April 5, 2021

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

RE: AMS-NOP-20-0041

NOC Comments to the National Organic Standards Board

SPRING 2021

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Virtual Meeting

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.

Below we provide comments on a wide range of topics for consideration by the Board.

Contents

State of the USDA National Organic Program

The National Organic Coalition (NOC) is a diverse, national coalition with a cross-sector approach. We represent a full spectrum of organic stakeholder groups, including farmer organizations, consumer and environmental groups, organic companies, retailers, and organic certification agencies. We use a consensus process to develop policy positions, so when NOC brings an issue forward, we have reached agreement across these diverse stakeholder groups, signaling likelihood of broad industry support. The new administration and new leadership at USDA present the organic community with the opportunity to articulate our top priorities to put organic back on solid footing and to address loopholes in organic regulations that have gone unaddressed for far too long. To this end, NOC has communicated six top priorities to the new administration in our efforts to advance organic agriculture and protect the integrity of the organic program.[1]

We have asked the Biden administration, USDA, and Congressional leaders to advance these top six priorities:

1. **Reinstate the Organic Livestock and Poultry Practices Rule.** This rule will require all organic poultry and egg operations to provide meaningful outdoor access for chickens and is essential for public trust in the certified organic label.

2. **Finalize an enforceable Origin of Livestock Rule without delay.** Organic dairy farmers are suffering and continued delays in implementing this rule will prolong the dire economic fate facing organic dairy farmers.

3. **Move expeditiously to finalize the Strengthening Organic Enforcement Rule.** This significant rewrite of the organic regulations addresses fraud in organic supply chains in a comprehensive manner.

4. **Restore the Organic Certification Cost Share Program to the full reimbursement rates.** The Trump administration slashed reimbursement levels in the midst of a period of higher costs and disrupted markets caused by the pandemic.

5. **Embrace organic agriculture as a key climate change solution.** Organic practices are systems approach of climate-friendly practices. The new administration should incentivize the adoption of organic agriculture and simultaneously support improvements in organic standards to solidify organic's role as the gold standard for climate-friendly agriculture.

6. **Build our food systems back better than before, using the lessons of the pandemic.** NOC has submitted detailed recommendations to the Secretary of Agriculture and to Congress about policy actions that should be taken to address challenges related to the coronavirus pandemic.[2]

Discussion

Unfinished Organic Rules

The NOSB has deliberated on many of the provisions contained in the three unfinished organic regulations that NOC has prioritized for immediate implementation with the new administration.

[1] National Organic Coalition Transition Recommendations: https://app.box.com/s/nr1tf7igrxh3k6k9j7p9vv7uu6iy03mi

[2] National Organic Coalition and Organic Farmers Association pandemic relief recommendations: https://app.box.com/s/khg95otgoko01huy63nthfa04pingn4w

1. **Reinstate the Organic Livestock and Poultry Practices Rule.**

2. **Finalize an enforceable Origin of Livestock Rule without delay.**

3. **Move expeditiously to finalize the Strengthening Organic Enforcement Rule.**

   Regarding the Strengthening Organic Enforcement rule, NOC appreciates that the proposed rule reflects amendments to the OFPA included in the Agricultural Improvement Act of 2018 which were widely advocated for by organic community stakeholders, and that portions of the proposed rule reflect NOSB recommendations. We are concerned, however, that the NOSB has not had an opportunity to weigh in on all aspects of the proposed rule, as required by OFPA.[3]

   NOC requests that the USDA Agricultural Marketing Service (AMS) provide the public and the members of the NOSB with a detailed analysis of the SOE rule's provisions to explain how each of those provisions align with recommendations made by the NOSB. The NOSB should also be given an opportunity to weigh in on provisions that it has not had a chance to consider. NOC is concerned that the SOE proposed rule does not state the position of the NOSB on the provisions of this rule, nor does it confirm that the agency consulted with the NOSB on the proposed rule. NOC is urging that the NOP make clear for all proposed rules and guidance documents how the provisions align with NOSB recommendations.

4. **Restore the Organic Certification Cost Share Program to the full reimbursement rates.**

5. **Embrace organic agriculture as a key climate change solution.**

   NOC believes the NOSB has an important role to play in solidifying organic's role as the gold standard for climate-friendly agriculture (priority #5 above). The organic regulations are strong because they require proper tillage, soil-building practices that sequester carbon, and pasture-based grazing for organic livestock. But the regulations are not being enforced as effectively as they should be. There are several areas where enforcement must be strengthened, and new regulations should be put into place to ensure that organic is the gold standard when it comes to climate change:

   a. The NOSB should ban ammonia extracts and restrict the use of other highly soluble sources of nitrogen in organic agriculture. Overreliance on highly soluble sources of fertility can short circuit soil-building practices that sequester carbon and is in violation of the foundational "feed the soil" principle in organic agriculture. Highly soluble sources of nitrogen should be included on the list of prohibited naturals (7 CFR §205.602 of the National List) with an annotation limiting them to no more than 20% of a crop's total annual nitrogen requirements with severe restrictions. NOC has provided more extensive comments on this topic in recent years and our detailed comments on ammonia extract are on page 26.

[3] See 7 U.S.C. § 6503(c) "In developing [the national organic production] program…the Secretary shall consult with the National Organic Standards Board"; see also 7 U.S.C. §6518(a) "The Secretary shall establish a National Organic Standards Board…to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of [OFPA]."

b. The NOSB should create a work agenda item which focuses on enforcement of soil-building, cover cropping, crop rotation, and biodiversity practices required in the organic regulations. The NOSB should identify and make recommendations to strengthen organic practices for climate mitigation, adaptation, and carbon sequestration. Such an effort would serve to bolster clarity and consistency of enforcement across certifiers, hold producers to foundational principles of organic production, and strengthen organic producers' position in the climate discussions and initiatives across the country.

   The NOSB should make recommendations about the circumstances under which certifiers should issue non-compliances for operations that fail to adhere to the soil fertility and crop nutrient management practice standards (§205.203) and crop rotation requirements (§205.205). Organic operations should not be allowed to plant the same crop continuously without implementing meaningful crop rotations. We are concerned that many certifiers are currently allowing operations to plant crops continuously without rotations and with only a brief "interruption" of a cover crop in the winter months.

c. The USDA National Organic Program (NOP) should fix regulatory and enforcement shortfalls for livestock and poultry that enable more highly concentrated operations to be certified and allow some operations to deny animals meaningful access to the outdoors and to pasture. Research shows that some of the most climate friendly farming systems are those that combine livestock and pasture in a symbiotic relationship, in contrast to those operations that confine livestock in concentrated feeding operations for long periods of time in excess of the carrying capacity of the land. The NOP should immediately reinstate the Organic Livestock & Poultry Practices rule, which was withdrawn by the previous administration in 2018. NOC is a plaintiff in a lawsuit, led by Center for Food Safety, challenging the withdrawal of this regulation.[4]

d. The NOP should finalize regulations on standards that eliminate incentives to convert native ecosystems to organic production, based on the NOSB recommendation on this topic in 2018.

Summary: NOC is requesting that the NOSB create a work agenda item related to carbon sequestration and enforcement of soil-health provisions in the organic regulations and that the NOSB recommend a detailed restriction on the use of highly soluble sources of nitrogen in organic agriculture. NOC is requesting that the NOP reinstate the Organic Livestock and Poultry Practices Rule, adequately enforce the pasture rule and soil health provisions in organic, and finalize regulations on standards that eliminate incentives to convert native ecosystems.

6. **Build our food systems back better than before, using the lessons of the pandemic.** Regarding this last priority, NOC recognizes that communities of color have been hit disproportionately hard by COVID-19. These disparities compound decades of racial discrimination, including discriminatory policies at USDA that have resulted in inequitable lending and land ownership policies. BIPOC (Black, Indigenous, and people of color) individuals are underrepresented as farm and ranch owners and operators, in conventional agriculture as well as organic systems. Although BIPOC individuals represent nearly 40% of the US population, only 3% of organic producers identify as BIPOC. Addressing racial equity in organic agriculture is an important priority for NOC. The NOSB can also play a role by considering the impact of

[4] https://www.centerforfoodsafety.org/press-releases/5294/organic-advocates-and-farmers-sue-over-trump-withdrawal-of-widely-supported-organic-livestock-welfare-rule

NOSB decisions on BIPOC farmers and by understanding some of the specific barriers to organic certification for BIPOC farmers. NOC has included more detailed comments on this topic on page 8.

The NOSB's Role and Authority

NOC disagrees with USDA's decision to limit the NOSB workplan to issues that are already priorities of the NOP. In its February 27, 2014, memo, the NOP stated that in order for an item to be added to the NOSB work plan it "must be a priority for the USDA/NOP."[5] However, OFPA gives the NOSB the duty "to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of this chapter."[6] This duty to advise transcends NOP priorities and includes the setting of NOP priorities.

The NOSB work should be driven by the public process—the NOP should not have the ability to veto critically important issues that the NOSB seeks to address. The NOSB was designed to maximize public input from a community with strong and diverse views and deep knowledge about the meaning of "organic." That input and the 2/3 "decisive vote" requirement ensure that NOSB proposals can only pass when they garner broad and diverse support from different stakeholder groups.

In the interest of protecting transparency, accountability, and the public process, NOC requests that the NOP provide more transparency regarding NOSB work agenda items that have been removed from the work agenda without explanation, included here at Appendix A. In addition, the NOSB should request that the NOP provide an update on all previous NOSB recommendations made and a plan and timeline for implementing these recommendations.

NOC also requests that notes from NOSB executive committee and subcommittee calls be made available to public stakeholders in a timely and more substantive way. We appreciate that the executive committee and subcommittee call notes are again being published, but waiting up to six months to publish these provides little benefit to public stakeholders who wish to engage in the process in real time. In addition, when the notes are published, they have been stripped to the bare minimum of information, which does not lend itself to a transparent process. The notes should include motions and votes on them, as well as a summary of discussions on issues.

In the Fall of 2020, NOC provided detailed comments to the NOSB on a wide range of topics, including cuts to the organic certification cost share program, recommendations for pandemic relief to address the needs of the organic community, organic's role as a climate change solution, the need for restrictions on highly soluble nutrients, oversight of the NOP's accreditation process, origin of livestock, hydroponics and container production, and many additional topics. Those comments can be found here, for the benefit of new Board members who may be interested in more detailed information on these topics.

Racial Equity

The 2017 Ag Census data shows that people of color are underrepresented in farming, including organic farming. For example, while over 13% of the US population identifies as Black or African American, fewer 1.4% of all

[5] AMS, USDA, NOP, *Memorandum to the National Organic Standards Board: NOSB Training Summary,* February 27, 2014, https://www.ams.usda.gov/sites/default/files/media/NOSB%20Memo%20Training%20Summary.pdf, p 3.
[6] 7 U.S.C. § 6518(a).

farms in the U.S. are owned by Black or African American farm owners. 98% of agricultural land is owned by white landowners.[7] **According to 2017 ag census data, although organic farmers are slightly "more diverse" than conventional farmers (94% of conventional farmers and, 92% of organic farmers identify as white), fewer than 1% of organic farmers identified as Black or African American, and 0.5% identified as American Indian or Alaska Native.[8]**

We recognize that access to the organic movement and organic certification has not been equal across racial groups. Systemic racism has kept our movement from reaching its full potential. The organic movement can only be stronger and better positioned to meet future challenges if it represents diverse participation. Attached in Appendix B is NOC's statement on Racial Equity. This statement is a "living" statement, and will be amended as we grow in our understanding. We also share our NOC Racial Equity in Organic Resource Page,[9] with resources collected with the help of many individuals and organizations.

NOC acknowledges our own privilege as a primarily white-led coalition, and is committed to prioritizing racial equity in our organization and strategies. NOC is committed to listening, understanding, learning, amplifying, working, and acting to address and dismantle systemic racism. We are holding ourselves accountable to ensure this is a deep, long term, and sustainable commitment.

We urge the NOSB to explore ways to encourage the NOP and organic stakeholders to expand their work and resources to further address this issue. Following are some concrete steps NOC believes the NOSB can take to move towards an equitable organic system.

First, through a preliminary literature review, NOC identified access to land, resources, and technical assistance as some of the main barriers to participation in organic agriculture for Black, Indigenous, and people of color (BIPOC) farmers.

1. **Access to land.** Land ownership and control over land is important for organic certification because organic operations must demonstrate that their land has been free of prohibited substances for a three-year period before crops can be harvested and sold as organic. In addition, land must have distinct and defined boundaries and buffer zones to prevent contact with prohibited substances. For these reasons, it is important to understand how BIPOC farmers have been dispossessed of land and the impact that has on their participation in organic certification.

    a. **Stolen land.** From the birth of our country to today, the United States Government seized 1.5 billion acres of native land. "As late as 1750—some 150 years after Britain established Jamestown and fully 250 years after Europeans first set foot in the continent—[Native Americans] constituted a majority of the population in North America […] Even a century later,

[7] Racial, ethnic and gender inequities in farmland ownership and farming in the U.S. Agricultural and Human Values 36 (2019)
https://link.springer.com/article/10.1007/s10460-018-9883-3
[8] 2017 Census of Agriculture: Characteristics of All Farms and Farms with Organic Sales, April 2019, United States Department of Agriculture, National Agricultural Statistical Service
https://www.nass.usda.gov/Publications/AgCensus/2017/Online_Resources/Organics_Tabulation/organictab.pdf
[9] NOC Racial Equity Resources
https://docs.google.com/document/d/1ncYsoIj503oBCqVd4zZ9C2ta5I1GvoozCJB2u7WdZoE/edit#heading=h.gjdgxs

in 1850, they still retained formal possession of much of the western half of the continent."[10] The 1887 General Allotment Act and 1906 Burke Act directly led to the loss of 90 million acres of Native American land.[11] The Morrill Act of 1862 worked by turning land expropriated from tribal nations into seed money for higher education. "Today, the vast majority of agricultural lands on reservations are leased to non-Indian ranchers, often at less than fair-market value. In addition, income from these lands goes off the reservation instead of to the Indian landowners who experience high rates of unemployment and often live in poor economic conditions.[4] According to the Bureau of Indian Affairs (BIA), the federal government holds about 46 million acres in trust for tribes (tribal trust land) and more than 10 million acres in trust for individual Indians (individual trust land).[12] The loss of tribal lands combined with the mixed ownership patterns within reservation boundaries poses serious challenges to the sovereignty and self-determination of Indian nations."[13]

b. **Black farmer dispossession.** In 1910, one in seven farmers were African Americans and African Americans held titles to approximately 16 to 19 million acres of farmland. Over the next century, 98% of Black farmers were dispossessed through discriminatory practices at USDA and various federal programs. These farmers were often denied loans and credit, lacked access to legal defense against fraud, and experienced "outright acts of violence and intimidation" resulting in a 90% loss of Black-owned farmland in the US.[14] Today, 98% of private rural land is owned by white people, while less than 1% is Black-owned. The USDA's systemic bias against Black and minority farmers is well documented and affirmed by the 2010 Pigford vs. Glickman class action lawsuit, which resulted in a $1.25 billion settlement. Black farmers continue to experience discrimination in access to credit, seeds, and other assistance, and face foreclosure at six times the rate of their White counterparts.[15] On March 25, 2021, an historic hearing convened by the House Agriculture Committee reviewed the "State of Black Farmers in the US." The hearing focused on the systemic discrimination Black farmers face and opportunities for USDA to take action to address the needs of Black farmers. Some of the suggested actions included targeted outreach and technical assistance to historically underserved farmers, appropriate and representative staffing at USDA agencies such as FSA, NRCS, and on committees, and partnering with local organizations that have built trust and proven track records of success.[16]

c. **Most of the agricultural land in the US is owned by white landowners**. "Organic farming is almost a mirror reflection of the mainstream food system in organic farm ownership and operation. As a result, conversations in the organic community are centered on the

[10] Watch how the U.S. Stole Land from Native Americans https://www.fastcompany.com/3040647/watch-how-the-us-stole-land-from-native-americans
[11] Indian Land Tenure Foundation https://iltf.org/land-issues/issues/
[12] Indian Issues, Agricultural Credit Needs and Barriers to Lending on Tribal Lands https://www.gao.gov/assets/700/699019.pdf
[13] High Country News, Land Grab Universities (March 2020) https://www.hcn.org/issues/52.4/indigenous-affairs-education-land-grab-universities
[14] Data for Progress: Land Access for Beginning and Disadvantaged Farmers https://filesforprogress.org/memos/land_access_for_beginning_disadvantaged_farmers.pdf
[15] Vann R. Newkirk III, "The Great Land Robbery," The Atlantic, September 2019. https://www.theatlantic.com/magazine/archive/2019/09/this-land-was-our-land/594742/
[16] A recording of this hearing and witness testimonies are available here: https://agriculture.house.gov/calendar/eventsingle.aspx?EventID=2141

understandings of white landowners and their understandings of their land holdings, farming practices, and an anthropocentric worldview."[17] This needs to be taken into consideration when reviewing rules and regulations pertaining to organic certification: what barriers are inherent in organic rules and regulations because of how land ownership and access is assumed?

Some of the recommendations addressing land access issues proposed by organizations (Data for Progress,[18] Soul Fire Farm,[19] National Young Farmers Coalition) and independent experts include the following:

a. Conduct research on land ownership and exclusion of BIPOC farmers in land ownership.
b. Strengthen loan guarantees, improved access to credit and technical assistance for BIPOC and beginning farmers.
c. Expand FSA grant and loan guarantee programs (such as the Highly Fractionated Indian Land Loan Program and Indian Tribal Land Acquisition Loan Program) for land acquisition for beginning and socially disadvantaged farmers under sustainable agriculture covenants. Establish lending guidelines for the Small Business Administration (SBA) and private loans to low-income resident farmers and BIPOC-led farmer cooperatives.
d. Earmark funds for down-payment assistance and financial support grants for new farms practicing sustainable agriculture through the first 10 years of operation.
e. Implement robust anti-discrimination guidelines and oversight of USDA practices.
f. Appoint a USDA-led "land commission" to conduct a periodic national-scale land tenure study to provide a holistic perspective on socio-economic, political, and market-based factors limiting BIPOC access to land.

2. Access to information. Similar discriminatory practices have led to an unequal distribution of technical assistance. Some recommendations include:
    a. Expand funding and training for organic agriculture.
    b. Increase funding for the USDA Conservation Programs, specifically the Conservation Reserve Program (CRP), Environmental Quality Incentives Program (EQIP), and Conservation Stewardship Program (CSP), with increased on-ground staff and technical assistance capacity to successfully service their regions.
    c. Ensure adequate training and information dissemination among FSA and NRCS staff at the county level regarding existing opportunities to support beginning farmers, such as the EQIP Advanced Payment Option for historically underserved producers.[20]
    d. Eliminate match requirement for USDA's Beginning Farmer and Rancher Development Program (BFRDP) grant awardees to ensure that all organizations and service providers can best train the next generation, particularly in areas of high need and low resources.

[17] How diverse is the organic movement, and how do we improve access? A-dae Romero-Briones (2020) https://rodaleinstitute.org/blog/how-diverse-is-the-organic-movement/

[18] *Memo: Land Access for Beginning and Disadvantaged Farmers,* Data for Progress, March 2020 https://www.dataforprogress.org/memos/land-access-for-beginning-disadvantaged-farmers

[19] Soul Fire Farm & Northeast Farmers of Color alliance – Food Sovereignty Action Steps (2018) https://docs.google.com/document/d/1dt0hicyhGdJSKlC3qyE1AbG9fdDrONjUh_M_bE0KMGs/edit#bookmark=id.rji88dqczea2

[20] EQIP Advance Payment Option https://www.nrcs.usda.gov/wps/portal/nrcs/detail/national/programs/financial/eqip/?cid=nrcseprd1502414

e. Support programs such as the Federally Recognized Tribal Extension Program which provides competitive grants to tribal extension programs that enhance tribal farming and ranching operations.

Second, on October 26, 2020, NOC hosted a virtual "pre NOSB meeting" which included a breakout session on barriers to certification for farmers of color. This group of 40 organic advocates identified seven ways to make organic certification more equitable. These strategies are outlined below.

1. **Make information, training, and technical assistance more accessible.** This includes increased targeted outreach, technical assistance, opportunities and support to BIPOC farmers from USDA and certifying agencies. It also means considering where BIPOC farmers are located and bringing the resources there. Finally, it means that educational resources and regulations should be easily available in languages relevant to all farmers.

   NOSB role – continue to encourage the NOP to make materials available in languages other than English.

2. **Reflecting on the certification process**. Because of the history of discrimination from agencies such as USDA, there is a justified distrust of the agency. Partnering with local organizations to help support completion of necessary paperwork and administrative process might encourage a more diverse participation in the process.

3. **Organic policies.** The group discussed policies, programs, and legislation that could encourage a more equitable support of organic farmers. This might include specific set asides for BIPOC farmers, increasing the reimbursement rate for the certification cost share program, and finally, encourage the certification of grower groups. On the consumer side, we know access to organic foods, which often come at a higher price, are not accessible by all. "Currently, organic products are not eligible for federal procurement in many institutional programs, effectively excluding access to the organic community by virtue of income—often excluding Black, Brown, or Indigenous people."[21] Including provisions for procurement of organic products in programs such as the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC),[22] which serves low income women, infants, and children up to age five, would expand access to organic food and nourish some of our nation's most vulnerable populations.

4. **Reallocating money and power.** It is obvious, if only by looking at the makeup of NOSB meeting attendees, that the organic community is not very diverse. In addition to discussing how specific programs and policies could make organic agriculture more equitable, the group discussed structural changes to make our community more representative—this includes transferring leadership to BIPOC communities, amplifying BIPOC voices, and encouraging USDA to increase diversity in staffing and advisory boards.

5. **Acknowledge context, history, and contributions of BIPOC farmers** to the organic movement. Our movement needs to not only acknowledge past and current issues of systemic discrimination, but also

[21] A-dae Romero-Briones. Organic Farmers Association. *Bringing Equity to Organic.* November 2020. https://organicfarmersassociation.org/news/bringing-equity-to-organic/#:~:text=Currently%2C%20organic%20products%20are%20not,consumer%20is%20most%20likely%20white

[22] The Truth Behind WIC: Organic is NOT an Option! https://www.organicconsumers.org/news/truth-behind-wic-organic-not-option

reframe what has been portrayed as a very white-centered history of organic agriculture, acknowledging the contributions of organic pioneers such as George Washington Carver, Booker T. Whatley, and the historical practices of multiple indigenous groups. This inclusive historical narrative of organic agriculture should be provided on prominent public space such as the USDA website.

6. **Training and recruitment for organic certification staff**. Recruiting and training BIPOC certifiers and inspectors.

7. **Support BIPOC farmers in accessing & keeping land**. The group recognized access to land and capital as one of the primary barriers to organic farming. The organic community should acknowledge this challenge common to all new and beginning farmers, and the specific barriers related to land access for BIPOC farmers.

NOSB Recommendations
In light of the barriers explored above, NOC is making the following recommendations to the NOSB.

1. Research

A first step to addressing disparities in representation is understanding the source of these disparities and underrepresentation. NOC encourages the NOSB to prioritize research into **understanding barriers to participation in organic certification for farmers of color**. This research should include continual learning and understanding of institutions that have perpetuated centuries of discrimination and provide relevant information to support the actions of USDA's Office of the Assistant Secretary for Civil Rights. Research into barriers to participation in organic certification should also support the development of technical assistance and outreach specifically designed to best serve BIPOC farmers and the unique challenges they face.

NOC also supports a research priority area suggested in Union of Concerned Scientists' Policy Brief of May 2020, to develop "markets for ethnic specialty crops and culturally relevant fruits and vegetables, leveraging the skills of immigrant and refugee farmers, helping them thrive while also contributing to local economies."[23] NOC also supports reexamining the national organic marketplace to support organic small farms, inclusive of Black and Indigenous small farmers.

Finally, NOC supports research to limit and avoid the contamination of Black and Indigenous farmlands and conservation lands by off-farm sources and neighboring farms.

2. Technical assistance

Technical assistance and outreach must serve farmers of color, recognizing traditional ecological knowledge and management as best practices. The contributions made by BIPOC individuals and communities to organic and sustainable food systems are vast and often go unacknowledged. NOC encourages the NOSB to recommend that USDA support investment in community programs offering materials in multiple languages and formats, providing translation assistance, and streamlined paperwork.

NOC also encourages the NOSB to recommend that the NOP reenergize previous outreach and education efforts on organic agriculture, with a specific focus on outreach to socially disadvantaged groups and ensuring this

[23] (May 2020) Union of Concerned Scientist & HEAL Food Alliance Policy Brief
https://www.ucsusa.org/sites/default/files/2020-06/leveling-the-fields.pdf

information is accessible (language, where the information is found, dissemination strategies, etc.). Examples of such previously existing programs include:

- The "Sound and Sensible Initiative," identifying and removing barriers to certification, streamlining the certification process, focusing enforcement, and working with farmers and processors to correct small issues before they become larger ones, with the overall goal to make organic certification accessible, attainable, and affordable for all operations.

- "Organic 101" series,[24] a USDA blog post series that explored different aspects of the USDA organic regulations in a digestible format.

- The Organic Integrity Learning Center. This resource could be widely promoted and made available to farmers. Modules could include farmer-focused lessons on organic transition, the organic certification and inspection processes, and common practices required in organic production, but which sometimes pose challenges for organic producers, such as cover cropping, crop rotation, and organic weed management.

For the outreach and support to be truly relevant, we encourage the NOSB to support the hiring of linguistically and culturally competent representatives both at the certifier level and at the agency level (USDA NOP, FSA, NRCS, and other USDA agencies). We also encourage the NOSB to support partnerships with local organizations that have high levels of trust with local communities.

3. Equity of Infrastructure and Information

The "NOP Documents and Resources Available in Spanish" page links to a copy of the regulations in English.[25] Creating an inclusive movement requires that materials be available in other languages. We understand that some certifiers, such as CCOF, have translated the regulations into Spanish, and would suggest that the NOP contract with CCOF or another entity to provide access to the translated materials on the NOP's website. NOC encourages the NOSB to work with the NOP to identify languages that the organic materials should be translated into, and then work to identify the appropriate means of acquiring those translated materials.

Furthermore, as outlined by NOSB member A-dae Romero-Briones in an insightful article for the fall 2020 issue of Organic Farmers Association's New Farms Magazine,[26] grower group certification could create a path to infrastructure development for not only many Indigenous and Tribal growers, but for marginalized small-scale growers as well. "*Domestic organic certifiers site lack of guidance on applicability to livestock or produce, limitations of number of growers within the group, and inspection expectation of grower members as some of the reasons there is reluctance to certify grower groups.*" NOC encourages the NOSB to consider looking closely at grower groups and their capacity to increase organic certification for BIPOC farmers.

4. Representation and Leadership

[24] Organic 101: Five Steps to Organic Certification, USDA blog, February 2017 https://www.usda.gov/media/blog/2012/10/10/organic-101-five-steps-organic-certification

[25] NOP Documents and Resources Available in Spanish, https://www.ams.usda.gov/sites/default/files/media/NOPDocumentsandResourcesAvailableinSpanish.pdf

[26] A-dae Romero-Briones. Organic Farmers Association. *Bringing Equity to Organic.* November 2020. https://organicfarmersassociation.org/news/bringing-equity-to-organic/#:~:text=Currently%2C%20organic%20products%20are%20not,consumer%20is%20most%20likely%20white

Appropriate and relevant representation is necessary to reach a truly equitable system. NOC encourages the NOSB to foster leadership of BIPOC participants in decision-making venues, including grant panels, advisory boards, and committees.

For example, the NOSB could recommend that:

- USDA create an Office of Equity to review policy proposals and mandate BIPOC participation on USDA decision-making boards.
- USDA empower the new office to legally address claims of discrimination in agricultural credit, land credit and markets, and conduct oversight of USDA practices.
- USDA examine the role of heirs property in the loss of land for Black farmers, and offer education and technical assistance for families to retain property.[27, 28]

The NOSB could also consult with federal advisory committees and organizations representing BIPOC farmers, such as the Native American Farmers and Ranchers Federal Advisory Committee, on issues related to organic agriculture, organic standards, and BIPOC participation in organic certification.

"A truly sustainable food system must be both science-based and equitable" (Union of Concerned Scientists & HEAL Alliance, 2020).[29]

CACS

Discussion Document

Human Capital Management

NOC will be hosting a conversation on the related topic of "Should the Cost of Organic Certification Go Up?" during our spring 2021 pre-NOSB meeting. We will be addressing questions including:

- Will more qualified inspectors mean more expensive certification?
- Will SOE (Strengthening Organic Enforcement) increase the cost of certification?
- How can the organic community transition to changes in the certification process and cost of certification to ensure that we recruit and retain the next generation of highly qualified organic inspectors, while simultaneously ensuring that organic certification is not out of reach for producers, especially beginning and low-resource producers.

Notes from this conversation will be available via the NOC website after the meeting. It is our hope that we can bring organic stakeholders together for a conversation that will contribute to the larger discussion.

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[27] *Memo: Land Access for Beginning and Disadvantaged Farmers,* Data for Progress, March 2020 https://www.dataforprogress.org/memos/land-access-for-beginning-disadvantaged-farmers

[28] *Leveling the Fields, Creating Farming Opportunities for Black People, Indigenous People, and Other People of Color,* Union of Concerned Scientist, HEAL Food Alliance, May 2020, https://landstewardshipproject.org/repository/1/3245/leveling_the_fields_final.pdf

[29] *Ibid.*

Supporting the Work of the NOSB

The work of the NOSB requires a great deal of time, commitment, and expertise (and/or willingness to learn). For many, if not most, NOSB members, NOSB work is added to a regular job. While some people may be relieved from other duties—thereby essentially being paid to be a board member—others are not. Working farmers are unlikely to have relief, which makes it difficult to recruit them to serve.

There are several ways in which NOSB members may be given support.

We support measures to assist NOSB members "to help conduct and provide literature reviews, write drafts, and otherwise support the work of NOSB members." This support may come in several forms:

1. NOSB members may have connections with people whom they could hire as research assistants.

2. NOP could assist NOSB members to find a research assistant at an independent institution, like a university.

3. NOP could provide NOSB with access to an open docket.

4. NOP could provide people to work as research assistants for NOSB members.

We believe that NOSB members should not be limited to a single mechanism, but we prefer options that preserve the independence of NOSB members—that is, #1-3 above, rather than #4. NOP should not screen the people who are hired to give assistance. We prefer that NOSB set a policy for reimbursement for such assistance that sets a maximum amount to be reimbursed to NOSB members.

NOP funding increases must translate into increases in NOSB support.

The published materials provide several related references regarding ways the NOSB is to be supported. Through the annual appropriations process, the NOP has received significant boosts in funding since Fiscal Year 2017, when the annual budget for the NOP stood at $9 million. By Fiscal Year 2021, the annual budget for the NOP had doubled to $18 million. These spending increases have translated into significant and much needed boosts in hiring for the NOP. What we have failed to see is increased support for the NOSB members and NOSB activities. We have heard repeatedly that there is limited money for Technical Reviews (TRs) and no capacity for additional task force work. As NOC continues to lobby for additional funding to support the NOP, with a request of $22 million for Fiscal Year 2022, our expectation is to see increased support for the NOSB.

Regardless of other options, the open docket should be provided.

NOC has historically advocated for and supported the need for a true open docket. The Policy and Procedures Manual (PPM)[30] states:

> **Policy for Public Communication between NOSB Meetings (Adopted April 11, 2013)**
> • The NOSB and NOP seek public communication outside of Board biannual meetings and public comment periods to inform the NOSB and NOP of stakeholders' interests, and to comment on the NOSB's and NOP's work activities year around.

[30] Section VII E. p. 34.

• The NOSB may post draft discussion documents and proposals between public meetings for review and public comment. Timely submission of comments will assist the NOSB and its Subcommittees in revising such documents for subsequent NOSB review.

The NOSB provided this discussion of the above policy:

> As a part of its responsibility to communicate with the organic community pertaining to the implementation of OFPA, the Board must receive and review information from the NOP and other sources during its deliberations. As a stakeholder Board, the input from the organic community is valuable in the deliberations of the Board, the NOP, and the community decision-making process. The procedures of the Board and NOP should facilitate public communication to inform these deliberations.
>
> Providing an online mechanism that allows the public to share information between official comment periods will help to facilitate public communication that informs the Board's and NOP's deliberations in several ways. The online system is intended to:
>
> 1. Inform discussions early in the materials or policy review process through the collection of complete background and perspectives;
>
> 2. Reduce the amount of new information coming to the Board and NOP late in its deliberations on an issue without adequate time to verify or fully assess it;
>
> 3. Increase transparency for the NOSB, NOP, and the public itself to ensure that everyone has access to the same information in a timely fashion;
>
> 4. Help the Board and NOP to become aware of issues that may not be on the work plan or may not have been generated internal to the NOP and NOSB process, but are important based on the experience and expertise of those in the organic community.
>
> Thus, an online public communication mechanism can help board members to discharge their "Duty of Care," which "calls upon a member to participate in the decisions of the Board and to be informed as to the data relevant to such decisions."(PPM, p. 6)

The biggest obstacle to assisting NOSB members is a culture of secrecy.
The public communication policy quoted above would ensure transparency as NOSB subcommittees deliberate. However, the current practice is one that prohibits NOSB members from sharing drafts and deliberations except through the mechanism of highly cleansed subcommittee notes. This practice stands in the way of adopting any of the mechanisms that give independence to NOSB members.

Since petitions no longer contain confidential business information, there is no excuse for secrecy in subcommittee deliberations.

NOC supports measures to assist NOSB members "to help conduct and provide literature reviews, write drafts, and otherwise support the work of NOSB members."

Other

CACS Work Agenda

As recently as July 16, 2019, the CACS requested to Work Agenda item on the topic of inconsistencies between certifiers.[31] This is a recognized issue that is addressed many times over through NOSB meetings, within published materials, and has been addressed during discussions regarding the proposed rule on Strengthening Organic Enforcement. NOC strongly encourages the CACS to pursue the Work Agenda item of inconsistencies between certifiers.

NOC is also requesting that the CACS:

- review and analyze NOP peer review audits;
- track progress made by the Organic Imports Interagency Working Group;
- ask the NOP to explain its risk-based approach to accreditation;
- request more information about how funding increases are being used to strengthen the NOP's capacity to fight fraud and support the NOSB; and
- to identify gaps that require further action to address enforcement challenges.

Clarity on 3-Year Transition Period

In August and September of 2020, the Accredited Certifiers Association, NOC, and Organic Farmers Association conducted a certifier survey to learn more about certifier practices regarding when a three-year transition is required after the application of a prohibited substance. The survey results demonstrate the high level of variation between certifiers in how they apply the three-year transition requirement in different situations. Our detailed comments summarizing the results of the survey from fall 2020 are available as Appendix C.

Despite the ongoing requests from the NOSB, NOC, certifiers, and other organic stakeholders for clarity, the NOP has not yet taken action to ensure that operations are held to a consistent standard regarding three-year transition requirements. NOC believes this lack of consistency is egregious given that the varying interpretations have significant economic impacts for producers, as some operations are being required to undergo a three-year transition for a particular set of circumstances, while other operations in the exact same circumstances are allowed to forgo the three-year transition.

Conclusion

The NOP must clarify the requirement for a three-year transition for crop production in greenhouses and facilities after the application of a prohibited substance. **The NOSB should actively engage in this process by requesting a work agenda item, requesting stakeholder input, making recommendations to the NOP, and by asking the NOP to provide clarity so all certifiers and organic operations are held to the same standard.**

[31] NOSB Executive Committee Meeting notes, Page 21 of 42, https://www.ams.usda.gov/sites/default/files/media/ESNotes2019Dec.pdf.

Crops Subcommittee

Proposals

Paper Pots – proposal

Proposal to add to §205.2 Terms Defined:

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

Proposal to add to §205.601 (o) Production Aids:

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

Meeting the challenge of paper planting aids.

NOC remains supportive of the work done by the Crops Subcommittee on paper pots, with reservations. Paper pots and other paper-based planting aids are low-tech solutions to labor-intensive situations. They are accessible to small-scale farmers who do not have access to expensive equipment. They do not consume fossil fuels in their use. However, there are challenges posed by known and unknown materials that may be used.

Do paper-based planting aids meet OFPA criteria?

While we could argue about the need for paper-based planting aids, we view the most important issue to be environmental impacts of using these aids. While the environmental impact of the proposed aids is unlikely to be worse than the impact of paper as currently allowed, the most recent technical review of newspaper and other recycled paper makes it clear that paper may have many additives, including polymers that might be classified as "microplastics." We believe that the NOSB should not promote the use of additional synthetic materials that will not degrade and may cause future harm. In addition, the principle of continuous improvement must be applied to paper-based planting aids.

It is made clear in the published materials that "the Technical Review clarified that the adhesives and non-paper synthetic fibers found in a variety of paper pots are also found in newspaper and recycled paper that are allowed for compost feedstock and mulch."[32] The CS further states that "small changes have been made to the annotation to reflect concerns from stakeholders," including: "Concern was expressed by stakeholders about substances that might be included in the 40% non-cellulose portion of the paper planting aids. They suggested language limiting those materials and specifying what their uses might be. That language has been added to the definition."[33] We are requesting a minor edit to the language so that when the definition is read separately from the published materials it is clear that the definition refers to the non-synthetic or synthetic strengthening fibers, adhesives, or resins that are typically found in paper having been reviewed as part of the paper TR and not just any non-synthetic or synthetic strengthening fibers, adhesives, or resins.

We suggest the addition of the words "typically in paper," to the proposed 205.2 Terms Defined, as follows:

[32] NOSB April 2021 proposals and discussion documents. Page 10 of 172.

[33] *Ibid.* Page 12 of 172.

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

Continuous improvement must be our clearly stated goal.
Our main reservation remains the same as expressed in our Fall 2020 comments—a missing requirement for continuous improvement. When newspaper was first placed on the National List (NL), it was a different material than what is it is now. Unfortunately, the change in composition implies that the listing for newspaper has changed over time for the worse, and we are now basing a new material petitioned to the NL on it. The organic community has been unknowingly pushed to accept a more synthetic material because this currently listed material has changed over time to consist of more synthetics. We appreciate the Board's acknowledgement, as stated in the published materials: "The Board acknowledges that the percentage specificities in this listing should be reviewed by future Boards as technology and materials change. It seems likely that there will continue to be advances in fiber types that can be used in these paper planting aids. If so, the percentage of cellulose or biobased materials could be increased. It is hoped that at some point in the future this listing could be changed to 100% biobased, biodegradable fiber content as well as examining adhesives to address biodegradability."[34]

In a previous comment we requested that commercial availability wording be applied to this listing. As it has been explained, we understand that even if a material was available that was 100% biobased, this does not guarantee biodegradability, as there can be fibers that are 100% biobased but non-degradable. After further discussion, and after reading the published materials on biodegradable biobased mulch film (BDM), we feel that it would be appropriate to apply a statement to paper planting aids similar to that suggested for BDM. "When 100% biobased biodegradable paper planting aids become commercially available, producers are required to use 100% biobased biodegradable content paper planting aids."

We suggest something similar to the listing at **§205.204 Seeds and planting stock practice standard**, which allows for the use of nonorganically produced, untreated seeds and planting stock when "an equivalent organically produced variety is not commercially available." Not only would a listing similar to this apply the commercial availability statement, but it could allow for variances based on functionality.

There must be continued research on the impact of the portion of the material that does not decompose, including the portions that partially decompose. All of the intermediate compounds that occur during decomposition may have an impact. There have not yet been many studies that test soil where these products have been used over time. When we are able to do those studies, if there is found to be a largely negative effect, we anticipate that we will be having these conversations again.

Finally, NOC neither supports nor opposes the inclusion of virgin paper due to a diversity of opinions on this matter within NOC.

[34] *Ibid.* Page 13 of 172.

Biodegradable biobased mulch annotation change – 205.601

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

§205.2.
Biodegradable biobased mulch film. A synthetic mulch film that meets the following criteria:

(1) Meets the compostability specifications of one of the following standards: ASTM D6400, ASTMD6868, EN 13432, EN 14995, or ISO 17088 (all incorporated by reference; see § 205.3);

(2) Demonstrates at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, according to one of the following test methods: ISO 17556 or ASTM D5988 (both incorporated by reference; see §205.3); and

Biodegradable plastic mulch films m*ust be *at least 80% biobased with content determined using ASTM D6866 (incorporated by reference; see §205.3).

NOC acknowledges that a biodegradable biobased mulch (BDM) film would be a great asset to producers; however, we continue to harbor great concerns regarding the agronomic, environmental, and health effects of the breakdown and subsequent incorporation into the soil. We do not feel that these concerns have been addressed adequately at this time. Frankly, these concerns cannot be addressed adequately until further research is done in a more long-term manner.

Biodegradability must be considered in a very broad way.
Biodegradability must be shown across many regions, soil types, and climate types. Requiring a material to be biodegradable does not make it so, as demonstrated by field testing done by Dr. Narayan, author of the study on biodegradable biobased mulch films commissioned by the NOP. In attempting to demonstrate that the use of BDM is superior to polyethylene (PE) mulch, he uses a scenario where the BDM will biodegrade completely under conditions that would be impossible to replicate in a real-life situation.[35]

Biodegradable plastic mulches must be thoroughly investigated to ensure they are safe and sustainable for use in agricultural systems. If biodegradable plastic mulches are to be tilled into the soil after use, their complete breakdown needs to be ensured and verified under the wide variety of soils and environments where they may be applied. Global use of plastic mulch is high and is increasing, thus there is a growing market for biodegradable plastic mulches. Incomplete breakdown of biodegradable plastic, however, could lead to an accumulation of plastic fragments and particulates in soils.[36]

To adequately regulate BDM, Materials Review Organizations (MROs) should review and list specific BDM materials. In addition, certifiers should verify that biodegradation is taking place in the local situation on the certified farm. We recognize that certifiers do not have the expertise to assess biodegradation of microscopic or

[35] Ramani Narayan. "Biodegradable Biobased Mulch Films in Organic Cropping Systems." September 2019. Page 4 of 21.
[36] Henry Y. Sintim and Markus Flury, "Is Biodegradable Plastic Mulch the Solution to Agriculture's Plastic Problem?" Environmental Science & Technology. 2017, 51, 1068-1069.

molecular residuals, but we feel they should at least verify that visible pieces of the material (mulch film fragments) are not persistent in the soil after a year. When BDM makes it into organic production, detailed questions regarding use, biodegradation, and soil conditions should become a part of the organic system plan (OSP), with inspectors providing feedback of visual observations.

Synthetic materials must meet all of the OFPA criteria.
As noted in the memorandum from Jennifer Tucker Ph.D. to the NOSB dated October 16, 2019, the NOP "determined that Policy Memorandum 15-1 (January 22, 2015) did not present new information or impose additional requirements compared to the 2014 final rule"[37] on biodegradable biobased mulch films in organic crop production. We thank the NOP for acknowledging that the 2014 rule and preamble establish the requirement that all polymer feedstock be 100% biobased. We fully agree.

Synthetic substances are allowed as per 205.601, provided they meet OFPA criteria, including that they do not contribute to contamination of crops, soil, or water.
The crops subcommittee in its published materials notes:

> "An argument can be made that even though the non-biobased polymers degrading into the soil originate from petroleum (a nonrenewable fossil fuel), the use of this product could be considered environmentally friendly because:
>
> - Many organic production systems rely on enormous amounts of plastic, mostly polyethylene (PE) films, to produce organic crops;
> - PE films likely shed micro plastics and leach chemicals into organic soil over the growing season;
> - Before and during removal, PE films can tear and breakdown, leaving plastic in the soils or migrating off-site into aquatic habitats;
> - PE films are generally not recyclable due to contamination by soils or the lack of recycling infrastructure;
> - Plastic used in annual production systems end up in landfills;
> - Biodegradable mulches potentially save labor and time, since the mulch does not have to be removed from the field and transported for disposal."[38]

On the other hand, one might argue that the ability to remove the plastic mulch at the end of the growing season offers a measure of control that would not be present with the partially biodegraded mulch film, which the grower does not even try to remove from the field. While synthetic substances are allowed as per §205.601 provided they meet OFPA criteria, including that they do not contribute to contamination of crops, soil, or water, micro- or nano particles could be produced in the degradation of the biodegradable biobased mulch film,

[37] "Biodegradable Biobased Mulch Film" Memorandum to the National Organic Standards Board from Jennifer Tucker, Ph.D., October 16, 2019.
[38] NOSB April 2021 proposals and discussion documents. Page 18 of 172.

potentially contaminating crops, soil, and/or water. Do we really want to trade removing plastic to guarantee that we are leaving microplastic behind?

Further, most of the bullet points listed above could be used as arguments against BDM. As noted previously, the global use of plastic mulch is high and is increasing, thus there is a growing market for biodegradable plastic mulches. Incomplete breakdown of biodegradable plastic, however, could lead to an accumulation of plastic fragments and particulates in soils.[39] Indeed, one of our committee members had the opportunity to visit the site in Tennessee where BDM was being tested, sharing that with visual observation alone it was apparent that the material was breaking apart and blowing across the field to be caught in the tree line.

> Another important consideration when measuring the amount of mulch remaining in the soil is mulch particles that are too small to see. Although measuring mulch surface area loss in field studies can provide a benchmark measurement for the biodegradation potential of a mulch product, it does not take into account the possibility that microfragments, nanofragments, or both persist in the soil (Rillig, 2012; Steinmetz et al., 2016). Recent work has focused on developing methods to detect microplastics in environmental samples (D€umichen et al., 2015; Majewsky et al., 2016), and these techniques could possibly be helpful to more accurately determine the amounts of mulch remaining after soil incorporation.[40]

Dr. Narayan, author of the study on biodegradable biobased mulch films commissioned by the NOP, further notes:

> "This accumulation of recalcitrant [polyethylene] PE mulch film fragments in agricultural soils around the world is cause for alarm because it decreases soil productivity by blocking water infiltration, impedes soil gas exchange, constrains root growth, and alters soil microbial community structures (3, 9). Plastic pollution of soils is also a threat to soil ecosystem health and function (10-12). PE micro fragments dispersed in soil and water readily absorb and concentrate toxins present in the environment (much like a sponge). Microorganisms colonize these fragments, and the birds and fishes eat them because they think it is food. This results in toxins and PE micro fragments being transported up the food chain (13)."[41]

We submit that the same could be said of biodegradable mulch film fragments. While Dr. Narayan offers his solution "to use completely soil-biodegradable mulch films that retain the performance characteristics of PE films but at the end-of-life can be plowed into the soil or recovered for on-farm composting" and attempts to demonstrate this in Scheme 1 in his paper, there are issues with his demonstration. Most obviously, the suggestion that the biodegradable mulch film would break down completely within 24 months of soil temperatures of approximately 25°C (77°F). What is the real-life situation where this would be the case? Further, how many years in the field would it take for complete degradation in less-than-ideal situations, especially the cold soils of the northern regions of our country?

Within the published materials it is noted that most of Dr. Narayan's report "focused on the positive aspects when mulch does biodegrade."[42] We would like to be clear in stating that while this may be the case, these "positive aspects when mulch does biodegrade" were under unachievable real-life conditions.

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[39] Henry Y. Sintim and Markus Flury, "Is Biodegradable Plastic Mulch the Solution to Agriculture's Plastic Problem?" Environmental Science & Technology. 2017, 51, 1068-1069.

[40] Miles et al. "Reliability of Soil Sampling Method to Assess Visible Biodegradable Mulch Fragments Remaining in the Field After Soil Incorporation." 2017

[41] Ramani Narayan. "Biodegradable Biobased Mulch Films in Organic Cropping Systems." September 2019. Page 4 of 21.

[42] NOSB April 2021 proposals and discussion documents. Page 19 of 172.

The crops subcommittee notes:

> Key concerns of current and past NOSB members include the possibility of soil, aquatic, and other environmental contamination by partially decomposed BDM films even if the materials pass ASTM laboratory-based standards. Of particular concern to NOSB members is the possibility that BDM films will not decompose thoroughly in dry or cold environments where there is less biological activity in soils. A related concern is that BDM films ploughed into soils may be out of reach of peak biological activity to break it down.[43]

NOC shares these concerns. "Although laboratory tests can assess the potential of a mulch product to biodegrade under certain conditions (ASTM International, 2012), results may vary widely under field conditions."[44]

> In theory, BDMs should be completely catabolized by soil microorganisms, converted to microbial biomass, CO2 and water (Malinconico et al., 2002; Feuilloley et al., 2005; Imam et al., 2005; Dintcheva and La Mantia, 2007; Kyrikou and Briassoulis, 2007; Kijchavengkul et al., 2008; Lucas et al., 2008). In practice, complete breakdown in a reasonable amount of time is not always observed (Li et al., 2014b). Regulators and growers cite concerns about unpredictable or incomplete breakdown and the ultimate fate of BDM constituents and their effect on soil ecosystems (Goldberger et al., 2015; Miles et al., 2017).[45]

"Currently, there is no established field method to measure the amount of BDM remaining in the soil after incorporation."[46] The impacts of BDM that does not degrade on soil and plant health is also unknown, but there is cause for concern.

> Traditional plant tests for toxicity have not been adapted to identify effects of compounds released from BDMs. First, different compounds are released at different times during the biodegradation process. Second, frequently used tests fail to reckon the changing needs and responses throughout plant development by only focusing on germination. Finally, the diversity of plant responses in the ecosystem is narrowly represented by tests that analyze early growth in a few, mostly vigorous, plant species. Despite these constraints, some effects have emerged. A phytotoxicity test of several chemicals used in bioplastics found that some exhibited a concentration-dependent inhibition of plant growth (Martin-Closas et al., 2014). Acrylate polymers used to maintain soil humidity damaged maize root and shoot development (Chen et al., 2016). Organic compounds released from mulch polymers have been found to be absorbed by crop plants (Du et al., 2009; Li et al., 2014c; Chen N. et al., 2017). Given some of the demonstrated effects on plants, these additives may also impact soil microbes and their functions, though these effects are largely unexplored.[47]

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[43] *Ibid.* Page 19 of 172.
[44] Miles et. al., 2017
[45] Bandopadhyay Sreejata, Martin-Closas Lluis, Pelacho Ana M., DeBruyn Jennifer M. "Biodegradable Plastic Mulch Films: Impacts on Soil Microbial Communities and Ecosystem Functions." *Frontiers in Microbiology*, Volume 9, 2018, Page 819.
[46] Miles et. al. "Reliability of Soil Sampling Method to Assess Visible Biodegradable Mulch Fragments Remaining in the Field After Soil Incorporation." 2017.
[47] Bandopadhyay Sreejata, Martin-Closas Lluis, Pelacho Ana M., DeBruyn Jennifer M. "Biodegradable Plastic Mulch Films: Impacts on Soil Microbial Communities and Ecosystem Functions." *Frontiers in Microbiology*, Volume 9, 2018, Page 819.

"[F]urther research is needed to understand the microbiological events that occur simultaneously, such as changes of microbial community composition and metabolic changes."[48] "Release of microplastics (MPs) and nanoplastics (NPs) into agricultural fields is of great concern due to their reported ecotoxicity to organisms that provide beneficial service to the soil such as earthworms, and the potential ability of MPs and NPs to enter the food chain."[49]

Of further concern is the fact that the material does not completely biodegrade and could be washed into a creek or other waterway. "While very little is known about the effects of biodegradable plastics in soil, it has been shown that plastic microparticles can be toxic to aquatic organisms."[50] Additionally, if these materials are getting into the soil water on a mixed livestock and vegetable farm, could they also be getting into the livestock through the water, forage, and feed?

Allowing the use of BDM is not the solution to organic "plasticulture."
The subcommittee expresses concern regarding "some small- and large-scale growing systems, such as organic 'plasticulture' strawberry production [that] are highly dependent on PE films, with thousands of acres of plastic used annually across the industry."[51] The allowance of BDM is not going to do away with organic "plasticulture" as long as container production is allowed under the organic standards.

Natural organic mulches should be the norm in organic production. The use of natural organic materials in compost and mulch is foundational to organic. In 2001, the National Organic Standards Board (NOSB)[52] gave this definition:

> Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. These goals are met, where possible, through the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system.

The NOSB went on to say that, among other things, an organic production system is designed to: "optimize soil biological activity;" "utilize production methods and breeds or varieties that are well adapted to the region;" "recycle materials of plant and animal origin in order to return nutrients to the land, thus minimizing the use of non-renewable resources;" and "minimize pollution of soil, water, and air." The use of natural mulches—including cover crops—contributes to all of these values.

Organic production systems are also intended to mimic natural ecosystems. In natural systems, plants are fed by the action of soil organisms breaking down plant residues and excreting substances that are plant nutrients.

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[48] Sathiskumar Dharmalingam, Douglas G Hayes, Larry C Wadsworth, Rachel N Dunlap. "Analysis of the time course of degradation for fully biobased nonwoven agricultural mulches in compost-enriched soil." *Textile Research Journal,* November 2015, SAGE Publications.
[49] Astner et. al. "Mechanical formation of micro- and nano-plastic materials for environmental studies in agricultural ecosystems." *Science of the Total Environment.* Volume 685, 1 October 2019, Pages 1097-1106.
[50] Lönnstedt, O. M.; Eklöv, P. "Environmentally relevant concentrations of microplastic particles influence larval fish ecology." *Science* 2016, 352, 1213–1216.
[51] NOSB April 2021 proposals and discussion documents. Page 19 of 172.
[52] NOSB Principles of Organic Production and Handling. NOSB Recommendation Adopted October 17, 2001.

Natural mulches provide a steady diet of organic matter for those soil organisms. This function is one way that we can judge the compatibility of synthetic mulches with organic values.

The comparative risk of the two production aids leaves some organic community members uncomfortable.[53] To be clear, we are currently unable to compare the risks without more research on the long-term effects of BDM. We have many concerns regarding the evidence of toxicity from secondary metabolites of BDM, but do not have answers to address these concerns. At this time, we are not even clear regarding all of the various secondary metabolites that may be left behind as BDM breaks down. Before we can fully begin to assess the comparative risk of PE mulch versus BDM, all secondary metabolites of BDM need to be identified. Organic agriculture relies on the precautionary principle, and the same should apply in the case of BDM and the concerns around the unanswered questions.

We, too, are "concerned about the precedent of allowing petroleum-derived products to be added directly to soils,"[54] especially in the quantity represented by this product. While NOC has continued to support the paper-based crop planting aids petition with reservations (as outlined in our comment on page 18), we are more comfortable in the fact that "paper-pot production aids are generally used by small farmers and their contribution to soil plastics is likely to be small compared to the thousands of acres of soil covered by PE films and their possible future BDM film replacements."[55]

Conclusion

NOC acknowledges that a biodegradable biobased mulch film would be a great asset to producers; however, we harbor great concerns regarding the environmental and health effects of the breakdown. Almost every paper we read notes that additional research is required.

> Biodegradable plastic mulches are a promising alternative to the currently used polyethylene-based mulches, but (additional) rigorous testing is needed to ensure their use is environmentally safe. (Further) in-field testing of biodegradation under different soil and climatic conditions is needed, with particular attention to release of micro- and nanoparticles from plastics and their long-term accumulation in soils and their effects on soil quality.[56]
>
> To address the current knowledge gaps, long term studies and a better understanding of impacts of BDMs on nutrient biogeochemistry are needed. These are critical to evaluating BDMs as they relate to soil health and agroecosystem sustainability.[57]

For almost every argument made for the use of biodegradable biobased mulch film, we could find a counter argument noting that more research is needed. We maintain that this product is "not ready for primetime." **The NOSB should vote no on this annotation change.**

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[53] *Ibid.* Page 19 of 172.
[54] *Ibid.* Page 19 of 172.
[55] *Ibid.* Page 20 of 172.
[56] Henry Y. Sintim and Markus Flury, "Is Biodegradable Plastic Mulch the Solution to Agriculture's Plastic Problem?" Environmental Science & Technology. 2017, 51, 1068-1069.
[57] Bandopadhyay Sreejata, Martin-Closas Lluis, Pelacho Ana M., DeBruyn Jennifer M. "Biodegradable Plastic Mulch Films: Impacts on Soil Microbial Communities and Ecosystem Functions." *Frontiers in Microbiology*, Volume 9, 2018, Page 819.

Petitions / Discussion Documents

Ammonia Extract

NOC agrees with the petitioner that nonsynthetic ammonia extracts should be listed on §205.602 as prohibited nonsynthetic inputs. Ammonia extracts—synthetic or nonsynthetic—are harmful to soil organisms and inconsistent with organic production. While the use of synthetic ammonia extracts can be prevented by merely not listing them on §205.601, the use of nonsynthetic ammonia extracts can be prevented only by listing them on §205.602.

NOC wants to take this opportunity to note that ammonia extracts are not the only nonsynthetic nitrogen fertilizers that are inconsistent with fundamental principles of organic production. Two widely used materials are Chilean nitrate and soybean hydrolysates. There are others and will be more. NOC believes that this is the time to regulate fertilizers that bypass the benefits from the soil fertility and crop nutrient management practices required by the organic standards and instead provide highly available crop nutrients.

Due to the number of new Board members, we feel it is important to share our fall 2020 comments regarding this petition. We are including additional information directly related to the discussion document that shows that the use of ammonia is caustic, decreases soil pH, and is known to decrease soil biotic activity.

Use of ammonia extracts is incompatible with organic production.

In contrast to the reductionism of "conventional" chemical-intensive agriculture, the origins of organic agriculture are in holistic and ecological thinking. Historically, perhaps the most important principle of organic production is the "Law of Return," which, together with the foundational philosophy "Feed the soil, not the plant" and the promotion of biodiversity, provide the ecological basis for organic production.[58] Together these three principles describe a production system that mimics natural systems.

The Law of Return. In an organic system, residues are returned to the soil by tillage, composting, or mulching. While most organic growers depend on some off-site inputs, most of the fertility in a soil-based system comes from practices that recycle organic matter produced on-site. The cycling of organic matter and on-site production of nutrients—as from nitrogen-fixing bacteria and microorganisms that make nutrients in native mineral soil fractions available to plants—is essential to organic production. The Law of Return is not about feeding plants, but about conserving the biodiversity of the soil-plant-animal ecological community.

The Law of Return says that we must return to the soil what we take from the soil. Non-crop organic matter is returned directly or through composting plant materials or manures. To the extent that the cash crop removes nutrients, they must be replaced by cover crops, crop rotation, animal manures, or additions of off-site materials, when necessary.

Feed the soil, not the plant. The dictum to "Feed the soil, not the plant" reminds us that the soil is a living superorganism that supports plant life as part of an ecological community. We do not feed soil organisms in isolation, to have them process nutrients for crop plants; we feed the soil to support a healthy soil ecology, which is the basis of terrestrial life.

[58] See Sir Albert Howard. The Soil and Health: The Study of Organic Agriculture (1940), and An Agricultural Testament (1947).

Biodiversity. Finally, biological diversity is important to the health of natural ecosystems and agroecosystems. Biodiversity promotes balance, which protects farms from outbreaks of damaging insects and disease. It supports the health of the soil through the progression of the seasons and stresses associated with weather and farming. It supports our health by offering a diversity of foods. Ultimately, holistically healthy, truly organic farms produce healthy plants that require far fewer applications of insecticides and fungicides (even if approved for organic production).

In the case of ammonia extracts, we are particularly interested in the principle of feeding the soil rather than the crop. OFPA §6513(b) requires that organic operations establish a plan designed to "foster soil fertility, primarily through the management of the organic content of the soil through proper tillage, crop rotation, and manuring."

Substances of high solubility, i.e., those materials that provide nutrients directly to the plant because they are quickly taken up into the plant from the soil solution, are counter to foundational organic principles, so they have always been restricted. Such materials are listed in §205.602—Nonsynthetic substances prohibited for use in Organic Crop Production or the "prohibited naturals" section of the National List:

1) Calcium chloride is limited to treating a physiological disorder;

2) Potassium chloride must be used in a manner that minimizes chloride accumulation in the soil; and

3) Sodium nitrate is restricted to no more than 20% of the crop's total nitrogen requirement. (The NOSB has voted to remove the annotation, making this an absolute prohibition, but NOP has not, as yet, implemented this recommendation; the USDA has stated that the listing with sodium nitrate with the 20% restriction on §205.606 is invalid.)

The organic regulations limit substances of high solubility.
In the preamble to the publication of the NOP Final Rule on December 21, 2000, NOP discusses how it decided to agree with the NOSB recommendation and to put specific regulation of substances of high solubility into the annotations for each of these materials where they appear on the National List of Allowed and Prohibited Substances. NOP goes on to say, "Based on the recommendation of the NOSB, the final rule would prohibit use of these materials [substances of high solubility], unless the NOSB developed recommendations on conditions for their use and the Secretary added them to the National List."

At the time, the discussion was about mined substances of high solubility because there were no concentrated, highly soluble plant nutrient materials other than mined sources available at that time. New materials of high solubility should be prohibited or restricted. These highly soluble materials, most of which are nonsynthetic, do not appear on the National List and are used in soil-based production, as well as in some hydroponic and container systems. Highly soluble sources of plant nutrients should be prohibited or restricted through listing on §205.602 so as to not allow organic producers to stray from the foundational principle of organic production to "feed the soil, not the plant."

Use of ammonia extracts is not necessary for organic production.
As discussed above, the principle of "feed the soil, not the plant" is foundational to organic production. Consequently, organic practices have grown up without the use of highly soluble nutrients. Organic producers instead use practices such as cover cropping, crop rotations, nitrogen fixing legumes, compost, manure, and other sources of fertility.

One commenter in favor of the allowance of ammonia extracts in organic production is quoted in the published materials as saying that, "The aspect of soil-biological fertility is beginning to recognize that bio-based fertilizers that are organic concentrates high in ammonium have a large impact on the release of nutrients from organic materials in the soil and offer the potential to increase our ability to supply nutrient dense foods to feed the world."[59] The "feed the world" argument used by conventional agriculture advocates no longer holds water. When discussing the Farming Systems Trial that is the longest running side-by-side comparison of conventional and organic grain farming in North America, scientist Yichao Rui, PhD, who oversees soil health research at the Rodale Institute, noted that, "Over the 40 years, on average, there's no statistical difference in yield between conventional and organic. Also, in climate change scenarios, like years of drought, organic keeps performing better than conventional. We have found 30% higher yields in organic than conventional in years of drought."[60]

"The long-term consequences of continued reliance on current conventional production practices will be a decline in soil productivity that increases the need for synthetic N fertilization, threatens food security, and exacerbates environmental degradation."[61] "For the sake of agricultural productivity and ecosystem stability, special attention must be given to soil organic matter because of its key role in maintaining soil aggregation and aeration, hydraulic conductivity and water availability, cation-exchange and buffer capacity, and the supply of mineralizable nutrients."[62]

Use of ammonia extracts is harmful to the environment, including soil organisms.
Ammonia is toxic, both to humans[63] and to soil organisms.[64] Applications of ammonia decimate soil fungi and nematodes.[65] Nitrogen fallout into forests is implicated in reduction of habitat suitability for native forest vegetation.[66] Highly soluble nutrients such as ammonia extracts move in runoff or eroded soil to surface water, where even extremely low concentrations harm aquatic life.[67] Ammonia gas released from agriculture is a contributor to biodiversity loss.[68] Ammonia gas is often found in the form of aerosols of small particles (PM 2.5).[69] PM 2.5 is considered a major environmental threat to human health because, when inhaled, it may reach

[59] NOSB April 2021 proposals and discussion documents. Page 55 of 172.
[60] Lisa Elaine Held. February 18, 2020. *The Real Climate Impact of Organic Farming.* Food Print. https://foodprint.org/blog/the-real-climate-impact-of-organic-farming/
[61] R.L. Mulvaney, S.A. Khan, T.R. Ellsworth. Synthetic Nitrogen Fertilizers Deplete Soil Nitrogen: A Global Dilemma for Sustainable Cereal Production. Journal of Environmental Quality. November 1, 2009. https://doi.org/10.2134/jeq2008.0527
[62] *Ibid.*
[63] https://pubchem.ncbi.nlm.nih.gov/compound/Ammonia#section=Toxicity.
[64] https://certifiedcropadviser.org/files/certifications/certified/education/self-study/exam-pdfs/157.pdf.
[65] Eno, C.F., Blue, W.G. and Good Jr, J.M., 1955. The effect of anhydrous ammonia on nematodes, fungi, bacteria, and nitrification in some Florida soils. *Soil Science Society of America Journal*, *19*(1), pp.55-58.
[66] McDonnell, T.C., Belyazid, S., Sullivan, T.J., Bell, M., Clark, C., Blett, T., Evans, T., Cass, W., Hyduke, A. and Sverdrup, H., 2018. Vegetation dynamics associated with changes in atmospheric nitrogen deposition and climate in hardwood forests of Shenandoah and Great Smoky Mountains National Parks, USA. *Environmental Pollution*, *237*, pp.662-674.
[67] https://www.mda.state.mn.us/ecological-effects-ammonia.
[68] Guthrie, Susan, Sarah Giles, Fay Dunkerley, Hadeel Tabaqchali, Amelia Harshfield, Becky Ioppolo, and Catriona Manville, Impact of ammonia emissions from agriculture on biodiversity: An evidence synthesis. The Royal Society, 2018. https://www.rand.org/pubs/research_reports/RR2695.html.
[69] Erisman, J.W. and Schaap, M., 2004. The need for ammonia abatement with respect to secondary PM reductions in Europe. *Environmental Pollution*, *129*(1), pp.159-163.

the peripheral regions of the bronchioles and interfere with gas exchange inside the lungs, where it contributes to cancer and respiratory and cardiovascular disease.[70]

The discussion document notes that "comments opposed to the prohibition noted that the addition of ammonia extract does not degrade soil health and that they would not have a negative impact on biological activity and organic matter changes. In fact, they would increase the ability of soils to cycle nutrients and would lead to increased soil organic matter."[71] In fact, these exacts do degrade soil health by reducing the biological condition of the soil and are not in line with improving soil organic matter content.

When considering the effects on soil organisms, most studies use the analysis of phospholipid fatty acids (PLFAs).

> Phospholipid fatty acids (PLFAs) are key components of microbial cell membranes. The analysis of PLFAs extracted from soils can provide information about the overall structure of terrestrial microbial communities. PLFA profiling has been extensively used in a range of ecosystems as a biological index of overall soil quality, and as a quantitative indicator of soil response to land management and other environmental stressors.[72]

In studies that compare the use of manuring versus inorganic fertilizers, it has been shown time and time again that "examination of the PLFA (phospholipid fatty acids) by functional groups showed that AN (ammonium nitrate) treatment generally shifted the PLFA functional groups in the opposite direction from manuring"[73] and that inorganic fertilizers contribution to "decline in soil pH and SOC (soil organic carbon) (Ozlu, 2018)."[74] In addition, studies show that "soil management practices, such as manuring, that result in accumulations of organic carbon will result in increased microbial biomass and changes in community structure."[75] "The microbial community resulting from the AN treatment was typified by lower biomass than in the manured treatments, and a higher relative proportion of Gram-positive bacteria when compared to the CT (no nutrient additions) and manured soils."[76] "Indeed, soil pH in the surface 0± 5 cm was significantly lower in the AN treatment, and it is likely that this had an impact on the microbial community."[77]

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[70] WHO (World Health Organization). 2005. Air quality and health. http://www.who.int/mediacentre/factsheets/fs313/en/index.html.

[71] NOSB April 2021 proposals and discussion documents. Page 53 of 172.

[72] Quideau, S. A., McIntosh, A. C., Norris, C. E., Lloret, E., Swallow, M. J., & Hannam, K. (2016). Extraction and Analysis of Microbial Phospholipid Fatty Acids in Soils. *Journal of visualized experiments : JoVE*, (114), 54360. https://doi.org/10.3791/54360

[73] A.D. Peacock, M.D. Mullen, D.B. Ringelberg, D.D. Tyler, D.B. Hedrick, P.M. Gale, D.C. White. *Soil microbial community responses to dairy manure or ammonium nitrate applications.* Soil Biology & Biochemistry. 33 (2001) 1011-1019. http://davidcwhite.org/fulltext/515.pdf

[74] Ekrem Ozlu, Saroop S. Sandhu, Sandeep Kumar, Francisco J. Arriaga. *Soil health indicators impacted by long-term cattle manure and inorganic fertilizer application in a corn-soybean rotation of South Dakota.* Scientific Reports. (2019) 9:11776. https://doi.org/10.1038/s41598-019-48207-z

[75] A.D. Peacock, M.D. Mullen, D.B. Ringelberg, D.D. Tyler, D.B. Hedrick, P.M. Gale, D.C. White. *Soil microbial community responses to dairy manure or ammonium nitrate applications.* Soil Biology & Biochemistry. 33 (2001) 1011-1019. http://davidcwhite.org/fulltext/515.pdf

[76] *Ibid.*

[77] *Ibid.*

Reactive nitrogen gases are a contributor to climate change.
Carbon dioxide is not the only concern when it comes to the global climate crisis. Reactive nitrogen released by agriculture is a contributor to climate change. Nitrous oxide (N_2O) is considered to be a potent greenhouse gas (GHG), with approximately 300 times the warming potential of carbon dioxide.[78,79,80] The largest sources of nitrous oxide in agriculture are fertilized soil and animal waste. "In the U.S. alone, the use of fertilizer has risen more than 200 percent over the past 60 years, even though the amount of cropland has stayed relatively constant. At the same time, the number of large industrialized livestock operations has also gone up, creating more manure 'lagoons' and excess manure, which is often over-applied on cropland."[81] These are exactly the types of conventional agricultural practices that organic guards against. Nonsynthetic ammonia extracts are derived from the manure from concentrated animal feeding operations (CAFOs), the same large, industrialized livestock operations that are contributing to excessive amounts of nitrous oxide being released into the atmosphere.

In addition, the decrease in soil pH with the use of ammonia extracts increases the need for liming. "CO_2 is produced when liming neutralizes soil acidity generated from nitrification."[82] The reduction of GHGs compared to industrial fertilizers is a positive aspect of organic farming.[83]

> While addressing the global warming outcomes, one should consider soil enzyme activities that may affect recalcitrant humic matter (Davidson, 2006) owing to their association with changes in temperature (Stott, 2010). The balance between these two competing processes determines how much C is sequestered and stabilized as well as contributing to microbial diversity and activity, and a host of enzyme properties that determine soil fertility and plant productivity (Powlson, 2011). Soil enzymes have significant association with temperature, moisture (Acosta-Martinez, 2004) (Dodor, 2005), soil porosity, and GHG emissions (Moelans, 2005).
>
> In comparison to manure addition, the application of INF [inorganic fertilizer, such as ammonia extracts] addition decreased the enzyme activities by limiting their energy and production by (i) decreasing the SOC [soil organic carbon], which is the energy source for soil microbial diversity and maintenance of their structure and functional capacity, (ii) declining the soil N content, which is the production source, and (iii) breaking down the soil aggregates. It is well known that soil physical and chemical environments are related to fertility and crop management systems, and are major determinants of microbial populations and activities (Garcia-Orenes, 2013). Manure increases SOM [soil organic matter], soil aggregation and N content, decreases soil bulk density and maintains the soil pH (Ozlu, 2018) those are beneficial in supporting soil microbial activities. The β-Glucosidase activity, which usually increased with

[78] Sabrina Shankman. *What is Nitrous Oxide and Why Is It a Climate Threat?* Inside Climate News. September 11, 2019. https://insideclimatenews.org/news/11092019/nitrous-oxide-climate-pollutant-explainer-greenhouse-gas-agriculture-livestock/.
[79] R.L. Mulvaney, S.A. Khan, T.R. Ellsworth. Synthetic Nitrogen Fertilizers Deplete Soil Nitrogen: A Global Dilemma for Sustainable Cereal Production. Journal of Environmental Quality. November 1, 2009. https://doi.org/10.2134/jeq2008.0527
[80] Ramaswamy, V., Boucher, O., Haigh, J., Hauglustaine, D., Haywood, J., Myhre, G., Nakajima, T., Shi, G.Y., and Solomon, S. Radiative forcing of climate change. p. 349–416. *In Climate change* 2001: The scientific basis. Cambridge Univ. Press, Cambridge, UK. 2001
[81] Shankman.
[82] R.L. Mulvaney, S.A. Khan, T.R. Ellsworth. Synthetic Nitrogen Fertilizers Deplete Soil Nitrogen: A Global Dilemma for Sustainable Cereal Production. Journal of Environmental Quality. November 1, 2009. https://doi.org/10.2134/jeq2008.0527
[83] Shade, J., Cattell Noll, L., Seufert, V., Galloway, J.N. and Erisman, J.W., *Decreasing reactive nitrogen losses in organic agricultural systems.* Organic Agriculture, pp.1-7.

> the increase in soil microbial biomass, would reflect on a soil's ability to break down plant residues and improve the availability of nutrients for subsequent crops (Stott, 2010). More optimal soil water content combined with greater levels of organic C and N, nutrient cycling, and a large amount of N is stored in the relatively labile microbial biomass which is associated with greater microbial activity in manure amended soils (Goyal, 1999). Therefore, it is important to consider soil enzyme activities among the soil health indicators to provide a better understanding of microbial activities and C-N dynamics.[84]

The allowance of ammonia extracts and other highly soluble fertilizers promotes fraudulent "organic" operations.
Allowing potentially unlimited use of soluble nitrogen fertilizer would give an advantage to unscrupulous producers who substitute these inputs for the practices that define organic production.

The California State Organic Program at the California Department of Food and Agriculture (CDFA) has stated that they have enough inspections at plants that through mass balance and unannounced inspections it would be very difficult for a manufacturer to mix in synthetic ammonia with nonsynthetic ammonia, but NOC remains skeptical that fraud can be prevented. Further, we understand that CDFA has noted that as long as you have a lot number and can obtain a sample of that lot for an isotopic analysis, you can then take a sample and do an isotopic analysis at the end user, and that ratio of C:N should not have changed. While some may find this well-reasoned, we share OMRI's concerns as noted in the published materials:

> While OMRI does not advocate for the allowance or prohibition of any specific material, it understands the risks of adulteration by synthetic substances to organic integrity. In the case of nonsynthetic ammonia sources, OMRI believes that the risk of adulteration by synthetic forms is significant due to the difficulties in identifying the sources of the material. The risk of adulteration is also higher for soluble nitrogen products given the potential economic gains from producing an input product with cheaper, synthetically derived nitrogen.[85]

The NOSB should create a work agenda item that focus on soil husbandry and a holistic approach to highly soluble sources of nitrogen.
Highly soluble sources of nitrogen cannot be addressed in a vacuum, and we cannot look at one material at a time. We must take a broader approach to limiting highly soluble sources of nitrogen as a whole. To evaluate and list each individually, even with a restriction, is a slippery slope and raises the concern of "stacking." Question #4 of the published materials effectively demonstrates this concern. It asks: "Should the use of natural ammonia extract be limited to a certain percent of nitrogen use in crops (similar to the Chilean nitrate restriction)?"[86] With this approach, producers could potentially "stack" highly soluble sources of nitrogen, using 20% of the crop's needs from Chilean nitrate, 20% of the crop's needs from another source, and 20% of the crop's needs from yet another source.

§205.203 *Soil fertility and crop nutrient management practice standard* mandates soil husbandry in organic production. While it is easy to focus on the negative aspects of highly soluble sources of nitrogen, we must go

[84] Ekrem Ozlu, Saroop S. Sandhu, Sandeep Kumar, Francisco J. Arriaga. *Soil health indicators impacted by long-term cattle manure and inorganic fertilizer application in a corn-soybean rotation of South Dakota.* Scientific Reports. (2019) 9:11776. https://doi.org/10.1038/s41598-019-48207-z
[85] NOSB April 2021 proposals and discussion documents. Page 57 of 172.
[86] *Ibid.* Page 57 of 172.

beyond that. In addition to the damage done, the use of highly soluble sources of nitrogen bypasses the benefits from the soil fertility and crop nutrient management practices outlined in §205.203.

Overreliance on highly soluble sources of fertility can short circuit soil-building practices that sequester carbon and is in violation of the foundational "feed the soil" principle in organic agriculture. Highly soluble sources of nitrogen should be included on the list of prohibited naturals (7 CFR § 205.602 of the National List), with the potential for an annotation limiting them based on an understanding of need during climatic emergency or extreme conditions. In concert with this, NOC encourages the NOSB to request a work agenda item related to carbon sequestration and enforcement of soil-health provisions in the organic regulations.

NOC believes the NOSB has an important role to play in solidifying organic's role as the gold standard for climate-friendly agriculture (priority #5 in our State of the USDA NOP comment). The organic regulations are strong because they require proper tillage, soil-building practices that sequester carbon, and pasture-based grazing for organic livestock. But the regulations are not being enforced as effectively as they should. There are several areas where enforcement must be strengthened, and new regulations should be put into place to ensure that organic is the gold standard when it comes to climate change.

The work agenda item focused on carbon sequestration and enforcement of soil-health provisions should focus on enforcement of soil-building, cover cropping, crop rotation, and biodiversity practices required in the organic regulations. The NOSB should identify and make recommendations to strengthen organic practices for climate mitigation, adaptation, and carbon sequestration. Such an effort would serve to bolster clarity and consistency of enforcement across certifiers, hold producers to foundational principles of organic production, and strengthen organic producers' position in the climate discussions and initiatives across the country.

The NOSB should address the related issue of other synthetic forms of ammonia.
During our discussion of ammonia extracts and soluble forms of nitrogen, a discussion arose regarding other synthetic forms of ammonia allowed by the National List, such as extractants. Specifically, the use of potassium hydroxide and ammonium hydroxide in the extraction of humic acid. Without an annotation that provides a threshold for use, excess extractant can be used in the manufacturer of these products, leaving them "fortified" with synthetic forms of ammonium or potassium.

An initial response is to suggest an annotation at §205.601(j)(3) Humic acids—naturally occurring deposits, water and alkali extracts only. *Solvent amount used is limited to that amount necessary for extraction*, similar to §205.601(j)(1). Indeed, this is the approach taken by the Canadian standards:[87]

> Humates, humic acid and fulvic acid
> Permitted if mined; produced through microbial activity; extracted by physical processes; or with:
> a) Table 4.2 Extractants; or
> b) potassium hydroxide—potassium hydroxide levels used in the extraction process shall not exceed the amount required for extraction.
> Levels (mg/kg) of arsenic, cadmium, chromium, lead and mercury shall not exceed the limits (category C1) specified in Guidelines for the Beneficial Use of Fertilising Residuals. Shall not cause a build-up of heavy metals or micronutrients in soil.

[87] Government of Canada. Organic Production Systems. CAN/CGSB-32.311-2020. Corrigendum No.1, March 2021. Page 12 of 64. http://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-311-2020-eng.pdf

After reaching out to several MROs and a manufacturer, we came to better understand the manufacturing process and the fact that when extracting humic compounds or seaweed compounds, in theory there would be an exact amount required to achieve full extraction with no reactant left. However, this would only be achievable in a highly controlled lab setting. Because all raw leonardite or kelp meal materials vary in the amount of humic/alginic compounds in them, one would first have to do a very detailed analysis of each batch to ascertain how much product could be extracted from the raw materials.

Through this discussion, it came to our attention that the other caveat with these alkali extracted products is that the more that is used, the higher the pH of the end product. Excessively high pH products are unsafe for handling, and their residues on plants could be harmful if ingested; therefore, another approach that may address the overuse of extractants would be to set a pH threshold in the end product.

It is our understanding that OMRI has a fortification policy for humic acid extracts where potassium hydroxide or ammonium hydroxide are used as extractants that is applied anytime these allowed synthetic extractants are used in a product that applies for OMRI certification. If a product exceeds the threshold allowance of the OMRI policy, their application is forfeited and not prohibited by OMRI. The forfeit means a product has not met OMRI's internal standards, while still being allowed for use in organic production based on its listing on the NL.[88]

Conclusion
We urge you to approve this petition to prohibit the use of ammonia extracts in organic production.

NOC is requesting that the NOSB create a work agenda item that focuses on soil husbandry and a holistic approach to highly soluble sources of nitrogen. In concert with this, we urge the NOSB to create a work agenda item related to carbon sequestration and enforcement of soil-health provisions in the organic regulations.

The NOSB should address the related issue of other synthetic forms of ammonia.

Kasugamycin for use as an approved active ingredient in organic crop production at 7 CFR 205.601.
NOC opposes the listing of kasugamycin on the National List.
We are dismayed to once again find ourselves reviewing a petition for an antibiotic for use in organic production. The reasons for rejecting the kasugamycin petition are the same as the reasons for eliminating streptomycin and tetracycline, and many will be repeated below. NOSB members who are not convinced by this reasoning should read the views presented in the dockets and transcripts of NOSB meetings from 2006 through 2014 concerning those other antibiotics. The CS proposal document on tetracycline in 2013 contains a history—mostly of efforts to remove the antibiotic.

The use of antibiotics is not compatible with organic production.
After reaching out to several fruit tree producers in the mid-west and west coast, we have learned that the fruit tree growers that we spoke to have not lost mature trees to fire blight since antibiotic use was taken off the NL. The producers we spoke with also noted that they would not support adding another antibiotic for this use to the NL. While some noted that it would be an easy fix, all agreed that it is not compatible with organic production.

[88] Private e-mail communication between Doug Currier, OMRI, and Christie Badger, NOC.

Using antibiotics in organic production is contrary to consumer expectations, as antibiotics are touted throughout organic marketing as being prohibited. Despite the difficulty, organic livestock producers have been doing without antibiotics for almost two decades. Many of our trading partners around the world do not allow antibiotic use in organic production.

Antibiotic resistance poses a serious threat to human health, and use of antibiotics in agriculture contributes to that threat.

Given the important role that antibiotics play in world health, it is crucial for organic production to eliminate their use for the benefit of human health worldwide. As noted by Beyond Pesticides in their spring 2021 comments to the NOSB:

> "Now that we have learned what a pandemic looks and feels like, with the astounding levels of infection, hospitalization, and death from COVID-19, we must take serious steps to prevent another pandemic on the horizon—this one tied to bacterial resistance to antibiotics. An important article in *The Lancet*[89] points to a 'looming potential pandemic' resulting from a 'rise in multidrug-resistant bacterial infections that are undetected, underdiagnosed, and increasingly untreatable, [which] threatens the health of people in the USA and globally."[90]

Perhaps of even more immediate importance is the role kasugamycin plays in medical and veterinary uses.

> "Kasugamycin was tested and proven to be effective against *Pseudomonas aeruginosa* urinary infections in humans.[91] Kasugamycin targets an enzyme important in the pathogenesis of COVID-19.[92] Kasugamycin can reduce the development of resistance to the anti-tuberculosis drug rifampicin and may itself prove to be an effective drug itself in fighting tuberculosis.[93] It has been used for animal infections.[94] Although it is not essential to our argument that kasugamycin itself is of medical and veterinary importance, the need for effective antibiotics is an important reason for avoiding agricultural uses that can lead to resistance in potentially valuable antibiotics."[95]

The discussion document itself is quite damning, noting, "Normal labeled use of kasugamycin has lead to field resistance in several pathogens,"[96] and "fire blight has grown resistant to every antibiotic used against it and there is good reason to believe it will become resistant to kasugamycin."[97]

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[89] Strathdee, S.A., Davies, S.C. and Marcelin, J.R., 2020. Confronting antimicrobial resistance beyond the COVID-19 pandemic and the 2020 US election. *The Lancet*, *396*(10257), pp.1050-1053. https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2932063-8.

[90] Terry Shistar. March 2021. Beyond Pesticides Comments on Kasugamycin. Page 1 of 9.

[91] https://pubchem.ncbi.nlm.nih.gov/compound/kasugamycin#section=Drug-and-Medication-Information.

[92] Kamle, S., Ma, B., He, C.H., Akosman, B., Zhou, Y., Lee, C.M., El-Deiry, W.S., Huntington, K., Liang, O., Machan, J. and Kang, M.J., Chitinase 3-like-1 is a Therapeutic Target That Mediates the Effects of Aging in COVID-19. *bioRxiv*, pp.2021-01.

[93] Chaudhuri, S., Li, L., Zimmerman, M., Chen, Y., Chen, Y.X., Toosky, M.N., Gardner, M., Pan, M., Li, Y.Y., Kawaji, Q. and Zhu, J.H., 2018. Kasugamycin potentiates rifampicin and limits emergence of resistance in Mycobacterium tuberculosis by specifically decreasing mycobacterial mistranslation. *Elife*, *7*, p.e36782.

[94] https://pubchem.ncbi.nlm.nih.gov/compound/kasugamycin#section=Drug-and-Medication-Information, citing Gerhartz, W. (exec ed.). Ullmann's Encyclopedia of Industrial Chemistry. 5th ed.Vol A1: Deerfield Beach, FL: VCH Publishers, 1985 to Present., p. V2: 523 (1985).

[95] Terry Shistar. March 2021. Beyond Pesticides Comments on Kasugamycin. Page 5 of 9.

[96] NOSB April 2021 proposals and discussion documents. Page 59 of 172.

[97] *Ibid.* Page 60 of 172.

Kasugamycin use is not necessary.
There are other ways to deal with fire blight.

> The alternative to kasugamycin is an integrated organic program that attacks fire blight at every point in its life cycle. Cultural controls can be combined with application of fixed copper sprays in dormant and pre-bloom periods, application of lime sulfur for mildew control and thinning of apple blossoms, biological controls such as Blossom Protect during bloom time, and bio-control antagonists such as Serenade later in the blooming period.[98]

Organic apple and pear production has not ceased since the use of streptomycin and tetracycline were prohibited. While the alternatives may have some downsides, none are as serious as the use of antibiotics.

Conclusion
Kasugamycin does not meet any of the OFPA criteria for the National List—it poses health and environmental dangers, is not necessary, and is incompatible with organic practices.

Sunset

Copper Sulfate 205.601(a)(3) – For use as an algicide in aquatic rice systems, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

Copper Sulfate 205.601(e)(3) – For use as tadpole shrimp control in aquatic rice production, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

NOC shares the concerns for copper sulfate used in organic aquatic rice systems outlined in the Crops Subcommittee published materials. We agree that it may be time to reconsider copper sulfate as an algicide and means of controlling tadpole shrimp in these production systems.

The CS indicates that "it appears there is sufficient evidence to conclude that:

1) use of copper sulfate in rice fields is environmentally detrimental,

2) alternative seeding practices could eliminate the need for the chemical as both algae and tadpole shrimp cease to be problematic once seedlings are established and

3) international standards do not allow for spraying of copper sulfate for organic rice production."[99]

While we wholeheartedly agree and point you in the direction of comments made by Beyond Pesticides that more fully explore the evidence in support of these points, there are additional considerations that have not been covered by the published materials.

[98] *Ibid.* Page 60 of 172.
[99] NOSB April 2021 proposals and discussion documents. Pages 28 & 29 of 172.

If copper sulfate remains on the NL for use in rice fields, the use restrictions in the annotations need to be clarified.
Since copper is an elemental product and cannot decompose, it can accumulate to toxic levels in the soil over time. In the long-run, and in the spirit of continuous improvement that remains at the core of OFPA, alternatives must be found to avoid the long-lasting adverse effects caused from the application of copper for disease control.

The use restrictions in the annotations need to be clarified.

Do growers use the annotations to allow them to use copper sulfate every year—alternating use as algicide with use as insecticide? If copper sulfate is not removed from the National List, the annotations should be revised to clarify that use of copper sulfate for any purpose is limited to once in 2 years.

Further, data on accumulation in the soil, as required by the annotation, should be provided to the CS and the public.

The annotations on both listings for copper sulfate state, "Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent." Those who certify organic rice producers should be, therefore, obtaining test results for copper. Those test results should be requested by the CS and provided to the public—listings may remain anonymous—prior to the Fall 2021 meeting.

There has always been an alternative to copper sulfate use in rice production.
Although the TR notes that "there isn't yet a viable organic alternative for copper in certain applications,"[100] it appears embarrassingly obvious that this simply is not true. As the CS explains (emphasis added):

> Transplanting in older seedings eliminates any threat from algal mats to the delicate young seedling stage, as do practices such as dry seeding the rice or ensuring that the rice is seeded directly at the time of flooding. Interestingly, transplanting seedlings has been the preferred method of rice production throughout most of human rice cultivation. In Asian rice cultivation, the tadpole shrimp are often deliberately introduced as a means of controlling algae and mosquitos. **The current approach of flooding the fields and then direct wet-seeding didn't gain popularity until broad chemical use was implemented,** and has been demonstrated to marginally reduce costs and increase yields.[101]

It would appear that our Western culture priorities of paying less for more have created yet one more agricultural practice that is detrimental to both human and environmental health.

Conclusion
There is an alternative to copper sulfate use in rice production. Copper sulfate as an algicide and means of controlling tadpole shrimp in aquatic rice systems should be delisted.

[100] *Ibid.* Page 28 of 172.
[101] *Ibid.* Page 28 of 172.

Peracetic acid 205.601(a)(6) – For use in disinfecting equipment, seed, and asexually propagated planting material. Also permitted in hydrogen peroxide formulations as allowed in §205.601(a) at concentration of no more than 6% as indicated on the pesticide product label.
Peracetic acid 205.601(i)(8) – For use to control fire blight bacteria. Also permitted in hydrogen peroxide formulations as allowed in §205.601(i) at concentration of no more than 6% as indicated on the pesticide product label.

NOC supports the relisting of Peracetic Acid to the National List for all uses.

However, we feel that the NOSB could benefit from a review of sanitizers and disinfectants as a class, to aid the NOSB with future reviews of these items as they come before the board either as a new petition or at sunset. We recognize that a wide variety of sanitizers and disinfectants are a necessary part of food production on the farm, as well as within food processing facilities. Materials are needed so they can be used in rotation in order to prevent the development of "super-bug" type pathogens when management options do not produce the expected results. Further, the diversity of situations encountered when producing and handling organic foods, including wet or dry, hot or cold, as well as the bacteria or viruses being targeted by use of these materials, require options.

The listing of this class of materials has been responsive to petitions and historical use, without the benefit of research into which could be most compatible with organic production. This type of research would provide the NOSB with the background they need make informed decisions when these materials come before the Board. The questions asked of the public concerning this material illustrate the need for a discussion on sanitizers and disinfectants as a whole and would benefit from a taskforce that could support the NOSB in moving forward with this important work.

Conclusion
NOC supports the relisting of Peracetic Acid to the National List for all uses. The NOSB and organic stakeholders would benefit from a review of sanitizers and disinfectants as a class.

EPA List 3 – inerts of unknown toxicity 205.601(m)(2) – For use only in passive pheromone dispensers.
The "inerts" listings on the NL remain an embarrassment to organic integrity, with the list of "inerts" that is referenced for review of products for organic certification was last updated in August 2004. The same issues are identified repeatedly every time inerts come up for sunset. In our Spring and Fall 2020 comments, NOC outlined a specific, succinct plan on how to move forward on List 4 inerts working with the Environmental Protection Agency's (EPA) Safer Choice Program. Those comments are included as Appendix D. The solution for List 3 "inerts" is even more specific and succinct—List 3 "inerts" should be delisted, with each individual material petitioned and reviewed to be added to the NL.

List 3 "inerts" should be delisted.
The NOSB has already recommended an expiration date for these chemicals.

In the spring 2012, the NOSB passed a motion to change the listing to:

> 2) Inert ingredients exempt from the requirement of a tolerance under 40 CFR 180.1122 that were formerly on EPA List 3 in passive polymeric dispenser products may be used until December 31, 2015,

after which point they are subject to individual review under 205.601, unless already covered by a policy adopted by the NOP for all other inert ingredients.

The NOP refused to codify this recommendation. In doing so, we believe it is in violation of OFPA §6517(d) (2) "No additions. The Secretary may not include exemptions for the use of specific synthetic substances in the National List other than those exemptions contained in the Proposed National List or Proposed Amendments to the National List."

The identities of the former list 3 "inerts" are known, and they should be examined relative to OFPA criteria. The CS proposal of spring 2012 identified the "inerts" formerly on List 3 that are covered by this listing and currently used in organic production. They are BHT (antioxidant), 2-Hydroxy-4-n-octyloxybenzophenone (UV absorber), and 2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole (UV stabilizer).[102]

During NOC's review process, we reached out to materials review experts at OMRI, WSDA, and PCO, who agreed that a resolution to this obsolete listing would be welcome. In addition to the three materials identified by the spring 2012 CS proposal, during our discussions with these review experts, it was made known that there may be a fourth inert in this category that is being used – benzaldehyde CAS #100-52-7. In looking at this fourth material, it immediately becomes apparent as to why these materials must be added to the NL for review. The EPA now classifies Benzaldehyde as approved for nonfood use and as a fragrance in nonfood uses. However, the FDA lists Benzaldehyde as GRAS for use as a flavoring agent or adjuvant. It is time for the NOSB to do their own review of these materials. As noted by Beyond Pesticides in their more thorough comments regarding these substances, "From our review of these chemicals, we think it quite likely that at least some will be found to be acceptable when reviewed by the NOSB."[103]

NOC encourages the NOSB to move forward in a way that provides a resolution to this obsolete listing. We encourage the NOSB to move forward boldly to address a listing that is an embarrassment to organic integrity by providing a timeline by which the currently used List 3 "inerts" must be petitioned and reviewed for addition to the National List.

Chlorine materials (i) Calcium hypochlorite. (ii) Chlorine dioxide. (iii) Hypochlorous acid - generated from electrolyzed water. (iv) Sodium hypochlorite 205.601(a)(2) – For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

COMPREHENSIVE REVIEW OF SANITIZERS, DISINFECTANTS, AND STERILANTS

As NOC has repeatedly contended, the NOSB would benefit from a comprehensive review of sanitizers, disinfectants, and sterilants to inform decision-making when a new material is petitioned or a material is reviewed at sunset. As noted in previous comments on this topic, we recommend the TR for sodium dodecylbenzene sulfonate (SDBS) as a starting place because this TR asks and answers many of the questions that would be appropriate to address in a comprehensive review of sanitizers, disinfectants, and sterilants.

[102] NOSB May 2012 proposals and discussion documents. Page 38 & 39 of 172. https://www.ams.usda.gov/sites/default/files/media/packetnm.pdf

[103] Terry Shistar. March 2021. Beyond Pesticides Comments on Crops Sunset Materials. Page 8 of 19.

The NOSB could refer to the sanitation materials review to judge whether other materials currently on the National List meet the same need, or whether there is a special characteristic of the material under review that justifies its placement or renewal to the NL. This comprehensive review may help identify areas where there are gaps in necessary sanitizers or disinfectants which aid crops, livestock, and/or handling operations in promotion of organic food safety.

Request for a comprehensive review of sanitizers. OFPA requires that materials on the National List be itemized "by specific use or application." This requires the NOSB identify the uses for which these materials are needed. A Technical Review (TR) that establishes and distinguishes needs, uses, and relative toxicities for sanitizers, disinfectants, and sterilants must be performed. In particular, the TR must address the following:

- The uses for which these materials are needed;
- Whether an antimicrobial is the appropriate way to address the identified need;
- Whether any uses of specific materials in this class are required by law;
- Whether there are uses for which no material is listed on the National List;
- Whether organizations researching least toxic materials (e.g., EPA's Safer Choice/Design for the Environment program[104] and the Toxics Use Reduction Institute at the University of Massachusetts, Lowell[105]) have identified least toxic practices and materials that should be considered for use in organic production;
- Which alternative practices and materials might be proposed for each use that is identified; and
- The hazards to humans and the environment of the various options identified.

Conclusion
While this topic as a whole is daunting, we would suggest that the NOSB begin to address this one step at a time by requesting a TR to address the questions put forth in the published materials and every time a sanitizer, disinfectant, or sterilant comes up for petition or sunset review moving forward.

Calcium chloride 205.602(c) – Brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.

NOC supports relisting of Calcium Chloride, a prohibited nonsynthetic material with an annotation that allows the material to be used as a foliar spray to treat a physiological disorder associated with calcium uptake.

One important example of a physiological disorder that is known to be linked with an inability to take up sufficient calcium is bitter pit in apples.[106] This disorder is not limited to any particular variety of apples and is not limited to any particular production region—it is recognized as an abiotic disorder found in all areas of the

[104] DfE for antimicrobials at https://www.epa.gov/pesticide-labels/design-environment-antimicrobial-pesticide-pilot-project-moving-toward-green-end. Safer Choice at https://www.epa.gov/saferchoice/safer-ingredients.
[105] https://www.turi.org/Our_Work/Cleaning_Laboratory.
[106] Apple: Bitter Pit, UC Davis Postharvest Technology website, 2016.
http://postharvest.ucdavis.edu/produce_information/Fruit_Physiological_Disorders/Apple_BitterPit/
"A mineral imbalance in the apple flesh develops with low levels of calcium and relatively high concentrations of potassium and magnesium. Low levels of calcium impair the selective permeability of cell membranes leading to cell injury and necrosis."

world.[107] It appears that while fruit remains on the tree, bitter pit can generally be reduced by ensuring the plant's ability to take up calcium. However, in some cases, the corky, dark patches on the skin and flesh of the fruits associated with bitter pit do not become apparent until the apples are in storage, when the disorder is much more difficult to control and can results in extensive losses.

Conclusion
While we agree that the NOP regulations require producers to use all management practices available to manage soil nutrients, we recognize that the extent of physiological disorders present in any growing season depends on many factors, some of which are beyond the grower's control. We conclude that calcium chloride is an important tool for managing problems with calcium uptake and is necessary to ensure production of market-quality crops.

Rotenone (CAS # 83-79-4) 205.602(f)

NOC supports the proposal to relist rotenone on §205.602, prohibited nonsynthetic materials. The Environmental Protection Agency's registration for rotenone was voluntarily cancelled for all uses except as a piscicide in 2006—and thus rotenone is not allowed in organic production in the United States. However, it continues to be allowed in other countries. Unless rotenone is relisted as a prohibited substance, organic farms in other countries will be able to use it for foods imported to the US and labeled organic. Organic agriculture had been widely criticized for using rotenone, which is associated with Parkinson's disease and other central nervous system damage in farmers and farmworkers.

Conclusion
NOC supports rotenone's continued listing at §205.602.

Handling Subcommittee

Proposals

Ion exchange filtration

NOC agrees with the NOP that it is time to clarify the role that ion exchange resins should play in organic food processing. The NOP got it right in their clarification to certifiers on May 7, 2019, when they noted that "nonagricultural substances used in the ion-exchange process must be present on the National List. This would include, but is not limited to, resins, membranes, and recharge materials."[108] We further applaud the NOP in their continued efforts to address inconsistencies between certifiers.

The NOSB must not abdicate from making a recommendation to the NOP.
We urge the NOSB not to give the NOP the final decision, but to remain true to the authority granted in OFPA to make recommendations regarding NL materials to the NOP/USDA. It becomes a slippery slope when the NOSB is tasked with a challenging topic and decides to pass the buck to the NOP for final decision making. Organic stakeholders have lobbied hard for the NOSB to continue to have the right to make these kinds of recommendations regarding NL materials.

[107] Integrated Pest Management For Apples and Pears. University of California, Division of Agriculture and Natural Resources, Publication 3340, 1991. ISBN 0-931876-94-X, Library of Congress Catalog Card No. 91-65337.
[108] NOSB April 2021 proposals and discussion documents. Page 63 of 172.

Ion exchange is a chemical change.
The Handling Subcommittee makes this argument quite thoroughly in the published materials.

"The NOP has determined, and some Materials Review Organizations have agreed, that the ion exchange process is a chemical one and does affect the food in a way that chemically changes it."[109]

In the simplified summary of ion exchange from OMRI shared in the published materials, they note, "The process chemically changes the resulting fluid," and then go on to provide examples. They then go on to note, "However, the use of synthetic cross-linked polymeric resins—such as styrene-divinylbenzene (S-DVB)—to remove certain constituents of liquids based on their chemical properties is a chemical process."[110]

"As noted in the 2020 TR, ion exchange filtration differs from physical filtration processes in that there is an actual chemical change in the ensuing product – ions (either cations or anions depending on the resin and desired outcome) that were present on the resin have been substituted in the final product while ions that were initially found in the product are left attached to the resin."[111]

"It seems difficult to argue that ion exchange filtration does not cause a chemical change in the final product, even though the chemical change may be beneficial. There is a different ionic makeup in the final product as compared to the initial product and the final product may behave slightly differently than the initial product.[112]

Food contact vs. direct food additive isn't the issue. OFPA must guide our decision-making process when it comes to organic production.

> "The fact that FDA considers some secondary direct food additives, (e.g. processing aids) to be food contact substances has no bearing on whether the substance is suitable for use in organic food production. The NOSB needs to follow the requirements of OFPA and the NOP regulations when it considers any ingredient or processing aid for use in organic production: they must be either organic or reviewed and appear on the National List for that use. Nowhere in OFPA or 7CFR Part 205 does it say that 'food contact substances' are exempt from review."[113]

Further, the fact that a manufacturer need only submit an application to FDA requesting the classification by FDA as a food contact substance without further review or public comment is not a further complication. It is a statement of fact that has nothing to do with the requirements of OFPA.

It is not true that "These technical and procedural issues are best left to legal interpretations and procedural interpretations that are beyond the capabilities of the NOSB."[114] They only seem to be such if one believes it essential to resolve questions such as when resins are food contact substance and when they are secondary food additives. But this is not necessary, or even consistent with OFPA, which requires that any synthetic

[109] *Ibid.* Page 61 of 172.
[110] *Ibid.* Page 61 & 62 of 172.
[111] *Ibid.* Page 62 of 172.
[112] *Ibid.* Page 62 of 172.
[113] Emily Brown Rosen, Comments to the NOSB Proposal on Ion Exchange Filtration Process and Materials Used, September 30, 2020, p.2.
[114] NOSB April 2021 proposals and discussion documents. Page 66 of 172.

substance added to organic food be on the NL, having been recommended by the NOSB. The HS has established that use of ion exchange resins can result in resins or their breakdown products being added to foods. Therefore, the NOSB must, based on OFPA, decide which resins may be used, and for which purposes. The NOSB may not contravene other laws, but it may (and must) take a precautionary approach based on the strictest interpretations of those laws.

"The organic regulations have their own special criteria that cannot be overlooked."[115]
Giving up oversight to the FDA, an organization that does not have an organic sensibility when they are reviewing materials, is problematic. Basing our decisions on what the FDA allows and does not allow sets a dangerous precedent.

> "For instance, a quick look finds FCN No. 2009, which allows a sanitizing spray containing sulfuric acid to be sprayed directly on seeds for sprouts and edible nuts. Clearly this is not permitted on organic food at present. If NOSB were to decide that ion exchange resins are permitted because of status as a food contact substance, would that precedent apply to all 1493 substances? NOSB cannot justify allowing this loophole to apply to one category of use (ion exchange) and not set a precedent for all these other substances."[116]

To be clear, within the organic program we follow a precautionary principle that guides our decision making, not what the conventional market requires. "While NOP regulations strive to be consistent with other federal regulations, the organic regulations have their own special criteria that cannot be overlooked. Not every substance approved by FDA is allowed in organic food production."[117]

Is ion exchange needed in organic processing?
Situations such as this are probably inevitable, given the exponential growth of organic markets and the influx of technologies from nonorganic production. However, it is crucial to the maintenance of organic integrity that the NOSB bite the bullet and make a real recommendation that is consistent with OFPA. In doing so, the NOSB must ask whether ion exchange is really necessary in organic processing.

Conclusions
The NOSB must not abdicate from making a recommendation to the NOP, but must remain true to the authority granted in OFPA to make recommendations regarding NL materials to the NOP/USDA.

OFPA must guide our decision-making process when it comes to organic production: they must be either organic or reviewed and appear on the National List for that use.

Petitions / Discussion Documents

Zein, petitioned for use at 205.606

The NOSB has received a petition to list zein, a product of nonorganic corn protein, on §205.606 of the National List. New materials should not be added to §205.606. The organic industry has matured to the point that all

[115] Rosen, p.4.
[116] Rosen, p.3.
[117] Rosen, p.4.

agricultural materials can be produced organically. Listing on §205.606 only stifles organic production of new organic crops and promotes chemical-intensive production. Although the specific petitioned use is as a food coating, the petition identifies a number of uses for zein: as an ingredient and as a processing aid, including as a glaze, coating, taste masker, wheat gluten substitute, and for use in micro- or nano-encapsulation.

The Handling Subcommittee notes in the published materials that there are three main considerations:

> The potentially contentious areas for understanding zein's suitability for inclusion on the National List fall under three main categories: a) the environmental impacts of the corn wet-milling process used to create the corn gluten meal, b) whether the zein product can be considered non-synthetic and c) whether zein fills a unique functionality not already filled by currently allowed substances.

While we agree these three areas must be addressed, we would add the fourth—What is the barrier for organic production?

The environmental impacts of the corn wet-milling process.
The published materials do a sufficient job of outlining the "legitimate concerns regarding the environmental impacts of the corn wet-milling process,"[118] while also noting:

> It is important to note that there does seem to be an effective pathway to avoiding the wet-milling process entirely in the production of zein. Researchers from the University of Illinois have developed another zein product that is created directly from whole corn. They plan to market this product under the name Amazein and point to the fact that direct production from corn bypasses need for sulfur dioxide or the other caustic chemicals that are used during the wet milling process that creates much of the corn gluten meal on the market. This method of direct extraction from whole organic corn may also allow for the creation of a truly organic zein product as organic ethanol [one of the raw materials used in the manufacturing process of zein] is available in the US, though perhaps prohibitively expensive.[119]

Cost is not a criterion for listing on the NL, so the fact that organic zein may be "prohibitively expensive" is not a reason for allowing zein as petitioned to be used in organic food. On the contrary, the difference in cost may be largely due to the ability to externalize the environmental and health costs of producing zein from nonorganic corn in the conventional manner.

There is no established precedent that zein is non-synthetic.
There is no established precedent that provides sufficient rationale that zein is non-synthetic. The discussion document notes that zein has never been petitioned to the NL previously, but "despite this, the rulings that have been made on corn steep liquor (CSL) are directly relevant to any review of zein as they are different products created during the same wet-milling process."[120]

To be perfectly clear, both the Organic Materials Review Institute (OMRI) and the NOSB voted that corn steep liquor is synthetic, as outlined in the published materials. Not only did OMRI have a decisive vote by their

[118] NOSB April 2021 proposals and discussion documents Page 109 of 172.
[119] *Ibid.* Page 109 of 172.
[120] *Ibid.* Page 108 of 172.

"Advisory Council, an independent body made up of experts in their fields," they had a decisive vote *twice.* Then, "In 2011, the NOSB reviewed corn steep liquor and through a similar rationale, came to the same conclusion."[121]

Perhaps the ruling by the NOP tried to establish a precedent; however, materials on the NL are subject to a decisive vote and recommendation by the NOSB, something the NOP never allowed to happen.

Zein does not fill a unique functionality that is not already filled by currently allowed substances.
Both the TR and published materials do an excellent job at identifying alternative products "currently on the National List that can serve a similar role to zein in forming a protective coating around foodstuffs. Examples of this include beeswax, shellac, vegetable proteins and carnauba wax."[122] The Handling Subcommittee's published materials go on to indicate that "zein's functionality is unique because it offers a vegan/vegetarian option to replace shellac and beeswax as coatings."[123] However, we already have a wax on the list that serves this functionality in carnauba wax, which is taken from the leaves of the *Copernicia prunifera* palm tree.[124]

What is the Barrier for Organic Production?
Every time a new material is petitioned to be added to §205.606, we find ourselves asking the question, "What is the barrier for producing these ingredients in organic form?" To address this issue, we offer our full comments from Spring 2020 as Appendix E, which includes a comprehensive list of questions that should be used when determining the barriers to organic production with new petitions to §606.

According to the information included in the published materials regarding the work being done at the University of Illinois, there does not appear to be one. The production method for the product they plan to manufacturer under the name Amazein is a "method of direct extraction from whole organic corn [that] may also allow for the creation of a truly organic zein product."[125] As noted above, cost is not a criterion for listing on the NL. In addition, NOC strongly takes issue with adding a material made from conventional corn to §205.606 when there is clearly organic corn readily available for use.

If, against our recommendation, zein is listed, the NOSB must explicitly prohibit use for nano-encapsulation.
All substances on the NL must be listed "by specific use or application." Since one use of zein is nano-encapsulation[126] and the NOP has failed to codify the recommendation of the NOSB prohibiting engineered nanomaterials in organic products, the NOSB must make clear that zein may not be use in nano-encapsulation.

Conclusion
New materials should not be added to §205.606. The organic industry has matured to the point that all agricultural materials can be produced organically. Listing on §205.606 stifles organic production of new organic crops and promotes chemical-intensive production.

Zein does not fill a unique functionality that is not already filled by currently allowed substances.

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[121] *Ibid.* Page 106 of 172.
[122] *Ibid.* Page 110 of 172.
[123] *Ibid.* Page 110 of 172.
[124] Lisa Williams. July 5, 2019. "What Is Carnauba Wax And Is It Okay For Vegans To Use?" https://happyhappyvegan.com/carnauba-wax/.
[125] *Ibid.* Page 109 of 172.
[126] TR line 28.

NOC strongly recommends that this petition be denied.

Fish Oil Annotation, re-issued Discussion Document

Within the published materials, the HS notes, "Several comments raised objections to the listing of fish oil on the National List. Those comments, however, are relevant to the sunset reviews and are not relevant to this proposed annotation."[127] To avoid the risk of our comments being rejected out of hand as "relevant to sunset reviews" and "not relevant to this proposed annotation," we will focus this comment on the proposed options and questions presented in the current published materials. However, because we believe that our full comments from Spring 2019 when the original discussion document was published **are** relevant to this proposed annotation to allow for a full review and understanding of the issue, our comments from Spring 2020 are included as Appendix F.

As described by the HS, the work agenda item approved by the NOP is "to propose an annotation to fish oil to address environmental concerns."[128] NOC supports this work agenda item.

The use of fish oil in organic production and products must protect the marine ecosystem.

In crafting the three options for consideration presented in the published materials, the HS noted that the first element considered was "that fish oil should be sourced from fishing industry by-product only."[129] The Fall 2020 NOSB recommendation on wild, native fish for liquid fish products included the following definition:[130]

> *Bycatch.* Incidental or discarded catch that have low economic value, fish that must be discarded because of management regulations, or fish that are unintentionally killed by fishing gear (mortality).

In our Fall 2020 NOSB comments on this definition, we expressed our preference to have "bycatch" removed from the annotation. The definition of bycatch originally read "Incidental or discarded catch that have no economic value." At our suggestion, the word "no" was changed to the word "low."

Many fish that we now consider to be high value were bycatch at one time. In 1997, the Organization for Economic Co-operation and Development defined bycatch as "total fishing mortality, excluding that accounted directly by the retained catch of target species." They further noted that "bycatch contributes to fishery decline and is a mechanism to overfish unintentional catch" as people can hide behind the word "bycatch" to go in and decimate a population because it is not considered economically viable.

The TR for fish-based fertilizers clearly states concerns for environmental impact: "Regardless of the intended use, harvesting wild, native fish can contribute to biodiversity loss, habitat destruction, and loss of ecosystem services."[131] Further, the TR states that when it comes to harvesting wild, native fish:

> "[T]heir population dynamics are not understood in many cases. It is also difficult to ascertain the effect of removing biomass, even from a sustainable fishery, considering that these species may be a food source for other species. Meal and oil fish can be critical to the function of entire ecosystems; for example, Pacific thread herring (Opisthonema libertate) and Pacific anchoveta (Cetengraulis mysticetus)

[127] NOSB April 2021 proposals and discussion documents Page 112 of 172.
[128] *Ibid.* Page 109 of 172.
[129] *Ibid.* Page 112 of 172.
[130] Formal Recommendation from the NOSB to the NOP. October 30, 2020. Wild, Native Fish for Fertilizer Production. Page 2 of 2. https://www.ams.usda.gov/sites/default/files/media/CSWildNativeFishLiquidFishProductsRec_webpost.pdf
[131] 2019 TR, Lines 327-328

are critical links in the Gulf of California, transferring energy through the food web and controlling the organization of these ecosystems."[132]

We believe this paragraph is important and speaks directly to the purpose of this work agenda item. Given that the importance of removing fish biomass is not well understood, either from the perspective of an energetic balance or from the perspective of food web dynamics, the organic industry should take a precautionary approach to protect marine ecosystems.

This is further supported by a 2014 fish stocks assessment report by FAO, which concluded that targeting pelagic species removes "one ecosystem component without considering cascading effects on the dependent species."[133] It further warns that, "[c]oncerns about the impacts of harvest strategies that fail to consider trophic relationships in a given ecosystem have been recognized for decades, and abundant scientific literature exists underpinning its possible negative impacts on the structure and functioning of aquatic ecosystems."[134] Sardines, anchovies, and herring play a key ecological role in the survival of larger predatory fish, mammals, and seabirds. They serve as an important link in the transfer of food energy from plankton to larger species in the marine food web, some of which may be endangered.[135] Further exploitation is not an option, particularly for organic, because the unsustainable practice of allowing a non-essential fish-based ingredient in organic food to endanger the food supply of marine life is wholly incompatible with organic systems of production.

Restricting the species and location of the harvest is not sufficient; the method is also important.
A satisfactory annotation must address not only the sustainability of harvest from the fisheries, but also the health of the marine ecosystems. Restricting the species and location of the harvest is not sufficient. The method is also important. For example, trawling activity has been reported on 75% of the global continental shelf area[136] and is one of the "most significant forms of physical disturbance on the seabed."[137] "[T]he proportion of seabed area exposed to bottom trawling ranges from <1% to >80% in different regions of the world. Trawling may modify sediment texture (grain size), the presence and nature of bedforms and chemical exchange processes. Trawling can also have direct and indirect impacts on populations and communities of benthic invertebrates."[138]

Further, there should be good practices in place that do not destroy those predatory species that are so important to the ecosystem chain. "Bycatch refers to 'discarded catch of marine species and unobserved mortality due to a direct encounter with fishing vessels and gear.' These unintentionally caught animals often suffer injuries or die."[139] "Bycatch can be fish, but also includes other animals such as dolphins, whales, sea

[132] 2019 TR, Lines 342-349
[133] FAO Fisheries and Aquaculture Department (2014), *supra* note 10, at 136.
[134] *Ibid.*
[135] *Ibid,* at 137.
[136] Luypaert T., Hagan J.G., McCarthy M.L., Poti M. (2020) Status of Marine Biodiversity in the Anthropocene. In: Jungblut S., Liebich V., Bode-Dalby M. (eds) YOUMARES 9 - The Oceans: Our Research, Our Future. Springer, Cham.
[137] Colloca, F., Scarcella, G. and Libralato, S., 2017. Recent trends and impacts of fisheries exploitation on Mediterranean stocks and ecosystems. *Frontiers in Marine Science*, *4*, p.244.
[138] Colloca, F., Scarcella, G. and Libralato, S., 2017. Recent trends and impacts of fisheries exploitation on Mediterranean stocks and ecosystems. *Frontiers in Marine Science*, *4*, p.244.
[139] NOAA Fisheries. *What is bycatch?* https://www.fisheries.noaa.gov/node/251

turtles, and seabirds that become hooked or entangled in fishing gear."[140] There are methods that minimize bycatch that are not always used.[141]

The options presented for consideration by the Handing Subcommittee:

> **Option 1 Current Proposal**
> 205.606 (e) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8) - stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606. ***Sourced from fishing industry by-product only and certified as sustainable by a third-party certifier.***

This option is unsatisfactory because it is too vague to offer value.

> **Option 2 Current Proposal**
> 205.606 (e) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8) - stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606. ***Sourced from fishing industry by-product only and certified as sustainable against a third-party certification that is International Social and Environmental Accreditation and Labeling (ISEAL) Code Compliant or Global Seafood Sustainability Initiative (GSSI) recognized with full utilization of said scheme.***

We have not been able to discern how protective the certifications allowed under this option are. We are not clear about how a certifier would apply the second option, which leads us to respond in the negative to question #2 posed by the HS, "Are these requirements clear and enforceable?"

> **Option 3 Current Proposal**
> 205.606 (e) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8) - stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606. ***Sourced from fishing industry by-product only and has either a green or yellow Seafood Watch rating or is eco-certified to a standard recommended by Seafood Watch (https://www.seafoodwatch.org/).***

This option is unsatisfactory because the yellow rating includes the warning, "be aware there are concerns with how they're caught, farmed or managed."[142]

Finally, the HS notes:

> This suggested reliance on third part certification for National List annotation raises several concerns, including:
>
> 1. Organic environmental sustainability standards would be sourced outside USDA and other U.S.government agencies;
>
> 2. There is potential for "greenwashing" if an unscrupulous third-party certifier did not meetenvironmental sustainability standards;

[140] *Ibid.*
[141] https://www.worldwildlife.org/threats/bycatch
[142] https://www.seafoodwatch.org/recommendations.

3. Requiring third - party certification could exclude smaller-scale producers that cannot affordthird party certification even though their fishery meets sustainability standards.[143]

Yes, yes, and yes – we wholeheartedly agree with these concerns.

Conclusion

The use of fish oil in organic production and products must protect the marine ecosystem. Given that the importance of removing fish biomass is not well understood, either from the perspective of an energetic balance or from the perspective of food web dynamics, the organic industry should take a precautionary approach to protect marine ecosystems.

Restricting the species and location of the harvest is not sufficient; the method is also important. A satisfactory annotation must address not only the sustainability of harvest from the fisheries, but also the health of the marine ecosystems. There should be good practices in place that do not destroy those predatory species that are so important to the ecosystem chain.

The proposed annotations are inadequate either because they fail to protect the marine ecosystem and/or because they are not clear and enforceable.

Other

Celery Powder

USDA has granted part of the request for changes to nitrates/nitrites labeling on meat products by Center for Science in the Public Interest (CSPI), and will no longer allow meat cured with celery powder to claim to be "nitrate-free" or “uncured.”

> “FSIS intends to conduct rulemaking to propose to prohibit the statements, ‘No Nitrate or Nitrite Added’ and ‘Uncured,’ on products that have been processed using any source of nitrates or nitrites.”[144]

USDA found that the current label noting that meats cured using celery powder are “nitrate free” is misleading to organic consumers. The proposed rule has a tentative publication date of May 2021.

Sunset

Agar-agar 205.605(a)

As agar is made from seaweed, this must be considered under the broader scope of marine materials.

NOC greatly appreciates the work of several Board members over the past few years in building toward the NOSB’s Fall 2020 recommendation on Marine Macroalgae. We strongly encourage the NOP to move forward on this recommendation.

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[143] NOSB April 2021 proposals and discussion documents Page 113 of 172.

[144] Elaine Watson. December 12, 2020. *USDA partially grants CSPI request for changes to nitrates/nitrites labeling on meat products. https://www.foodnavigator-usa.com/Article/2020/12/12/USDA-partially-grants-CSPI-request-for-changes-to-nitrates-nitrites-labeling-on-meat-products?utm_source=newsletter_daily&utm_medium=email&utm_campaign=14-Dec-2020*

The Fall 2020 NOSB recommendation is designed to protect marine ecosystems from damage from harvesting marine macroalgae. The NOSB recommended an annotation to listings of synthetic macroalgae products used in crop production:

> Prohibited harvest areas: established conservation areas under federal, state, or local ownership, public or private, including parks, preserves, sanctuaries, refuges, or areas identified as important or high value habitats at the state or federal level. Prohibited harvest methods: bottom trawling and harvest practices that prevent reproduction and diminish the regeneration of natural populations. Harvest practices should ensure that sufficient propagules, holdfasts, and reproductive structures are available to maintain the abundance and size structure of the population and its ecosystem functions. Harvest timing: repeat harvest is prohibited until biomass and architecture (density and height) of the targeted species approaches the biomass and architecture of undisturbed natural stands of the targeted species in that area. Bycatch: must be monitored and prevented, or eliminated in the case of special status species protected by U.S. Fish and Wildlife Service or National Marine Fisheries Service.[145]

In addition, "A new listing at 205.602 is further recommended to prohibit marine macroalgae unless harvested to the same parameters, with an exemption for non-commercial harvests."[146] These protections should also be applied to macroalgae used for organic food inputs.

The ecological impacts of the use of seaweed must be considered as part of the larger Marine Materials/Marine Macroalgae topic. The increased harvesting of seaweed leads to questions regarding sustainability and overharvesting. The organic regulations require that organic production utilize "practices that foster cycling of resources, promote ecological balance, and conserve biodiversity."[147] Consumers who choose organic foods expect this to be true from farm to fork, including the inputs used by organic farmers.

Conclusion
Ensuring that marine plants and algae used in organic production 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.

The Fall 2020 NOSB recommendation on Marine Macroalgae is a strong start, and should continue to move forward.

Animal enzymes 205.605(a)

Since animal enzymes are produced from nonorganic livestock, who have been feed nonorganic feeds, and could have been given GMO feeds, non-approved animal by-products, etc., our goal should be to obtain these enzymes from organic animals. While animal enzymes are mostly known as coagulants in making cheese, they are also used in other food products, such as a processing aids, and as digestive supplements. We encourage the

[145] NOSB. October 30, 2020. Formal Recommendation Marine Macroalgae in Crop Fertility Inputs. Page 1 of 3. https://www.ams.usda.gov/sites/default/files/media/MSMarineMaterialsRec_webpost.pdf
[146] *Ibid.* Page 1 of 3.
[147] 7 C.F.R. §205.2.

NOSB to continue the search for organic animal enzymes, and if not available, to discover the barriers and how to overcome them.

One way to begin addressing obtaining animal enzymes from an organic source would be working with a pilot plant on a smaller scale that would help understand what kind of issues one might run into when sourcing this material as organic. Sourcing animal enzymes from organic animals would be an opportunity to use as much of the animal as possible in organic production and gain an organic price on the marketplace. We did find a source for organic all natural dry calf rennet powder and feel that if someone has done it, more production should be encouraged. As noted in the published materials, "The 2000 TAP for animal derived enzymes indicated that animal derived enzymes could be produced from organic livestock."[148]

Conclusion
Our goal should be to obtain these enzymes from organic animals. We encourage the NOSB to continue the search for organic animal enzymes, and if not available, to discover the barriers and how to overcome them.

Carrageenan 205.605(a)

NOC opposes relisting carrageenan on the National List. Our position on carrageenan has not changed since we commented for the 2012 sunset review. We continue to urge the NOSB to remove carrageenan from the National List.

We strongly support the Fall 2016 NOSB recommendation to remove carrageenan from the NL. As noted in the Board's recommendation memo to the NOP, "Because there was intense scrutiny about carrageenan, each OFPA criteria was reviewed carefully and all public comment was acknowledged."[149] Our comments will focus on the review of the OFPA criteria at 7 CFR 6518(m), as the Board's did during their last review.

The production of carrageenan results in adverse ecological impacts.

> 7 CFR 6518(m)(3) The probability of environmental contamination during manufacture, use, misuse, or disposal of such substance; there may be negative impacts on the environment from harvesting wild seaweed. Indications are that most of this species of seaweed is now farmed, and some farming methods are more sustainable and ecologically sound than others. It appears that it might be possible for the seaweed to be farmed organically, and this might improve the environmental footprint. Additionally, there are several ways to manufacture the carrageenan from seaweed. Some of these would result in a non-synthetic version, while at least one method might be considered a synthetic extraction.[150]

The ecological impacts of the use of seaweed must be considered as part of the larger Marine Materials/Marine Macroalgae topic. The increased harvesting of seaweed leads to questions regarding sustainability and overharvesting. The organic regulations require that organic production utilize "practices that foster cycling of

[148] NOSB April 2021 proposals and discussion documents Page 73 of 172.
[149] Sunset 2018 Review Summary. NOSB Final Review. Handling Substances §205.605(a), §205.605(b), §205.606. November 2016. Page 4 of 9.
[150] *Ibid.* Page 4 of 9.

resources, promote ecological balance, and conserve biodiversity."[151] 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 production 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.

Carrageenan may have adverse effects on the health of consumers.

> (4) The effect of the substance on human health; The research indicating that there may be negative health effects on all humans in terms of inflammation, glucose intolerance, or tumors does not seem to be replicated in the large body of scientific literature. There are many anecdotal reports of sensitivity to carrageenan in foods from individuals in public comments. These concerns have not been studied in the literature, however they are acknowledged. This was not seen as a primary reason to remove carrageenan since it is listed on the labels as a food ingredient.[152]

Degraded carrageenan is a List 2B carcinogen according to the World Health Organization's International Agency for Research on Cancer (IARC).[153] Research, including industry-sponsored research, suggests that consuming foods with food-grade carrageenan exposes consumers to degraded carrageenan.[154] After a discussion of the impacts of "degraded carrageenan," the 2011 TR continues,

> Today, both concern and debate exists over human health hazards from not only direct use of degraded carrageenan in foods, but also based on the idea that acid hydrolysis in the stomach following consumption of non-degraded carrageenan could result in formation of degraded carrageenan, which could then potentially promote colon cancer (Tobacman, 2001; Carthew, 2002).[155]

The more recent (2015) technical review specifically examined potential health impacts of carrageenan. On the question of whether less hazardous high molecular weight carrageenan can be degraded in the digestive system to more hazardous lower molecular weight forms: "The research is not fully conclusive but seems to suggest that degradation is possible."[156] More research is needed to determine the extent to which degraded

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[151] 7 C.F.R. §205.2.

[152] Sunset 2018 Review Summary. NOSB Final Review. Handling Substances §205.605(a), §205.605(b), §205.606. November 2016. Page 4 of 9.

[153] International Agency for Research on Cancer (IARC), Agents Classified by the IARC Monographs, Volumes 1-110. http://monographs.iarc.fr/ENG/Classification/ClassificationsGroupOrder.pdf

[154] Marinalg International, "Status Report on the work of Marinalg International to measure the molecular weight distribution of carrageenan and PES in order to meet the EU specification: less than 5% below 50,000 daltons."

Capron I, Yvon M and Muller G (1996) In-vitro gastric stability of carrageenan. Food Hydrocolloids 10(2): 239-244
Ekström, L.G. (1985) Molecular-weight-distribution and the behaviour of kappa-carrageenan on hydrolysis. Part II. Carbohydrate Research 135: 283-289
Ekström L.G. and Kuivinen J (1983) Molecular weight distribution and hydrolysis behaviour of carrageenans. Carbohydrate Research 116: 89-94

[155] Lines 571-582.

[156] Lines 40-41.

carrageenan occurs in the food supply, and the extent to which food-grade carrageenan degrades in the acidic environment of the digestive system.

NOC urges the NOSB to use the Precautionary Principle in its review of carrageenan. When scientific evidence points to potential harm, and no consensus has been reached between independent scientists and industry-funded scientists, we should act with caution and in the interest of public health. Carrageenan has not been proven to be safe, given the scientific data pointing to harm, and the burden of proof should not fall on the people who buy foods with carrageenan.

Is the substance essential for organic production?

> (6) The alternatives to using the substance in terms of practices or other available materials; an extensive list was prepared of all the food product categories in which carrageenan is used. In most of the product types there are versions that are currently being sold that do not contain carrageenan. These often contain other types of gums such as gellan, guar, or xanthan. Products for vegetarians where carrageenan is used in place of gelatin will be the most difficult to produce without it, but the majority of NOSB members were not concerned about this class of products being impacted.[157]

Carrageenan has no nutritional value; rather, food processors add carrageenan as a stabilizer and to change the texture, structure, and physical appearance of foods, such as dairy foods, plant-based beverages, and lunchmeats. As noted during the NOSB discussion at the November 2016 meeting, carrageenan fails the essentiality criterion.

Carrageenan is not essential for the production of organic food. Alternatives to carrageenan include other gums on the National List, a "Shake Well" label on the product package, or in some cases, like whipping cream, the alternative to carrageenan is nothing at all.

In 2012, it was already apparent that carrageenan is not an essential ingredient. For every organic product that contains carrageenan, another organic product by a different processor can be found on store shelves without it (the exception may be ready-to-eat infant formula). As public awareness of the potential human health effects of carrageenan has grown over the years, consumer demand has led many companies to remove carrageenan from their products. Even products that companies claimed in 2012 could not be made without it, like aseptic chocolate milk, are now made without carrageenan even by the largest processors.

Unfortunately, some processors still make organic foods with carrageenan despite the wide availability of carrageenan-free alternatives. This places consumers in a bind, for example, when organic whipping cream with carrageenan appears in the store next to a conventional whipping cream product with cream as its only ingredient. We urge the NOSB to consider the impacts on consumer trust and organic farmers when non-essential ingredients like carrageenan appear in organic foods.

Carrageenan is incompatible with a system of sustainable agriculture.

> (7) Its compatibility with a system of sustainable agriculture; A majority of NOSB members believed that this ingredient is not compatible with sustainable agriculture because it is so controversial and they

[157] Sunset 2018 Review Summary. NOSB Final Review. Handling Substances §205.605(a), §205.605(b), §205.606. November 2016. Page 4 of 9.

wanted to invoke the Precautionary Principle. Also invoked were the NOSB Guidance on Compatibility from the Appendix of the NOSB Policy and Procedures Manual that poses this factor (out of 12) for consideration, "Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products"?[158]

We point you to our above comments. We agree that this ingredient is not compatible with sustainable agriculture and encourage you to invoke the Precautionary Principle. Carrageenan does not satisfy expectations of the organic consumer regarding the authenticity and integrity of organic products.

Further, Carrageenan is an unnecessary synthetic material. Volatile synthetic solvents are used in at least some of its manufacturing processes.[159] Depending on the production method, it may contain residues of other synthetic materials including polysorbate 80 and epichlorohydrin.[160] In some cases, it is used as a preservative.[161]

NOSB recommendation from November 2016 to remove carrageenan from the National List.
On January 17, 2018, the NOP published a proposed rule to amend the NL that would implement 29 NOSB recommendations beginning as far back as 2000. This proposal left out a critical recommendation: to remove carrageenan from §205.605(a) of the National List. The NOSB recommended removal of carrageenan from the National List at its November 2016 meeting.

While the NOP is not legally required to take a nonsynthetic material off the NL based on an NOSB recommendation, the NOP is required to base the National List on NOSB recommendations. We are alarmed and disappointed when we have consensus within the NOSB and the NOP does not follow through with that recommendation. We expect a greater level of transparency and justification when the NOP does not follow an NOSB recommendation to remove a NL item.

Conclusion
Carrageenan is incompatible with a system of sustainable agriculture.

The production of carrageenan results in adverse ecological impacts. NOC greatly appreciates the work of several Board members over the past few years in building toward the NOSB's Fall 2020 recommendation on Marine Macroalgae. We strongly encourage the NOP to move forward on this recommendation. With the 2020 recommendation as the foundation, we encourage the Board to continue work in this vein.

Carrageenan is not necessary–organic processors have been moving away from the use of carrageen due to consumer pressure since it was last considered for sunset.

NOC supports the NOSB recommendation from November 2016 to remove carrageenan from the National List. NOC opposes relisting carrageenan on the National List. Our position on carrageenan has not changed since we commented for the 2012 sunset review. We continue to urge the NOSB to remove carrageenan from the National List.

[158] *Ibid.* Pages 4 & 5 of 9.
[159] 2011 TR lines 287-294.
[160] TAP review pages 3, 4, 7.
[161] 2011 TR line 415.

Glucono delta-lactone 205.605(a) – Production by the oxidation of D-glucose with bromine water is prohibited. The current annotation –"production by the oxidation of D-glucose with bromine water is prohibited"—was added to ensure that glucono delta-lactone would be produced by microbial or enzymatic processes and hence be nonsynthetic. However, the 2016 technical review (TR) states, "There are many chemical methods of gluconic acid synthesis other than bromine water." Hence, the current annotation is not sufficient to ensure that the glucono delta-lactone (GDL) in use in organic processing is nonsynthetic.[162] It also states that some enzymes used in the production of GDL may be genetically engineered.

Conclusion
The NOSB should not relist GDL without an annotation change to correct these classification issues.

Tartaric acid 205.605(a) – Made from grape wine.
As listed on the National List, tartaric acid must be made from grape wine. The evaluation of tartaric acid must thus take into consideration the use of pesticides in the non-organic production of grapes and the availability of organic grape wine for this purpose, as well as the potential availability of the tartaric acid from organic grape wine if the demand existed.

In preparing our comments, NOC reached out to Phil LaRocca of LaRocca Vineyards, a certified organic operation in business since 1984. During our discussion, we asked Phil if there was any reason that tartaric acid could not be made from organic wine, to which he immediately replied, "Absolutely not." While we realize that given the number of wineries using tartaric acid, it would take time for manufacturers to develop an organic version at the necessary scale, we are also aware that this market will never emerge as long as tartaric acid is listed at §205.605(a) on the NL. (Organic hops anyone?)

Conclusion
The HS should investigate whether tartaric acid from organic grape wine is available or could be available. Since tartaric acid is a waste product from winemaking, its sale could provide additional revenue to organic vintners. The current listing discourages the development of organic tartaric acid as there is no incentive to do so as long as non-organic tartaric acid can be used in organic wines.

Chlorine materials 205.605(b) – Disinfecting and sanitizing food contact surfaces, *Except,* That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act. (i) Calcium hypochlorite. (ii) Chlorine dioxide. (iii) Hypochlorous acid—generated from electrolyzed water. (iv) Sodium hypochlorite

COMPREHENSIVE REVIEW OF SANITIZERS, DISINFECTANTS, AND STERILANTS
As NOC has repeatedly contended, the NOSB would benefit from a comprehensive review of sanitizers, disinfectants, and sterilants to inform decision-making when a new material is petitioned or a material is reviewed at sunset. As noted in previous comments on this topic, we recommend the TR for sodium dodecylbenzene sulfonate (SDBS) as a starting place because this TR asks and answers many of the questions that would be appropriate to address in a comprehensive review of sanitizers, disinfectants, and sterilants.

[162] Lines 281-287.

The NOSB could refer to the sanitation materials review to judge whether other materials currently on the National List meet the same need, or whether there is a special characteristic of the material under review that justifies its placement or renewal to the NL. This comprehensive review may help identify areas where there are gaps in necessary sanitizers or disinfectants which aid crops, livestock, and/or handling operations in promotion of organic food safety.

Request for a comprehensive review of sanitizers. OFPA requires that materials on the National List be itemized "by specific use or application." This requires the NOSB identify the uses for which these materials are needed. A Technical Review (TR) that establishes and distinguishes needs, uses, and relative toxicities for sanitizers, disinfectants, and sterilants must be performed. In particular, the TR must address the following:

- The uses for which these materials are needed;
- Whether an antimicrobial is the appropriate way to address the identified need;
- Whether any uses of specific materials in this class are required by law;
- Whether there are uses for which no material is listed on the National List;
- Whether organizations researching least toxic materials (e.g., EPA's Safer Choice/Design for the Environment program[163] and the Toxics Use Reduction Institute at the University of Massachusetts, Lowell[164]) have identified least toxic practices and materials that should be considered for use in organic production;
- Which alternative practices and materials might be proposed for each use that is identified; and
- The hazards to humans and the environment of the various options identified.

Conclusion
While this topic as a whole is daunting, we would suggest that the NOSB begin to address this one step at a time by requesting a TR to address the questions put forth in the published materials and every time a sanitizer, disinfectant, or sterilant comes up for petition or sunset review moving forward.

Potassium hydroxide 205.605(b) – Prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.

OFPA states, "The [National List] shall contain an itemization, by specific use or application, of each synthetic substance permitted under subsection (c)(1) or each natural substance prohibited under subsection (c)(2)." The annotation of potassium hydroxide (as well as that of sodium hydroxide) presents problems for review in that it specifies uses that *are not* allowed rather than those that *are* allowed. Identification of the uses is not only required by law, it is also essential for the NOSB review of the substance. However, framing an annotation in the negative creates an open-ended set of allowable uses instead of a closed list of the permitted uses or applications. Therefore, we urge the NOSB to examine the uses of potassium hydroxide in organic processing and propose a revised annotation that reflects those uses.

[163] DfE for antimicrobials at https://www.epa.gov/pesticide-labels/design-environment-antimicrobial-pesticide-pilot-project-moving-toward-green-end. Safer Choice at https://www.epa.gov/saferchoice/safer-ingredients.
[164] https://www.turi.org/Our_Work/Cleaning_Laboratory.

Are there adverse impacts on humans or the environment?
Severe adverse impacts of potassium hydroxide (lye) have been identified by both the 2001 technical advisory panel (TAP) review and the 2016 technical review (TR). The health hazards are derived from lye's high corrosivity, which can result in severe burns to eyes, skin, and mucous membranes.[165] The TAP review points out environmental concerns due to the disposal of large volumes of water with soluble potassium and alkali ions.[166] Mercury cells are used to produce most of the KOH in the United States.[167,168]

Is potassium hydroxide essential for organic processing?
The 2016 Technical Review (TR) identifies a number of food processing uses of potassium hydroxide:[169]

> Uses of potassium hydroxide that are Generally Recognized As Safe (GRAS) by the U.S. Food and Drug Administration (FDA) include use as a formulation aid, pH control agent, processing aid, stabilizer and thickener [21 CFR 184.1631(b)].

Potassium hydroxide's main food processing uses include use as a pH adjuster, cleaning agent, stabilizer, thickener, fruit and vegetable peeling agent, and poultry scald agent. It is used in dairy products, baked goods, cocoa, fruits, vegetables, soft drinks and poultry. The main foods processed with potassium hydroxide are chicken, cocoa, coloring agents, ice cream and black olives.

Soft soap is manufactured with potassium hydroxide.

Is potassium hydroxide used for all these purposes in organic processing? Is it necessary?
The TR and TAP review mostly addressed the use for peeling fruits and vegetables for canning or freezing. Although the annotation restricts this use to peaches, the handling subcommittee notes say, "A member added that it is used extensively and is also used for nectarines."[170] The essentiality of lye for canning or freezing peaches is still unclear. Most home canning and freezing uses hot water treatment,[171] and although heat in a certain range is avoided in commercial preparation using potassium hydroxide, steam treatment is a possibility for peeling peaches commercially.[172] TAP Reviewer #3 said, "Suitable equipment exists to remove the peels and pits by mechanical means."[173]

Is potassium hydroxide compatible with organic processing?
It is impossible to judge the compatibility of potassium hydroxide without knowing its uses. The 2001 TAP review was equivocal regarding the peeling of peaches, citing the incompatibility of using a synthetic substance to perform a mechanical function such as peeling as opposed the greater availability of an organic product.[174]

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[165] Lines 118-122.
[166] Lines 165-166.
[167] Lines 185-186.
[168] Lines 369-374.
[169] Lines 52-61.
[170] HS notes for January 19, 2016.
[171] https://extension.purdue.edu/extmedia/HHS/HHS-808-W.pdf
[172] https://archive.org/stream/commercialfreezi0703josl/commercialfreezi0703josl_djvu.txt
[173] Lines 557-558.
[174] Lines 239-243.

Conclusion
Potassium hydroxide is a hazardous material, possibly (with sodium hydroxide) one of the most hazardous and toxic on the National List.[175] The 2016 TR does not seem to have resolved the issue of the essentiality for potassium hydroxide in processing peaches, but the essentiality of other allowed uses also needs to be examined. We suggest that the HS address the following questions:

- For what purposes is potassium hydroxide used in organic processing?
- What are the alternatives for those uses?
- Is further annotation necessary?

Silicon dioxide 205.605(b) – Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.

In 2011, the NOSB voted to annotate the listing to recognize and encourage the use of organic rice hulls as an alternative for most uses of silicon dioxide. The NOSB recommended the following annotation: "Allowed for use as a defoamer. May be used in other applications when non-synthetic alternatives are not commercially available.'' The NOP proposed and put into regulation instead this annotation: "Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available." NOP justified this change as follows, "AMS understands that the intent of the NOSB's recommendation is to allow the continued use of silicon dioxide as a defoamer and to require the use of a nonsynthetic substance instead of silicon dioxide when possible. To ensure clarity and consistency within the USDA organic regulations, AMS is proposing a modification to the NOSB's recommendation." The annotation in the final rule is less restrictive than the NOSB recommendation, and therefore allows the use of the synthetic silicon dioxide in cases where there is a nonsynthetic alternative other than organic rice hulls," which is contrary to OFPA §6517(d)(2).[176] According to the 2010 Technical Review (TR), other plant materials may be the basis for biogenic silica products.[177]

Conclusion
The NOSB should revisit the annotation to determine whether it should be changed to the language as originally passed by the NOSB or to a slightly less restrictive version (but still more restrictive than the version adopted into the regulations), "Permitted as a defoamer. Allowed for other uses when an organic substitute is not commercially available."

Potassium lactate 205.605(b) – For use as an antimicrobial agent and pH regulator only.
Sodium lactate 205.605(b) – For use as an antimicrobial agent and pH regulator only.

NOC does not support the relisting of sodium and potassium lactate to the National List. Sodium and potassium lactate are synthetic preservatives and are not appropriate for use in organic food.

Sodium lactate and potassium lactate are synthetic.
As described in the Lactic Acid and Lactates Technical Review (TR), sodium lactate and potassium lactate are

[175] TAP lines 376-378.
[176] "The Secretary may not include exemptions for the use of specific synthetic substances in the National List other than those exemptions contained in the Proposed National List or Proposed Amendments to the National List."
[177] Lines 438-448.

manufactured by a reaction of lactic acid with a synthetic chemical, generally sodium or potassium hydroxide.[178] Thus, they would be classified as synthetic according to the NOP draft classification guidance.

As stated in the Technical Review, The USDA Food Standards and Labeling Policy Book says:

> It should be noted that meat products that contain sodium and potassium lactates can no longer be labeled as "natural" without a case-by-case assessment of what function these materials are serving in the product, and at what levels (USDA FSIS 2005). The reason is that the lactates are likely to be used as "chemical preservatives," rather than as flavors.

We agree with comments submitted by our member organization PCC Natural Markets:

> Since sodium lactate is not acknowledged by the FSIS for use in meat products labeled "natural" (except potentially on a case-by-case basis at the time of label approval), it seems logical that sodium lactate should not be allowed for use in certified organic products. Consumers expect organic standards to be more rigorous than standards for "natural." It seems incongruous that organic would allow something that "natural" would not allow automatically.[179]

The use of sodium lactate and potassium lactate for the listed use is prohibited by organic regulations at §205.600(b)(4).

Both chemicals are used as preservatives, to prevent the growth of microorganisms. In addition, they are also considered flavor and color enhancers. They may also be combined with sodium diacetate.[180] Since sodium diacetate is not on the National List and is added for its functional effect of reducing pH, certainly any lactate product containing it should not be allowed.

§205.600(b)(4) of the regulations states:

> (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:
> (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;

Conclusion

Since the purpose for which the lactates were petitioned is as a preservative, and other uses include flavor and color enhancement, sodium lactate and potassium lactate have no place on the National List.

Potassium lactate and sodium lactate are synthetic chemicals used for purposes not allowed in organic processing. Therefore, they should not be relisted on the National List.

[178] Lines 519-548.
[179] Letter from Trudy Bialic, December 7, 2009.
[180] Lines 266-326.

Livestock Subcommittee

Sunset

Foreword

In writing these comments, we reached out to livestock experts working in the field. Our comments reflect those of our membership, with input from those who work on organic dairies and with livestock daily. We heard repeatedly that prevention is our best weapon, and that modifying diets is a best practice in treating many of the issues livestock producers face. While many livestock producers rarely use any of the materials we are discussing because they excel at preventative medicine, it is vital to the welfare of animals that the tools are available when needed. Maintaining clearly listed materials is important to producers and is essential for consistency among certifiers when applying the standards.

Activated charcoal (CAS # 7440-44-0) 205.603(a)(6) – Must be from vegetative sources.

NOC supports the relisting of activated charcoal as essential to organic livestock health care and production. Activated charcoal is the preferred therapeutic treatment as needed for suspected poisoning by plants and moldy silage. Activated charcoal removes toxic chemicals by adsorption and is then excreted.

Calcium borogluconate (CAS # 5743-34-0) 205.603(a)(7) – For treatment of milk fever only.

NOC supports relisting as one of three types of available calcium that can be found in supplements for treatment of milk fever. Because organic dairies often have older cows in their herd than their conventional counterparts, having materials that treat milk fever, to which these older cows are more susceptible, is important and can be lifesaving.

It is the healthcare treatment that likely provides the most miraculous, short term recovery to any bovine malady. If a cow is down with milk fever (down meaning flat on their side, unable to rise, urinate, defecate, or digest, etc.), their muscles are no longer working because of lack of calcium. If left untreated, the cow will die. But given a bottle or two of calcium borogluconate intravenously, within an hour or two, the cow will recover and arise (unless she has also suffered some physical injury) and be ready to fully go back to life.

Listing this outside of the broad category of electrolytes leaves it less open for interpretation by certifiers.
Prior to listing calcium borogluconate on the NL for treatment of milk fever, some certifiers would not allow it for use as an electrolyte. For example, OMRI prohibited its use as an electrolyte, and many certifying agents followed their lead. This may have been due to not considering the use of it to treat milk fever to be an electrolyte use. Or, and more likely, this was because calcium borogluconate is *injected* for treatment of milk fever and it was not specified on the NL that electrolytes could be injected. Both of these theories were addressed in the 2015 technical report for electrolytes, which identified calcium borogluconate as an electrolyte. This showed that it is clearly allowed under the listing for electrolytes at 205.603(a)(11). This technical report does also mention the use of calcium borogluconate to treat milk fever, so it seems to indicate that injecting calcium borogluconate to treat milk fever is an allowed use for the substance, again under the listing for electrolytes at 205.603(a)(11).

At the same time that calcium borogluconate was added to the NL, injectable nutritive supplements, including vitamins, minerals, and electrolytes, were also specifically added to the National List at 205.603(a)(21). This does

appear to make the separate listing for calcium borogluconate redundant, as certifiers can allow it as an injectable electrolyte under the listings at 205.603(a)(11) and (21).

With that being said, if calcium borogluconate was not listed separately on the NL, there may still be some certifiers out there that are inexperienced in material review and may prohibit calcium borogluconate used to treat milk fever erroneously if the product is not identified or labeled as an electrolyte. While the majority of certifiers, if not all, would allow calcium borogluconate as an injectable electrolyte under the listings at 205.603(a)(11) and (21) even if calcium borogluconate was not specifically separately listed on the NL, having the separate listing assures this is the case.

A Note on Off-Label Uses of Livestock Drugs
The standards of the Food and Drug Administration are different from organic standards. However, OFPA §6519(c)(6) does require compliance with Federal Food, Drug, and Cosmetic Act (FFDCA). The requirements of OFPA and the organic regulations can only go beyond what is required by the FFDCA, so the NOSB must be able to get a clear sense of what FDA requires. The electrolytes technical report states,

> The FDA consider electrolyte formulations to be animal drugs, but many of the formulations have not been formally approved by the FDA. Often this is because they are non-proprietary, general use materials, and no company has applied for a New Animal Drug Approval (NADA) (OMRI 2013; USDA 2005b).
>
> Over 3,000 animal drugs currently being marketed have not been formally approved by the FDA. Many are benign, and have a long history of safe use. For instance, calcium borogluconate formulations have been in use since 1935. FDA enforcement and regulation of these unapproved drugs has a low priority. They are generally marketed without FDA interference (USDA 2005b) via FDA's use of regulatory discretion with illegally marketed drugs (US FDA 2011).

We come back to this periodically with animal drugs. For example, use of xylazine and tolazoline that is allowed by the organic regulations appears to be contrary to FDA regulations. How can NOP depend on FDA assessments of "illegally marketed drugs" sold "without FDA interference"? It puts organic producers, the NOSB, certifiers, and inspectors in a difficult position if we are relying on an agency that is not doing anything.

It is not clear what the NOSB can do about this situation besides recommending that NOP request a written clarification from FDA.

Conclusion
NOC supports the relisting of calcium borogluconate outside of the broad listing of electrolytes.

Calcium propionate (CAS # 4075-81-4) 205.603(a)(8) – For treatment of milk fever only.
NOC is generally supportive of relisting calcium proprionate on the NL for the treatment of milk fever for all of the same reasons given regarding calcium borogluconate. However, we—and the NOSB—are at a disadvantage in evaluating this material because a recent technical review is not available. The TAP review from 2002 raised the following issues and concerns:

- The level of concern is different for the routine use as a mold inhibitor than for the therapeutic use for milk fever.

- Most of the TAP review was concerned with the use as a mold inhibitor, and the therapeutic use was not examined as closely.
- It is not clear how calcium propionate compares with other materials in treating milk fever.
- The use as a mold inhibitor (i.e., a synthetic preservative) does not appear to be compatible with organic production.

Calcium propionate was used in organic cows for milk fever before 2018 by virtue of its inclusion as an electrolyte. There is a 2015 technical review of electrolytes, which has little to say about calcium propionate. While we have found reports of illness when calcium propionate is used as a preservative in food,[181] we cannot determine the relevance of these reports to the use for treatment of milk fever, and encourage the LS to seek a TR on calcium propionate.

Conclusion
NOC is generally supportive of relisting calcium proprionate on the NL for the treatment of milk fever; however, we encourage the LS to seek a more updated TR.

Chlorine materials 205.603(a)(10) – Disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act. – (i) Calcium hypochlorite. (ii) Chlorine dioxide. (iii) Hypochlorous acid—generated from electrolyzed water. (iv) Sodium hypochlorite

COMPREHENSIVE REVIEW OF SANITIZERS, DISINFECTANTS, AND STERILANTS
As NOC has repeatedly contended, the NOSB would benefit from a comprehensive review of sanitizers, disinfectants, and sterilants to inform decision-making when a new material is petitioned or a material is reviewed at sunset. As noted in previous comments on this topic, we recommend the TR for sodium dodecylbenzene sulfonate (SDBS) as a starting place because this TR asks and answers many of the questions that would be appropriate to address in a comprehensive review of sanitizers, disinfectants, and sterilants.

The NOSB could refer to the sanitation materials review to judge whether other materials currently on the National List meet the same need, or whether there is a special characteristic of the material under review that justifies its placement or renewal to the NL. This comprehensive review may help identify areas where there are gaps in necessary sanitizers or disinfectants which aid crops, livestock, and/or handling operations in promotion of organic food safety.

Request for a comprehensive review of sanitizers. OFPA requires that materials on the National List be itemized "by specific use or application." This requires the NOSB identify the uses for which these materials are needed. A Technical Review (TR) that establishes and distinguishes needs, uses, and relative toxicities for sanitizers, disinfectants, and sterilants must be performed. In particular, the TR must address the following:

- The uses for which these materials are needed;
- Whether an antimicrobial is the appropriate way to address the identified need;
- Whether any uses of specific materials in this class are required by law;

[181] For example, Dengate, S. and Ruben, A., 2002. Controlled trial of cumulative behavioural effects of a common bread preservative. *Journal of Paediatrics and Child Health*, *38*(4), pp.373-376.

- Whether there are uses for which no material is listed on the National List;
- Whether organizations researching least toxic materials (e.g., EPA's Safer Choice/Design for the Environment program[182] and the Toxics Use Reduction Institute at the University of Massachusetts, Lowell[183]) have identified least toxic practices and materials that should be considered for use in organic production;
- Which alternative practices and materials might be proposed for each use that is identified; and
- The hazards to humans and the environment of the various options identified.

Conclusion
While this topic as a whole is daunting, we would suggest that the NOSB begin to eat the elephant one bite at a time by requesting a TR to address the questions put forth in the published materials and every time a sanitizer, disinfectant, or sterilant comes up for petition or sunset review moving forward.

Kaolin pectin 205.603(a)(17) – For use as an adsorbent, antidiarrheal, and gut protectant.
Pectin can be synthetic or nonsynthetic and would not need to be on the National List if only the nonsynthetic was allowed. As a natural, it never needed to be petitioned.

In contrast to activated charcoal, it coats the stomach and gut lining to some extent and helps "dry up" excessive fluid in the gut (which is the definition of diarrhea). Activated charcoal is an adsorbent organic carbon that can draw toxins to itself and "whisk" them away out of the digestive tract and thus not be absorbed. Not all producers may be as familiar with charcoal in place of kaolin pectin. In addition, availability may play a role: in areas where conventional livestock prevail, access to products is always an issue. This is an important tool for raising organic calves, as calf raising is generally one of the toughest areas to deal with on a dairy.

Conclusion
NOC supports relisting of kaolin pectin.

Mineral oil 205.603(a)(20) – For treatment of intestinal compaction, prohibited for use as a dust suppressant.
NOC received feedback that producers and veterinarians may not know they are allowed to use this material for this use in organic production, while others thought that people were using it for intestinal compaction before it ever got put on the NL. NOC is supportive of relisting. According to Dr. Hue Karreman, "Mineral oil has the property of not being absorbed by the gut and thus can coat the gut so there is no absorption and possible reabsorption downstream of toxins. It can be used for frothy bloat. It is indispensable to me as a practitioner to quickly reverse digestive upsets."[184]

Nutritive Supplements 205.603(a)(21) – Injectable supplements of trace minerals per paragraph (d)(2) of this section, vitamins per paragraph (d)(3), and electrolytes per paragraph (a)(11), with excipients per paragraph (f), in accordance with FDA and restricted to use by or on the order of a licensed veterinarian.

[182] DfE for antimicrobials at https://www.epa.gov/pesticide-labels/design-environment-antimicrobial-pesticide-pilot-project-moving-toward-green-end. Safer Choice at https://www.epa.gov/saferchoice/safer-ingredients.
[183] https://www.turi.org/Our_Work/Cleaning_Laboratory.
[184] Private e-mail communication between Dr. Hubert Karreman and Christie Badger, NOC.

NOC supports relisting of nutritive supplements.

Modifying diets comes up as the best way to treat many of the issues organic livestock producers face. Prevention is the best weapon. However, the nature of organic dairy is to have cows out on grass as much as possible, and even the best managed pastures can be nutrient poor under some weather conditions. Jill Smith, Pure Erie Dairy shared, "The challenge arises in ration formulations, grass quality, where your farm is located and known deficiencies by area make these essential."[185]

While in an ideal world every farm would have a perfect mineral program and every cow would get the proper minerals she needs, this is not always the case. Dr. Dayna Locitzer, Green Mountain Bovine Clinic shared with us, "So many of the farmers I work with and talk to have mineral issues. This is especially true for grass-fed dairies who cannot feed minerals in a grain ration. Many of these farmers use free-choice minerals, which have no proven efficacy in providing all animals in a herd with the minerals they need to not only maintain themselves but do the extra work of fertility and making milk."[186]

Nutritive supplements are important for animals that are off feed and not eating or not eating well enough to ensure intake of vitamins and minerals. Nutritive supplements ensure a precise amount of nutrients can be provided to animals, as needed. Dr. Hue Karreman notes, "The whole reason for the injectable electrolytes is for sick animals to be treated and rehydrated and boosted to fortify their immune system in the face of infection or other malady. If this category were removed, we would go back to the dark ages."[187]

Propylene glycol (CAS #57-55-6) 205.603(a)(27) – Only for treatment of ketosis in ruminants.
We had mixed reviews of this material from the livestock experts that we consulted. Review from Jill Smith, Pure Eire Dairy, spoke about the importance of prevention. Prevention of ketosis is by proper nutrition, not propylene glycol. In concert with this, it is important to review the recommendations on ketosis of Dr. Paul Dettloff.[188] Dr. Dettloff does not mention propylene glycol, but gives a number of suggestions for prevention (maintaining a high-energy diet before calving, including dry long-stemmed hay) and treatment (glucose IV, homeopathic lycopodium, molasses, and Wellness Tonic containing apple cider vinegar and aloe vera, with tinctures of rose hips, dandelion root and plantain.)[189] Dr. Hue Karreman noted, "We had devised various other methods of treating ketosis—there are various commercial preparations utilizing molasses, glycerin, and herbs that support liver function. Those methods are consistent with those outlined by Dr. Detloff."[190]

Alternatively, Dr. Dayna Locitzer, Green Mountain Bovine Clinic, noted that propylene glycol "is a very effective and easy treatment against ketosis. Before this, farmers were administering bottles of dextrose intravenous, which is not only a subpar treatment for the disease, it also is dangerous both for the farmer and for the cow. Intravenous Dextrose causes blood sugar spikes, preventing the cow from regulating her own blood sugar levels. It also causes abscesses under the skin when administered improperly. Also, when a cow is ketonic, she can be aggressive, making giving an IV dangerous. Glycerin was another option that was used in the past on organic

[185] Private e-mail communication between Jill Smith, Pure Eire Dairy, and Christie Badger, NOC.
[186] Private e-mail communication between Dr. Dayna Locitzer, Green Mountain Bovine Clinic, and Christie Badger, NOC.
[187] Private e-mail communication between Dr. Hubert Karreman and Christie Badger, NOC.
[188] Paul Dettloff, 2009. *Alternative Treatments for Ruminant Animals*, revised and expanded edition. Acres U.S.A. Austin, TX.
[189] Details at http://drpaulslab.net/dairy-treatment/ and http://drpaulslab.net/products/.
[190] Private e-mail communication between Dr. Hubert Karreman and Christie Badger, NOC.

farms and in study after study, it has been shown to not be as effective in resolving ketosis as propylene glycol."[191] Along these lines, Jill Smith also noted that intravenous treatments "are harder and harder to use as we have less people skilled in treating cows. The propylene glycol drenches are the easiest route."[192]

Zinc sulfate 205.603(b)(11) – Allowed for use in hoof and foot treatments only.
NOC supports relisting zinc sulfate and would suggest the following annotation: **Zinc Sulfate for use as a hoof treatment. Substance must be used and disposed of in a manner that minimizes accumulation of zinc in the soil, as shown by routine soil testing.**

While we recognize there are environmental and health risks in the production of this material, we also understand the need for this material, especially as an animal health tool for organic sheep and other hoofed mammals. The petition and Technical Review describe the environmental and health risks. Since sheep cannot use the current footbath substance listed, copper sulfate, and hoof problems are significant in this species, zinc sulfate has a place on the National List of approved synthetics. Organic sheep are a multi-use breed, providing fiber, dairy products, and meat to organic consumers.

NOC sees the use of zinc sulfate similar to the use of copper sulfate used for cattle foot baths and would like to see the NOSB work towards adding a similar annotation as listed above to the current copper sulfate livestock wording on the national list. **205.603 (b) (1) Copper sulfate. Substance must be used and disposed of in a manner that minimizes accumulation of copper in the soil, *as shown by routine soil testing.***

This proposed annotation for copper sulfate and zinc sulfate as allowed for organic livestock brings the livestock listing into harmony with the various copper listings in the crops section of the National List.

As the disposal method for footbath solutions containing either or both copper sulfate and/or zinc sulfate could include mixing with manure and spreading on fields, we feel that the organic farmer should be monitoring this application. The use and disposal must not bring up the zinc or copper levels in the soil to a percentage that causes concern. Organic certification agencies can easily track the compliance to this annotation through monitoring of soil tests, similar to what is currently done under the crops annotation for coppers.

As with all synthetics of toxicological concern, we hope the organic livestock community will continue to research more benign materials for topical or footbath use, so we can eventually remove these materials from the allowed portion of the National List.

Materials Subcommittee

Discussion Documents

Excluded Methods

NOC applauds and appreciates the efforts of the NOSB in moving the work on excluded methods forward. New genetic manipulation techniques are being introduced at an increasingly rapid pace. Organic stakeholders and

[191] Private e-mail communication between Dr. Dayna Locitzer, Green Mountain Bovine Clinic, and Christie Badger, NOC.
[192] Private e-mail communication between Jill Smith, Pure Eire Dairy, and Christie Badger, NOC.

accredited certifiers must have clarity on which genetic techniques and methods are allowed and which are prohibited under the organic regulations. The NOSB and NOP must provide that clarity in a transparent way.

In 2011 and 2012, a number of confusing issues came before the NOSB and the NOP. This sparked a reexamination of the excluded methods definition, years of sustained work on the part of the NOSB, and open dialogue within the organic community. An NOSB discussion document on excluded methods was put forward in 2013, which generated significant public comment. A second NOSB discussion document posted in September 2014 and in April 2015 analyzed the comments received and proposed options for the NOSB review and evaluation of new GE technologies and methods. The NOSB also acknowledged that this issue would require continuous work on their part to evaluate and provide recommendations to the NOP about new technologies as they emerge.

Throughout this entire process of dialogue and debate, the organic community and NOSB has been clear in their opposition to genetic engineering in organic agriculture and the need to provide a transparent process and certainty to the organic community - including certifiers, operations, and consumers - about what is excluded, what is allowed, and why.

Further, during the National Organic Program Update at the fall 2019 NOSB meeting in Pittsburgh, PA, Dr. Tucker clearly stated in her presentation (emphasis added):

- The **Excluded Methods** definition in the USDA organic regulations does not allow for gene editing: it is prohibited.
- USDA encourages continued **robust dialogue** about the role of new technologies and innovations in organic agriculture.
- Changing the definition of Excluded Methods is **not** on the USDA regulatory agenda.[193]

This is a complicated area, and the NOSB and NOP must be a place where the organic community can go to find answers and direction. We cannot have inconsistency between certifiers in what they allow when considering methods. The framework put in place by the NOSB in the fall of 2016 should be formally adopted by the NOP and codified as a guidance document. The NOSB process of defining and clarifying what should be excluded as a method uses and builds on the current excluded methods definition in the organic regulations to encompass new technologies that have emerged since this definition was adopted in 1995 due to rapid advances in recombinant DNA biotechnology.

Since 2016, the NOSB has clarified in unanimous recommendations that the following eleven methods are excluded in organic: Targeted genetic modification, gene silencing, accelerated plant breeding techniques, synthetic biology, cloned animals and offspring, plastid transformation, cisgenesis, intragenesis, agro-infiltration, transposons developed via use of in vitro nucleic acid techniques, and induced mutagenesis through in vitro techniques. **The NOP should codify the prohibition in organic for these eleven methods by publishing a guidance document for the NOP handbook to ensure clarity for all stakeholder groups.**

All of the NOSB recommendations on excluded methods since fall 2016 have been unanimous, which reflects the organic community's united stance that genetic engineering should be prohibited in organic. Genetic engineering is a threat to the integrity of the organic label. Both organic producers and consumers reject the inclusion of genetic engineering in organic production.

[193] National Organic Program Update, October 2020, Slide 30 of 32.

The NOSB has also passed unanimous recommendations that marker assisted selection, transduction, embryo rescue in plants, and embryo transfer in animals should be allowed in organic. **The NOP should codify that these four methods are allowed in organic by publishing a guidance document for the NOP handbook to ensure clarity for all stakeholder groups.**

The NOSB is still receiving public comment and evaluating the status of 6 'to be determined' techniques: protoplast fusion, cell fusion within plant family, tilling, double haploid technology, some forms of induced mutagenesis, and transposons produced from chemicals, ultraviolet radiation, or other synthetic activities. In addition, continued work to evaluate which techniques should be prohibited in organic will be necessary as new technologies emerge.

The NOSB must move forward with urgency, but with great care, to determine the status for these 'to be determined' technologies and other GE technologies that emerge to provide clarity to all stakeholder groups. The NOSB must solicit input from scientists, plant breeders, and other organic stakeholder groups in making these determinations. **In particular, failure to continue work in this area will negatively impact organic plant breeders and the organic seed industry, who need certainty to advance plant breeding efforts that meet the needs of organic operations.**

NOC strongly supports the four evaluation criteria used to determine if methods should be excluded. **The NOP should codify these criteria by publishing a guidance document for the NOP handbook to ensure clarity for all stakeholder groups.** We encourage the NOSB to continue to bring methods forward for evaluation in a transparent way that allows input from all stakeholder groups.

The NOSB process of defining and clarifying what should be excluded as a method uses and builds on the current excluded methods definition in the organic regulations to encompass new technologies that have emerged since this definition was adopted in 1995 due to rapid advances in recombinant DNA biotechnology.

NOC would also like to note that the majority of the seed planted on organic farms is conventional, untreated seed. Consistent application of organic seed requirements is fundamental to promote the investment in breeding and production of varieties for organic farming systems and developed within organic frameworks. We applaud the work of the NOSB to pass updated organic seed regulations and guidance in recent years, and strongly urge the NOP to adopt these changes through rule making and guidance documents. We see the topic of organic seed requirements as being closely connected to the topic of excluded methods because decisions and actions for the NOSB and NOP on both topics have significant impacts on organic plant breeding. We encourage the NOSB and NOP to continue to focus energy on strengthening organic seed availability, usage, and enforcement among organic growers. As long as the loophole in the organic seed usage regulation exists, organic growers will continue to source conventional untreated seed of varieties that may have been developed using excluded methods, but remain undisclosed.

We will attempt to provide answers to the questions posed in the published materials.

1. **What new emerging methods in biotech should be added to the TBD list? Please also describe the primary purpose and how far from commercialization for use in food processing and/or agriculture the method is in its development.**

We have no newly identified emerging methods in biotech that should be added to the TBD list at this time.

2. **Please prioritize the remaining TBD list methods according to the definitions, principles and criteria established in the 2016 Proposal.**

On average, it takes 7-10 years from an initial cross of two or more parent lines before a variety is ready for commercialization. NOC understands that there is a currently a challenge because organic plant breeders will be hesitant to utilize parent material that contains traits developed through the techniques on the TBD list if there is a risk that halfway into their breeding program they may have to discontinue variety development when a technique that had previously been used for organic plant breeding is later determined to be excluded.

NOC recommends that the NOSB vote on the TBD methods at the Fall 2021 NOSB meeting. Creating an ad hoc committee to provide further details on these methods and the implications of a yes or no vote is critical in the intervening months. The composition of this ad hoc committee is an important consideration, and should include representatives from the commercial seed industry who are engaged and committed to promoting organic seed.

We would also like to encourage the NOSB to include definitions for each of the methods in the chart displayed on pages 156 to 159 of the excluded methods discussion document. The NOSB should seek out and rely on accepted scientific definitions to ensure that the NOSB is clearly defining what is and is not included.

   a. **Would methods newly determined to be excluded by the NOSB/NOP be retroactive for commercial varieties already in the marketplace?**

Attempting to implement a timeline for when a method becomes excluded only further complicates the indisputable challenge of how this guidance would be enforced. Plant breeding is an iterative process. New varieties do not just appear de novo, but are derived from older varieties. The methods remaining on the TBD list are all techniques that have been used by breeders for years, and some for decades. Even if the direct parent lines of a new hybrid cross were not manipulated using the list of TBD methods, the pedigree of those parent lines (previous generations of the line) could have been developed with a TBD method. Uncovering that genealogy, especially for hybrid parent lines that are, in many cases, a trade secret held by the breeding company, is a near impossibility.

While identifying a cut-off time before which an excluded method is permitted may seem like a clear demarcation, in practice it would add further burden not only to plant breeders and seed companies developing organic varieties, but also to organic growers. Before purchasing any seed, an organic grower would not only be required to attempt to uncover if the variety was developed using an excluded method, but when the excluded method was introduced into the pedigree. Such information is just not readily available and trying to track it down for commercial varieties is not practical. The net result would be fewer quality varieties available for organic growers, and less investment from seed companies in organic trait priorities. For these reasons, we do not recommend implementing a date before which an excluded method is allowed.

We point the NOSB in the direction of the 2013 NOP memo on cell fusion,194 which may begin to address questions regarding allowance in plant breeding and providing a jumping off point for discussion of other techniques.

b. Should the NOSB grandfather in methods that have long been used in organic plant breeding (e.g., double haploids) and focus its energy entirely on new and emerging technologies?

Until evaluations are made on all of the methods, it is too soon to say whether any of these methods should be allowed or excluded.

c. How do we regulate technologies used to develop new seed varieties that companies are otherwise under no obligation to disclose?

As noted above, uncovering that genealogy, especially for hybrid parent lines that are, in many cases, a trade secret held by the breeding company, is a near impossibility.

3. Are unintentional excluded methods hiding in organic systems when the actual material produced and used has no trace of excluded method in the final organic product? Do we have the inspection, testing, and enforcement tools to keep prohibited methods out of the organic marketplace?

Some of our members have noted that testing may be a viable way of detecting excluded methods, and we will work on providing additional information on this.

4. Given the lack of transparency around emerging technology entering food and agricultural systems, how can Organic producers, handlers, certifiers, and this Board, etc. stay educated on emerging methods and the potential for contamination?

NOC encourages the Board to continue to engage expertise from the community at large. We recommend the NOSB create an ad hoc organic seed committee that can work more directly on issues related to organic seed, including promoting organic supply, organic seed treatment regulations, and closing the organic seed usage loophole. The composition of this ad hoc committee is an important consideration, and should include representatives from the commercial seed industry who are engaged and committed to promoting organic seed.

We also encourage the NOSB to continue to request information about emerging technology from the US Department of Agriculture (USDA) and US Food and Drug Administration (FDA).

Conclusion

- **The NOP should codify the prohibition in organic for the eleven methods identified by the NOSB by publishing a guidance document for the NOP handbook to ensure clarity for all stakeholder groups.**
- **The NOP should codify that the four methods identified by the NOSB are allowed in organic by publishing a guidance document for the NOP handbook to ensure clarity for all stakeholder groups.**

[194] USDA Policy Memorandum. February 1, 2013. *Cell Fusion Techniques used in Seed Production.* https://www.ams.usda.gov/sites/default/files/media/NOP-PM-13-1-CellFusion.pdf

- **The NOP should codify the four evaluation criteria used to determine if methods should be excluded by publishing a guidance document for the NOP handbook to ensure clarity for all stakeholder groups.**
- **Failure to continue work in this area will negatively impact organic plant breeders and the organic seed industry, who need certainty to advance plant breeding efforts that meet the needs of organic operations.**

While NOC refers to guidance in this comment as a way to implement the NOSB recommendations on excluded methods, we ask the NOP and NOSB to discuss the best ways to have these recommendations be consistent between certifiers and enforceable on all operations. This may include having some of the criteria and definitions incorporated into the regulations. To provide stronger consistency between certifiers and give clear direction to accreditation auditors, placing the list of excluded and allowed methods in an instruction to certifiers should be considered.

Research Priorities 2020

NOC suggested a research priority be added based on the February 4, 2021, Congressional Report that documented substantial levels of the heavy metals arsenic, lead, cadmium, and mercury in infant foods.[195]

Background

On February 4, 2021, a staff report produced for the Subcommittee on Economic and Consumer Policy of the Committee on Oversight and Reform of the US House of Representatives concluded:

> "The Subcommittee's investigation proves that commercial baby foods contain dangerous levels of arsenic, lead, mercury, and cadmium. These toxic heavy metals pose serious health risks to babies and toddlers. Manufacturers knowingly sell these products to unsuspecting parents, in spite of internal company standards and test results, and without any warning labeling whatsoever."[196]

As stated in the report, some of the serious health impacts caused by heavy metals, especially in young children, include: "permanent decreases in IQ, diminished future economic productivity, and increased risk of future criminal and antisocial behavior."[197]

In their February 16, 2021, response, the Food and Drug Administration (FDA) noted:

> "Because these elements occur in the environment, currently they cannot be completely avoided in the fruits, vegetables, or grains that are the basis for baby foods, juices, and infant cereals made by companies or by consumers who make their own foods. They also cannot be completely avoided by using organic farming practices."[198]

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[195] Staff Report. February 4, 2021. *Baby Foods are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury.* Produced for the Subcommittee on Economic and Consumer Policy of the Committee on Oversight and Reform of the U.S. House of Representatives. https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf

[196] *Ibid.* Page 59 of 59.

[197] *Ibid.* Page 2 of 59.

[198] US Food & Drug Administration. February 16, 2021. *FDA Response to Questions About Levels of Toxic Elements in Baby Food, Following Congressional Report.* https://www.fda.gov/food/cfsan-constituent-updates/fda-response-questions-about-levels-toxic-elements-baby-food-following-congressional-report

Because heavy metal contamination occurs in organic as well as nonorganic baby foods and in food ingredients as well as additives such as vitamin mixtures, it is important to discover the sources from which heavy metals enter the food. Some sources are known—it is known that some vitamin mixes are contaminated. It is known that rice—especially brown rice—contains arsenic as a result of historical use of arsenic pesticides and the fact that rice concentrates arsenic. Other sources are more speculative, but there are three main possible sources—pesticide residues in agricultural products, food contact with processing machinery and containers, and food additives.

Growing food organically eliminates additions to the heavy metal burden of soils but does not eliminate existing residues in the soil and environment generally. Organic processing standards must be strengthened to address problems associated with food contact contaminants and contaminated additives. While background levels and action levels set by FDA standards are one measure, under the Organic Foods Production Act, the National Organic Standards Board must set its own standards for contaminants of added substances in organic food production and processing, taking into account background levels in the environment.

After decades of polluting practices in agricultural production under risk assessment standards that allowed contamination at "acceptable levels," we have a legacy problem with background contamination of farmland. As a result, manufacturers of processed food may not be able to source ingredients without these unacceptable contaminants. Therefore, we need to first define the scope of the problem and then consider remediation measures that may be needed on the agricultural land used to grow crops that are ingredients in baby food and the food supply generally.

With the problem fully defined, we can launch a national clean-up program—from farmers to processors and packagers—to eliminate the contamination from the food supply. As a part of this national program, FDA must set strict regulations on heavy metal concentrations in finished products. The heavy metal contamination occurs regardless of organic production and processing methods. Organic standards are based on practices rather than purity, but consumers do expect that organic foods will be free of hazardous contaminants. Therefore, regardless of actions that may be taken by Congress or the Food and Drug Administration (FDA) affecting foods in general or baby foods in general, the NOSB and NOP should, to the extent possible, ensure that organic food, especially infant food, is free from heavy metal contamination.

Besides distinguishing food ingredients grown according to organic standards from ingredients allowed in processing by virtue of their inclusion on the National List, another distinction needs to be recognized—contamination of ingredients as opposed to contact contamination that may arise from processing machinery or packaging.[199] Hence, the NOSB should recommend research examining the following potential sources of contamination:

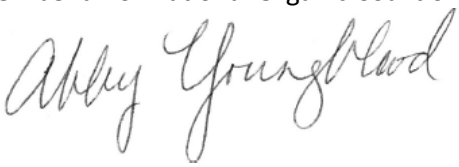
1. Organic crop and livestock production practices and the land;
2. National List ingredients;
3. Processing and handling processes; and
4. Packaging materials.

[199] Muncke, J., Backhaus, T., Geueke, B., Maffini, M.V., Martin, O.V., Myers, J.P., Soto, A.M., Trasande, L., Trier, X. and Scheringer, M., 2017. Scientific challenges in the risk assessment of food contact materials. *Environmental Health Perspectives*, *125*(9), p.095001.

Conclusion
Heavy metal contamination of organic food can come from many sources, and consumers expect organic products to be free of harmful contaminants. Eliminating or reducing this contamination will require a comprehensive effort involving research in several areas to inform a comprehensive action plan. We encourage the NOSB to make heavy metal contamination a priority research topic and to work with NOP to identify possible actions to reduce contamination of organic foods.

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
Consumer Reports
Equal Exchange
Maine Organic Farmers and Gardeners Association
Midwest Organic and Sustainable Education Service
National Co+op Grocers
Nature's Path
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

NOSB work agenda items that have been removed from the work agenda without explanation

USDA Agricultural Marketing Service | National Organic Program
National Organic Standards Board (NOSB) Work Agenda
Work agendas under review by NOP or petitions under review by NOSB - no work should be done other than sufficiency or requesting/scoping

Started	Status	Item	NL Section	Type	Requestor	Priority	Subcommittee	Last Action	Last Action Date	Next Action	Next Action Date	Expected Full NOSB	Next Meeting Action
5/9/2016	HOLD	(Manure treatments) Anaerobic Digestate - Food Waste 205.601(j) and other manure issues		Material	NOP	2	Crops	Public Input/Full NOSB Review	11/2/2017	HOLD	TBD	TBD	Not on Agenda
7/1/2014	HOLD	Prohibition of NPEs in inerts - annotation change/ EPA List 4 Inerts annotation change		Material	NOSB	3	Crops	HOLD - pending IWG/EPA/Safer Choice program	Fall 2015	HOLD	TBD	TBD	Not on Agenda
9/6/2016	HOLD	Field and greenhouse container production		Practice	NOSB	3	Crops	Subcommittee discussion	2/6/2016	HOLD	TBD	TBD	Not on Agenda
1/12/2014	HOLD	Packaging substances used in organic food handling - including BPA		Material	NOP	2	Handling	Technical Review Sufficiency Determination	8/1/2017	HOLD	TBD	TBD	Discussion
1/12/2016	HOLD	Nutrient Vitamins and Minerals - annotation change	205.605(b)	Material	NOSB	3	Handling	Subcommittee Discussion	Fall 2015	None	TBD	TBD	Not on Agenda
11/19/2013	HOLD	Contamination issues of farm inputs	NA	Material	NOSB	3	Materials	Subcommittee discussion	10/8/2019	Subcommitte	11/12/2019	TBD	TBD
5/30/2012	HOLD	Aquaculture-CO2, (for aquatic plants)	205.609	Material	Petition	1	Crops	Referred back to Subcommittee	5/2/2014	HOLD	HOLD	TBD	Not on Agenda
5/30/2012	HOLD	Aquaculture-Chlorine (for aquatic plants)	205.609	Material	Petition	1	Crops	Referred back to Subcommittee	5/3/2014	HOLD	HOLD	TBD	Not on Agenda
6/8/2012	HOLD	Aquaculture-Micronutrients (for aquatic plants)	205.609	Material	Petition	1	Crops	Referred back to Subcommittee	5/4/2014	HOLD	HOLD	TBD	Not on Agenda
07/302012	HOLD	Aquaculture-Lignin sulfonate (chelating agent for aquatic plants) CAS #s 9009-75-0, 8062-15-5, 8061-51-6	205.609	Material	Petition	1	Crops	Referred back to Subcommittee	5/5/2014	HOLD	HOLD	TBD	Not on Agenda
8/10/2012	HOLD	Aquaculture- Vitamins (B1, B12, H) for aquatic plants	205.609	Material	Petition	1	Crops	Referred back to Subcommittee	5/6/2014	HOLD	HOLD	TBD	Not on Agenda
6/4/2012	HOLD	Aquaculture - Biologics: Vaccines for Aquatic Animals	205.611	Material	Petition	1	Livestock	Referred back to Subcommittee	5/7/2014	HOLD	HOLD	TBD	Not on Agenda

Action being taken by USDA or another agency; NOSB and Subcommittee work should hold pending action by agency.

NOSB-Work-Agenda_121520 draft HOLD pending action Work Agenda

Started	Status	Item	NL Section	Type	Requestor	Priority	Subcommittee	Last Action	Last Action Date	Next Action	Next Action Date	Expected Full NOSB	Next Meeting Action
5/30/2012	HOLD	Aquaculture - Chlorine (for aquatic animals)	205.611	Material	Petition	1	Livestock	Referred back to Subcommittee	5/8/2014	HOLD	HOLD	TBD	Not on Agenda
5/30/2012	HOLD	Aquaculture - Tocopherols (for aquatic animals)	205.611	Material	Petition	1	Livestock	Referred back to Subcommittee	5/9/2014	HOLD	HOLD	TBD	Not on Agenda
5/30/2012	HOLD	Aquaculture - Vitamins (for aquatic animals)	205.611	Material	Petition	1	Livestock	Referred back to Subcommittee	5/10/2014	HOLD	HOLD	TBD	Not on Agenda
6/8/2012	HOLD	Aquaculture - Trace Minerals (for aquatic animals)	205.611	Material	Petition	1	Livestock	Referred back to Subcommittee	5/11/2014	HOLD	HOLD	TBD	Not on Agenda

Appendix B

NOC Statement on Racial Equity – working draft

This version of NOC's Racial Equity Statement is a working draft. NOC is actively seeking and welcomes feedback and suggestions from partner and ally organizations and individuals. This statement is a "living" statement, and will be amended as we grow in our understanding.

04.01.2020

As NOC, we acknowledge our own privilege, as currently mostly white, middle class, educated people who were born in the United States. We acknowledge the institutional racism that has formed our current agricultural landscape and food system, robbed indigenous peoples and other people of color of their land, enslaved and systematically disenfranchised people of color, and continues to impact people's relationships with their food, their communities, their access to land, their relationship to agriculture, and with one another as individuals.

We recognize other systems of oppression at work in our communities - sexism, heterosexism, ageism, linguicism, ableism, discrimination based on immigration status, and of persistent poverty. We know that these many systems of oppression play out and interact in the lives of those with multiple marginalized identities.

We believe sustainable agriculture work must be addressed in partnership with racial equity work. We know that environmental degradation and agricultural infrastructure cannot be addressed when people feel undernourished, unseen, unheard, and unsafe. We know true sustainability is not just an environmental goal, but also a social one.

The contributions made by people of color to organic and sustainable food systems are vast and often go unacknowledged. We recognize that access to the organic and "good food" movements, and to organic certification has not been equal across racial groups. Systematic racism has kept our movement from reaching its full potential. The organic movement can only be stronger and better positioned to meet future challenges if it supports equity, intentional inclusion, and prioritization. .

Because we know better, we must do better, and so NOC puts forth this statement to share our intention. We will revisit this statement and our specific ways of putting it into action as we move forward.

We will continue to strive toward our shared mission of safeguarding and advancing organic food and agriculture and ensuring a voice for organic integrity, which means strong, enforceable, and continuously improving standards to maximize the multiple health, environmental, and economic benefits that organic agriculture provides. In so doing, we pledge to hold ourselves accountable to the knowledge we possess and to partner with others who are at the forefront of equity and justice work - leaders in the arenas of racial equity in food systems, of black farmers, of indigenous farmers, of LGBTQIA+ farmers, of farmworkers and others, to ensure we do our work in a way that lifts the voices of those historically marginalized. We will respect and seek to learn from the wisdom inherent in communities of color, immigrant farmers, and others, who have developed resilient social and agricultural systems for their communities and environment.

We will:

- **Listen** to how the organic movement is perceived among diverse groups, be present in, and support spaces led by people of color;
- **Understand** the history of institutionalized racism and white supremacy, and how this has led to the inequities in organic food and agriculture that continue to the present day;

- **Seek** information regarding the ways in which current policies are impacting the demographics of the organic industry;
- **Work** to diversify NOC membership and NOC affiliates to include organizations and businesses focused on racial equity and social justice;
- **Train** ourselves and our community so that we can be effective advocates and allies;
- **Become** vigilant regarding race and social justice issues that we, as organic advocates, support and promote through our work;
- **Build** processes to help us view the work through a lens that evaluates impacts and opportunities from racial, class, and gender perspectives; and
- **Create** paths for leadership and influence in organic food and farming for people of color, in partnership with other organizations.

We know this will not be easy, and that we will make mistakes. We will strive to work with humility and to hold ourselves and one another accountable. We also know we are not alone in this work, and that our colleagues and sister organizations will support and challenge us as we proceed. We look forward to learning in community, and to working together toward an inclusive, diverse, thriving organic agriculture movement. Until we engage as active participants in dismantling systemic racism, we will not be able to achieve the future we work towards: maximizing the health, environmental, and economic benefits that organic agriculture provides to all.

Appendix C

Clarity on 3-Year Transition Period – NOC Fall 2020 NOSB Comments

In August and September of 2020, the Accredited Certifiers Association, Organic Farmers Association, and NOC partnered to conduct a survey with certifiers on certifier policies regarding the circumstances under which they require a three-year transition period after the spraying of a prohibited substance.

The goals of this survey are to:

1. Inform the work of the ACA's working group, which is focused on the *June 3rd, 2019 NOP memo on Land based Production affecting Greenhouse and Container Production*.[200] The working group intends to begin creating guidelines in the coming weeks and months to address inconsistencies and identify best practices in three-year transition period requirements.
2. Use the aggregated data we have collected to inform the National Organic Program and NOSB, identify where there is a lack of uniform interpretation, and request their review and clarification.
3. Ultimately the goal of the survey is to bring all certifiers into alignment in this area so that together they uphold high organic integrity and provide uniform interpretation of the organic standards.

34 certifying agents participated in the survey. This represents about 44% of NOP accrediting certifying agents and 54% of ACA's membership.

The survey results demonstrate the high level of variation between certifiers in how they apply the three-year transition requirement in different situations. The survey results are attached in aggregate form as Attachment A.

There was certifier consistency for only one scenario presented in the survey. The survey results indicate that all certifier respondents require a three-year transition period after the application of prohibited substance in a greenhouse or hoop house that is growing crops in the ground.

NOC's preliminary analysis indicates that for other situations, certifiers were either evenly split or most certifiers, but not all, followed the same practices with notable outliers. Some certifiers indicated "other" for some scenarios and described various circumstances under which they would either require or not require a transition period.

In the following scenarios, certifiers were split evenly between requiring a three-year transition period and not requiring a transition period:

1. After the application of prohibited substance in a greenhouse or hoop house with a permeable floor (i.e. soil, sod, rocks, plastic, fabric, etc.) that is growing crops in containers on tables or benches.
2. After the application of prohibited substance in a greenhouse or hoop house that is growing crops hydroponically or with an aquaponic system. Most certifier respondents (61.3%) do not certify these systems at all, but for those who do, there is a lack of clarity on this issue.

[200] https://www.ams.usda.gov/sites/default/files/media/2019-Certifiers-Container-Crops.pdf

3. After the application of prohibited substance inside an indoor facility that is growing crops hydroponically or with an aquaponic system. Most certifier respondents (61.3%) do not certify these systems at all, but for those who do, there is a lack of clarity on this issue.

Based on the survey results, the three above scenarios are situations for which there is a high level of inconsistency and no clear consensus among certifiers. As a result, providing clarity in these three situations should be a high priority for the NOP, NOSB, and the organic community. NOC believes further deliberation must take place to develop consensus within the organic community.

The following scenarios are ones in which *most* certifier respondents require a three-year transition, but for many of these situations there is a noteworthy minority of certifiers who do not require the transition period. Some certifiers responded "other" to indicate that they do not require the three-year transition uniformly for these scenarios:

1. After the application of a prohibited substance in a greenhouse or hoop house that has a permeable floor (i.e. soil, sod, rocks, plastic, fabric, etc.) and is growing transplants (grown on the ground, on pallets, on tables or benches) – 66.7% of certifier respondents require a three-year transition.
2. After the application of prohibited substance in a greenhouse or hoop house that is growing crops in containers on the ground or on a permeable ground covering (i.e. soil, sod, rocks, plastic, fabric, etc.) – 87.1% of certifier respondents require a three-year transition.
3. On the land upon which poultry houses are located after the application of a prohibited substance if the poultry house has a permeable floor (i.e. dirt or other) – 83.3% of certifier respondents require a three-year transition.
4. For the outdoor access area for a poultry house after the application of a prohibited substance – 90% of certifier respondents require a three-year transition.

The following scenarios are ones in which *most* certifier respondents do not require a three-year transition, but for many of these situations there is a noteworthy minority of certifiers who do require the transition period. For many certifiers, the presence of an impermeable floor is a key factor. Some certifiers responded "other" to indicate that they do not require the three-year transition uniformly for these scenarios, but do sometimes require it depending on circumstances (for example):

1. After the application of prohibited substance in a greenhouse or hoop house that has an impermeable (i.e., concrete, etc.) floor and is growing transplants (grown on the ground, on pallets, on tables or benches) – 57.6% of certifier respondents do not require a three-year transition.
2. After the application of prohibited substance in a greenhouse or hoop house that is growing crops in containers on an impermeable ground (i.e., concrete, etc.) – 61.3% of certifier respondents do not require a three-year transition.
3. After the application of prohibited substance in a greenhouse or hoop house with an impermeable floor (i.e. concrete, etc.) that is growing crops in containers on tables or benches – 64.5% of certifier respondents do not require a three-year transition.
4. After the application of prohibited substance inside an indoor facility that is producing crops in containers – 58.1% of certifier respondents do not require a three-year transition.
5. After the application of prohibited substance inside an indoor facility that is producing transplants – 58.1% of certifier respondents do not require a three-year transition.

6. After the application of prohibited substance inside an indoor facility that is producing mushrooms – 58.1% of certifier respondents do not require a three-year transition.
7. After the application of prohibited substance inside a greenhouse or an indoor facility that is producing sprouts – 58.1% of certifier respondents do not require a three-year transition.
8. On the land upon which poultry houses are located after the application of a prohibited substance if the poultry house has an impermeable floor (i.e. concrete or other) – 60% of certifier respondents do not require a three-year transition.

In our survey, we also asked respondents if they would allow operations with greenhouses or facilities that produce both conventional and organic crops, transplants, or planting stock simultaneously within the same greenhouse or facility to become certified as organic. For example, if someone put up a wall to separate conventional and organic production within the greenhouse, we asked certifiers to indicate if they would you allow this greenhouse to become certified. 74.2% of certifier respondents indicated that they do allow this situation.

We also asked survey respondents if they would allow operations with greenhouses or facilities that produce both conventional and organic crops, transplants, or planting stock not simultaneously but within the same greenhouse or facility to become certified as organic. 67.7% of certifier respondents indicated that they would allow this situation.

Finally, 56.7% of certifier respondents would allow poultry operations that raise both conventional and organic chickens simultaneously or not simultaneously within the same facility to become certified as organic.

The survey results indicate that very few certifier respondents have standard definitions for the following terms: Greenhouse, Hoop house, Facility. 84.6% do not have any standard definitions. NOC believes clearly defining these different types of production structures would be helpful in providing clarity about which situations require a three-year transition after a prohibited substance is sprayed.

Request for Clarity

We appreciate the memo dated June 3, 2019, explaining to certifiers the rules they must follow to determine eligibility and compliance for container systems that receive organic crop certification.[201] In its memo, the NOP uses the term "container system" to include container, hydroponic, and other plant pot-based systems (with or without soil as a growing media). NOC appreciates the clear statement from the NOP that these systems must undergo a three-year transition period. We understand that up until that point, some certifiers had been certifying container systems without requiring a three-year transition from the last application of a prohibited substance, so this clarification was urgently needed to ensure the integrity of the organic program.

As the survey results indicate, however, this memo left a lack of clarity regarding how it applies to crop production in greenhouses and facilities. While some organic certifiers and certified producers read the memo to include crop production in greenhouses and facilities under the three-year transition requirement, other organic certifiers and certified producers read the memo to not require greenhouse operations and facilities that produce crops to comply with the three-year transition requirement.

As climate change challenges organic producers to establish new production technologies and the organic market continues to grow at a rapid pace, greenhouse production is estimated to increase. We must, as an

[201] https://www.ams.usda.gov/sites/default/files/media/2019-Certifiers-Container-Crops.pdf

organic community, regulate and enforce organic greenhouse production under uniform national standards. When there are important differences in interpretation that have economic consequences for producers, we need clarity from the National Organic Program to make sure the USDA and accredited certifiers are working together to enforce the standards, ensuring a level playing field for producers, and protecting consumer confidence in the integrity of the USDA Organic Seal.

The current disparity of interpretation for a three-year transition is inhibiting the National Organic Program's ability to provide consistent and fair enforcement, leaving our nation's organic standards unfair and inconsistent.

The NOP must clarify the requirement for a three-year transition for crop production in greenhouses and facilities after the application of a prohibited substance. **The NOSB should actively engage in this process by requesting a work agenda item, requesting stakeholder input, making recommendations to the NOP, and by asking the NOP to provide clarity so all certifiers and organic operations are held to the same standard.**

Appendix D

EPA List 4 – Inerts of minimal concern – NOC Spring 2020 NOSB Comments

205.601(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances. (1) EPA List 4 – Inerts of Minimal Concern.

Regarding EPA List 4 – Inerts, NOC strongly supports the crops subcommittee's statement that "the current situation, where NOP policies are tied to long outdated US EPA guidance, is broken." It is an embarrassment to organic integrity that "the list of 'inerts' that is referenced for review of products for organic certification was last updated in August 2004."[202] The same issues are identified repeatedly every time inerts come up for sunset. The NOSB has made recommendations on how to move forward in resolving these issues, and in February 2016, the NOP issued the following response to the Fall 2015 NOSB recommendation:

> The NOP has reviewed the NOSB's recommendation and plans to collaborate further with EPA's Safer Choice Program to develop a program for inert ingredient review, and to initiate notice and comment rulemaking to revise the annotations for inert ingredients at 205.601(m) and 205.603(e).[203]

The NOP has an opportunity to act on this collaboration and put to rest the extinct EPA List references when it comes to "inerts."

We agree with the crops subcommittee that "the EPA Safer Choice Program is well established and offers a strong partner to identify acceptable inert materials, without each material needing to be reviewed individually by the NOSB."[204] We offer greater details below on how the NOP could contract with the EPA to prepare Technical Reviews (TRs) and review "inerts" to the OFPA criteria.

But first NOC recognizes the need to hire a National List (NL) manager to be able to accomplish these goals, and would suggest that perhaps there is a need for more than one NL manager at this time. While we know it is the preference of the Program that the NL manager work in the D.C. office, NOC strongly encourages the NOP to consider well-qualified individuals that live in the D.C. area, or are willing and able to relocate, as well as those that would work remotely. By limiting the search to only those who live in or are willing to relocate to the D.C. area, the NOP is severely limiting the opportunity to find the most qualified individual for the job.

Further, we recognize the need for an individual within the NOP to be able to work with the NOSB members and act as a liaison between the NOP, NOSB, and EPA. We further recognize that the NOP interacts with many other government agencies, and could envision building a job based on being a liaison with other departments within the USDA, with the EPA, and with other agencies. We support the NOP's efforts to increase their workforce in order to be able to accomplish the goals put before you. The NOP must identify a staff person who can devote him or herself to working with the EPA and NOSB to move this work on inerts forward.

The remainder of our comments will focus on answering questions posted by the subcommittee.

[202] NOSB April 2020 proposals and discussion documents Page 33 of 115.
[203] Miles McEvoy, February 29, 2016 Memorandum to NOSB.
[204] NOSB April 2020 proposals and discussion documents Page 36 of 115.

Are there specific inert ingredients used in organically approved pesticide formulations that raise human health or environmental concerns?

Nonylphenol ethoxylates, and especially their precursor and degradates nonylphenols, are toxic and disruptive to the reproductive system. They were among the first environmental contaminants to be identified as "gender benders" – that is, chemicals that act as estrogens in the environment. According to the TR, "Virtually every environmental compartment can be contaminated through the use of NPEs. These substances generally enter the environment through wastewater, although large-scale applications of NPE dispersing agents in pesticide mixtures will also result in releases to soil, groundwater and neighboring surface waters. In the long term, contamination associated with NPE use occurs in the form of the more toxic and persistent metabolite, NP [nonylphenols]."[205]

NPs have higher levels of toxicity, estrogenic activity and environmental persistence than NPEs. The TR says, "However, release of NPEs to the environment from agricultural and consumer products ultimately leads to the introduction of more highly toxic and persistent NP residues. A lifecycle analysis of NPEs therefore highlights a conflict between use of these substances and the principles of organic agriculture, which seeks to avoid contamination of the environment with toxic and persistent substances."[206]

Because of concerns about the adverse health and environmental effects of NPEs, EPA's Design for the Environment (DfE) completed an alternatives assessment for synthetic surfactants, like NPEs, that are endocrine disrupting chemicals. DfE's goal is to assist in the voluntary phase-out of NPEs used in industrial detergents. The DfE assessment for NPEs reviewed several alternatives to NPE surfactants that are comparable in cost, readily available, and rapidly biodegrade to non-polluting, lower hazard compounds in aquatic environments.[207]

The European Union prohibits the use of NPE's in pesticides and teat dips.[208] Because major importers of dairy products in other countries are concerned about NPEs, teat dips containing NPEs are no longer available for either organic or nonorganic dairy production.[209] **The NOSB should have no trouble prohibiting NPEs in teat dips.** At this time, we would consider the prohibition of NPEs in teat dips a good start in the right direction.

NOC fully supports the removal of all NPEs as so-called "inert" ingredients in pesticides. So-called "inert" ingredients in pesticide products are neither chemically nor biologically inert. They are designed to enhance the pesticidal activity of pesticide products and can have toxic properties that do not meet the standards of the Organic Foods Production Act (OFPA). We point you to the more detailed comments on NPEs by our member organization, Beyond Pesticides, for further details.

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[205] 2015 Limited Scope TR: Nonylphenol Ethoxylates (NPEs), Lines 647-651, https://www.ams.usda.gov/sites/default/files/media/NPE%20Technical%20Evaluation%20Report%20%282015%29.pdf.

[206] 2015 Limited Scope TR: Nonylphenol Ethoxylates (NPEs), Lines 553-556, https://www.ams.usda.gov/sites/default/files/media/NPE%20Technical%20Evaluation%20Report%20%282015%29.pdf.

[207] Mark R. Servos, 1999. Review of the Aquatic Toxicity, Estrogenic Responses and Bioaccumulation of Alkylphenols and Alkylphenol Polyethoxylates, Water Qual. Res. I. Canada,Volume 34, No. 1, 123-177. A support document for Environment Canada's environmental assessment under the Canadian Environmental Protection Act.

[208] EPA, 2011. DfE Alternatives Assessment for Nonylphenol Ethoxylates.

[209] https://s3.amazonaws.com/static.boumatic.com/archive/16-DairySS_CAN_ENG_WEBview.pdf, https://extension.usu.edu/dairy/files/UtahStateDairyVetNewsletterNov2014.pdf.

Are there any alternatives for updating this listing other than the review of each substance individually or adoption of the EPA Safer Choice Program?
Although the recommendation passed by the NOSB at its fall 2015 meeting is inadequate to ensure that "inerts" meet OFPA criteria, the Safer Choice Program (SCP) and Safer Chemical Ingredients List (SCIL) can be helpful to the NOSB in reviewing these materials. While the current ratings for the SCIL "address many issues covered in the NOSB reviews according to the OFPA criteria, they do not address some important elements of OFPA reviews, including impacts on soil organisms and agroecosystems, essentiality/need, hazards associated with manufacturer, transportations, and disposal, and compatibility with organic systems."[210] This can be addressed by the SCP, in conjunction with the NOSB and NOP, creating a list of criteria that apply to the new class and subclasses suggested below that includes OFPA criteria, currently included in the checklist used by the NOSB.

Below we outline a detailed description of NOC's suggested procedure for evaluating "inerts" to be covered by a Memorandum of Understanding (MOU), that should be established between the EPA and NOP, along with a description of the responsibilities of each body (NOP, EPA, NOSB). The procedure we are recommending is based on the outstanding NOSB recommendations made from fall 2012 and fall 2015. NOC is recommending that the Inerts Working Group (IWG) be reestablished, with membership consisting of NOSB members with support from a NOP staff person.

Suggested Procedure

1. NOP should immediately (as stated in the NOP response to the Fall 2012 proposals) conduct a public notice and comment process including:
    a. Notification to the public of "inert" ingredients known to be in use in organic production;

    b. Notification to the public of NOSB's review plan;

    c. A request for public comments regarding any other "inert" ingredients currently used in organic production that are not identified in the list provided by NOP; and

    d. A description of this MOU as a description of the means of implementing the Fall 2015 NOSB recommendation. It will state that "on the Safer Chemical Ingredients List (SCIL)" means "on the section of the SCIL identified as 'Ingredients Other than Active Ingredients in Pesticides Used in Organic Production.'"

2. EPA will create a new section of the Safer Chemical Ingredients List (SCIL) for "Ingredients Other than Active Ingredients in Pesticides Used in Organic Production." This list will contain sublists by the function – such as surfactants, chelating agents, and antioxidants – that they perform in the pesticide product.

3. EPA will identify products in use in organic production in which the "inerts" identified by NOP are used, the function of each "inert" ingredient within the products, and alternative materials that serve the same function. In concert with NOP and the NOSB, EPA will divide the list of "inerts" into five groups. The EPA will review one group per year and provide their review in the form of a TR to the NOSB. One year's review group may include one or more functional classes. For example, Surfactants and Anti-Oxidants may be reviewed in one year, with Chelating Agents and Solvents reviewed the next.

[210] Shistar, T. "Inert" Ingredients Used in Organic Production. Beyond Pesticides, Washington, D.C., 2017, p. 24.

4. EPA will evaluate the "inerts" identified by NOP and the EPA alternatives according to the criteria appropriate for the substance's function and will assign ratings according to the current practice within the Safer Choice Program (SCP) – i.e. green circle, green half-circle, yellow triangle, and gray square. This system of review would result in prohibition of some currently approved inert ingredients, such as NPEs, a class of substances that has raised concerns at past NOSB meetings. Additionally, EPA's review will cover all topics covered in a technical review (TR) commissioned for the NOSB, as well as the topics required to rate the substances according to the SCP. To minimize duplication of work and ease NOSB review, a single review will cover chemicals in the same functional class.

5. EPA will provide a public version of the information it reviews to the NOSB, which will be used as a TR. It will be posted on the NOP website for public viewing. It will contain the following:
    a. A chart of all inerts in the class identified by the Chemical Abstracts Service (CAS) number with their chemical properties, uses, types of product categories in which they occur, and EPA regulatory-status, including data gaps.

    b. A description of how inerts within the class are related and how different, especially outliers that are significantly different from others.

    c. A chart that evaluates each inert in the class under the screening steps suggested by EPA and any additional screening recommended by the NOSB, with input from the IWG.

    d. OFPA criteria will be addressed that are not usually covered in the EPA review (environment, interactions, and alternatives or essentiality).

6. Based on results of the group TR, the NOSB Crops Subcommittee, working with the Livestock Subcommittee as appropriate, will accept the class to move forward to the NOSB agenda, or single out one or more substances for individual review – in which case, the group will then move forward without that substance and that one substance will be re-reviewed in more detail, if necessary, and noted in the NOSB published materials for stakeholder review separately. This substance can be commented on and voted on separately at the NOSB meeting.

7. The NOSB will review the information provided by EPA according to its usual materials review procedures, subjecting them to OFPA criteria based on the TR information provided for the class – or on individual materials that have been "singled out," as described in #6 above.

8. In accordance with its meeting and notice procedures, after NOP publishes the NOSB proposal for listing a class of "inerts" on the National List (as part of the SCIL sublist for "Ingredients Other than Active Ingredients in Pesticides Used in Organic Production"), the NOSB will vote on the proposals and recommend listing or not listing each class.

9. NOP will publish recommendations from the NOSB for public comment according to its usual National List procedures, gather public comment, and finalize the listing.

10. EPA will add the approved chemicals, with approved annotations, to the appropriate subsection of the SCIL sublist for "Ingredients Other than Active Ingredients in Pesticides Used in Organic Production."

11. Stakeholders may submit applications for individual inert ingredients to EPA for inclusion on the Safer Chemical Ingredients List and/or petition the NOP for inclusion on the National List.

Suggested Responsibilities:
NOP:

- NOP should immediately (as stated in the NOP response to Fall 2012 proposals) conduct a public notice and comment process including:
    - Notification to the public of "inert" ingredients known to be in use in organic production;
    - Notification to the public of NOSB's review plan; and
    - A request for public comments regarding any other "inert" ingredients currently used in organic production that are not identified in the list provided by NOP.

- NOP will publish for public comment a description of this MOU as a description of the means of implementing the Fall 2015 NOSB recommendation. It will state that "on the SCIL" means "on the section of the SCIL identified as 'Ingredients Other than Active Ingredients in Pesticides Used in Organic Production.'" This may be the same Federal Register notice as the above notice.

- NOP will publish in the Federal Register recommendations from the NOSB for public comment according to its usual National List procedures, gather comments, and send the finalized listing to EPA.

- NOP will provide expertise as needed to EPA to address issues not generally covered by EPA's Safer Choice reviews.

EPA:

- EPA will create a new section of the Safer Chemical Ingredient List (SCIL) for "Ingredients Other than Active Ingredients in Pesticides Used in Organic Production." This list will contain sublists by the function –such as surfactants, chelating agents, and antioxidants—they perform in the pesticide product.

- EPA will identify products in use in organic production in which the "inerts" identified by NOP are used, the function of each "inert" ingredient within the products, and alternative materials that serve the same function.

- In concert with NOP and the NOSB, EPA will divide the list of "inerts" into five groups and review one group per year. Each group may contain one or more functional class.

- EPA will evaluate the "inerts" identified by NOP and the EPA alternatives according to the criteria appropriate for the substance's function and will assign ratings according to the current practice within the Safer Choice Program –i.e., green circle, green half-circle, yellow triangle, and gray square.

- EPA will provide a public version of the information it reviews in the form of TRs to the NOSB.

- EPA will list in the appropriate section of "Ingredients Other than Active Ingredients in Pesticides Used in Organic Production" those "inerts" approved by the NOSB and NOP.

NOSB:

- The NOSB will review the information provided by EPA according to its usual materials review procedures, subjecting them to OFPA criteria.

- In accordance with its meeting and notice procedures, after NOP publishes NOSB proposals for listing of "inerts" on the National List and the SCIL sublist for "Ingredients Other than Active Ingredients in Pesticides Used in Organic Production," the NOSB will vote on the proposals and recommend listing or not listing for each.

- The NOSB will review petitions for "inerts" to be added to or removed from the appropriate SCIL sublist for "Ingredients Other than Active Ingredients in Pesticides Used in Organic Production." These will be treated as any other petitioned substance, with TRs contracted through the EPA.

We offer the "'Inert' Ingredients Used in Organic Production" authored by Terry Shistar, PhD, for Beyond Pesticides as an attachment to our comments. This report offers many more details into "inerts" in general, NPEs, the timeline of NOSB actions on "inerts," a comparison of Safer Chemical and NOSB approach, and the Safer Chemical Ingredients List (SCIL), as well as other valuable information.

What would be the consequences of a NOSB recommendation to delist List 4 Inerts?

As pointed out by the subcommittee, delisting List 4 inerts and having the NOP act on the 2015 recommendation "would encourage innovation of new products, lessen concerns of stakeholders over environmental and health concerns, and make future reviews of inert materials much easier."[211] Continuing to address the same issues over inerts repeatedly at each sunset review is a waste of everyone's time and efforts.

[211] NOSB April 2020 proposals and discussion documents Page 34 of 115.

Appendix E

Petition Process for §205.606 – NOC Spring 2020 NOSB Comment

Now that any agricultural material can be produced organically, additions to §205.606 should be rare, and materials should be removed from the list whenever possible in order to encourage processors to source organic forms. We encourage the Handling Subcommittee to further consider that 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 or relisting.

It is time to stop adding listings to §606 and phase out current listings.

Organic production is grown up now, and any agricultural commodity can be produced organically. Listing on §606 only stifles organic production of new organic crops and promotes chemical-intensive production. Finally, in the time that it takes to add new regulations, petitioners could develop the demand for the organic product.

Questions that need to be addressed before renewing any listing on §606.

Materials on §205.606 are allowed in products labeled as organic if they are agriculturally produced, but have been found to not be commercially available as organic. The NOSB needs to know what the barriers are to producing the product organically. The Handling Subcommittee should get documented answers to the following questions in determining the barriers to organic production, for both petitions and sunsets.

1. What are the proximity constraints for either a manufactured or raw agricultural commodity in organic form? Examples include perishability, political climate (e.g., war zone) of the area where the agricultural production occurs, and the location of the manufacturing facility.

2. 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.

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 (climate, transportation, war etc.), 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 non-organic production near a manufacturing facility, what are the barriers to having these producers transition some or all of their production to organic?

6. Have the petitioner and 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 (domestic and international) 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 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 instant 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 by which this product is manufactured patented, and if so, is the manufacturer willing to produce an organic equivalent?

11. Is there documentation of the petitioner's efforts to develop organic production?

12. Can the petitioner prove that a specific flavor profile can only be achieved from the petitioned material grown in a specific region?

Appendix F

Fish oil annotation – NOC Spring 2020 NOSB Comment

Proposed annotation to fish oil: 205.606 (e) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8) - stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606. ***Sourced from fishing industry by-product only. Where within NOAA's jurisdiction, only from fish species and regions not listed on NOAA's current "Overfishing" or "Overfished" list. Where outside NOAA's jurisdiction, only from fish species and regions not listed on FAO's "Overexploited," "Depleted," or "Recovering"***

While we appreciate the HS's attempt to address concerns regarding fish oil, the proposed annotation is not only insufficient to "mitigate environmental concerns from the overexploitation of fishing,"[212] it is insufficient to address the concerns regarding contaminants and failure to meet the essentiality/necessary criteria as outlined in OFPA, as it is not a necessary organic food ingredient. Further, the health benefit claims of fish oils in processed foods are questionable. Fish oil production is incompatible with organic principles.

The proposed annotation is insufficient to meet environmental concerns.
The TR for liquid fish fertilizer clearly states these concerns: "Regardless of the intended use, harvesting wild, native fish can contribute to biodiversity loss, habitat destruction, and loss of ecosystem services."[213] Further, the TR states that when it comes to harvesting wild, native fish:

> "[T]heir population dynamics are not understood in many cases. It is also difficult to ascertain the effect of removing biomass, even from a sustainable fishery, considering that these species may be a food source for other species. Meal and oil fish can be critical to the function of entire ecosystems; for example, Pacific thread herring (Opisthonema libertate) and Pacific anchoveta (Cetengraulis mysticetus) are critical links in the Gulf of California, transferring energy through the food web and controlling the organization of these ecosystems."[214]

We believe this paragraph is important and speaks directly to the purpose of this work agenda item. Given that the importance of removing fish biomass is not well understood, either from the perspective of an energetic balance or from the perspective of food web dynamics, the organic industry should take a precautionary approach to protect marine ecosystems.

This is further supported by a 2014 fish stocks assessment report by FAO, which concluded that targeting pelagic species removes "one ecosystem component without considering cascading effects on the dependent species."[215] It further warns that, "[c]oncerns about the impacts of harvest strategies that fail to consider trophic relationships in a given ecosystem have been recognized for decades, and abundant scientific literature exists underpinning its possible negative impacts on the structure and functioning of aquatic ecosystems."[216] Sardines, anchovies, and herring play a key ecological role in the survival of larger predatory fish, mammals, and seabirds. They serve as an important link in the transfer of food energy from plankton to larger species in the marine food web, some of which may be endangered.[217] Further exploitation is not an option, particularly for organic,

[212] NOSB April 2020 proposals and discussion documents Page 50 of 115.
[213] 2019 TR, Lines 327-328
[214] 2019 TR, Lines 342-349
[215] FAO Fisheries and Aquaculture Department (2014), *supra* note 10, at 136.
[216] *Ibid.*
[217] *Ibid,* at 137.

because the unsustainable practice of allowing a non-essential fish-based ingredient in organic food to endanger the food supply of marine life is wholly incompatible with organic systems of production.

The proposed annotation is insufficient to address concerns regarding contaminants.
Contaminants in the ocean environment present health risks to consumers who eat organic processed foods that contain fish oil as an ingredient. The presence of persistent contaminants, including DDT, PCBs, mercury, and dioxins is well-documented by our member organization, Beyond Pesticides, in their Fall 2019 comments.[218]

> Fish are known to bioconcentrate a number of toxic substances. Several studies have examined contaminants in fish oil supplements. They have found a wide variation in contaminant levels, even in those products labeled "purified."[219] The Food and Drug Administration (FDA) says, in the case of components or extracts of whole fish (e.g., dietary supplements, dietary ingredients, and flavors), the component or extract may contain higher or lower concentrations of environmental chemical contaminants and pesticides than the whole fish from which it was derived. For example, organochlorine contaminants, such as PCBs, are oil soluble. When producing fish oil and fish meal, any PCBs present will become more concentrated in the oil fraction and less concentrated in the water fraction, as compared with the levels in the whole fish.[220]

FDA also gives guidance to those using fish for reducing contamination in their products.[221]

Fish oil is not a necessary/essential organic food ingredient.
According to OFPA, §6517(c)(1)(A) (emphasis added),

(1) Exemption for prohibited substances in organic production and 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 chapter 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

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[218] Terry Shistar. September 17, 2019. BP Comments on Handling Sunsets. Pages 27-29. https://www.beyondpesticides.org/assets/media/documents/BP%20Comments%20Sunset%20605-606.f2019.final.pdf
[219] "Purified" -- http://www.webmd.com/diet/news/20111206/some-fish-oil-supplements-fishy-on-quality reporting on Consumers Reports study. Press release on ConsumerLab study: http://www.consumerlab.com/news/ReviewofFishOilandOmega-3SupplmentsbyConsumerLab.com/8_22_2012/ Also: Rawn DF, Breakell K, Verigin V, Nicolidakis H, Sit D, Feeley M., 2009. Persistent organic pollutants in fish oil supplements on the Canadian market: polychlorinated biphenyls and organochlorine insecticides. J Food Sci. Jan- Feb; 74(1):T14-9 http://onlinelibrary.wiley.com/doi/10.1111/j.1750-3841.2008.01020.x/pdf; Storelli MM, Storelli A, Marcotrigiano GO, 2004. Polychlorinated biphenyls, hexachlorobenzene, hexachlorocyclohexane isomers, and pesticide organochlorine residues in cod-liver oil dietary supplements. J Food Prot. Aug; 67(8):1787-91. Covaci, A., Voorspoels, S., Vetter, W., Gelbin, A., Jorens, P. G., Blust, R., & Neels, H., 2007. Anthropogenic and naturally occurring organobrominated compounds in fish oil dietary supplements. *Environmental science & technology*, *41*(15), 5237-5244.
[220] FDA Guidance: Environmental Chemical Contaminants and Pesticides. http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM252404.pdf P. 1 (pdf numbering, p. 155 in original).
[221] FDA Guidance: Environmental Chemical Contaminants and Pesticides. http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM252404.pdf Pp. 4-23 (pdf; 158-177 in original.)

(iii) is consistent with organic farming and handling;

Nonorganic ingredients are otherwise prohibited. The regulations at §205.606(c) reinforce this: "Nonsynthetics used in organic processing will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518)."

Only supplemental ingredients required to be in a food by federal or state regulations, or required to meet an FDA standard of identity, should be considered essential to organic handling. On November 6, 2015, the FDA clarified its policies on fortification and enrichment of foods, and stated that **the agency does require any nutrient to be added to any food.**

The full relevant excerpt from the FDA's November 2015 Guidance for Industry document[222] is important to note:

> **A6. Is nutrient fortification of foods mandatory in the United States?**
> With the exception of some standardized foods, fortification is not mandatory in the United States. Foods subject to certain standards of identity may be required to be fortified with certain vitamins and minerals. For example, enriched flour must contain particular levels of thiamin, riboflavin, niacin, iron, and folic acid specified in 21 CFR 137.165. However, you are not required to enrich your products. For every standard of identity for an enriched product, we have a corresponding standard of identity for the unenriched product.

The FDA does not require the enrichment or fortification of any foods (with the exception of infant formula).

Health benefit claims of fish oils in processed foods are questionable.
Recent studies show that "[s]upplementation with n−3 fatty acids did not result in a lower incidence of major cardiovascular events or cancer than placebo."[223] This is further supported by comments from our member organization, Center for Food Safety, in their Fall 2015 fish oil comments:

> Food manufacturers add fish oil to organic products so that they can make additional health claims on the package and differentiate their products in the marketplace. However, benefits attributed to the consumption of processed foods that contain added fish oil are not supported by scientific evidence. While organic foods have numerous scientifically defensible health benefits, the addition of fish oil is not one of them. Allowing manufacturers to add fish oil and make unsubstantiated and potentially false health claims threatens to undermine consumer trust in the organic label.
>
> In its exploration about health claims of fish oil consumption, the 2015 Technical Review (TR) primarily cites studies that investigated diets with high fish consumption, not diets containing fish oil supplementation. According to a 2015 New York Times article: "From 2005 to 2012, at least two dozen rigorous studies of fish oil were published in leading medical journals, most of which looked at whether fish oil could prevent cardiovascular events in high-risk populations…All but two of these studies found that compared with a placebo, fish oil showed no benefit."[224]

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[222] http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm470756.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

[223] "Marine n−3 Fatty Acids and Prevention of Cardiovascular Disease and Cancer," JAMA, Jan. 2019, https://www.nejm.org/doi/full/10.1056/NEJMoa1811403.

[224] O'Connor, A. (2015). "Fish Oil Claims Not Supported by Research," *New York Times* (March 30). Available at: http://well.blogs.nytimes.com/2015/03/30/fish-oil-claims-not-supported-by-research/?_r=0.

The assumption that processed food containing extracted fish oil will confer the same health benefits as consuming fish oil via the direct source—fatty and oily fish—is unsupported. Increasing evidence demonstrates that dietary supplements, generally, do not confer comparable health benefits to the natural food sources. A study of diets high in fruits and vegetables containing beta-carotene, lycopene, and other carotenoids conducted by the University of Maryland Medical Center, concluded that such diets may reduce the risk of heart disease and stroke. However it further concluded that supplements containing these same nutrients do not reduce these risks.[225] Another study in the *Journal of the American Medical Association* found that women taking vitamin E supplements had no significant overall health benefits compared to women that do not take supplements.[226]

Consumption of a supplement can interact with other aspects of a person's diet or health in a way that the natural food sources do not. For example, smokers taking beta-carotene supplements are at increased risk of lung cancer and mortality, but that is not the case with beta-carotene from foods.[227] Similarly, fish oil supplements can be hazardous to consumers when combined with aspirin or other blood thinners, making them more susceptible to nosebleeds and bruising.[228]

Conclusion

We appreciate that there are those individuals who want to get their non-organic fish oil directly from the milk they are drinking, or those who feel that it is necessary to have fish oil in baby formula. We understand that there is some evidence that EPA and DHA are necessary for infant brain development. But we maintain that adding fish oil to organic products is not necessary or essential, and we are well-aware that infants can receive their fish oil from a dropper.

Fish oil was allowed in organic foods "due to the incorrect interpretation of the FDA fortification policy."[229] Fish oil is not "necessary to the production or handling of the agricultural product," and is not required by the FDA's policies on fortification and enrichment of foods.

While we appreciate the HS's attempt to address concerns regarding fish oil, the focus is too narrow. Fish oil is not a necessary organic food ingredient. It should be removed from §205.606.

[225] Simon, H., MD. (2013). "Vitamins," *University of Maryland Medical Center Medical Reference Guide: In-Depth Patient Education Reports* (January 1). Available at: http://umm.edu/health/medical/reports/articles/vitamins.
[226] Lee, I-M et al. (2005). "Vitamin E in the Primary Prevention of Cardiovascular Disease and Cancer," *The Journal of the American Medical Association, 294(1)* (July 6). Available at: http://jama.jamanetwork.com/article.aspx?articleid=201172.
[227] Simon (2013), *supra* note 26.
[228] O'Connor (2015), *supra* note 25.
[229] National Organic Program, "Proposed Rule for Vitamins and Minerals in USDA Organic Products." January 9, 2012.