who have been born, weaned, raised, fed, slaughtered, and processed often using the very worst practices, possibly in countries without any regulatory oversight – from chemically-intensive Concentrated Animal Feeding Operations (CAFOs) anywhere in the world. CAFOs routinely administer antibiotics and other pharmaceuticals to add weight and keep animals alive in an unhealthy environment. CAFOs feed animals GMO alfalfa, GMO corn, GMO soy, GMO beets, and other GMO crops. CAFOs are not humane. CAFOs routinely discharge toxic urea and manure containing medical residues, bacterial pathogens, and antibiotic-resistant microbes into air, land, and water.

We agree with Beyond Pesticide's assessment that collagen gel casings are synthetic and point to their more detailed comments, showing cellulose is present in the finished product in approximately the same concentration as collagen and has a functional effect in the casings, so it is an ingredient, not an ancillary substance. Cellulose is listed as a synthetic on the National List at §205.605(b), so collagen gel casings must be considered synthetic.

NOC opposes the listing of collagen gel casings on §606 because collagen gel casings are synthetic, the listing is unnecessary and discourages the development of organic collagen gel casings, and the listing would promote chemical-intensive production.

## Other

### §205.606

We were encouraged to see a discussion regarding section §205.606 and commercial availability took place on the November 6, 2018, Handling Subcommittee call and the recognition that "once items are on 205.606, there is less of an incentive to grow organic forms."[29] We encourage further discussion of the 2006 NOSB recommendation about commercial availability that was not implemented, along with consideration of our previously submitted comments. The organic program is not what it was in 2006, and we feel the NOSB recommendation from then is valuable for consideration, but will need to be revisited in light of industry growth. A greater burden to clearly define the barriers preventing the organic production of the petitioned substance must be imposed on the petitioner before the NOSB and organic stakeholders can make an informed decision regarding listing. Our spring 2015 comments are attached as part of Appendix A.

[29] https://www.ams.usda.gov/sites/default/files/media/HSNotes2018JanDec.pdf, p 19.

## Clarify products of fermentation.

Fermentation is a biological process in which sugars are metabolized to acids, gases, and/or alcohol. Depending on the fermenting organism and the food source, other byproducts may be produced. Fermentation processes used for agricultural inputs and food processing are both in need of clarification, but the issues surrounding them are different. Here we address fermentation with respect to food processing.

Fermentation processes produce foods or food ingredients in several ways:

1. **Foods and ingredients that are organisms grown by fermentation—that is, the biomass produced by the fermentation process.** These include nutritional yeast and baking yeast. Yeast may be certified organic when produced in compliance with an approved organic systems plan.30 Marroquin International petitioned to have yeast reclassified as agricultural and listed on §205.606. It made the argument that yeast, like mushrooms, should be considered livestock under OFPA. "Microorganisms" are listed on §205.605(a).

2. **Food processing changes raw agricultural ingredients into new products defined by the products of fermentation.** These include wine, beer, vinegar, lactic acid pickles, yogurt, and miso.

3. **Production of food additives through fermentation of specific strains of microorganisms.** These include nucleotides, various vitamins, etc. that are isolated from the products of fermentation. They may be either **primary metabolites** –substances produced by the fermenting organism that are essential to its growth, such as nucleotides, nucleic acids, amino acids, proteins, carbohydrates, lipids, etc.—or **secondary metabolites** –which have no obvious role in the metabolism of the cultured organisms, such as antibiotics and other drugs.

There are products of fermentation permitted in organic food in all of these categories. A number of them are up for sunset review. Those up for sunset in 2019 are marked with *. Materials on §205.605(a) that are products of fermentation include:

1. Food organisms: yeast*.

2. Fermented foods do not need to be listed, but yeast*, microorganisms*, and dairy cultures*, which are the agents that ferment the food, are listed.

3. Metabolites: L-lactic acid*, citric acid*, L-malic acid, gellan gum, glucono delta-lactone, enzymes*.

[30] NOP, Certification of Organic Yeast. NOP 5014 issued March 2, 2010.

Materials on §205.605(b) that are products of fermentation include metabolites: glycerin, xanthan gum, various vitamins that may be produced by fermentation (B2, B12, C, D2, E, K2, biotin, and some combinations)*.

Finally, there are metabolites of fermentation listed on §205.606:[31] fructooligosaccharides (FOS), Inulin – oligosaccharide enriched (IOE), whey protein concentrate.

**Classification: agricultural vs. nonagricultural**

The fact that products of fermentation are included on three different lists for processing is a sign that the classification of products of fermentation needs to be clarified. In particular, the Handling Subcommittee (HS) stated, "Glycerin, produced organically by fermentation is an agricultural product as defined in 7 CFR 205.2, since it is a processed product produced from an agricultural commodity, e.g. cornstarch."[32] This is also consistent with the NOP classification decision tree, which preserves the nonagricultural classification through fermentation. However, it is not consistent with the definition of a "nonagricultural substance" in the regulations.

The regulations define "agricultural products" (following the OFPA definition) and "nonagricultural" (without a definition in OFPA) in §205.2:

> *Agricultural Products.* Any agricultural commodity or product, whether raw or processed, including any commodity of product derived from livestock that is marketed in the United States for human or livestock consumption.
>
> *Nonagricultural substance.* A substance that is not a product of agriculture, such as a mineral or a bacterial culture that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product **so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.** [Emphasis added.]

Perhaps some of the inconsistency in the classification of materials as agricultural or nonagricultural could be resolved by asking, "What makes a product of fermentation agricultural?" If the product of fermentation is agricultural, then it can be certified organic, and we need to define acceptable practices in organic fermentation processes.

NOP policy on organic yeast allows yeast to be a certified organic nonagricultural ingredient. Following that approach would allow other organic substances on 205.605(a). It is tempting to view yeast and other products of fermentation as agricultural. Issues surrounding the classification and listing of food additives produced by fermentation or extracted from fermentation products would be easier to resolve

[31] Materials on §205.606 are addressed in comments on that section.
[32] NOSB Handling Subcommittee proposal for glycerin, October 14, 2014.


if fermentation processes were regarded as agricultural production systems. It may be argued that defining what organic production means in the context of vat fermentation is no more difficult than defining organic aquaculture.

However, the NOSB has been clear that soil-less systems are not organic.[33] Organic agriculture is premised on a belief that the foundation of healthy plants and animals is healthy soil. This, indeed, is a problem in defining organic aquaculture.

Thus, the materials classification guidance, which treats fermentation as a processing method that does not change the classification of the substrate from agricultural to non- agricultural only works if both the substrate and the product of fermentation meet the definition of agricultural, and not nonagricultural substances. Thus pickles, wine, and cheese are all agricultural, but substances whose relationship to the substrate is unrecognizable – such as glycerin, as a product of fermenting cornstarch—are nonagricultural. Fructooligosaccharides (FOS), a product of fermenting glucose, and inulin enriched with oligosaccharides (which contains FOS) are also inappropriately listed on §205.606 because they are nonagricultural.

**Classification: Synthetic vs. Nonsynthetic**
The classification of some "nonsynthetic" substances needs to be revisited. For example, citric acid and L-lactic acid were originally added to the National List based on TAP reviews that gave a simplified version of their production using fermentation. Commercial production of these acids, however, involves synthetic chemical reactions that were not considered in the original classification decision.

**Other issues**
A number of products of fermentation that are on the National List may be made using genetically engineered organisms or genetically engineered substrate. Both of these issues should be addressed by annotation or in a general policy.

In some cases, fermentation may create undesirable byproducts. The TAP review for glucono delta-lactone, for example, recommended annotating to ensure that it is not produced by a strain that produces a toxin. (This was not included in the listing.)

**Therefore, in addition to the material-specific comments below, we request that the Materials/GMO Subcommittee add to its workplan the development of criteria for evaluating products of fermentation processes.**

[33] NOSB recommendation, Production Standards for Terrestrial Plants in Containers and Enclosures (Greenhouses), April 29, 2010.

## Sunset

### Ancillary substances

NOC applauds the Handling Subcommittee's continued efforts to keep a list of ancillary substances associated with materials in anticipation of the NOP determination on how to move forward with the previous 2016 NOSB recommendation.

### Fish oil 205.606

NOC does not support the relisting of Fish Oil due to concerns related to environmental impacts and ecological sustainability. It is NOC's understanding that fish oil production utilizes forage fish relied upon by larger fish, seabirds, and marine mammals for survival. Further, we harbor concerns related to the persistence of heavy metals, and appreciate the Handling Subcommittee raising such questions in the meeting materials. Finally, NOC questions how the review of fish oil as a handling material relates to the larger questions and decisions to be made regarding Marine Materials.

### Gelatin 205.606

NOC requests clarification regarding the barriers preventing the production of organic gelatin. Without that information, it is impossible to make an informed decision regarding relisting.

### Orange pulp, dried 205.606

NOC applauds the questions raised by the Handling Subcommittee, and requests clarification regarding the barriers to the production of organic orange pulp. Without such information, we are unable to make an informed decision regarding relisting.

### Seaweed, Pacific kombu 205.606

### Seaweed, Wakame (Undaria pinnatifida) 205.606

NOC requests that the two seaweed materials be reviewed within the broader context of Marine Materials. As part of the review, please consider the addition of an annotation related to harvest restrictions and risk-based testing for toxic materials, using a decision tree to identify harvesting areas where testing would need to be performed.

### Alginic acid 205.605(a)

NOC holds that Alginic acid, like Seaweed and Fish oil, be reviewed within the broader context of Marine Materials. As part of the review, please consider the addition of an annotation related to harvest restrictions and risk-based testing for toxic materials, using a decision tree to identify harvesting areas where testing would need to be performed.

### Calcium chloride 205.605(a)

We consider the level of impurities –up to 6%-- to be high for a food grade material. The presence of calcium bromide is troublesome. We recommend that the HS investigate this more closely.

## Citric acid 205.605(a)

## Lactic acid 205.605(a)

**Classification: Synthetic vs. Nonsynthetic**

The classification of some "nonsynthetic" substances needs to be revisited. Citric acid and L-lactic acid were originally added to the National List based on TAP reviews that gave a simplified version of their production using fermentation. Commercial production of these acids, however, involves synthetic chemical reactions that were not considered in the original classification decision.

Citric acid should be classified as synthetic unless it is possible to define nonsynthetic citric acid by annotation. If it is possible to define nonsynthetic citric acid, then it should be annotated on §205.605(a). Otherwise, it should be removed from §205.605(a) and considered for listing on §205.605(b).

L-lactic acid should be reclassified as synthetic and considered for listing on §205.605(b). L-lactic acid is also present in some foods by virtue of *in situ* fermentation, and this is not synthetic. The microorganisms responsible for the fermentation are on the National List.

We refer you to our full comment on "clarify products of fermentation."

## Dairy cultures 205.605(a)

NOC applauds the Handling Subcommittee's continued efforts to keep a list of ancillary substances associated with materials in anticipation of the NOP determination on how to move forward with the previous 2016 NOSB recommendation. It is our understanding that dairy cultures, especially as a liquid product, contain preservatives such as sodium benzoate that should be reviewed as ancillary substances.

We refer you to our full comment on "clarify products of fermentation."

## L-Malic acid 205.605(a)

**The classification as nonsynthetic should be revisited,** based on information provided in patent 3,063,910 Method of Producing L-Malic Acid by Fermentation.[34]

L-Malic acid should be allowed to sunset due to lack of sufficient information for review. Information on manufacture provided by HS is incomplete. Lack of sufficient information due to 2003 TAP review evaluated DL-malic acid and not L-malic acid. At that time, all three reviewers determined that DL-malic acid is synthetic and recommended against its listing on the NL, based on their understanding of the manufacturing process. As of Spring 2019, a more recent TR was not available.

[34] http://www.google.com/patents/US3063910


We refer you to our full comment on “clarify products of fermentation.”

## Microorganisms 205.605(a)

**Fall 2014 NOC Comments**

A clear definition of the term microorganisms is needed. The definition is critical for microorganisms in use currently, and can be used to determine whether additional organisms, such as unicellular algae, should be considered microorganisms.

We refer you to our full comment on “clarify products of fermentation.”

## Nutrient vitamins and minerals 205.605(b)

The current annotation for “nutrient vitamins and minerals,” which references 21 CFR 104.20, is currently used by some food manufacturers to justify adding synthetic and non-organic ingredients to organic foods when they do not appear on the National List, as long as they can be considered a “nutrient.”

This includes several additives that have been reviewed by the NOSB and rejected for use in organics.

NOC opposes the relisting of “nutrient vitamins and minerals” with the current annotation, for the following reasons:

- We do not think that categorical listings on the National List are appropriate. The National List is for individual substances, not groups of substances, and this should apply to “nutrient vitamins and minerals” as well.

- We do not think that referencing FDA regulations in an annotation in the organic standards is appropriate. The NOSB and USDA should review and approve individual substances as outlined in OFPA and the organic standards. Annotations that reference FDA regulations give that authority to another agency whose standards differ from OFPA standards.

Synthetic or non-organic additives used for nutrient supplementation or fortification should be limited to those that are essential. This does not mean those that are considered “essential nutrients,” but rather those that are essential to making an organic product because fortification or supplementation is required by law.

NOSB should remove “nutrient vitamins and minerals” from the National List and continue the process of individual substance review. Only a handful of nutrients that are essential to organic handling would still need to be reviewed.

# CROPS SUBCOMMITTEE (CS)

## Petitions

### Allyl isothiocyanate (AITC) – 205.601

NOC agrees with the crops subcommittee that AITC is a broad-spectrum antimicrobial compound and "is not compatible with a system of sustainable agriculture. In addition, the availability of cultural methods or use of natural mustard plant cover crops precludes AITC from being essential to organic agriculture." We support the subcommittee's recommendation that AITC not be added to the National List. [35]

### Ammonium Citrate – 205.601

### Ammonium Glycinate – 205.601

NOC supports the subcommittee's recommendation to not add this material to the National List based on the fact that "this substance is a synthetic material designed for enhancing uptake of micronutrients, a process which naturally occurs in soils, and for which a range of alternatives already exist."[36]

### Calcium Acetate – 205.601

NOC supports the subcommittee's recommendation that calcium acetate not be added to the National List. Calcium is rarely limiting in the soil, and a rapidly accessible calcium source is not in alignment with organic principles.

## Proposal

### Strengthen & clarify the requirements for use of organic seed (NOP 5029)

NOC thanks the Crops Subcommittee (CS) for the continued good work done on this proposal and for consideration given to the comments received during the fall 2018 NOSB meeting. We find the published document to be well-organized, and we appreciate the effort put into clearly outlining suggested changes from the fall 2018 NOSB proposal. NOC supports this revised proposal and we encourage the NOSB to pass it.

We commend the NOSB on passing the amendment to the regulations at 205.204 in the fall, and feel that significant improvements have been made to the published proposal on the practices listed within the current NOP guidance 5029. We agree that the implementation of these practices is not anticipated to have negative economic impact on organic operations, other than a few additional farm activities and increased documentation that would need to be maintained.

Our comments will focus on three areas of the proposal and the suggested changes made to these areas: 4.1.6, 4.2.1(b), and 4.2.1(b)(3).

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[35] NOSB April 2019 proposals and discussion documents, p. 175, Retrieved from https://www.ams.usda.gov/sites/default/files/media/NOSBProposalsAllApril2019.pdf.
[36] NOSB April 2019 proposals and discussion documents, p. 181, Retrieved from https://www.ams.usda.gov/sites/default/files/media/NOSBProposalsAllApril2019.pdf.


**4.1.6 Proposed Language**

> 4.1.6 Use of non-organic planting stock to produce organic crops is subject to commercial availability as per §205.204.(a)(1). If planting stock is from a non-organic source and is used to produce perennial crops, then that planting stock may be sold, labeled or represented as organic planting stock **or an organic vegetative crop only** after 12 months of organic management §205.204 (a)(4).[37]

We feel that the proposed language is a step in the right direction on an issue that has become increasingly complicated over time. In speaking with past NOSB members and long-time organic stakeholders, it is our understanding that the allowance for nonorganic strawberry planting stock to be treated as an annual and harvested within 7-9 months was the original scenario approved in this manner. Over time, strawberries are harvested much sooner than 7-9 months from these nonorganic strawberry plants. While this language does not address that situation, we do feel it is a step in the right direction in closing the loophole that §205.204(a)(4) creates. To further clarify the issue, it would be helpful for the NOSB to clearly state whether or not strawberry fruit is the only crop that may be harvested prior to one year in organic management from nonorganic planting stock, and whether or not this applies to both nonorganic plugs and bare root stock.

**4.2.1(b)(1)(i-vii) The search and procurement methods used to source organic seed and planting stock varieties.[38]**

We are supportive of the emphasis on the quality of the seed search over the quantity of suppliers searched. We note that it will be important for certifiers to communicate these requirements to certification specialists, inspectors, and organic producers; develop verification methods; and for USDA to have the will to enforce the standards across all certifiers and all producers. We are pleased to see the work done by the Accredited Certifiers Association on a Best Practice document for improving consistency in organic seed search.

**4.2.1(b)(3)(a-e) If seed/planting stock is sourced or mandated by the buyer of a contracted organic 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.[39]**

NOC echoes the comments of our colleagues at Organic Seed Alliance (OSA):

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[37] NOSB April 2019 proposals and discussion documents, p. 200, Retrieved from https://www.ams.usda.gov/sites/default/files/media/NOSBProposalsAllApril2019.pdf.
[38] NOSB April 2019 proposals and discussion documents, pp. 201-202. Retrieved from https://www.ams.usda.gov/sites/default/files/media/NOSBProposalsAllApril2019.pdf
[39]NOSB April 2019 proposals and discussion documents, p. 202. Retrieved from https://www.ams.usda.gov/sites/default/files/media/NOSBProposalsAllApril2019.pdf


*We view this new language as an improvement. It's important to note, however, that organic farmers are still being held responsible for the practices of others. To make more progress in increased sourcing of organic seed, the role of buyers directly involved in seed decisions will need to support organic producers in meeting the seed requirement. The measures above are a place to start. One additional challenge is that not all buyers are certified organic handlers and therefore can't be held accountable through the review and inspection process.*

We appreciate the efforts of the proposed language regarding the need for an organic seed search and direction on obtaining one; however, **the organic producer continues to be held responsible for the actions or inactions of those who cannot be held accountable through the NOP; this needs to be addressed.**

While we understand that the regulations do not require handlers (certified or not) to source and use organic seed when commercially available, the reality of the situation is:

1. Producers need to have evidence of the search having happened per the regulations. Sometimes the handler does the search for them, sometimes not. If the handler is certified, they have a much better chance of understanding why the search needs to happen and the potential outcomes, should the requirement not be met over time. To them, the NOP and certifier are bodies of some authority.

2. Uncertified handlers are not accountable to NOP or to a certifier, so they are not incentivized in any way (officially or culturally) to do the search, and thus it sometimes never happens.

3. There is one additional challenge here, and that is that sometimes grain growers are contracted to grow out "foundation" seed, which is a first step to breeding an organic seed variety which starts as untreated/non-gmo. NOC suggests that this practice be allowed with appropriate documentation.

**4.4.4(a)(b)(i-iv) Certifying agents should review an operation's progress in obtaining organic seeds, planting stock and transplants by comparing current source information to previous years.[40]**

NOC is supportive of this language and appreciates the additional language that clarifies what constitutes a noncompliance.

**Organic Seed/Planting Stock Database**

NOC supports the comments from our member organization, OSA:

[40] NOSB April 2019 proposals and discussion documents, p. 209. Retrieved from https://www.ams.usda.gov/sites/default/files/media/NOSBProposalsAllApril2019.pdf


*OSA agrees that a central clearinghouse of organic seed availability information is essential to more consistency in locating organic seed and verifying compliance with the regulation. We support exploring ways that the NOP can facilitate the collection of organic seed data. Missing from the discussion in this proposal is that the Organic Seed Finder website, managed by the Association of Official Seed Certifying Agents (AOSCA), is a platform that already exists. Our State of Organic Seed (2016) findings show that 95% of organic certifiers already point their clients to this website as a resource for finding organic seed. We would like the crops subcommittee to explore ways that certifiers and/or the NOP can work with AOSCA to broaden the list of variety offering on this site.*

**Accredited Organic Certifier and Inspector Training**
NOC agrees with our colleagues at OSA that both certification staff and inspectors will greatly benefit from further training related to the commercial availability clause on how to assess a valid organic seed/planting stock search. We encourage the NOP to regularly include organic seed topics in certifier trainings. In addition to national trainings, regional trainings would also be helpful.

We point to OSA's more detailed comments regarding topics for organic seed training.

**Conclusion**
We appreciate the opportunity to provide comments on how best to strengthen the NOP's organic seed regulation and guidance, and hope that the NOSB will support the passage of this proposal. We thank the NOSB for its commitment to organic seed to ensure that organic integrity begins with this critical first link in the production chain.

## Discussion Document

### Paper Pots

NOC is in support of Beyond Pesticides' request that additional information – beyond that presented in the 2017 technical review (TR) for newspaper and other recycled paper – be developed for the board's consideration of the paper pot petition.

It is our understanding that the requirement that newspaper and other paper used in organic crop production be recycled comes from a resource conservation perspective. At this point in time, with the knowledge we have gained from the TR, it is evident that the NOSB may not have all the information needed to evaluate paper pots with respect to the criteria in the Organic Foods Production Act (OFPA).

A technical review addressing paper pots in reference to OFPA criteria has been requested. That review of paper pots should provide more information about the paper and adhesives used in the paper pots, the source of the pulp used in pots produced by the petitioner and others, as well as an estimate of the scale of production, so that the NOSB can better assess the environmental impacts of these pots in comparison to recycled paper that is now allowed as mulch.

Based on the information in the new TR, the CS should develop a proposal that contains an annotation clarifying the materials and manufacturing processes that would be allowed. The NOSB should facilitate support for the domestic production of paper pots that are compatible with organic principles.

## Sunset

### Hydrogen Peroxide – 205.601(a)(i)

NOC supports relisting hydrogen peroxide to the National List.

### Oils, horticultural (narrow range oils) – 205.601(e)(i)

**Subcommittee question:**

1. **Are non-petroleum-based oils available and could they be substituted for petroleum-based oils?**

   We are not aware of any non-petroleum-based oils available that would not wash off quickly and too easily to be effective.

### Pheromones – 205.601(f)

In the spring of 2011, the CS and NOSB struggled with an annotation describing a group of pheromones that they felt comfortable approving as a class. Lacking a technical review at the time, the board ended up approving the simple listing. Although EPA standards are not the same as the standards of OFPA, the EPA conditions for pheromone products that are exempt from regulation under FIFRA come close to describing products that could be allowed in organic production without further examination, and **we support the following listing, which we believe captures the sense of the conditions for exempting pheromone products from regulation:**

**§205.601(f) As insect management. Pheromones, provided that they are identical to or substantially similar to natural pheromones as defined in 40 CFR 152.25(b), in passive dispensers, without added toxicants, and with only approved inert ingredients.**

### Ferric phosphate – 205.601(h)

NOC would need to see independent and peer review studies of the efficacy for the use of sulfur as a molluscicide before serious consideration is given to the removal of ferric phosphate from the NL.

### Magnesium sulfate – 205.601(j)

Magnesium sulfate is a rarely used material that will provide an available form of magnesium to crops. It is rarely used because in most situations where the soil pH is being adjusted with limestone if magnesium is needed as well then dolomitic limestone (dolomite) is used and it provides enough magnesium as well as raising the pH. In addition, when supplying a soil amendment for potassium if magnesium is needed then sul-po-mag would be used. Magnesium sulfate is used only as a rescue

treatment where the soil pH and potassium levels are already optimum, but magnesium is still needed for optimum crop production.

Dolomite is not an alternative to magnesium sulfate. It is a magnesium rich soil amendment used in a different situation compared to magnesium sulfate.

NOC will support relisting of magnesium sulfate with the current annotation.

### Hydrogen chloride – 205.601(n)

Organic cotton growers in the U.S. currently do not have a lot of choice about how their seed is prepared for planting. U.S. organic cotton production is small and concentrated in west Texas. Cotton growers are limited to using the technology available in that area. There is, however, on-going research into the development of mechanical delinting mechanisms that would eliminate the need for hydrogen chloride. The NOSB should support these alternatives by making alternatives to hydrogen chloride a research priority. This is the kind of "minor" use that deserves special support. It appears to us that there are alternative technologies ripe for development, and that very little is needed to move them into the stage of being able to meet the demand of organic cotton growers. The NOSB should also recommend that USDA support the infrastructure needed to deliver mechanically delinted seed to organic cotton growers.

### Ash from manure burning – 205.602(a)

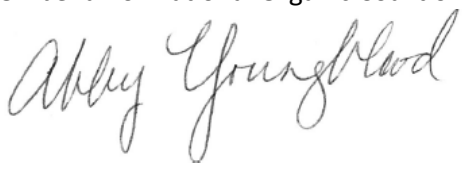
NOC supports relisting ash from manure burning at 205.602(a) without reservation.

### Sodium fluoaluminate 205.602(f)

NOC supports relisting sodium fluoaluminate at 205.602(f) without reservation.

Thank you for your consideration of these comments.

On behalf of National Organic Coalition Members:



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**National Organic Coalition Members:**


Beyond Pesticides
Center for Food Safety
Consumers Union
Equal Exchange
Food and Water Watch
Maine Organic Farmers and Gardeners Association
Midwest Organic and Sustainable Education Service
National Co+op Grocers
Northeast Organic Dairy Producers Alliance
Northeast Organic Farming Association
Ohio Ecological Food and Farm Association
Organic Seed Alliance
PCC Community Markets
Rural Advancement Foundation International – USA

# APPENDIX A

## NOC Fall 2018 Comment

### Silver dihydrogen citrate

**Nanosilver?**

Citric acid/citrate is used to control the size and shape of silver nanoparticles.[41] Although the petition does not mention nanotechnology, nanosilver would be allowed if the petition is approved without an annotation to exclude it. The NOSB, noting universal public opposition to the use of nanotechnology and engineered nanomaterials in organic production, voted to exclude engineered nanomaterials in 2010.[42] NOP did not follow the recommendation, but said that petitions for nanomaterials would be treated as any other petitions.[43]

The fact that an annotation would be required in this case to exclude a nanomaterial from use is an example of the need for the general prohibition on nanomaterials. Lacking such a policy, the persistent oversight of public interest groups is required to ensure that the NOSB does not approve a material that may be produced as an engineered nanomaterial.

**Ionic silver is also toxic.**

The petitioner disputes the idea that silver dihydrogen citrate is nanosilver and states that it is ionic silver. However, much of the research on the toxicity of nanosilver is pertinent to ionic silver. One cause of the toxicity of nanosilver is the fact that it provides a slow-release form of ionic silver.

The HS recommended annotation, "limited to particle sizes greater than 300 nm," would prevent other products that do contain nanosilver from being used if this petition is approved. However, there are problems with ionic silver *per se* that should result in a denial of this petition.

**Silver dihydrogen citrate is hazardous to humans and the environment.**

There is ample evidence, as should have been documented in a technical review, that both ionic silver and nanosilver are toxic not only to microbes, but to other species as well.[44] It is disappointing that the TR relied so

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[41] Rycenga, M., Cobley, C.M., Zeng, J., Li, W., Moran, C.H., Zhang, Q., Qin, D. and Xia, Y., 2011. Controlling the synthesis and assembly of silver nanostructures for plasmonic applications. *Chemical reviews*, *111*(6), pp.3669-3712. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3110991/pdf/nihms280337.pdf. Henglein, A. and Giersig, M., 1999. Formation of colloidal silver nanoparticles: capping action of citrate. *The Journal of Physical Chemistry B*, *103*(44), pp.9533-9539. https://pubs.acs.org/doi/abs/10.1021/jp9925334.

[42] NOSB Recommendation, "Guidance Document -- Engineered Nanomaterials in Organic Production, Processing and Packaging." October 2010. https://www.ams.usda.gov/sites/default/files/media/NOP Materials Final Rec Engineered Nonomaterials.pdf. See also: NOSB, 2009. Nanotechnology in Organic Production, Processing, and Packaging. https://www.ams.usda.gov/sites/default/files/media/Nano%20NOSB%20Materials%20Committee%20Recommendation%20%282009%29.pdf.

[43] NOP Policy Memorandum 15-2, "Nanotechnology" March 24, 2015. https://www.ams.usda.gov/sites/default/files/media/NOP-PM-15-2-Nanotechnology.pdf.

[44] See, for example, Hadrup, N. and Lam, H.R., 2014. Oral toxicity of silver ions, silver nanoparticles and colloidal silver–a review. *Regulatory Toxicology and Pharmacology*, *68*(1), pp.1-7; Beer, C., Foldbjerg, R., Hayashi, Y., Sutherland, D.S. and Autrup, H., 2012. Toxicity of silver nanoparticles—nanoparticle or silver ion?. *Toxicology letters*, *208*(3), pp.286-292. https://s3.amazonaws.com/academia.edu.documents/40028264/Toxicity_of_silver_nanoparticles-Nanopar20151115-30668-wuznkt.pdf?AWSAccessKeyId=AKIAIWOWYYGZ2Y53UL3A&Expires=1534088201&Signature=U%2FOUnlTRyPcN%2FRdM9MHqQ5LCzqo%3

heavily on conclusions drawn by EPA and FDA, which operate under different laws, with different standards – weaker in many ways than the Organic Foods Production Act (OFPA).

**Toxicity**

Studies show that the toxicity of nanosilver is at least partly due to the toxicity of ionic silver.[45] Ionic silver is released by the nanoparticles, and thus nanosilver serves as a sustained-release form of ionic silver.[46] As summarized by a news story in *Environmental Science and Technology*, "[Sam] Luoma, who recently authored the Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies report, *Silver Nanotechnologies and the Environment: Old Problems or New Challenges?* … says that 'baseline risk comes from the amount of silver that's in the environment —the amount of silver ions. Nanoparticles can then add to that risk,' whether by facilitating ions' behavior or disrupting cell activity on their own."[47] Other research has pointed to nanoparticle-specific mechanisms of toxicity of nanosilver.

In view of the position taken by the NOSB on engineered nanomaterials, the Board should not list silver dihydrogen citrate without the proposed annotation prohibiting nanosilver. However, regardless of whether it is an engineered nanomaterial, there are sufficient demonstrated health and environmental hazards associated with silver dihydrogen citrate as a source of ionic silver to reject the petition.

Silver is deposited in many or all organs, and there is evidence that it may persist in the body for weeks to months.[48] The accumulation of silver in soft tissues is responsible for the most widely known effect, argyria, which lends a grayish hue to the skin –but silver is also deposited in the liver, spleen, adrenal glands, muscle tissue, and brain.[49] High doses can be lethal.[50] Other health effects that have been documented include weight loss, hypoactivity, altered neurotransmitter levels, altered liver enzymes, altered blood values, enlarged heart, and immunological effects.[51] Reproductive and developmental impacts include testicular and sperm toxicity in males, ovarian histopathology in females, reduced reproductive success, effects on the neurological

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D&response-content-disposition=inline%3B%20filename%3DToxicity_of_silver_nanoparticles_Nanopar.pdf; Aitken, R.J., Hankin, S.M., Ross, B., Tran, C.L., Stone, V., Fernandes, T.F., Donaldson, K., Duffin, R., Chaudry, Q., Wilkins, T.A. and Wilkins, S.A., 2009. EMERGNANO: A review of completed and near completed environment, health and safety research on nanomaterials and nanotechnology Defra Project CB0409. *Institute of Occupational Medicine Report TM/09/01*; Senjen, R. and Illuminato, I., 2009. Nano and biocidal silver: Extreme germ killers present a growing threat to public health. Friends of the Earth, Victoria, Australia. https://foe.org/resources/nano-biocidal-silver/.

[45] Lubick, N., 2008. Nanosilver toxicity: ions, nanoparticles –or both? *Environ. Sci. Technol.*, 42 (23), pp 8617–8617.; Kawata, K., Osawa, M. and Okabe, S., 2009. In vitro toxicity of silver nanoparticles at noncytotoxic doses to HepG2 human hepatoma cells. *Environmental science & technology*, *43*(15), pp.6046-6051; Beer, C., Foldbjerg, R., Hayashi, Y., Sutherland, D.S. and Autrup, H., 2012. Toxicity of silver nanoparticles—nanoparticle or silver ion?. *Toxicology letters*, *208*(3), pp.286-292; Hadrup, N. and Lam, H.R., 2014. Oral toxicity of silver ions, silver nanoparticles and colloidal silver–a review. *Regulatory Toxicology and Pharmacology*, *68*(1), pp.1-7.

[46] Hadrup, N. and Lam, H.R., 2014. Oral toxicity of silver ions, silver nanoparticles and colloidal silver–a review. *Regulatory Toxicology and Pharmacology*, *68*(1), pp.1-7.

[47] Lubick, N., 2008. Nanosilver toxicity: ions, nanoparticles –or both? *Environ. Sci. Technol.*, 42 (23), pp 8617–8617.

[48] Hadrup, N. and Lam, H.R., 2014. Oral toxicity of silver ions, silver nanoparticles and colloidal silver–a review. *Regulatory Toxicology and Pharmacology*, *68*(1), pp.1-7.

[49] Lansdown, A.B.G., 2007. Critical observations on the neurotoxicity of silver. *Critical reviews in toxicology*, *37*(3), pp.237-250.

[50] Hadrup, N. and Lam, H.R., 2014. Oral toxicity of silver ions, silver nanoparticles and colloidal silver–a review. *Regulatory Toxicology and Pharmacology*, *68*(1), pp.1-7.

[51] Hadrup, N. and Lam, H.R., 2014. Oral toxicity of silver ions, silver nanoparticles and colloidal silver–a review. *Regulatory Toxicology and Pharmacology*, *68*(1), pp.1-7.

development of offspring, and behavioral changes.[52] Since silver accumulates in the body, it is dangerous to discount these effects as being associated with higher doses than would be predicted by exposure to silver dihydrogen citrate as petitioned.

**Antimicrobial resistance**

The spread of antimicrobial resistance is a health care crisis of major proportions. The Centers for Disease Control (CDC) call it "one of the world's most pressing public health problems."[53] Many bacterial infections are becoming resistant to the most commonly prescribed antibiotics, resulting in longer-lasting infections, higher medical expenses, and the need for more expensive or hazardous medications. The development and spread of antimicrobial resistance are the inevitable effect of the use of antimicrobials.[54] Microbes evolve quickly, and antimicrobials provide strong selection pressure for those strains with genes for resistance.

Silver is an antimicrobial with medical uses, so it is important to avoid unnecessary use that could lead to resistance. The TR states that bacterial resistance to the petitioned substance has not been reported, but we found several research papers documenting resistance to silver ions. Sütterlin et al. found, "Despite a restricted consumption of silver-based products in Swedish health care, silver resistance genes are widely represented in clinical isolates of *Enterobacter* and *Klebsiella* species. To avoid further selection and spread of silver-resistant bacteria with a high potential for healthcare-associated infections, the use of silver-based products needs to be controlled and the silver resistance monitored."[55] Davis et al. isolated two silver-resistant strains of *Enterobacter cloacae* from infected teeth containing dental restorations; both were also resistant to ampicillin, erythromycin, and clindamycin.[56] Larimer et al. easily induced resistance to silver ions and nanosilver in the laboratory, and the resulting resistant bacteria also showed increased resistance to the antibiotic isoniazid.[57] S. Silver documents widespread resistance to silver and its genetic basis, with the warning, "The wide and uncontrolled use of silver products may result in more bacteria developing resistance, analogous to the world-wide emergence of antibiotic- and other biocide-resistant bacteria."[58] Hobman and Crossman document a long history of resistance to silver and other heavy metals –often carried on the same genetic elements as antibiotic resistance— and conclude, "The continuing widespread presence of antimicrobial metal resistance genes often intimately associated with other antimicrobial resistance genes suggests that it is unlikely that they are going to go away soon, and we must take resistance gene co-carriage and co-selection into account when we think about strategies to combat antimicrobial and antibiotic resistance. Persistence of these metal resistance genes points to what the future for antibiotic resistance gene persistence could be." [59]

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[52] Ema, M., Okuda, H., Gamo, M. and Honda, K., 2017. A review of reproductive and developmental toxicity of silver nanoparticles in laboratory animals. *Reproductive Toxicology*, *67*, pp.149-164.

[53] CDC, "Get Smart: Know When Antibiotics Work." http://www.cdc.gov/getsmart/antibiotic-use/fast-facts.html.

[54] Thomas F. O'Brien, 2002. Emergence, Spread, and Environmental Effect of Antimicrobial Resistance: How Use of an Antimicrobial Anywhere Can Increase Resistance to Any Antimicrobial Anywhere Else, Clinical Infectious Diseases 2002; 34(Suppl 3):S78–84.

[55] Sütterlin, S., Dahlö, M., Tellgren-Roth, C., Schaal, W. and Melhus, Å., 2017. High frequency of silver resistance genes in invasive isolates of Enterobacter and Klebsiella species. *Journal of Hospital Infection*, *96*(3), pp.256-261.

[56] Davis, I.J., Richards, H. and Mullany, P., 2005. Isolation of silver-and antibiotic-resistant Enterobacter cloacae from teeth. *Oral microbiology and immunology*, *20*(3), pp.191-194.

[57] Larimer, C., Islam, M.S., Ojha, A. and Nettleship, I., 2014. Mutation of environmental mycobacteria to resist silver nanoparticles also confers resistance to a common antibiotic. *BioMetals*, *27*(4), pp.695-702.

[58] Silver, S., 2003. Bacterial silver resistance: molecular biology and uses and misuses of silver compounds. *FEMS microbiology reviews*, *27*(2-3), pp.341-353.

[59] Hobman, J.L. and Crossman, L.C., 2015. Bacterial antimicrobial metal ion resistance. *Journal of medical microbiology*, *64*(5), pp.471-497.

Considering the medical uses of silver and evidence of the existence of genes for silver resistance –and especially the fact that silver- and antibiotic- resistant genes are frequently transmitted together—it is important to avoid promoting unnecessary uses of silver that can increase the spread of resistance.

While silver dihydrogen citrate is petitioned for use on food, the NOSB must also consider possible impacts on the environment from discharges and food waste. Microbial life in the soil is important to organic production, and waterways provide a breeding ground for resistant microbes.[60]

**Ancillary substances**

The petition lists as ancillary substances:

- Citric acid: this substance is a component of the solution and is used as a stabilizer and pH control agent.
- Sodium lauryl sulfate: this substance is intentionally added during manufacturing to act as a stabilizer for the solution.

Since these have a technical or functional effect in the final product (stabilizers, pH control), they are ingredients, not ancillary substances, and should be evaluated.[61]

**Chemical interactions**

The petition says,

> *Ionic silver rapidly reacts with chlorides and some other anions that will result in low solubility silver salts. This reaction would potentially affect stability of the product. We recognize that two chloride salts, calcium and potassium, are permitted for use in organic processing, but the chloride salts are not expected to be used during the early processing stages. Therefore, the silver dihydrogen citrate would not be anticipated to have the opportunity to react with those substances and adversely impact the stability of the product.*

The technical review states, "Silver dihydrogen citrate is incompatible with aluminum sulfate, aluminum ammonium chloride, aluminum orthophosphate, chlorides, sequestering agents designed to remove transition metals from solution, ethylenediaminetetraacetic acid (EDTA, above 1.5%), and calcium hardness above 300 ppm. These substances are not on the National List for organic handling."

The following chlorides are on the National List, §205.605: calcium chloride, potassium chloride, and magnesium chloride. In addition, sodium chloride (table salt) is implicitly allowed by OFPA and may be present during processing and in the finished product. It is possible that the presence of these chlorides poses no problem through interaction with silver dihydrogen citrate, but that is something to be established rather than ignored.

**Silver dihydrogen citrate is not essential to organic production and handling.**

The petitioner has not argued in the petition justification that silver dihydrogen citrate is essential to organic production and handling. It has presented arguments of the benefits of the material –arguments that should be considered in a comprehensive review of cleansers, disinfectants, and sanitizers. Only through such a review – which would establish the need for such materials in organic production and handling, as well as the relative

[60] Icgen, B. and Yilmaz, F., 2014. Co-occurrence of antibiotic and heavy metal resistance in Kızılırmak river isolates. *Bulletin of environmental contamination and toxicology*, *93*(6), pp.735-743.

[61] TR lines 138-141; 181-182.

benefits of available materials— can the essentiality for a petitioned sanitizer be established. Information in the petition and technical review is not sufficient.

The TR says, "When processing agricultural products, biocides like SDC are paramount in ensuring the safety of consumer. There is no reported literature describing other antimicrobial practices that are available for direct and indirect food contact sanitization in the processing of agricultural products other than the application of biocide solutions."[62] However, national and international agencies stress the importance of non-chemical sanitation measures. These practices begin with construction of facilities to be "cleaning friendly," meaning that easy access is provided to all surfaces and equipment and that surfaces are smooth and made of materials that can be easily cleaned. Rodents and insects should be excluded, rather than poisoned. Such facilities can be cleaned by physical methods and may often be disinfected with steam or hot water rather than biocides. Clean facilities offer fewer opportunities to contaminate food.[63] Sanitizers used in disinfecting food production facilities offer fewer possibilities for contamination of food than do chemicals used directly on food.

**Silver dihydrogen citrate is incompatible with organic production.**
Nanosilver forms of silver dihydrogen citrate should not be considered for use in organic production because the NOSB has recommended against the inclusion of engineered nanomaterials on the National List.

Ionic silver is inconsistent with organic production because it has not been shown to be in compliance with other applicable criteria.[64]

**Conclusion**
NOC opposes the petition for silver dihydrogen citrate. Although the proposed annotation does not allow nanosilver, silver dihydrogen citrate poses health and environmental risks –particularly the risk of increasing resistance to antibiotics and silver-based medications. The technical review has many flaws, some of which have been pointed out above. The petition for SDC must be denied to protect the effectiveness of remaining antimicrobial medications.

## NOC Spring 2015 Comment

### §205.606 of the National List

To provide further details regarding our concerns for the continued use of §205.606 of the National List, we are including our comments on this topic submitting during the spring 2015 NOSB meeting.

Improvements needed for the first review, as well as the sunset review, of items on §205.606 of the National List

Items on §205.606 must be agricultural and be shown to not be "commercially available" in an organic form. The only other place commercial availability is used is for organic seed. Historically, the review of materials on §205.606 has only included a marketplace search for these ingredients allowed in organically labeled foods.

[62] TR lines 385-388.
[63] Food and Agriculture Organization, 2007. Meat Processing Technology. http://www.fao.org/docrep/010/ai407e/AI407E00.htm; USDA Cooperative Extension, 2010. Meat Plant Sanitation, http://articles.extension.org/pages/27418/meat-plant-sanitation.
[64] NOSB Guidance on Compatibility With a System of Sustainable Agriculture and Consistency With Organic Farming and Handling, NOSB Recommendation Adopted April 29, 2004.

The prospect of considering the many different inputs and methods of nonorganic farming can be seen as a daunting task when reviewing materials to the full Organic Foods Production Act criteria.

However, in further review of the Organic Foods Production Act, the National Organic Program final rule, and the First Circuit's decision in *Harvey v. Veneman, 396 F.3d 28 (1st Cir. 2005),* the point could be made that these ingredients on the National List must also be reviewed to the full criteria required of all items on the National List. The citations supporting this position of full criteria review are noted at the end of this discussion on §205.606. The National Organic Coalition requests the National Organic Program and the National Organic Standards Board discuss and define the scope of criteria for the review of §205.606 ingredients with consideration of these citations in a transparent manner, since this section of the National List results in the inclusion of products in organically labeled foods to be grown and processed using materials that are prohibited in organic ingredients. We understand that historically §205.606 ingredients have not been reviewed to the full OFPA criteria. As we continue to refine our materials review process, it is important that the NOP, the NOSB, and the organic community continually refer back to the OFPA and the rule to make sure our procedures and review processes reflect the letter of the law.

The NOSB has reviewed and clarified the protocols that producers who wish to use nonorganic seed in organic production under the "commercial availability" exemption must use, in order for the growers to meet both the letter and spirit of the law. The same clarification and consistency of implementation has not been done for materials used in handling present on §205.606, which are also subject to a "commercial availability" requirement. It is time to provide these protocols to both petitioners of new items to be put on the §205.606 list and also items up for renewal under the sunset review process.

**The regulations at §205.2 define:**

> ***Commercially available.*** ***The ability to obtain a production input in an appropriate form, quality or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.***

Many people choose to eat organic food because organic production minimizes impacts on farmworkers, water resources, wildlife, and pollinators, in addition to producing more healthy food products. These impacts can be taken into account in decisions to list or relist nonorganic agricultural ingredients on §205.606, by reviewing all barriers to the production of an organic alternative and not allowing the product to be on §205.606 unless a truly comprehensive understanding and review of the barriers to commercial availability has been done. Only after it is clearly shown that the barriers are insurmountable, then the nonorganic agricultural product would be allowed on §205.606 when commercial availability is being considered. **There has been significant enough growth in organic production over the past decade, that if a crop can be produced nonorganically, it could probably be produced organically as well. The National Organic Program must implement systems that would result in more aggressive development of organic equivalents for the nonorganic ingredients on §205.606, as well as those that may be petitioned in the future.**

Currently, the petitioner must show they have searched for the item and not found it as organic, and the NOSB verifies this search to be found true. However, many, if not all, of these agricultural ingredients are subject to many different types of production and manufacture norms in the marketplace. Many times, there are minimum production runs in order for a manufacturer to consider the production of an organic equivalent, making it difficult to source in small amounts. However, if handlers worked with others, and it is understood these others may be their competitors, to consolidate their orders to meet the minimum run

requirements, it may become possible to produce that same product organically, making it commercially available. Another roadblock might be the need to contract for agricultural production of organic crops necessary for manufacturing a product. **Unless producers know there is a market for a particular crop**, they will probably not grow it or manufacture it—a contract with a buyer can help overcome that barrier. A consistent checklist should be developed to help the NOSB determine whether or not the final ingredient on the National List is available as organic, but must also identify the stumbling blocks to producing it organically. Such information would help highlight ideas for overcoming these stumbling blocks by one or numerous petitioners.

All new petitioners of materials to be listed on §205.606 must aid the National Organic Standards Board in understanding the issues related to production of an organic equivalent of the material they are petitioning. **Simply stating that an organic agricultural ingredient is not available is insufficient.** While the argument can be made that items on §205.606 are an invitation for manufacturers to develop organic equivalents, we are seeing that this has not actually happened. In consideration of ingredients for processed products, we must remember that the higher price of an organic ingredient cannot be part of the determination of commercial availability, just as organic farmers are mandated to use organic seed when available, without consideration of its price.

For manufacturers of minor agricultural ingredients used in organically labeled products, there is less incentive to develop and produce these ingredients in an organic form, unless the marketplace shows a strong demand with the accompanying determination to have these ingredients available to them as organic. **Standing ready to buy a product is just one aspect, petitioners and manufacturers may need to do some development work.** The buyers must have an understanding of the barriers to organic ingredient development and work creatively in overcoming those barriers in order to produce the organic ingredient.

As a start, the following questions should be answered by all new petitioners and Technical Reviews could be performed to aid the NOSB when reviewing both new and sunset items for §205.606. Not only should the product currently be unavailable in the marketplace in its organic form, the barriers to its production should be extremely difficult to impossible to overcome, in order for the ingredient to be listed on §205.606.

**What are the barriers to producing this ingredient in an organic form?**

1. Is there insufficient raw organic agricultural production within the necessary proximity of the main manufacturing facility? Shipping costs are not to be part of the consideration.
2. What proximity constraints are in place for either a manufactured or raw agricultural commodity in organic form? Examples include perishability, political climate (war zone) of the area where the agricultural production occurs, or the location of the manufacturing facility.
3. Are there other manufacturing facilities that may have organic agricultural raw ingredient production nearby, or could be enticed to produce this ingredient in an organic form?
4. If raw agricultural production is required in a specific climate or soil type where there currently is no organic production and prospects for organic production are difficult, has production in other areas of the world been researched and work begun to develop new sources of organic crop production of the source ingredients for this product?
5. If there is only nonorganic production nearby to a manufacturing facility, what are the barriers to having these producers transition some or all of their production to organic?
6. Has the petitioner or users of this §205.606 ingredient worked with both the manufacturing facilities

and pools of growers in the area, to develop a supply of raw organic crops to produce this ingredient?
7. Is the demand for this ingredient across the organic industry sufficient to meet the minimum manufacturing production run?
8. Have all possible manufacturers of this ingredient been researched to determine their minimum production runs and regions where the raw agricultural ingredient or ingredients are grown?
9. Can the ingredient be manufactured from not only raw agricultural ingredients, but possibly from a secondary manufactured ingredient, such as beet color made not only from raw organic beets, but also from a preprocessed beet juice or beet powder that could be obtained in an organic form? Another example would be instantized nonfat dry milk powder made not just from liquid organic skim milk, but from non-instant organic nonfat dry milk powder?
10. Is the process under which this product is manufactured a patented product, and if so, is the manufacturer willing to produce an organic equivalent?
11. If the ingredient is of limited quantity due to manufacturing constraints other than lack of availability of raw organic crops, what are these constraints?
12. Is there an exclusive use agreement with one buyer or select buyers that effectively removes access to an organic or 205.606 ingredient by their competitors, causing them to request a different ingredient to be put on 205.606 as a replacement? Is this market constraint agreement transparent and considered an acceptable reason for inclusion on 205.606 by the NOSB?
13. If this 205.606 ingredient is a fraction of another agricultural ingredient, such as wheat germ from wheat, has the availability of this organic fraction been requested not only as the requested product, but have the manufacturers of whole agricultural product been thoroughly researched as to not just the availability, but their willingness and capability to produce the required organic sub-ingredient?
14. If the nonorganic ingredient is typically a crop that is grown mostly or wholly on contract, and may be a perennial, such as hops, has the petitioner explained to the satisfaction of the NOSB why pre-contracting with organic producers for the ingredient is impossible or extremely difficult.
15. Depending on the ingredient, there may be other barriers to organic production that are not listed above, and the petitioner, as well as the NOSB, should be researching these barriers and deciding whether they are sufficiently difficult that these nonorganic ingredients must be put on the National List.

**The case for using the full OFPA criteria for review of §205.606 ingredients, beyond just commercial availability.**

Environmental, consumer, and organic farming advocates have made a strong argument that a significant percentage of the synthetic substances used pervasively in nonorganic agriculture could be classified as being harmful to human health or the environment, even if this determination has not been made by the USDA or other US government agencies. Crops and food ingredients produced with known carcinogens, endocrine disrupters, or damaging to pollinators and other wildlife should be avoided to the best of our ability in organic foods.

From the Organic Food Production Act:
§6517(c)(1) *Exemption for prohibited substances in organic production or handling operations*

> *The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this title only if—*

***(A)*** *The Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that the use of such substances—*

***(i)*** *would not be harmful to human health or the environment;*

***(ii)*** *is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products; and*

***(iii)*** *is consistent with organic farming and handling*

**From the NOP final rule**

***§205.600 Evaluation criteria for allowed and prohibited substances, methods,*** **and ingredients.**

*The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:*

*(a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).*

*(b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:*

*(1) The substance cannot be produced from a natural source and there are no organic substitutes;*

*(2) The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;*

*(3) The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations;*

*(4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law;*

*(5) The substance is listed as generally recognized as safe (GRAS) by Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; and*

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

*(c) Nonsynthetics used in organic processing will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).*

***§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."***

*Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as "organic," only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.*

***§205.2 Terms Defined***

*Ingredient. Any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed.*

Since ingredients are defined as substances, and since they are agriculturally produced, they would be nonsynthetic. It could be interpreted that these §205.606 ingredients should be reviewed under the full OFPA criteria and not just for commercially availability.

**Text from the First Circuit court decision in *Harvey v. Veneman*, 396 F.3d 28 (1st Cir. 2005).**

*Harvey correctly points out that §§ 6517 and 6518 of OFPA require all specific exemptions to the Act's ban on nonorganic substances to be placed on the National List following notice and comment and subject to periodic review. See 7 U.S.C. §§ 6517(a), (d), (e); 6518(k), (l ), (m).Harvey argues that the challenged provision allows ad hoc decisions regarding the use of synthetic substances, in contravention of these statutory procedural requirements.*

*In the District Court and before this court, the Secretary has taken the position that § 205.606 does not create a blanket exemption, as Harvey contends, but rather permits use only of the ingredients specifically listed in that section. In other words, the Secretary maintains that the list of five products in § 205.606 is a part of the National List and that the provision emphasized above and challenged by Harvey should be interpreted simply as a further limitation on the addition of new nonorganic ingredients to the National List.*

*We agree with the District Court that the interpretation advanced by the Secretary is a plausible interpretation of the language of § 205.606 that eliminates any conflict with OFPA's requirements. The District Court was correct to conclude that, under the Secretary's interpretation, § 205.606 is not in contravention of OFPA.*

*However, the District Court did not clarify that it is necessary to interpret the *36 Rule in this manner in order to find this portion of the Rule valid. Under other interpretations, § 205.606 might exceed the Secretary's authority under OFPA. In particular, the*

*interpretation suggested by Harvey, although it is at odds with OFPA's evident requirements, is not an implausible construction of the language of § 205.606 considered alone. Indeed, the Secretary herself appears to have espoused exactly this interpretation in the past. See 65 Fed.Reg. 80,616 ("In the regulation, a nonsynthetic and nonorganic agricultural product ... used as a processing aid does not have to appear on the National List. Such products are included in the provision in § 205.606 that nonorganically produced agricultural products may be used in accordance with any applicable restrictions when the substance is not commercially available in organic form.").*

*In light of this possibility, it is insufficient for this court simply to affirm the District Court's judgment that § 205.606 is, as it stands, consistent with OFPA. Instead, to clarify that this portion of the Rule may not be interpreted in a way that contravenes the National List requirements of OFPA, we remand to the District Court for entry of a declaratory judgment that § 205.606 does not establish a blanket exemption to the National List requirements for nonorganic agricultural products that are not commercially available*.


# APPENDIX B

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Washington, DC 20250-0268 Docket: AMS-NOP-18-0071

January 2, 2019

**RE: Materials Subcommittee Proposal: "Genetic Integrity Transparency of Seed Grown on Organic Land"**

Thank you for the opportunity to provide additional comments on the Materials Subcommittee's proposal, titled: "Genetic Integrity Transparency of Seed Grown on Organic Land" (August 14, 2018). We, the undersigned, appreciate the subcommittee's attention on the issue of genetic integrity of seed used by organic producers.

Organic crop producers, seed producers, and seed companies are responding to the challenge that genetically engineered (GE) traits, an excluded method, pose to the integrity of seed used by organic farmers through testing, prevention strategies, and redirecting organic seed lots to conventional markets when detectable levels are high. In important ways, some players in the seed trade are taking leadership in this area by being transparent about detectable levels of GE traits in the seed they sell and by protecting the genetic integrity of their seed through purification and prevention practices, including isolating their seed production.

The issue is complex, as evidenced by previous discussion documents and public comments. We are pleased to see ideas fleshed out by the subcommittee but believe the current proposal is the wrong approach. In short, we find the proposal confusing and impractical, and are concerned it puts farmers at unnecessary risk. We are also concerned about the unintended consequence of limiting the diversity of seed available to organic field corn growers. Thank you for taking the following comments into consideration.

**1. Achieving more transparency in the seed marketplace should not burden farmers**

We believe this proposal overly burdens organic growers. First, requiring growers to retain seed samples is problematic in two ways: 1) organic growers' capacity (time and storage space) to collect these samples, and 2) the importance of storing seed in a way that protects the viability of the samples. This requirement will become even more challenging should this protocol expand to include additional crops. Second, the proposal places an unfair burden on organic farmers who source non- organic field corn seed and are required to navigate the testing and reporting process of detection levels. We appreciate that this requirement incentivizes sourcing organic seed; however, this requirement means that some organic field corn growers will have to navigate the complexity of taking appropriate samples, where to send them for testing, and then cover the cost of that testing.
Some growers may view even minor additional costs as unacceptable. Third, this proposal forces farmers into the impossible position of deciding whether to knowingly plant seed with detectable levels of GE traits


or scrambling to find an alternative, which would increase operating costs, effectively penalize them for the presence of GE traits in the seed they source, and complicate issues of liability for them and the seed companies they source from. This pilot project could set the unintended precedent of farmers assuming liability for detectible levels that are out of their control.

**2. Achieving transparency in the seed marketplace should build off of existing good practices**

As far as we can tell, the proposed pilot project aims to achieve two goals: 1) collect more data to understand the problem of unintended GE presence in field corn used in organic systems, and 2) establish a complicated testing and reporting protocol to achieve more transparency in the marketplace. It is counterintuitive to address both of these needs simultaneously, since the results of the first step greatly inform the feasibility, structure, and stakeholders involved in the second.

In other words, the 17-step pilot project in this proposal is not a small undertaking, and may involve more stakeholders than is necessary at this time. We encourage the subcommittee to take a step back and closely consult all stakeholders impacted by this proposal, especially seed companies, but also certifiers and organic field corn growers. Some seed companies were consulted in the development of this proposal; however, these same companies were caught off guard by the end result of this proposal, and are very concerned about the direction the subcommittee is headed.

It is important for the subcommittee to hear the on-the-ground reality of seed companies who deal with at-risk crops, like field corn, to understand if this proposal would help or harm the progress they are making in delivering more diverse options in organic seed. As a leader in encouraging agriculture toward policies and practices that enhance biodiversity, the NOSB must be cautious in recommending a project that risks increasing genetic uniformity in our fields and undermining progress toward expanding the availability of organic seed.

One idea to consider is to collect data from organic seed suppliers for a couple years, or sooner if these companies have a backlog of testing data they are willing to share under a non-disclosure agreement. That data (which would include conventional untreated seed when available) could be collected, combined, and analyzed anonymously and used by the subcommittee to help understand the range and concentration of detectable levels of GE content in seed used by organic growers. This process would be a first step in better understanding the actual problem. After looking at this data provided by companies, the subcommittee could then conduct a similar effort on shipments of organic field corn. With this data the subcommittee can decide what, if any, additional information is needed, if testing should be required, if organic seed companies should be required to report detectable levels in their Organic Systems Plan, or if the subcommittee should recommend a more comprehensive testing and reporting protocol.

**3. Achieving transparency in the seed marketplace requires a practical approach**

In addition to the burden on farmers, there are a number of factors that make the current proposal impractical. First, intellectual property rights can restrict an organic seed company's ability to test for GE traits. For example, some organic seed companies do not have internal breeding programs and must rely on licensing inbred lines for producing the hybrid corn seed varieties they sell. At times the licensing agreements to access these inbred lines are written in a way that prohibits testing for traits developed by

excluded methods. This limitation could have a real impact on an organic seed supplier's ability to fulfill the testing and reporting requirement outlined in this proposal, at least for some varieties, since doing so could violate a legal agreement. Second, it is impractical to expect testing of "all known GE traits available" in a crop species, which could be construed as covering: 1) commercially available traits in production, 2) commercially approved traits not in production, and 3) unapproved traits that are in the experimental stage in open-air field trials. Third, we are concerned about the potential burden on certifiers to track and submit to the NOP detectible levels collected by their certified corn operations. Any proposal moving forward should limit the burden on certifiers.

**We agree that farmers' access to appropriate seed and information on detectible levels of GE traits in seed used by organic growers is a worthy goal to strive for. We also understand that some farmers experience losses in the form of rejected loads or failure to meet thresholds established in production contracts. But we strongly believe that the proposal as written is not the most effective and efficient way to help these farmers and to achieve the goal of transparency in the seed marketplace. We want to reiterate that the issue of transparency is important and needed on a broader scale. We look forward to working with the subcommittee on a different path that is based on using data to understand the scope of the problem, and is more practical, farmer friendly, and builds off of existing good practices in the organic seed trade.**

Sincerely,

Albert Lea Seed
American Seed Trade Association
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Organic Farmers' Agency for Relationship Marketing (OFARM)
Organic Seed Alliance
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