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

RE: AMS-NOP-19-0095

NOC Comments to the National Organic Standards Board

SPRING 2020

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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

NOC Recommendations for organic agriculture during COVID-19 Pandemic

We are deeply concerned about the impact of COVID-19 on organic farmers, farmworkers, businesses, certifiers and inspectors, and consumers. We are mindful of the need to protect the health and safety of all who are involved in organic agriculture, certification, and compliance. We also seek to advocate for responsible actions that will protect the integrity of the USDA organic seal during this difficult time.

The recently enacted CARES Act includes a $9.5 billion emergency fund:

> "to prevent, prepare for, and respond to coronavirus by providing support for agricultural producers impacted by coronavirus, including producers of specialty crops, producers that supply local food systems, including farmers markets, restaurants, and schools, and livestock producers, including dairy producers."

It is critical that organic farmers and others in the organic community are included in the emergency response actions taken by USDA. NOC is asking USDA Secretary Perdue to take the following actions. **We urge the NOSB to also make recommendations to Secretary Perdue to protect organic agriculture during this crisis**.

Support Organic Farmers

- Provide direct payments to farmers, including organic farmers, to keep them solvent during this critical production season in the face of lost or disrupted marketing channels.

- USDA should provide financial assistance for farms setting up virtual platforms to facilitate the sale of their products, as well as "on-farm" stands, curbside pickup, and other direct to consumer "no-touch" distribution channels that minimize interaction.

- Increase organic certification cost-share assistance for certified organic farms and handlers and provide immediate payment to organic operations. Consider making payments directly to organic certification agencies to cover their costs of certifying organic operations so that organic farmers and handlers do not have to bear that cost during these extreme times of market disruption.

- Re-open the 2020 sign-up period for the Dairy Margin Coverage (DMC) Program to allow new participants in the program. Give existing DMC participants the opportunity to reconsider their coverage decisions for 2020 given the extraordinary and unforeseen dairy market collapse related to the pandemic.

Address the Challenges of Organic Certification in the Face of Social Distancing Requirements

- Provide technical and financial assistance to organic operations so they can maintain their certifications during the pandemic by providing required records to certification agencies through virtual platforms. Some organic accredited certification agencies (ACAs) could also benefit from financial assistance to facilitate the adoption of new virtual platforms.

Relax USDA Nutrition Program Rules to Give Low Income Consumers Greater Access to Nutritious Food During the Pandemic

- Allow Supplemental Nutrition Assistance Program (SNAP) payments to be made online directly to farms and CSAs.

- Provide waivers and direction to States to broaden their WIC-approved food lists to allow WIC participants to purchase organic foods.

- Issue an emergency waiver to all States to allow food banks to skip the normal paperwork and recordkeeping requirements for gathering information from each customer. These paperwork procedures are greatly slowing down the food distribution process at already overburdened food banks, making it difficult to maintain social distancing protocols.

- Support the ability of food banks and other emergency feeding programs to purchase organic products directly from farmers at market prices.

Move Critical Rulemaking Forward to Protect Organic Integrity

- The rulemaking to improve organic enforcement, both domestically and internationally, (aka the "strengthening organic enforcement" rule) must move forward without delay.

- The final rule on Origin of Livestock (OOL), to close loopholes with regards to the organic standards related to the transitioning of conventional dairy cows into organic dairy operations, is another critical regulation for the organic sector. USDA must prioritize completing the OOL final rule by June 17, 2020, as mandated by Congress.

Designate Farms, Farmers Markets, Farm Stands, and Community Support Agriculture (CSA) Operations as Essential

As consumers turn more to local sources of food during the pandemic crisis, it is critical that these marketing channels be deemed essential. These marketing venues should be required to institute social distancing protocols, just as retail grocery stores are doing.

The Department of Homeland Security has issued some general recommendations about what should be considered essential industries. Food and agriculture are on that list. However, we are concerned that the DHS advisory does not explicitly include local marketing venues, such as farmers markets, farm stands, and community supported agriculture (CSA) operations. As a result, many local and state governments are shutting down those venues.

- USDA should advocate for a revision to the DHS recommendation and advocate with the President, to urge that the federal declarations of essentiality of all food production and marketing venues be enforced with more rigor.

Assist Farms with Labor Needs and Protect Farmworkers

- Establish a program to provide relief workers for sick farmers and farmworkers.

- In order to ensure uninterrupted food, crop, and commodity production, recognize all H-2A, as well as any other non-immigrant visa petitions involving an agricultural worker, visa consular processing functions as "essential" and direct the U.S. Consulates to treat all agricultural worker appointments as emergency visa services.

- Provide farmworkers who are currently employed on a farm with the same payments as any other workers without questions about their status as citizens, and make farmworkers eligible for paid sick leave, SNAP, health coverage, childcare, and workmen's compensation.

Include Farmers and Agricultural Food Cooperatives in the New Emergency Response Program Administered by the Small Business Administration (SBA)

- The Small Business Administration (SBA) is maintaining that farms and agricultural businesses are ineligible for emergency Economic Injury Disaster Loan (EIDL) programs. They are maintaining that only aquaculture enterprises, agricultural cooperatives, and nurseries are eligible for SBA disaster assistance. It is imperative that farmers be able to access SBA disaster assistance as these programs can help fill the void that many farm businesses are currently feeling due to COVID-19.

- In addition, the SBA should clarify that agricultural cooperatives and consumer food cooperatives are eligible for the Paycheck Protection Program (PPP) during the pandemic emergency. Many of these cooperatives are under a great deal of economic stress as result of the pandemic. Short-term access to the PPP will allow these cooperatives to maintain their staff so that they are able to serve their farmer and consumer owners during the emergency.

Please see the detailed letter submitted on April 2, 2020, to Secretary Perdue by the National Organic Coalition, Organic Farmers Association, and Organic Farming Research Foundation describing our requests in greater detail; attached here as Appendix A.

State of the USDA National Organic Program

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Each year, the National Organic Coalition (NOC) identifies the top priorities that we believe require sustained focus, advocacy, and leadership from the organic community to strengthen the integrity of organic agriculture and the USDA National Organic Program. For 2020, NOC has prioritized advancing organic as a climate change solution, strengthening enforcement of the organic regulations to prevent fraud, and restoring fairness in the organic dairy sector. For each of these areas of work, we would like to share our analysis of the progress made to date, future areas of work, and some thoughts on the role of the NOSB and USDA National Organic Program (NOP) to advance these priorities.

1. Advancing organic as a climate change solution

Healthy soil is the cornerstone of organic agriculture and a critical solution for addressing climate change. The organic law and regulations require that certified organic farms "foster soil fertility, primarily through the management of the organic content of the soil through proper tillage, crop rotation, and manuring." Organic producers are required to "maintain or improve" soil organic matter. The regulations also prohibit the use of synthetic fertilizers and pesticides, which are significant contributors to greenhouse gas (GHG) emissions and can harm soil life.[1]

[1] https://1bps6437gg8c169i0y1drtgz-wpengine.netdna-ssl.com/wp-content/uploads/2019/08/PecticidesSoilHealth_Final-1.pdf

The use of soil-building practices on organic farms helps to sequester carbon and increases resilience, allowing organic systems to tolerate, adapt to, and recover from extreme weather conditions.

NOC is working hard to educate Members of Congress about the role of organic agriculture in fighting climate change, and we have some good science to back us up. For example:

- "The Rodale Farming Systems Trial, which is the longest running organic comparison study in the United States, documented that after 22 years, soil organic carbon increased by 15-28% in organically managed soils compared to 9% in conventionally managed soils."[2]

- Nitrous oxide is a powerful GHG with 310 times the global warming potential of carbon dioxide.[3] An evaluation of organically and conventionally managed soils at UC Davis demonstrates that "conventionally managed soils release 56% more N_2O than organically managed soils."[4]

- According to the Organic Farming Research Foundation, if the standard practices used by organic farmers to maintain and improve soils were implemented globally, it would increase soil organic carbon pools by an estimated 2 billion tons per year – the equivalent of 12% of the total annual GHG emissions worldwide.[5]

- According to a recent policy brief from the National Sustainable Agriculture Coalition, as well as CCOF's summary of the scientific literature, organic systems release fewer GHG emissions and sequester more carbon than conventional no-till grain production systems.[6, 7]

- According to recent research, "confinement- and pasture-raised ruminants emit similar amounts of enteric methane, but their other environmental impacts differ greatly. Advanced grazing systems, particularly management-intensive rotational grazing, have been shown to improve soil, forage, and livestock health dramatically, to reduce water pollution, and to sequester large amounts of carbon. Well-managed grazing systems also mitigate manure-related water impacts and GHG emissions."[8]

NOC has worked with the House Select Committee on the Climate Crisis and Members of Congress to advocate for policy proposals to:

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[2] Benador, L., Damewood, K. & Sooby, J. (2019). *Roadmap to an organic California: Benefits Report*. Santa Cruz, CA: California Certified Organic Farmers (CCOF) Foundation, p. 20.

[3] Schonbeck, M. et al. (2018) Soil Health and Organic Farming, Organic Practices for Climate Mitigation, Adaptation, and Carbon Sequestration, Organic Farming Research Foundation, p. 2. https://ofrf.org/soil-health-and-organic-farming-ecological-approach

[4] Benador, L. et al. (2019), p. 21.

[5] Schonbeck, M. et al. (2018) p. 42.

[6] National Sustainable Agriculture Coalition. 2019. "Agriculture and Climate Change: Policy Imperatives and Opportunities to Help Producers Meet the Challenge." Washington D.C., p. 18.

[7] Benador, L., Damewood, K. & Sooby, J. (2019). Roadmap to an organic California: Benefits Report. Santa Cruz, CA: California Certified Organic Farmers (CCOF) Foundation, p. 21.

[8] National Sustainable Agriculture Coalition. 2019. "Agriculture and Climate Change: Policy Imperatives and Opportunities to Help Producers Meet the Challenge." Washington D.C., p. 49.

1. incentivize the adoption of climate-friendly farming practices and the transition to organic agriculture,

2. increase funding for research and the dissemination of research on effective climate change strategies for the agricultural sector, and

3. bolster public plant and animal breeding efforts so farmers have access to seeds and breeds that are adapted to changing climates and optimize production using climate-smart farming systems.

In February of 2020, NOC endorsed the Agriculture Resilience Act (H.R. 5861), which was introduced by Chellie Pingree (D-ME). This new legislation would increase research and incentivize the adoption of climate-friendly farming practices with the goal of creating a food and farm system that achieves net zero carbon emissions. The bill includes several of NOC's climate action priorities,[9] including providing incentives for farmers to shift to the use of agricultural practices commonly used in organic farming, such as composting, cover cropping, and crop rotations, and increasing the maximum annual organic certification cost share reimbursement from $750 to $1000 per certification scope. In addition, the legislation calls for increased resources and the creation of a strategic plan to develop resource-efficient, stress-tolerant, regionally adapted livestock breeds, and crop cultivars that help build agricultural resilience to climate change.

The House Select Committee on the Climate Crisis has not yet released their recommendations, but NOC is hopeful that these recommendations will include provisions that support a transition to organic and regenerative systems of agriculture, as well as other elements of the policy proposals NOC submitted to the committee in November 2019.

Work that remains in the months and years ahead:
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:

1. The NOSB should restrict the use of 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 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. NOC has included a detailed comment on highly soluble nutrients on page 19.

2. 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. The NOSB should make recommendations about the circumstances under which certifiers should issue noncompliances for operations that fail to

[9] More details about NOC's climate action priorities are available online here: https://www.nationalorganiccoalition.org/blog/2019/12/3/noc-weighs-in-on-the-climate-crisis

adhere to the soil fertility and crop nutrient management practice standard (§205.203) and other requirements in the organic regulations related to soil health. 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.

3. The 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 implement the Organic Livestock & Poultry Practices rule, which was withdrawn by the current administration in 2018. NOC is a plaintiff in a lawsuit, led by Center for Food Safety, challenging the withdrawal of this regulation. [10]

4. 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 for 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 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 finalize regulations on standards that eliminate incentives to convert native ecosystems.

2. Strengthening enforcement of the organic regulations to prevent fraud

As a result of our collective advocacy, the NOP is better resourced and has new authorities to combat fraud. The Farm Bill, which passed in December of 2018, authorized $5 million in one-time mandatory funding for a new import tracking system and improvements to the USDA Organic Integrity Database. We anticipate that the NOP will be piloting this new import tracking system soon.

The Farm Bill also provided for the creation of a new organic imports interagency working group between the USDA and Customs and Border Protection (CBP) and required rulemaking to address gaps we have in the organic certification system to require more operations to become certified.

Through the annual appropriations process, NOC and other advocates have succeeded in boosting funding for the National Organic Program. The Fiscal Year 2020 spending legislation that passed on December 20, 2019, included a $2 million increase for the NOP up to $16 million from last year's annual funding level of $14 million. NOC has been pushing for these increases to ensure that the NOP has the necessary resources and staff capacity to effectively enforce the organic regulations and prevent organic fraud. Steady increases in funding over a period of several years have allowed the NOP to hire more staff, which has been critical to increasing oversight and enforcement activities domestically and with international supply chains. In 2020, NOP is intending to increase their staff team from around 45 individuals to more than 60.

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

NOC has been encouraged to see the NOP take the following enforcement actions:

- Over 200 operations in Black Sea region have surrendered their certificates; 100,000 acres in production have been suspended according to NOP public statements.
- The Turkey office of Control Union was suspended in May 2019; after that suspension, some operations exited; some were denied certification by other certifiers.
- In addition, approximately 10% of domestic certifiers now have compliance actions with the NOP according to NOP public statements. The NOP website includes information about settlement agreements and notices of suspension or revocation by the NOP. In 2019, the NOP entered into settlement agreements, revocations, or suspensions of accreditation with the following certification agencies: Control Union Turkey Office, Texas Department of Agriculture, EcoCert ICO, Organic Food and Certification Development Centre of China (OFDC), SRS Certification GmbH, Boliviana de Certificacion, Basin and Range Organics (BARO).

Work that remains in the months and years ahead:

Although NOC believes progress has been made in garnering increased resources and authority to address fraud, NOC is dismayed that we are still waiting for the Strengthening Organic Enforcement proposed rule to come forward. It is much delayed, as Congress gave USDA the deadline of Dec 20, 2019. Once published, this new regulation will have a 60-day comment period. Organic stakeholder groups should comment on the proposed rule and ensure that the following key provisions are included:

- The Farm Bill provided USDA with the authority to require import certificates for all imports. The SOE proposed rule should require that all imported organic products carry an electronic import certificate, to help prevent fraudulent labeling of conventional product as organic.
- The SOE should close loopholes in supply chain traceability by requiring additional handlers and brokers to become certified, as required by the 2018 Farm Bill.
- The SOE should require more frequent unannounced inspections for operations and regions where increased risk has been identified, both domestically as well as internationally.
- The SOE should strengthen the training requirements and qualifications for inspectors and require robust mass balance and trace back audits for regions and supply chains that have been flagged for increased risk of fraud.
- The SOE should make product and acreage reporting mandatory for certifiers. A sound and sensible approach should be used to ensure that certifiers working with small, diversified producers, can capture data in a reasonable way. AMS must establish meaningful crop categories, ideally ones that are harmonized with the NASS codes used in the 2014 and 2015 Organic Certifiers Surveys that NASS conducted. Accredited Certifying Agents (ACAs) should be required to report aggregated production area certified by crop and location at least on an annual basis to the Organic Integrity Database (OID), and should be required to update the OID within 72 hours when an operation surrenders its certificate or its certificate is suspended or revoked.

- The SOE should implement NOSB recommendations on grower groups to better ensure these recommendations can be enforced.

- The SOE should require that information about operations is communicated across certifiers so operations are not able to switch certifiers in an effort to evade detection of fraudulent activity.

NOC is also dismayed that recent import data from the USDA's Foreign Agriculture Service shows that imports of corn from Turkey are back up in 2018 (613,203 metric tons) and 2019 (more than 532,000 metric tons), after a drop in volume to 370,500 metric tons in 2017 following the 2016 surge. In 2019, Turkey accounted for 73% of total U.S. imported volume of organic corn. We are concerned that some of these imports may be fraudulent.

The NOSB and NOP must take further actions to strengthen enforcement.

NOC is asking that the NOP:

- **Subject certifiers' foreign satellite offices to greater scrutiny**. The executive summary from the 2018 American National Standards Institute (ANSI) Peer Review Panel Report determined that "satellite offices of certifiers, especially international locations, are not audited on a frequent enough basis to reduce risk and prevent potential fraud."

- **Conduct more frequent audits:** The NOP should conduct more frequent audits, both unannounced and regular audits, in specific geographic areas where risk has been identified, such as Eastern European countries, or Texas/California as recommended in the executive summary from the 2018 American National Standards Institute (ANSI) Peer Review Panel Report.

- **Strengthen communication with foreign governments**: The NOP should strengthen communication procedures with the European Union, Canada, and other governments with whom we have organic equivalency arrangements to flag fraudulent activity.

- **Adopt criteria for risk-based accreditation oversight**: The NOP should adopt criteria for risk-based accreditation oversight based on the NOSB recommendation on this topic from October 2018. For example, the NOP should give additional scrutiny to a certifier whose accreditation has been revoked by a nation with which the U.S. has an organic equivalency arrangement and should work closely with other accreditation bodies operating in the region where fraud has been found.

- **Use a data-driven approach to fraud detection**: The NOP should implement a policy to conduct an automatic investigation whenever there is a significant surge in imports for a specific product to determine if fraudulent activity is contributing to that increase.

- **Leverage additional resources & ideas**: The NOP should identify other industries/products that have a longer history of dealing with fraud and learn from the measures they took and their outcomes. NOP should continue to work to leverage the resources of other USDA departments and other federal agencies to include them in the effort to deter fraud in organic supply chains.

- **Make peer review audits public:** NOC has repeatedly requested that the NOP release the 2018 peer review panel report in full, and we urge the NOSB to join us in requesting that the results of this and future reports be made accessible to the NOSB and public stakeholders.

NOC is asking the NOSB to:

- **Review and analyze peer review audits**: The NOSB should review the 2019 and 2018 peer review audits, which provide information about strengths and weaknesses in the NOP's accreditation process. We believe the NOSB should demand access to the full results of these audits, flag areas where further improvements are needed in the NOP accreditation system, and assess progress made towards addressing areas of concern. For example, the 2018 peer review audit determined that the NOP does not have a sufficient number of auditors to oversee its accreditation functions. NOC believes the NOSB should use the results from subsequent peer review audits to assess if the NOP has sufficiently addressed this area of weakness and to highlight issues that have emerged from peer review audits that require further action. NOC submitted more detailed comments on the 2018 peer review audit in the fall of 2019, and we have attached those comments in Appendix B.

- **Track progress made by the USDA-CBP interagency working group:** The CACS should ask for regular updates from the NOP regarding the progress made through the Organic Imports Interagency Working Group, as well as an account of the measures that the USDA Agricultural Marketing Service is taking to ensure that imports fumigated with prohibited substances are not sold as organic.

Ask the NOP to explain its risk-based approach to accreditation: The NOSB should ask the NOP to explain in regular updates how the NOP's accreditation and enforcement activities reflect a risk-based approach, based on the NOSB recommendation from 2018.

- **Ask the NOP to explain how increased funding is being used to address fraud and strengthen accreditation, enforcement, and oversight activities at the NOP.**

- **Identify additional actions that are needed.** In partnership with the organic community, determine additional actions beyond the provisions in the 2018 Farm Bill and the Strengthening Organic Enforcement regulation that are necessary to minimize fraud in the organic supply chain.

NOC believes the organic community must consider whether further measures are necessary to stem fraud, including the following steps:

1. Currently, the U.S. government only tracks the value and quantity of a limited number of organic import product categories based on the limited number of codes in the harmonized tariff schedule. More complete data on organic imports is essential in order to flag areas of risk.

2. The USDA-CBP working group should assess whether new legislation is needed to improve the ability to track organic imports. For example, can CBP currently require bills of lading for incoming shipments to include more detailed information about the contents of the shipment to give the

ports of entry information that would be useful in the inspection process, or would additional legislative authority be needed to implement such a requirement?

Summary: New resources and authorities are helping the NOP to strengthen systems to prevent fraud, but the NOSB, NOP, and organic community must continue work to stem fraudulent activity. NOC is requesting that the CACS review and analyze 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 to identify gaps that require further action.

3. Restore fairness in the organic dairy sector

In 2019, NOC worked with NOC members, organic dairy producers, and partner organizations to get rulemaking on Origin of Livestock back on the regulatory agenda. The NOSB weighed in on this issue with a resolution in the Fall of 2018 urging the USDA to issue a final rule for Origin of Livestock.[11] A proposed regulation had been put forward in 2015 to close a loophole that has allowed the continuous transition of conventional animals into organic dairy herds. But that regulation was never finalized and was then completely dropped from the regulatory agenda in 2018. Closing this loophole is a top priority for NOC because it has contributed to a lack of fairness and low prices for the many organic dairy producers who are following the letter and spirit of the organic regulations.

NOC waged a campaign in 2019 to urge action on Origin of Livestock and worked with partners to lobby Congress to pass legislation requiring that USDA issue a final regulation on Origin of Livestock by June 17, 2020. USDA reopened the 2015 regulation for public comment again in the fall of 2019 and is now working to incorporate public comments from 2015 and 2019 to finalize the regulation. NOC is hopeful that the regulation will be finalized by the June deadline set by Congress, and we urge the NOP, USDA, and Office of Management and Budget to act swiftly to finalize this long overdue regulation.

As mentioned above, NOC is encouraged that we have successfully advocated to increase resources for the USDA National Organic Program. Some of these funds have been used to roll out the USDA's Dairy Compliance project and to hire two livestock compliance specialists at the NOP in 2019. The USDA has been conducting unannounced inspections and investigations of high-risk livestock operations and these investigations have generated non-compliances and enforcement actions. For example, the Texas Department of Agriculture is no longer able to accept any new livestock clients and must conduct at least one unannounced inspection of each of its livestock operations by the end of April 2020, as the result of a settlement agreement with the NOP from August 2019.[12]

The NOP must adequately enforce the pasture rule. NOC is continuing to track this issue. We appreciate that the NOP has made a training on Organic Dairy Compliance available through the Organic Integrity Learning Center to provide additional training to certifiers and inspectors.

Work that remains in the months and years ahead:
In 2020, NOC will continue to push for finalization and implementation of new Origin of Livestock regulations to ensure that dairy operations are not able to continuously transition conventional dairy livestock into organic herds or to cycle dairy animals in and out of organic production. NOC will also assess

[11] https://www.ams.usda.gov/sites/default/files/media/OOLResolution.pdf
[12] https://www.ams.usda.gov/services/enforcement/organic/settlements-2019

with partners the impact of the NOP's Dairy Compliance Project, as well as NOP efforts to ensure that the pasture rule is being adequately enforced. The NOSB should request full transparency and updates regarding the outcomes from the Dairy Compliance Project. It is imperative that bad actors in the dairy sector and their certifying agents are brought into compliance or are excluded from the program.

Summary: The NOP should issue a final rule on Origin of Livestock and continue enforcement activities to ensure that the pasture rule and other requirements are adequately enforced, especially for high risk organic dairy operations and certifiers who do not adequately enforce the standards.

Additional priority work for the NOSB

In addition to these top three areas of priority for NOC, we are requesting that the NOSB make progress in several other key areas:

Prohibitions against genetic engineering in organic

The NOSB should defend against the inclusion of genetic engineering (GE) in organic agriculture, including new GE technologies. The NOSB must uphold the definitions and framework that was put in place by the NOSB in 2016. There are also 6 new GE techniques that the NOSB has identified for review, and we urge the NOSB to make progress as swiftly as possible to move this work forward. **The NOSB should urge the NOP to codify the prohibitions in organic for new genetic engineering techniques by publishing a guidance document in the NOP handbook to ensure clarity for all stakeholder groups.** NOC has provided a more detailed comment on this topic on page 57.

Hydroponics and Container Production

There is a lack of consistency from one certifier to the next regarding which practices are allowed in organic for hydroponic and container systems. 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 ask the NOP to provide that clarity so that all certifiers and organic operations are held to the same standard.**

Hydroponic systems and many container systems are inconsistent with both the foundational principles of organic farming and the certification requirements of the National Organic Program as set forth in OFPA, especially with regards to soil fertility. Fostering soil fertility is not optional, and any allowed practices that cannot meet this mandatory requirement are inconsistent with OFPA. The continued allowance of hydroponic systems is also in opposition to the 2010 NOSB consensus recommendation and the separate OFPA mandate that development of the organic program be done in consultation with the NOSB.[13] The NOP's policy on hydroponic and container systems should be guided by NOSB recommendations.

For these reasons, the Center for Food Safety, a NOC member organization, along with a coalition of organic farms and stakeholders, filed a lawsuit in March 2020 challenging the United States Department of Agriculture's (USDA's) decision to allow hydroponic operations to be certified organic. The lawsuit asks the Court to stop USDA from allowing hydroponically produced crops to be sold under the USDA Organic label.[14]

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[13] 7 U.S.C. § 6503(c) (OFPA §6503 (c) ("In developing the program under subsection (a), and the National List under section 6517 of this title, the Secretary shall consult with the National Organic Standards Board established under section 6518 of this title.")

[14] https://www.centerforfoodsafety.org/press-releases/5941/farmers-and-nonprofits-sue-trumps-usda-over-organic-soil-less-loophole

Racial Equity
We recognize that access to the organic movement and 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 represents diverse participation. NOC encourages the NOSB to prioritize research into barriers to participation in organic certification for farmers of color and technical assistance needs for these communities.

In addition, 2012 and 2017 Ag Census data shows that people of color are underrepresented in farming overall, including organic farming. For example, while the black/African American population is above 13%, fewer than 2% of all farms in the U.S. are owned by blacks/African Americans. The percent of farms with organic sales owned by blacks/African Americans is even lower.[15, 16] **According to 2017 ag census data, there are more than 100,000 farming operations owned by native American and black farmers in the US, but fewer than 300 are certified organic.** There is a need for research into the barriers to participation in organic certification for farmers of color as well as technical assistance or other policy solutions to overcome those barriers. While we are aware that there are individuals within our community who do not believe that the work of racial equity is central or necessary to the work of the organic community, we heartily disagree. The organic principles are built on the foundation of not only the letter of the law, but the spirit of the law.

The contributions made by people of color to organic and sustainable food systems are vast and often go unacknowledged. Attached in Appendix C 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, with resources collected with the help of many individuals and organizations.

We encourage those who create a statement or want to be more involved in our work to reach out to us. Further, we encourage the NOSB to begin to explore ways to encourage the NOP and organic stakeholders to expand their work and resources to further address this issue.

We would also note that we are disappointed by the fact that the NOP Documents and Resources Available in Spanish page provides a link to the USDA Regulations in Spanish that does not actually provide a copy of the regulations in Spanish, but rather links to the regulations in English.[17] We believe creating an inclusive movement requires that we make materials available in other languages. We understand that different certifiers, such as CCOF, have translated the regulations into Spanish, and would suggest that the NOP purchase the translated materials to be published 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.

Inert Ingredients Allowed in organic production
There continues to be an unconscionable delay in implementing existing NOSB recommendations for replacing the obsolete references to EPA List 3 and List 4 "inert" ingredients on the National List with listings of actual approved non-active ingredients in pesticide products. The board voted unanimously in

[15] 2012 Census of Agriculture: Characteristics of All Farms and Farms with Organic Sales, September 2014, United States Department of Agriculture, National Agricultural Statistical Service, pg.5. https://www.nass.usda.gov/Publications/AgCensus/2012/Online_Resources/Special_Organics_Tabulation/organictab.pdf
[16] https://www.nass.usda.gov/Publications/AgCensus/2017/Online_Resources/Organics_Tabulation/organictab.pdf
[17] NOP Documents and Resources Available in Spanish, https://www.ams.usda.gov/sites/default/files/media/NOPDocumentsandResourcesAvailableinSpanish.pdf

2012 to begin a review process of "inert" ingredients, identified the "inerts" requiring review, and established a measured process of review over 5 years. "Inert" ingredients frequently compose as much as 99% of pesticide products, and due to NOSB scrutiny of active ingredients, they may be the most hazardous ingredients in pesticide products used in organic production. In these comments, we suggest a process for moving forward.

The NOSB should not delay in evaluating nonylphenol ethoxylates (NPEs).

We urge the NOSB to insist that NOP move forward quickly with implementation of the NOSB recommendations on "inert" ingredients, beginning with the MOU between USDA and EPA that establishes the responsibilities of NOP, EPA, and the NOSB. This process is laid out in detail in our crops comments on page 31.

Compliance, Accreditation, Certification Subcommittee (CACS)

CACS Work Agenda

As recently as July 16, 2019, the CACS requested to work on the topic of inconsistencies between certifiers.[18] 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 anticipated 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 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 to identify gaps that require further action.

Crops Subcommittee (CS)

Other

Hydroponics, Container Production, and Lack of Clarity about Three-Year Transition Period

The NOP's allowance of hydroponic and container systems is not consistent with the Organic Food Production Act (OFPA) and NOSB recommendations.

The NOP has allowed for the certification of both hydroponic and container systems. This NOP interpretation runs counter to the 2010 NOSB recommendation on hydroponic production[19] and a subsequent resolution from the NOSB in 2016,[20] as well as early attempts by the NOSB to develop greenhouse standards[21] where hydroponic production was rejected as an organic production method.

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

[19] https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20Production%20Standards%20for%20Terrestrial%20Plants.pdf

[20] https://www.ams.usda.gov/sites/default/files/media/CSHydroponicsResolution.pdf

[21] https://www.ams.usda.gov/sites/default/files/media/Recommended%20Greenhouse%20Standards.pdf

While the NOP has argued that hydroponic and container systems are allowed because they have not explicitly been prohibited, NOC disagrees with this interpretation of the Organic Foods Production Act (OFPA) and its requirements.

Section 6512's mandate to allow production and handling practices not otherwise prohibited comes with a critical caveat: "unless it is determined that such practice would be inconsistent with the applicable organic certification program."[22]

Hydroponic systems and many container systems are inconsistent with both the foundational principles of organic farming and the certification requirements of the National Organic Program as set forth in OFPA, especially with regards to soil fertility. As a foundational organic principle, organic farmers steward soil ecology on the farm, including the myriad organisms that support thriving soil ecosystems. OFPA embodies this principle and the vision of ecosystem complexity that is contrary to using bags of approved nutrients to feed crops as a basis for organic certification.

OFPA established a strong framework that mandates integration of this soil-stewardship principle by including the following provision:

> **OFPA §6513(b) An organic plan shall contain provisions designed to foster soil fertility, primarily through the management of the organic content of the soil through proper tillage, crop rotation, and manuring.[23]**

Fostering soil fertility through the specified means is not optional and any allowed practices that cannot meet this mandatory requirement are inconsistent with OFPA. The continued allowance of hydroponic systems is also in opposition to the 2010 NOSB consensus recommendation and the separate OFPA mandate that the organic program be developed in consultation with the NOSB.[24] The NOP's policy on hydroponic and container systems should be guided by NOSB recommendations.

The Center for Food Safety, a NOC member organization, along with a coalition of organic farms and stakeholders, has filed a lawsuit challenging the USDA's decision to allow hydroponic operations to be certified organic. The lawsuit asks the Court to stop USDA from allowing hydroponically produced crops to be sold under the USDA Organic label.[25]

NOP Must Clarify Policy on the 3-Year Transition Period for Greenhouses and Facilities Producing Organic Crops

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.[26] 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

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[22] 7 U.S.C. § 6512.

[23] 7 U.S.C. § 6513(b); see also §§ 6512 and 6513(a)(1).

[24] 7 U.S.C. § 6503(c) (OFPA §6503 (c) ("In developing the program under subsection (a), and the National List under section 6517 of this title, the Secretary shall consult with the National Organic Standards Board established under section 6518 of this title.")

[25] https://www.centerforfoodsafety.org/press-releases/5941/farmers-and-nonprofits-sue-trumps-usda-over-organic-soil-less-loophole

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

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.

Within the organic community, however, this memo left a lack of clarity regarding how it applies to crop production in greenhouses and facilities.

The memo documented the OFPA definition of a farm, Section 6502, as "a farm, or portion of a farm, or site where agricultural products or livestock are produced." The memo tied that section to USDA implementation of OFPA Section 6504 through USDA organic regulations on these requirements at 7 CFR 205.202, stating that "'any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as "organic," must… have had no prohibited substances, as listed in §205.105, applied to it for a period of 3 years immediately preceding harvest of the crop.' This requirement is referred to as the three-year transition period."

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. This lack of clarity was noted in numerous public testimonies and written comments at the Fall 2019 National Organic Standards Board meeting in Pittsburgh, Pennsylvania.

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. Yet, we must, as an 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 for greenhouse production is inhibiting the National Organic Program's ability to provide consistent and fair enforcement, leaving our nation's organic standards unfair and inconsistent.

The strong public-private partnership between USDA and the organic industry has created a foundation that has allowed the industry to grow into a $50 billion market. This provides economic opportunities for U.S. farmers and businesses and produces one of the most highly trusted labels by consumers.

The NOSB should urge the NOP to move quickly to clarify that the June 3, 2019, memo includes crop production in greenhouses and facilities under the definition of "farm," and thus the requirement for a three-year transition after the application of a prohibited substance. If the memo does not include crop production in greenhouses and facilities, the NOP must provide clarity for accredited certification bodies so that all organic operations are being held to the same standards.

Inconsistencies in certification weaken the organic label; consistency should be achieved through rulemaking.

NOC finds the differing implementation of the NOP standards by certifiers for hydroponic and container systems disturbing and evidence of why drafters of OFPA required production and processing methods to

be vetted with a critical eye towards organic program consistency. The issues of inconsistent certification that remain even after the June 3 memo was issued are only a few of many that weaken the organic label, and reflect poorly on the industry.

For this reason, we believe that additional clarifications regarding hydroponic and container systems should be conducted through rulemaking, based on recommendations from the NOSB, and vetted through the public comment process. These clarifications must be made in order to ensure consistency and integrity in the organic program and compliance with OFPA.

Highly Soluble Nutrients

OFPA embodies a vision of ecosystem complexity as a basis for organic certification that is contrary to using "bags of nutrients" to feed crops. 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."

The NOP followed OFPA and the original certifiers' insistence on soil management when they wrote the organic regulations. Key provisions in the organic regulations include:

- 7 CFR § 205.105 prohibits the use of synthetic substances, including synthetic fertilizers.

- 7 CFR § 205.203 requires that producers implement tillage and cultivation practices that maintain or improve soil health and that producers manage soil health using crop rotations, cover crops, and plant and animal manures. Producers are also required to "maintain or improve" soil organic matter. This section of the regulations leaves no room for exceptions. Sections 205.203 (a), (b), and (c) say that the producer must improve the soil, must manage crop nutrients and soil fertility through rotations, cover crops and application of plant and animal materials, and that the producer must manage plant and animal materials to maintain or improve soil organic matter. In other words, the organic regulations require that the organic production system be based on "feeding the soil, not the plant."

- 7 CFR § 205.205 requires farmers to implement crop rotations to improve soils, prevent erosion, and to manage nutrient levels and pests.

Compliance with these provisions is verified through annual inspections and review by a third-party certification agency.

Substances of high solubility are allowed, but regulated.

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, have always been allowed. However, these materials are counter to foundational organic principles, so they have always been regulated. The early certification agencies allowed them but limited their use. OFPA leaves a place for them, but still requires that soil management be the heart of organic production. Additionally, the USDA National Organic Program did a good job in crafting organic regulations that allow substances of high solubility, but limit their use to essentially "rescue treatments" of a soil that otherwise is managed by methods consistent with organic principles. The NOP wisely put such materials into 7 CFR § 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 organic regulations limit substances of high solubility.

There is a preamble to the publication of the NOP Final Rule on December 21, 2000. In the preamble, the NOP discusses how they 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.

The 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, but that is because there were not any concentrated, highly soluble plant nutrient materials other than mined sources available at that time. New materials of high solubility that are now used similarly miss the aim of organic production systems, and should be regulated in the same way mined sources are. These highly soluble materials, most of which are non-synthetic, do not appear on the National List and are used in both soil-based production, as well as in some hydroponic and container systems.

In other words, concentrated, highly soluble sources of plant nutrients should not be prohibited altogether. Instead, they should be regulated by being added to 7 CFR § 205.602 so as to not allow organic producers to stray from the foundational principle of organic production, i.e. “feed the soil, not the plant.” One way to do this would be to add these substances to the list of prohibited naturals with annotations that limit their use to no more than 20% of the crop's total nutritional need. In order to simplify the work of certifiers, we suggest that nitrogen fertilizers be used as an indicator. For example, the following could be added to 205.602, "Highly soluble sources of nitrogen – unless use is restricted to no more than 20% of the crop's total annual nitrogen requirement.”

Conclusion

The organic community must take further steps to ensure that organic continues to rest on the foundation of “feed the soil, not the plant.” Giving further scrutiny to the use of highly soluble nutrients in organic would help to ensure that soil-building and carbon sequestration processes on organic farms are the heart of organic production and that this foundation is not short-circuited through the use of fast-acting highly soluble nutrients.

To this end, NOC recommends the NOSB add an item to its work agenda that focuses on identifying and strengthening organic practices for climate mitigation, adaptation, and carbon sequestration. Included in this agenda item should be an evaluation of highly soluble nutrients and container production practices through this lens. 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.

Petitions / Vote

Paper Pots

Petitioned to the National List: §205.601(o) production aids- Plant pot or growing container- hemp or other paper, without glossy or colored inks.

NOC is supportive of the work done by the Crops Subcommittee on paper pots. We are pleased that there is a differentiation being made between paper materials used with the intent of degrading in the soil versus paper materials that are intended to be removed after use, and we support the proposed definition of a "planting aid" as put forward in the published materials:

> Add to 205.2 Terms Defined: *Paper-based crop planting aid*. A material that is comprised primarily of cellulose-based paper, including pots, seed tape, and collars that are placed in or on the soil and are intended to degrade into the soil. Contains no less than 85% biobased content with biobased content determined using ASTM D6866 (incorporated by reference; see §205.3).

We understand the reasoning behind not including a biodegradability standard in the proposal due to the time and cost needed for testing to that standard. To further address these concerns, we suggest that producers using these products must document in their Organic System Plan how their site-specific conditions are conducive to the full degradability of the product at the end of the growing season. An annotation to this point was included in the listing recommendation for biodegradable biobased mulch film in 2012, though it was not included in the NOP's listing.

Ideally, adhesives and synthetic fibers would be reviewed and listed separately on 205.601 as allowed synthetics. We understand that at the current time 85% biobased and 15% synthetic fibers is the lowest synthetic content that is currently commercially available in both single pots and paper chain pots. While we appreciate having an annotation that represents the market's current reality, we strongly urge the Board to keep at the fore the goal of moving towards 100% biobased content in future sunset reviews, and suggest below a way to achieve this.

Although it is cumbersome to spell out which specific additives will be allowed, we remind the board that failing to do so at the beginning can lead to being overwhelmed later on, as with "inert" ingredients and ancillary substances. We favor making specific recommendations about the allowed reinforcing fibers and adhesives that can be changed as technology improves—rather than remaining vague and hence opening the door to possible undesirable additives.

NOC is generally supportive of the proposed annotation, as put forward in the published materials:

> Add to 205.601(o) Production Aids: Paper-based crop planting aids as defined in 205.2. Virgin or recycled paper without colored or glossy inks. If these paper-based crop planting aids are commercially available with 100% biobased fiber content, these must be used.

We provide the following thoughts on the goal of moving towards 100% biobased fiber content in the future, and we request the following be included in the final proposal to ensure future Board review:

- Only nonsynthetic reinforcing fibers should be allowed. At each future sunset, a review of the progress towards nonsynthetic reinforcement fibers should be assessed towards the goal of 100% nonsynthetic reinforced fibers. The NOSB should require that the 15% allowance for non-biobased components be revisited during sunset, stepping down the allowance by 5% every sunset until a goal of 100% biobased fiber content is achieved.

- The examination of adhesives needs to address biodegradability, and the annotation should allow only those that biodegrade completely to nontoxic byproducts.

Discussion Documents

Wild, Native Fish for Liquid Fish Products

205.601(j)(7)

205.601(j) As plant or soil amendments (7) Liquid fish products —can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

NOC supports the purpose of this work agenda item, as outlined in the Discussion Document, "to assess the impact of harvesting wild, native fish for fertilizer and to ensure that liquid fish and other fish-based fertilizer products used in organic production are not harmful to the environment." Harvesting wild-caught fish for the exclusive use of fertilizer is a misuse of a resource from the ocean and should not be supported by organic production. Our comments will focus on the questions put forth by the subcommittee.

Spring 2020 Discussion Questions:

1) **Given the results of the TR indicating that there are no species of wild, native fish harvested exclusively for use in LFPs, please provide feedback on any next steps the subcommittee should take on this issue.**

We consider the results of the TR indicating there are no species of wild, native fish harvested exclusively for use in LFPs to be questionable, specifically given the information provided by OMRI during Spring 2018:

> "As of March 29, 2018, the OMRI Products List contains 110 fish fertilizer products listed in the categories "Fish Products," "Fish Products, Liquid-stabilized," "Fish Products, multi-ingredient," or "Fish Meal and Powder" in the class "Crop Fertilizers and Soil Amendments." These products represent various OMRI Listed fish fertilizers, including both liquid and dry formulations, and stabilized and un-stabilized formulations. This information is not limited only to products that are permitted under §205.601(j) because the concerns about environmental impact from sourcing fish for fertilizers is relevant to all forms of fish fertilizers, including nonsynthetic forms.
>
> Of the 110 OMRI Listed fish fertilizer products,
> - 2 are derived exclusively from farmed sources
> - 70 are derived exclusively from wild sources
> - 38 are derived from a combination of wild, farmed, and/or unknown sources."

Further noting:

> "Of the OMRI Listed fish fertilizer products that utilize only wild sources of fish,
> - 39 are derived exclusively from waste from processing of wild market fish.
> - 30 are derived exclusively from whole fish solely harvested for fertilizer. Species include sardine species (*Sardinops caeruleus* or *Sardinella longiceps*), menhaden species (*Brevoortia patronus* or *B. tyrannus*), *Opisthonema libertate, Etrumeus teres, Cetengraulis mysticetus,* tuna, salmon, finfish, skate, and/or other unknown species.
> - 1 is derived from a combination of waste from processing of wild market fish and from whole fish solely harvested for fertilizer.

- None are derived from by-catch.[27]"

Have these 30 products that utilize only wild sources of fish "derived exclusively from whole fish solely harvested for fertilizer" changed their sources so dramatically in two years since March 29, 2018? We realize that OMRI co-authored the TR and would be interested in hearing more from them and other MROs on this topic.

2) **The TR outlines the wet reduction process for fish meal, oil, and solubles and states that solubles are a byproduct of meal (solid phase) and oil (liquid phase) production. Because of the multiple products derived, it did not consider fertilizers using them to be from fish harvested exclusively for fertilizer. Please comment.**

NOC considers this to be a misleading statement and a rationalization.

3) **Please provide any additional information you may have to help answer the TR questions, particularly:**
   - **During the Spring 2018 public meeting, the Crops Subcommittee asked if there are manufacturers using exclusively wild-caught, native fish to manufacture liquid fish fertilizers and learned that there are. Public testimony suggested that other non-synthetic fish-based fertilizers, such as fishmeal, may also be derived from wild fish harvested solely for fertilizer production. Is any new information available about the impact of fish fertilizer manufacturing on the sustainability and health of wild, native fish stocks harvested solely for fertilizer production?**
   - **Do different methods, locations, and/or frequencies of harvest pose different levels of risk for wild, native stocks?**
   - **Please provide examples of non-regulatory/practice-based approaches (e.g. training, guidance) that should be considered.**

In addition to our comments above, we will address the statement in the published materials that notes:

> "We explored the merits of an annotation to Section 205.601(j)(8) prohibiting the use of wild, native fish harvested solely for the manufacture of those materials, as well as listing wild, native fish harvested solely for fertilizer on Section 205.602. Ultimately, the subcommittee agreed that a prohibition on 205.602 alone would suffice as it would cover any products on 205.601(j)(8). There is no intention to exclude the use of farmed fish or invasive species that are harvested to protect native ecosystems."

While we approve of the concept, there are several issues that need to be addressed.

The first being, will it work? The 602 listing says, "May not be used in organic crop production," but does not say anything about use in synthetic products used in organic crop production. Would the listing on 602

[27] OMRI Spring 2018 NOSB Comments, https://www.regulations.gov/document?D=AMS-NOP-17-0057-1433.

preclude any percentage of wild native fish, or does it have to be 100% wild native fish to be prohibited? Can wild native fish be used as ingredients in other products, if it is not the main ingredient?

The second issue needing addressed, and our main concern, is that a targeted prohibition against the use of wild, native fish is unenforceable.

The most attractive option is the use of "invasive" species to process into fish products. While we recognize that this idea has merit, there are unintended consequences that must be considered.

Careful consideration needs to be given to the fact that a species that is "invasive" in one place is native to someplace else. Asian carp species – probably what most people think of when they think of an "invasive fish" – are native to Asia and are considered vulnerable to extinction in the wild, but a pest in many other places. How do we know where that carp might have been caught?

Rainbow trout is native to the western U.S., but when introduced elsewhere, outcompetes native species and may carry disease. Largemouth bass and other species popular among anglers can cause problems where they have been stocked for sport fishing. The enforcement issue is how to distinguish fish where they are considered "invasive" from the same fish where they are native or purposely introduced.

Bycatch is also a problem with "invasive" fish, as with wild, native fish.

Some may suggest farmed fish; however, farmed fish do not solve the problem. Aquaculture regulations have not been adopted, so farmed fish are not organic. According to the 2019 TR, "Formulated feeds for herbivorous and omnivorous fish can contain soybean, cottonseed, and peanut meals as well as protein obtained from fish and terrestrial animals. Formulated feeds for carnivorous fish are composed of large proportions of fish meal and fish oil, which include the essential amino acids lysine and methionine."[28] Therefore, use of farmed fish does not remove the pressure on wild fish and additionally adds contaminants, including pesticides and their metabolites, that occur in the nonorganically raised feeds.

In addition, farmed fish are routinely treated with antibiotics, leading to high residues in fish and antibiotic resistance genes in the fish and the water.

Finally, a targeted prohibition against wild, native fish in liquid fish fertilizer products does not protect the marine environment. The TR makes contradictory statements. On one hand, it seems to suggest that because fish are not harvested solely for fertilizer, the use as fertilizer really doesn't matter, while on the other hand stating, "Regardless of the intended use, harvesting wild, native fish can contribute to biodiversity loss, habitat destruction, and loss of ecosystem services."[29] Further, the TR states:

> While none of the fish species known to be harvested for fish reduction purposes and which are incorporated into fish-based fertilizer products are threatened or endangered species (see Table 2), their 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

[28] 2019 TR, lines 601-604.
[29] 2019 TR, Lines 327-328

(*Cetengraulis mysticetus*) are critical links in the Gulf of California, transferring energy through the food web and controlling the organization of these ecosystems.[30]

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.

Harvesting wild-caught fish for the exclusive use of fertilizer is a misuse of a resource from the ocean and should not be supported by organic production. Fish fertilizer should be allowed from waste products only—and only if this requirement is enforceable.

Biodegradable biobased mulch film

205.601

NOC acknowledges that a biodegradable biobased mulch (BBM) film would be a great asset to producers; however, we harbor great concerns regarding the agronomic, environmental, and health effects of the breakdown. NOC appreciates the detailed questions posed by the Crops Subcommittee.

Questions put forth by the Crops Subcommittee:

1. **Is the biodegradability of the mulch film the main issue, or should a future annotation include other issues?**

While the biodegradability of the mulch film is one of the main issues, it is not the only issue that needs to be addressed. We address several additional items here, although we in no way believe this to be an exhaustive review of all that needs to be considered.

Biodegradability must be considered in a very broad way.

Biodegradability must be shown across many regions, soil types, and climate types. We offer further thoughts on this topic below.

We feel that 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.[31]

We feel that regulation of BBM should not only be reviewed and specific materials listed by MROs, but also see a need for verification by certifiers 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 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.

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[30] 2019 TR, Lines 342-349

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

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"[32] 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.

To be clear, both biobased and biodegradability are equally important. In organic agriculture, the origins of materials are important, as well as what happens to them in the ground.

Synthetic substances are allowed as per 205.601, provided 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 since it replaces plastic mulches that are currently removed at the end of the harvest season and end up in landfills that do not breakdown for decades if not centuries. The biodegradable mulches from petroleum-based polymers save labor and time, since the mulch does not have to be removed from the field and transported for disposal."[33]

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 you do not even try to remove from the field. While synthetic substances are allowed as per §205.601 provided 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, potentially contaminating crops, soil, and/or water.

> 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.[34]

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

[32] "Biodegradable Biobased Mulch Film" Memorandum to the National Organic Standards Board from Jennifer Tucker, Ph.D., October 16, 2019.

[33] NOSB April 2020 proposals and discussion documents Page 14 of 115.

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

> 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)."[35]

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?

"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."[36]

> 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).[37]

"Currently, there is no established field method to measure the amount of BDM remaining in the soil after incorporation."[38]

> 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

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

[36] Miles et. al., 2017

[37] 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.

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

effects on plants, these additives may also impact soil microbes and their functions, though these effects are largely unexplored.[39]

"[F]urther research is needed to understand the microbiological events that occur simultaneously, such as changes of microbial community composition and metabolic changes."[40] "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."[41]

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."[42] 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?

2. **Is there information on the toxicity or effect of all secondary metabolite residues as the product breaks down?**

We have touched on much of this previously, and would note that the answer would appear to be that yes, there is evidence of at least some toxicity from secondary metabolites. We have many concerns regarding this issue, and we are not hearing clear answers about whether these metabolites are going to be a problem. If you have it, please share that clear information with us.

Unfortunately, it would appear that the USDA/NOP commissioned this report by Dr. Narayan ("This work was supported by the U.S. Department of Agriculture's Agricultural Marketing Service under Agreement No. 19-NOPXX-MI-0002."[43]) without input from the NOSB to guide Dr. Narayan to ask the very questions that have been put forth in this discussion document.

Further, this question presupposes that we know what all of the various secondary metabolites are that may be left behind as the product breaks down. Before we can fully answer this question, all secondary metabolites need to be identified. Organic agriculture relies on a precautionary principle, and the same should apply in the case of BBM and the concerns and unanswered questions that are being raised.

3. **What is your opinion on mulch films that could be engineered to include macro or micro-nutrients or pesticides that would then make the mulch film provide more benefits than just a mulch?**

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[39] 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.

[40] 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.

[41] 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.

[42] Lönnstedt, O. M.; Eklöv, P. "Environmentally relevant concentrations of microplastic particles influence larval fish ecology." *Science* 2016, 352, 1213−1216.

[43] Ramani Narayan. "Biodegradable Biobased Mulch Films in Organic Cropping Systems." September 2019. Title Page.

Nutrients – Macro & Micro

Macronutrients are supplied by natural sources in organic production, and thus should not be supplied by synthetic mulch. Under §205.601(j)(7), "micronutrient deficiency must be documented by soil or tissue testing or other documented and verifiable method as approved by the certifying agent." Applying marco- or micronutrients through mulch film would not present an issue, as long as the standards are met. The sources of the macro- and micronutrients may present a concern, however.

Pesticides

From NOC's perspective, this is a nonstarter. Blanket application of pesticides assuming that you are going to need them is not a part of the organic standards, nor in line with the principals of Integrated Pest Management. There would have to be a change of the standards to allow this, and we would be opposed to any such change. It is irresponsible and far outside of the organic realm to suggest this would be a practice allowed in organic production.

4. **Is the risk/benefit of keeping plastic mulches out of landfills part of the Organic Food Production Act criteria the NOSB should consider when reviewing this material?**

Please see our detailed comments under question #1 above.

5. **Are there any studies that track the impact on livestock or wildlife (terrestrial, avian and aquatic) that might be attracted to consume pieces of the biodegradable plastic before it has completely degraded in 2 years or secondary metabolites that remain in the soil and are taken up by crops?**

Please see our detailed comments under question #1 above. It is our understanding that the EPA is doing work on how plastics move through all levels of the ecosystem. Perhaps there will be more knowledge to be gained in this area from the work of the EPA and independent researchers.

6. **Should a future annotation try to include consideration that different soils and climates might not be able to meet the biodegradability standard set in the annotation, and how would certifiers be able to verify the use of the material met the biodegradability standard?**

We recognize that certifiers do not have the expertise to assess biodegradation of microscopic or molecular residuals, but we feel that at least they should verify that visible fragments of the material are not persistent in the soil after a year, should a biodegradable biobased mulch product be approved for use.

Conclusion

NOC acknowledges that a biodegradable biobased mulch (BBM) 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.[44]

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.[45]

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."

Sunset

Soap-based algicide/demossers

205.601(a)(7) – As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.

NOC is in support of this material remaining on the NL for use in irrigation system cleaning systems and other hard surfaces. We do not support use otherwise, such as in a body of water where one might want to get rid of algae. The annotation should specify which uses should be covered by the listing. In the absence of being able to make an annotation change during sunset review, the NOSB should make it clear in the record that this material is meant for land-based irrigation lines.

Ammonium carbonate

205.601(e) As insecticides (including acaricides or mite control). (1) ammonium carbonate —for use as bait in insect traps only, no direct contact with crop or soil.

NOC is not opposed to the continued listing of ammonium carbonate at 205.601(e), although we look forward to reviewing comments submitted in answer to the questions in the published materials.

Aquatic plant extracts (other than hydrolyzed)

205.601(j) As plant or soil amendments (1) Aquatic plant extracts (other than hydrolyzed) – Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount used is limited to that amount necessary for extraction.

As the NOSB and NOP strive to clean up the NL to help create clarity and eliminate discrepancies in interpretations among certifiers, the annotation for the listing of aquatic plant extracts (other than hydrolyzed) needs to be addressed.

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

[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.

Some certifying agencies only allow the hydroxides for extraction, while others assume the hydrolyzed extracts are nonsynthetic, making them included, as well. Interpreting the parenthetical clause "(other than hydrolyzed)" is confusing, making it unclear as to what is allowed and what is not.

NOC continues to be supportive of the work done to address the environmental impacts of the use of marine algae in organic production. When considering this listing in the broader context of that work, the NOSB should consider the different types of seaweeds and different characteristics of each when it comes to both community biodiversity and marine algae species characteristics. Further, a better understanding of the different locations where harvesting takes place, as well as wild harvest versus cultivation of seaweed, is needed for informed decision-making.

Lignin sulfonate

205.601(j) As plant or soil amendments. (4) Lignin sulfonate – chelating agent, dust suppressant.

NOC supports relisting lignin sulfonate as a widely used and valuable chelating agent and dust suppressant. We have heard back from industry professionals that they would be unable to pelletize material without it, and that the dust associated with many materials that are pelletized would likely be unhealthy for the people applying it. Moreover, finer particles do not spread well and wouldn't be thrown as far by spinners, and with any wind would be lost. In addition, it is our understanding that organic feed mills would be adversely affected if this material were to be removed from the National List.

EPA List 4 – Inerts of minimal concern

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."[46] 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).[47]

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

[46] NOSB April 2020 proposals and discussion documents Page 33 of 115.
[47] Miles McEvoy, February 29, 2016 Memorandum to NOSB.

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."[48] 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.

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]."[49]

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."[50]

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[48] NOSB April 2020 proposals and discussion documents Page 36 of 115.

[49] 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.

[50] 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.

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.[51]

The European Union prohibits the use of NPE's in pesticides and teat dips.[52] 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.[53] **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.

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."[54] 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

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[51] 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.

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

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

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

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.

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."[55] Continuing to address the same issues over inerts repeatedly at each sunset review is a waste of everyone's time and efforts.

Arsenic

205.602
NOC supports relisting arsenic at 205.602 without reservation.

Strychnine

205.602
NOC supports relisting strychnine at 205.602 without reservation.

Handling Subcommittee (HS)

Other

Petition Process for §205.606

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.

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

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

Discussion Documents

Ion exchange filtration

We applaud the National Organic Program (NOP) in their continued efforts to address inconsistencies between certifiers. It is time to clarify the role that ion exchange resins play in organic food processing.

The NOSB should recommend that only resins and their associated recharge materials approved for this use should be allowed in organic food processing. Chemicals added during the ion exchange process must be listed on the label.

As noted in the published materials, "The FDA considers ion-exchange membranes and resins to be secondary direct food additives, since there is an effect on the food that is run through this process."[56] Ion exchange introduces new chemicals, and the resins and membranes are considered by FDA to be secondary direct food additives. The comments from OMRI quoted in the HS discussion document are worth repeating:

> Other processing aids that are considered secondary food additives required petitions in order to be considered. In addition to the filtering / clarifying / fining agents mentioned above, these also included the boiler water additives, antifoaming agents, and certain enzymes. Other additives that are considered 'de minimis' in conventional processing—such as disinfectants and atmospheric gases—also required petitions, reviews, and recommendations to be added to the National List. Ion exchange resins are known to leak from columns and thus become incidental additives in the food.[57]

The NOSB should recommend that only resins and their associated recharge materials approved for this use should be allowed in organic food processing. Chemicals added during the ion exchange process must be listed on the label.

Fish oil annotation

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,"[58] 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.

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[56] NOSB April 2020 proposals and discussion documents Page 43 of 115.
[57] NOSB April 2020 proposals and discussion documents Page 44 of 115.
[58] NOSB April 2020 proposals and discussion documents Page 50 of 115.

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."[59] 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."[60]

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."[61] 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."[62] 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.[63] 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.

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.

> 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."[64] The Food and Drug Administration (FDA) says,

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[59] 2019 TR, Lines 327-328

[60] 2019 TR, Lines 342-349

[61] FAO Fisheries and Aquaculture Department (2014), *supra* note 10, at 136.

[62] *Ibid.*

[63] *Ibid,* at 137.

[64] "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

> 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.[65]

FDA also gives guidance to those using fish for reducing contamination in their products.[66]

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

(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[67] is important to note:

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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.

[65] FDA Guidance: Environmental Chemical Contaminants and Pesticides. http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM252404.pdf P. 1 (pdf numbering, p. 155 in original).

[66] FDA Guidance: Environmental Chemical Contaminants and Pesticides. http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM252404.pdf Pp. 4-23 (pdf; 158-177 in original.)

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

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."[68] 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."[69]
>
> 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.[70] Another study in the *Journal of the American Medical Association* found that women taking

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[68] "Marine n−3 Fatty Acids and Prevention of Cardiovascular Disease and Cancer," JAMA, Jan. 2019, https://www.nejm.org/doi/full/10.1056/NEJMoa1811403.
[69] 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.
[70] 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.

vitamin E supplements had no significant overall health benefits compared to women that do not take supplements.[71]

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.[72] 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.[73]

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."[74] 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.

Reclassification of L Malic Acid

The Handling Subcommittee is considering a change to the classification of L-malic acid from a nonagricultural (nonorganic) non-synthetic allowed substance to a nonagricultural synthetic allowed substance and move the substance from §205.605(a) to §205.605(b).

In our fall 2019 comments, NOC opposed the relisting of L-malic acid to 205.605(a), and noted that listing to 205.605(b) should not be automatic. NOC is pleased that the HS has put out this discussion document on the reclassification as synthetic.

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

1. There still appears to be some disagreement whether the process described in this document results in a synthetic form of L-malic acid. Is the determination that the two-step process described in this document and in the 2019 TR results in a synthetic form of L-malic acid accurate?

The new TR identifies three major processes of producing L-malic acid by fermentation. Although two of these processes involve microbial fermentation of nonsynthetic substrates, the third – most commonly used – is a two-step process that starts with a synthetic substrate. A fourth method of producing L-malic acid is entirely synthetic. Since the listing on 205.605(a) does not specify a production method, L-malic acid

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[71] 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.

[72] Simon (2013), *supra* note 26.

[73] O'Connor (2015), *supra* note 25.

[74] National Organic Program, "Proposed Rule for Vitamins and Minerals in USDA Organic Products." January 9, 2012.

must be assumed to be synthetic, and hence it should be removed from 205.605(a) and petitioned for 205.605(b).

In the absence of clarity that would be provided by additional information on products of fermentation, logic would dictate that if something starts with a synthetic substrate, it is synthetic.

We refer you to our full fall 2019 comments on "clarify products of fermentation" included here at Appendix D.

2. Would classification of L-malic acid when manufactured from synthetic fumaric acid as a synthetic substance affect the classification of other substances currently on 205.605(a)?
Most likely, yes. Again, we refer you to our full comments on "clarify products of fermentation" included below.

Materials on §205.605(a) that are products of fermentation include:

- Food organisms: yeast.
- Fermented foods do not need to be listed, but yeast, microorganisms, and dairy cultures, which are the agents that ferment the food, are listed.
- Metabolites: L-lactic acid, citric acid, L-malic acid, gellan gum, glucono delta-lactone, and enzymes.

Materials on §205.605(b) that are products of fermentation include:

- Metabolites: glycerin, xanthan gum, various vitamins that may be produced by fermentation (B2, B12, C, D2, E, K2, biotin, and some combinations).

Materials on §205.606 that are metabolites of fermentation:

- Fructooligosaccharides (FOS), Inulin –oligosaccharide enriched (IOE), and whey protein concentrate.

A better understanding of products of fermentation is needed for informed decision-making. We request that the Materials Subcommittee (MS) add fermentation processes to its workplan.

3. If the Subcommittee recommends an annotation that limits sources of fumaric acid used in the production of L-malic acid to non-petroleum sources, are there sufficient quantities to meet current demand in organic production?
Nonsynthetic is not the same as non-petroleum. The annotation must limit the sources of fumaric acid to nonsynthetic sources.

Sunset

Kaolin

205.605(a)

Kaolin is a fine clay, consisting primarily of hydrous aluminum silicate. Because of the small particle size, it has a high surface-to-volume ratio, making it a highly absorptive material. Although the TAP review identifies it as an anticaking agent and a processing aid that is not present in the final product, there is no annotation to limit its use. Kaolin is also produced in nano-sized particles.[75] Kaolin should be annotated to specify allowed uses and prohibit the use of nano-kaolin.

[75] https://www.researchgate.net/publication/297841906_The_properties_of_Nano-kaolin_mixed_with_kaolin.

Waxes – nonsynthetic (wood resin)

205.605(a) Waxes – nonsynthetic (Carnauba wax; and Wood resin)

There is a possibility that wood rosin extracted by a processor who is not certified may have been extracted using volatile synthetic solvents. There is also a possibility that some certifiers or materials review organizations may permit formulation using ancillary substances that are not permitted in organic products. Finally, consumers should be informed of the presence of nonorganic waxes –organic fruits and vegetables are generally assumed to be 100% organic. Therefore, the listing for wood rosin should be annotated with, "Not extracted using volatile synthetic solvents; contains only ancillary substances approved for organic production; presence must be labeled on individual items."

Calcium phosphates (monobasic, dibasic, and tribasic)

205.605(b)

Phosphates have a number of impacts when used as food additives. According to the TAP review for sodium phosphate, "The toxicity of sodium phosphates is generally related to the sequestration of calcium and the subsequent reduction of ionized calcium. It is an irritant, and ingestion may injure the mouth, throat, and gastrointestinal tract, resulting in nausea, vomiting, cramps, and diarrhea."[76]

More recent studies have shown that inorganic forms of phosphate, such as calcium and sodium phosphates, cause hormone-mediated harm to the cardiovascular system. A review found that they "may harm the health of persons with normal renal function. This judgment has been made on the basis of large-scale epidemiological studies and is supported by the latest findings of basic research."[77] This is an important line of research.

As outlined in detail in the comments of Consumers Union in 2015 and Spring 2016, research has shown that high intake of phosphorus is associated with negative impacts on bone health, kidney health, and heart health. Research also shows that phosphate food additives are more readily absorbed during digestion and lead to a higher phosphorus load, compared with phosphorus found naturally as a component of whole foods.

In Fall 2016, the HS issued a discussion document on phosphates, which made these points:

- Outside the US and Canada, the only phosphate additive allowed in organic processed food is monocalcium phosphate, and only as a leavening agent.

- During the 2015 Sunset review, the NOSB received comments including new research that indicates potential serious human health impacts from the cumulative effects of phosphates which are added to processed foods.

- The NOSB may recommend increased restrictions through annotations or removal of phosphate food additives.

[76] TAP Review for Tetrasodium Pyrophosphate, July 29, 2002, Page 3 of 13.

[77] Ritz, E., Hahn, K., Ketteler, M., Kuhlmann, M. K., & Mann, J. (2012). Phosphate Additives in Food—a Health Risk. *Deutsches Ärzteblatt International*, *109*(4), 49–55.

- Because the health effect comes from the cumulative impact, rather than any specific phosphate alone, the NOSB was reluctant to remove any one phosphate from the National List.

Since it can be concluded that phosphates other than monocalcium phosphate as a leavening agent are unnecessary, they should be phased out. Presumably, this would greatly reduce the phosphate exposure to organic consumers. Alternatives to monocalcium phosphate should also be explored, but the action of removing other phosphates would reduce the likelihood of problems arising from use of monocalcium phosphate as a leavening agent.

Ozone

205.605(b)

We are reminded every time the NOSB receives a petition for a new sanitizer or a sanitizer, disinfectant, or cleaner is reviewed at sunset of the value of a tool to aid the NOSB in determining which materials should be added to the National List.

The NOSB would benefit from a comprehensive review of sanitizers, disinfectants, and cleaners to address when a new material is petitioned or a material is reviewed at sunset. The NOSB could refer to the sanitation materials review to judge whether other materials currently on the National List meet the same need, or if there is a special characteristic to 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.

NOC encourages the NOSB and the NOP to continue to move forward with this work agenda item.

Sodium hydroxide

205.605(b) – prohibited for use in lye peeling of fruits and vegetables

Sodium hydroxide is a hazardous substance that has many uses. In contrast to the OFPA requirement that National List materials be listed "by specific use or application," the annotation for sodium hydroxide states only prohibited uses. The HS and NOSB should investigate the essentiality of sodium hydroxide for its various uses and annotate the listing to limit its use to those essential uses.

Inulin-oligofructose enriched

205.606(l) Inulin-oligofructose enriched (CAS # 9005-80-5)

In Fall 2015, the NOSB voted unanimously to remove inulin-oligofructose (IOE) from the National List. At the time of the Federal Register notice, three commenters came forward, noting that IOE is not interchangeable with the separate listing for "fructooligosaccharides" (FOS) due to the unique properties of IOE. IOE is made from chicory root, which commenters noted provides the functionality and differentiates it significantly from FOS.

While this may be true, IOE does not belong on §205.606. It is a product of fermentation, and according to the patent included in the petition, IOE consists of inulin extracted from chicory "co-processed" with FOS. The inulin is extracted with hot water followed by a purification process involving treatment with lime, in which the calcium hydroxide reacts with carbon dioxide and absorbs unwanted components, leaving a

residue that is further treated with ion exchange and carbon filtration. Up to that stage, it could be called an agricultural product. However, the addition of FOS, a synthetic nonagricultural, creates a synthetic nonagricultural product. Therefore, IOE does not belong on §205.606, but should be petitioned for §205.605(b).

Kelp

205.606(m) Kelp—for use only as a thickener and dietary supplement

While we appreciate the questions put forth by the Handling Subcommittee, we submit that these questions cannot be answered until the term "kelp" has been defined.

"Kelp" is not well-defined. As stated in the Fall 2016 discussion document on marine materials,

> **Kelp** is a broad generic term for brown seaweeds, Class *Phaeophyceae,* in the Order *Laminariales,* with at least 30 genera and many species, and in the Order *Fucaceae* such as *Ascophyllum nodosum.* However, the term "kelp" as used in fertilizer means ANY macroalgae seaweed, brown *(Phaeophyceae),* red *(Rhodophyceae)* or green *(Chlorophyceae)* (Assoc. of American Plant Food Controls (AAPFC)). Kelp used in organic livestock production must be certified organic, but for use in processing for humans non-organic kelp is allowed. Pacific Kombu, and *Undaria innatifida* are also Kelp species. *Fucus* species are intertidal, but Laminaria species are deep water.[78]

Of the species identified as "kelp," at least two are considered to be both ecologically significant due to the structural habitats they provide and at risk of being overharvested.[79] Although kelp itself recovers from intensive harvesting,[80] kelp harvesting can have significant impacts on other members of the ecosystem.[81] There is evidence that kelp concentrates heavy metals, and it is used to monitor heavy metal contamination.[82] Arsenic poisoning has been documented from kelp supplements.[83]

While the NOSB considers, in broad terms, an approach to ensuring that organic production does not endanger marine plants and algae, the board still has a responsibility to look at the impacts of individual listings of seaweeds. Delisting kelp from §606 would be a positive step, since it would require kelp to be organically produced, which would require that harvesters comply with §205.207(b) "A wild crop must be harvested in a manner that ensures that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop." Species that can be cultivated must be produced in compliance with the definition of "organic production," that is, "managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating

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[78] NOSB November 2016 proposals and discussion documents Page 57 of 279.

[79] Marine plants and algae TR, 2018. Lines 523-524, 528-535, 356-360.

[80] Rothman, M. D., Anderson, R. J., & Smit, A. J. (2006). The effects of harvesting of the South African kelp (Ecklonia maxima) on kelp population structure, growth rate and recruitment. *Journal of applied phycology*, *18*(3-5), 335-341.

[81] Lorentsen, S. H., Sjøtun, K., & Grémillet, D. (2010). Multi-trophic consequences of kelp harvest. *Biological Conservation*, *143*(9), 2054-2062.

[82] David A. Roberts, Emma L. Johnston, Alistair G.B. Poore, 2008. Contamination of marine biogenic habitats and effects upon associated epifauna. Marine Pollution Bulletin 56:1057–1065.

[83] Eric Amster, Asheesh Tiwary, and Marc B. Schenker, 2007. Case Report: Potential Arsenic Toxicosis Secondary to Herbal Kelp Supplement. Environmental Health Perspectives 115(4): 606-608.

cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity."[84]

Cornstarch (native)

205.606(v)

The 2015 HS proposal provided useful information about the types of corn used for cornstarch and the types of cornstarch. Nevertheless, it is unclear whether the statement, "A supplying company and a trade association indicated that there is not a supply of organic moulding cornstarch, or the type with very high amylose content, or special strains with freeze-thaw properties"[85] describes one type of cornstarch or three.

As noted in the HS published materials, there are 13 suppliers of "cornstarch" listed in the Organic Integrity Database (OID); however, there are an additional 42 suppliers listed for "corn starch," for a total of 55 suppliers listed in the OID. It would appear that some cornstarch is sufficiently available in organic form – if not all. Should the NOSB hear back that there are forms that continue to be unavailable in organic form, we highly encourage the addition of an annotation to the listing that would accurately reflect those unavailable in organic form.

Whey protein concentrate

205.606(z)

In Fall 2015, the NOSB voted unanimously to remove whey protein concentrate from the National List. At the time of the Federal Register notice, one comment came in from a trade association noting that the received information after the NOSB comment period had closed that whey protein concentrate is both essential to organic processed products and not commercially available in organic form.[86] There was no additional information provided regarding the number of commenters, the forms of whey protein concentrate not available organically, or the barriers to producing those forms or other whey products in an organic form.

In 2017 when the NOP did not remove whey protein concentrate from §205.606, a search of the organic integrity database found approximately 10 manufacturers (one or two may have been brokers) of organic whey protein concentrate, as well as three suppliers of whey protein isolate and one supplier of whey protein hydrolysate. In January 2020, a search of the organic integrity database found twenty-seven manufacturers (some may be brokers) of organic whey protein concentrates. In addition, there were four suppliers of organic whey protein isolate and one supplier found for whey protein hydrolysate. Other whey products listed as available as organic in the NOP organic integrity database in January 2020 include: Liquid whey, concentrated whey, demineralized whey protein, sweet whey powder, condensed liquid whey, instant whey powder, agglomerated whey powder, grassfed whey powder, lactose powder (in a variety of forms), whey permeate, whey protein phospholipid concentrate (WPPC), and whey solubles.

Here is the list of the suppliers of organic whey protein products:

Whey protein concentrate

[84] §205.2.

[85] NOSB October 2015 proposals and discussion documents Page 189-190 of 358.

[86] Organic Trade Association, National Organic Program (NOP): Sunset 2017 Amendments to the National List P 2 of 3.

Agropur MSI LLC in La Crosse WI- Whey protein concentrate along with various flavors of this concentrate
All American Foods, Inc in Waseca MN- whey powder 90%
Columbia River Technologies LLC in Boardman Oregon- whey protein concentrate 80%
Country Life LLC in Hauppauge NY- whey protein powders
CROPP Cooperative in La Farge, WI – Whey, whey protein concentrates 75%, 80%
Empresa Brazieira De Bebidas E Alimentos S/A in Aracati Brazil- whey powder
Elemental Market Inc, dba Vital Proteins LLC in Elk Grove Village, IL – Whey protein concentrate
Foremost Farms in Plover, WI- reduced lactose whey, reduced minerals whey powder 90%, whole sweet whey powder
Frieslandcampina Ingredients North America in Delhi NY- whey protein concentrate
Gallo Cattle Company in Atwater CA- whey protein concentrate plain and with flavors
Grassland Dairy Products DBA Greenwood Milk Products in Greenwood WI- whey protein concentrate
Jonker and Schut BV in Barneveld, Netherlands- whey powder
LRM Packaging Inc. in South Hackensack NJ – whey protein concentrates plain and with flavors
Mane, Inc. in Lebanon OH- sweet whey powder
Milk Specialties Company in Norfolk NE and Visalia CA - whey protein concentrate
Muscoda Protein Products in Muscoda WI- whey protein concentrate
OS Holdings in Portland OR- whey powder
Particle Control in Albertville, MN- whey protein concentrate 80%
Plainview Milk Products Cooperative in Plainview MN- condensed whey (also makes milk powders)
Pro Amino in Morningside Queensland Australia- whey powder plain and flavored
Rumiano Cheese Company in Crescent City and Willows, CA- whey protein concentrate 80%
Saputo Cheese in Waupun WI- sweet dairy whey powder
Spring Hill Jersey Cheese DBA Petaluma Creamery in Petaluma CA- whey protein concentrate 80% and 45%
Tradin Organic Agriculture in Amsterdam, Netherlands EU- whey protein concentrate
Wisconsin Specialty Protein DBA Bioriginal in Reedsburg WI - whey protein concentrate plain and flavors 85%, 80%, 70%, 60%
WNY Enterprise LLC in Pavilion NY- whey protein concentrate
Zumbro River Brand Inc. in Albert Lea MN- whey protein concentrate with lecithin, without soy 80%

Whey protein isolate

CROPP Cooperatives in LaFarge WI- whey protein isolate 90%
Gallo Cattle Company in Atwater CA-whey protein isolate 90%
Naturalife EcoVite Laboratories DBA Paragon Laboratories in Torrance, CA
Wisconsin Specialty Protein DBA bioriginal in Reedsburg WI- whey protein isolate

Whey protein hydrolysate

Wisconsin Specialty Protein DBA bioriginal in Reedsburg WI -whey protein hydrolysate 80%

With almost three times the number of manufacturers (some possible brokers) of organic whey protein concentrate listed in the OID today than at last sunset, when there was a unanimous vote by the Board to remove whey protein concentrate from the National List, it is time to get the job done. In the fall, the NOSB should once again vote for removal.

NOC is disappointed that the NOP relied on one comment to keep whey protein concentrate on the National List rather than trusting their own advisory board. At the time the one comment was received on the federal register, the NOP merely had to look to their own Organic Integrity Database to determine the organic supply available at the time. We feel strongly that if the NOP is going to ignore the will of their own advisory counsel, they need to have a much stronger reason than one comment. As per OFPA, the

National List is to be based on the recommendations of the NOSB.[87] "The National List established by the Secretary shall be based upon a proposed national list or proposed amendments to the National List developed by the National Organic Standards Board."[88]

Carnauba wax

205.606(a)

Non-organic carnauba wax should not be used if organic carnauba wax is available. Since the TR documents the availability of organic carnauba wax, the HS should consider delisting it.

There is a possibility that carnauba wax extracted by a processor who is not certified may have been extracted using volatile synthetic solvents. There is also a possibility that some certifiers or materials review organizations may permit formulation using ancillary substances that are not permitted in organic products. Finally, consumers should be informed of the presence of nonorganic waxes –organic fruits and vegetables are generally assumed to be 100% organic. Therefore, we request that the listing for carnauba wax be annotated with, "Not extracted using volatile synthetic solvents; contains only ancillary substances approved for organic production; presence must be labeled on individual items."

Colors (18)

205.606(d) Colors derived from agricultural products - Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(1) Beet juice extract color (pigment CAS #7659-95-2);
(2) Beta carotene extract color
(3) Black currant juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
(4) Black/Purple carrot juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
(5) Blueberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
(6) Carrot juice color (pigment CAS #1393-63-1)
(7) Cherry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
(8) Chokeberry—Aronia juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
(9) Elderberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
(10) Grape juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
(11) Grape skin extract color (pigment CAS#'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
(12) Paprika color (CAS #68917-78-2)—dried, and oil extracted
(13) Pumpkin juice color (pigment CAS #127-40-2)
(14) Purple potato juice (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134- 04-3)

[87] 7 U.S.C. § 6503(c) (OFPA §6503 (c) ("In developing the program under subsection (a), and the National List under section 6517 of this title, the Secretary shall consult with the National Organic Standards Board established under section 6518 of this title.")
[88] 6517(d) Procedure for establishing National List (1)

(15) Red cabbage extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)
(16) Red radish extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3
(17) Saffron extract color (pigment CAS #1393-63-1).
(18) Turmeric extract color (CAS #458-37-7)

We are disappointed that the NOSB was unable to vote to delist a number of colors at the Fall 2015 meeting. Now that any agricultural material can be produced organically, materials should be removed from §205.606 whenever possible in order to encourage more processors to source organic forms. It is clear from examining the Organic Integrity Database that many colors are commercially available in organic form in sufficient supply.

We appreciate the subcommittee's very pointed questions to help determine the exact barriers preventing the organic production of each specific color, if any, and encourage the NOSB to place a greater burden on those stakeholders that maintain that a specific color must stay on the NL to provide detailed information as to the reasoning. Should those stakeholders interested in maintaining a particular color on §205.606 not respond, the NOSB should take that as an indication that the color no longer needs to be listed on §205.606 and vote to remove it.

As noted in the published materials, colors were discussed in-depth at the Fall 2015 sunset review. While the NOSB ultimately supported relisting all colors at that time, it was obvious that not all colors needed to be relisted. It is time to take a closer look at each individual color listed and remove those that are commercially available in organic form in sufficient supply.

Glycerin (CAS #56-81-5)

205.606(h)

As stated in the spring 2015 published materials, "Petitioner has requested removal of glycerin from §205.605(b) (synthetic materials for handling), stating that there is now sufficient quantity of organically produced glycerin and that synthetic glycerin is no longer required."[89] If this is true, and it appears as if there are many listings for glycerin on the Organic Integrity Database, then the listing of glycerin on §606 would appear to be unnecessary.

Livestock Subcommittee (LS)

Discussion Documents

Fenbendazole for use in poultry

NOC opposes the use of fenbendazole in poultry as proposed – to expand the use of fenbendazole to poultry by adding an annotation to 7 CFR §205.603(a)(23)(i) to include laying hens and replacement chickens intended to become laying hens with no withholding period and no defined parameters for use. The NOSB cannot rely on the 2015 TR covering parasiticides used in mammalian livestock to support a decision to allow the use of fenbendazole in poultry.

[89] NOSB April 2015 proposals and discussion documents, page 1 of 249.

The definition of "emergency" has not been put into regulations.
Currently, operations using parasiticides must meet standards listed at §205.238. In the spring of 2018, the NOSB unanimously recommended clarifying "emergency" for use of synthetic parasiticides in organic livestock production. As the expanded use of parasiticides in organic production is being considered, it is imperative that the spring 2018 recommendation passed by unanimous vote be added to the rule, as follows:

> Add this definition to §205.2
> Emergency treatment to allow synthetic parasiticide use in livestock: A livestock emergency is an urgent, non-routine situation in which the organic system plan's preventive measures and veterinary biologics are proven, by laboratory analysis or visual inspection, to be inadequate to prevent life-threatening illness or to alleviate pain and suffering. In such cases, a producer must administer the emergency treatment (§205.238(c)(7)). Organic certification will be retained, provided that such treatments are allowed under §205.603 and the organic system plan is changed to prevent a similar livestock emergency in individual animals or the whole herd/flock in future years as required under §205.238(a).
>
> Add to § 205.238 (b)
> (4) Organic breeding, dairy and fiber bearing animals when meeting the following conditions:
>
> (i) Organic livestock has been managed according to 238(b) and 238(c)(2), 238(c)(4), and 603(a)(23) and only in the event of an emergency where management strategies have been proven insufficient to prevent or control parasites within the accepted threshold for specific parasites, age and species of the animal. These management strategies include but are not limited to, forage height and plant diversity to maintain parasite levels below treatment thresholds and monitoring with documentation of parasites through use of methods such as fecal monitoring and FAMACHA (FAffa MAlan CHArt—used for tracking anemia in goats and sheep).
>
> (ii) The organic system plan is changed to prevent a similar livestock emergency in individual animals or the whole herd/flock in future years.

The definition of "livestock emergency" has not been adopted into regulation and therefore the NOSB cannot rely upon it to prevent misuse of parasiticides. Furthermore, §205.238(b) applies only to breeder stock, dairy animals, and fiber bearing animals, and thus does not allow administration of parasiticides to poultry.

Inconsistencies in interpretation among certifiers is a recognized issue.
Further, in the published materials the livestock subcommittee says, "Producers and certifiers would need to work together to define what an emergency is for each producer."[90] As the NOSB and NOP strive to clean up the NL to help create clarity and eliminate discrepancies in interpretations among certifiers, this would only serve to create more inconsistencies.

As recently as July 16, 2019, the CACS requested to work on the topic of inconsistencies between certifiers.[91] This is a recognized issue that is addressed many times over through NOSB meetings, within

[90] NOSB April 2020 proposals and discussion documents, Page 84 of 115.
[91] NOSB Executive Committee Meeting notes, Page 21 of 42, https://www.ams.usda.gov/sites/default/files/media/ESNotes2019Dec.pdf.

published materials, and has been addressed during discussions regarding the anticipated proposed rule on Strengthening Organic Enforcement. Clear guidelines need to be provided, and the use of a parasiticide must depend on a definition of "livestock emergency" in the NOP regulations.

Residues of fenbendazole will be present in eggs.

While NOC recognizes that fenbendazole is already permitted under restrictive conditions for other livestock species, it is permitted with a withholding period, as appropriate, for each class of animal, based upon residue present in the organic product – whether it be wool or milk. The discussion document clearly states that "fenbendazole in eggs of treated chickens at zero-day withdrawal are well below the safe concentration of 2.4 ppm for residues in eggs." This alone supports a withholding period – organic consumers expect that there will be no chemical residue in organic foods.

We refer you to the more in-depth comments from Beyond Pesticides regarding residues in eggs and the metabolism of fenbendazole in poultry.

Use of fenbendazole should reflect a level playing field in organic.

In the discussion document, the LS notes:

> Even though the current listing for fenbendazole for cattle, sheep, goats, and other dairy species lists withdrawal times, the Subcommittee is not suggesting a withdrawal time for the use of fenbendazole on poultry. During the review of fenbendazole's use as an approved animal drug the FDA did not require a withdrawal time on the label for poultry as compared to other animals. "The data in study #S12173-00-DWF-MET-PO show that total residues of fenbendazole in eggs of treated chickens at zero-day withdrawal are well below the safe concentration of 2.4 ppm for residues in eggs. (https://animaldrugsatfda.fda.gov/adafda/app/search/public/document/downloadFoi/3083)

To be clear, the FDA does not require a withdrawal time on the label for milk from dairy cattle, either, but within the organic program we follow a precautionary principle that guides our decision making, not what the conventional market requires.

Organic dairy producers are already working from uneven ground, with unclear standards for dairy when it comes to livestock living conditions, pasture requirements, and outdoor access that are not in place for poultry. We have heard the NOSB and NOP continually express a desire for a level playing field for all producers, and we agree. The withdrawal period for fenbendazole for use in organic poultry needs to be at the same high standards set for all other areas within organic production.

The need for fenbendazole has not been established.

In trying to establish a need for the use of fenbendazole in organic poultry production, the discussion document notes:

> Currently poultry producers use a diatomaceous earth product to help control intestinal worms. There are several concerns with this product including amount needed to be ingested in relation to daily feed intake (non-balanced diets), worker and animal health hazards (respiratory concerns) and many producers feel that diatomaceous earth does not control severe parasite infestations.

A study conducted by Bennett et. al. to evaluate "the effectiveness of diatomaceous earth (DE) as a treatment against parasites and to increase feed efficiency and egg production of organically raised free-range layer hens as evaluated in 2 breeds of commercial egg layers" commonly used in organic production

today – Bovan Brown (BB) and Lowmann Brown (LB)[92] showed positive results for both feed efficiency and egg production, as well as control of parasites.

For both breeds, the "hens fed the diet containing DE were significantly heavier, laid more eggs, and consumed more feed, but feed efficiency did not differ." In addition, the "BB hens consuming the DE diet laid larger eggs containing more albumen and yolk than hens consuming the control diet." The results of this study indicate that "DE has the potential to be an effective treatment to help control parasites and improve production of organically raised, free-range layer hens."

A further study conducted by Isabirye et. al. in 2019 showed "that DE has the potential to control A. galli; and ectoparasites in chicken." This study further noted that "to quicken the action of DE against ectoparasites, organic approaches should be studied."[93] While producers may "feel" that diatomaceous earth does not control severe parasite infestations, it would appear that there are larger production method issues that must be addressed.

There are larger production method issues that must be addressed.

The discussion document notes, "Organic producers will need to utilize preventative management practices defined in their Organic System Plan as a first line of defense for internal parasites, and if those preventative practices fail an emergency treatment of fenbendazole may be required to control internal parasites." These "preventative management practices" must be clearly defined. Without clear poultry living condition standards in organic regulations, "preventative management practices" become an issue of subjectivity, and yet another area of inconsistency among certifiers.

Practices that are currently required by the standards for use with ruminant livestock, specifically, good pasture management methods to control parasites, are not required for poultry. It is common knowledge that rotational pasture management is one of the most effective ways to reduce the number of parasites that animals consume. Subjectivity surrounding the issue of outdoor access in poultry is already problematic among certifiers and producers.

"No parasiticides and no chemical residue in our eggs."

If organic allows fenbendazole for treatment of laying hens, there will be producers – both organic and conventional – who, based on good management practices, do not need to use it. Further, there will be commercial producers who will not allow its use, and this will become another label claim and marketing tool – "No parasiticides and no chemical residue in our eggs." Consumers will understand that organic will be left with an inferior quality product.

Conclusion

NOC opposes the use of fenbendazole in poultry as proposed – to expand the use of fenbendazole to poultry by adding an annotation to 7 CFR §205.603(a)(23)(i) to include laying hens and replacement chickens intended to become laying hens with no withholding period and no defined parameters for use.

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[92] "Effect of diatomaceous earth on parasite load, egg production, and egg quality of free-range organic laying hens," by Bennett et al. from 2011 *Poultry Science.* https://www.researchgate.net/publication/51219180_Effect_of_diatomaceous_earth_on_parasite_load_egg_production_and_egg_quality_of_free-range_organic_laying_hens

[93] "Efficacy of diatomaceous earth on Ascaridia galli, blood parameters: and on ectoparasites in chickens," by Isabirye et al. from 2019 *Journal of Agriculture Food Science and Technology.* https://www.researchgate.net/publication/338409541_Efficacy_of_Diatomaceous_Earth_on_Ascaridia_galli_Blood_Parameters_And_on_Ectoparasites_In_Chicken.

The NOSB cannot rely on the 2015 TR covering parasiticides used in mammalian livestock to support a decision to allow the use of fenbendazole in poultry. Further, the discussion document leaves much open to interpretation without clear standards to guide both certifiers and producers.

Sunset

Poloxalene

205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(21) Poloxalene (CAS #-9003-11-6)—for use under 7 CFR part 205, the NOP requires that poloxalene only be used for the emergency treatment of bloat.
Given the existence of preventive measures and more compatible treatments for the treatment of bloat in organic animals, the NOSB should not relist poloxalene unless there is strong evidence of need.

Formic acid

205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(2) Formic acid (CAS # 64-18-6) - for use as a pesticide solely within honeybee hives.
NOP must adopt apiculture rules, which would provide a framework for making decisions about materials used in organic beekeeping. Until such standards are developed, we have a difficult time commenting on materials for use in organic apiculture.

Excipients

205.603(f) Excipients, only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application.

As defined in:
§205.2 Excipients. Any ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (e.g., enhancing absorption or controlling release of the drug substance). Examples of such ingredients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents.
Like “inert” ingredients in pesticide products, excipients in animal medications are not necessarily biologically or chemically inactive, and are not always listed on the label. If the Board is to do its job in reviewing excipients in accordance with OFPA, it must have adequate information about the identity and function of excipients. Therefore, it must seek information from materials review organizations and animal drug manufacturers to identify the excipients that are present in products used in organic livestock production so that they can be evaluated by the Board.

Inconsistencies in interpretation among certifiers is a recognized issue.
How excipients are currently being reviewed in livestock health products by certifiers causes discrepancies. As the NOSB and NOP strive to clean up the NL to help create clarity and eliminate discrepancies in interpretations among certifiers, the issue of excipients needs addressed.

As pointed out in the 2015 technical evaluation report on excipients, and mentioned in the Best Practices for Common Material Review Issues document from the Accredited Certifiers Association (ACA):

> Although synthetic excipients did not appear at §205.603 until 2007, they have been used in livestock drugs and health care products with various interpretations by certification agencies and Material Review Organizations (MROs) as to their allowance (NOSB 2009). Since their listing on §205.603, there has still been some confusion among certification agencies about direct vs. indirect food additives, how those may be used, and their compliance with the excipient annotation (since the annotation does not stipulate 'direct' food additives and only says "approved by the FDA as a food additive"). Some certification agencies permit the use of indirect food additives only in health care products that are intended for external application (e.g., teat dips) while others do not permit them at all. Others permit indirect food additives in all types of health care products, including oral and injectable formulas. Further, despite the fact that injectable vitamins and minerals do not appear on the National List, certification agencies appear to be consistently permitting their use with excipients as part of the formula. Finally, there is some confusion about whether excipients appearing in the FDA Inactive Database for NADAs and NDAs can be used in illegally marketed drugs as well, or if only NADAs and NDAs may contain excipients from that particular database (Fernandez-Salvador 2014; personal experience).[94]

In addition, it is our understanding that there are also discrepancies among certifiers for the allowance of GRAS materials with the "letter of no question GRAS." Some certifiers do not allow materials that are "letter of no question GRAS," because this procedure was not evaluated by the NOSB when the listing for excipients was created, but other certifiers do allow these materials as GRAS excipients.

In 2015, CCOF said that the present annotation is not clear. It allows for almost anything to be allowed as an excipient, but materials reviewers have to research using multiple databases (CFR title 21, GRAS database, EAFUS database, etc.) to gather that information. A clear annotation should state which specific excipients, if any, would not be allowed.

The LS should make a commitment to addressing the issue of excipients used in organic production. We could envision this being done similarly to how we suggest addressing inerts – see our full comments on inerts under Crops.

EPA List 4 – Inerts of Minimal Concern

205.603(e) 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

See NOC's full comments on EPA List 4 – Inerts of Minimal Concern under Crops.

[94] 2015 Technical Review on Excipients in Livestock, lines 226-239.

Strychnine

Reference: §205.604 Nonsynthetic substances prohibited for use in organic livestock production. The following nonsynthetic substances may not be used in organic livestock production: (a) Strychnine.

NOC supports relisting strychnine at §205.604 of the National List.

Materials Subcommittee (MS)

Excluded Methods

New genetic manipulation techniques are being introduced at an increasingly rapid pace. Organic stakeholders and 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 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.[95]

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 genetic modification techniques. 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

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

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.

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.**

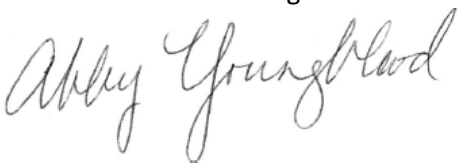
NOC urges the NOSB to move forward in its evaluation of remaining technologies that have not yet been determined with a transparent process that solicits input from key stakeholder groups and to act with great care to ensure that excluded methods are kept out of organic production.

Marine Materials

NOC continues to be supportive of the work done to address the environmental impacts of the use of marine materials in organic production. We look forward to continuing this work in concert with the NOSB during the fall 2020 semester. While we are appreciative of the discussion documents brought forth by the crops subcommittee on wild, native fish for liquid fish products, and the handling subcommittee on fish oil, we encourage the NOSB to continue to work on the marine materials agenda item as a comprehensive way to address all marine materials listings across all subcommittees.

Thank you for your consideration of these comments.

On behalf of National Organic Coalition Members:



Abby Youngblood
Executive Director, National Organic Coalition
646-525-7165; Abby@NationalOrganicCoalition.org

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

Appendix A

Letter to Secretary Perdue regarding COVID-19 pandemic

April 2, 2020

The Honorable Sonny Perdue
Secretary
U.S. Department of Agriculture
1400 Independence Avenue, SW
Washington D.C. 20250

Dear Secretary Perdue:

We are writing to make recommendations about emergency actions that your agency can take to address the impact of the COVID-19 pandemic on the organic sector. We offer our recommendations with full understanding that all sectors of agriculture are now in crisis and that we must all work together to address these challenges.

We are deeply concerned about the impact of COVID-19 on organic farmers, farmworkers, businesses, certifiers and inspectors, and consumers. We are mindful of the need to protect the health and safety of all who are involved in organic agriculture, certification, and compliance. We also seek to advocate for responsible actions that will protect the integrity of the USDA organic seal during this difficult time.

Because of the annual organic certification process and the need to protect the integrity of the USDA organic seal during this time of extreme market disruption, some of our concerns and recommendations may be unique from those raised by other sectors of agriculture.

Support for Organic Farmers

The recently enacted CARES Act includes a $9.5 billion emergency fund:

> "to prevent, prepare for, and respond to coronavirus by providing support for agricultural producers impacted by coronavirus, including producers of specialty crops, producers that supply local food systems, including farmers markets, restaurants, and schools, and livestock producers, including dairy producers."

As you make plans to implement this section of Act, we would like to point out that organic farmers represent a significant percentage of the farmers in each of the specialty crop, livestock and dairy, and local food supply categories prioritized by Congress. Therefore, it is critical that organic farmers be included in any emergency response actions taken to implement this provision of the Act. The following financial assistance recommendations would be extremely helpful for the organic sector:

- While it is certainly a blunt instrument, providing direct payments to farmers including organic farmers, to keep them solvent during this critical production season in the face of lost or disrupted marketing channels, may be the most direct way to bolster our nation's food supply. While the awful human health implications of the pandemic may peak and subside over the next couple of

months, the long-term food security implications of a year of lost markets for U.S. farmers could have even longer lasting impacts on our society. In making direct payments, it is critical that the criteria used to distribute those payments be more fine-tuned to support the diversity and richness of U.S. agriculture than was reflected in the recent trade mitigation payments, and that more reasonable payment limitations govern those payments to ensure that more farmers get help with these funds.

- Most organic and small farms have not traditionally accessed food purchasing programs run by the agency using Commodity Credit Corporation funding. As you develop new purchasing programs to both aid farms and procure food for emergency feeding or other nutrition programs, we urge you to make the procurement process flexible enough to work for organic and small farms, not just large conventional operations. This should include purchases of a diverse set of crops, not just commodity crops.

- As farmers innovate to respond to the social distancing recommendations related to the pandemic, USDA should provide financial assistance for farms setting up virtual platforms to facilitate the sale of their products, as well as "on-farm" stands, curbside pickup, and other direct to consumer "no-touch" distribution channels that minimize interaction. In the same way as restaurants across the nation have shifted to take-out pick up options, farmers too are shifting to this model. But farmers need some financial assistance to facilitate this shift.

- Increase organic certification cost-share assistance for certified organic farms and handlers and provide immediate payment to organic operations. Consider making payments directly to organic certification agencies to cover their costs of certifying organic operations so that organic farmers and handlers do not have to bear that cost during these extreme times of market disruption.

- Dairy is one of the leading sectors of organic. Unfortunately, organic dairy farmers have been slow to embrace the new Dairy Margin Coverage (DMC) program because it is perceived as only being relevant to conventional dairy farmers. However, historically major declines in conventional dairy prices have resulted in downward pressure on organic dairy prices as well. Therefore, we urge you to re-open the 2020 sign-up period for the Dairy Margin Coverage (DMC) Program to allow new participants in the program. In addition, reopening the sign-up period would allow existing DMC participants to reconsider their coverage decisions for 2020 given the extraordinary and unforeseen dairy market collapse related to the pandemic.

Addressing the Challenges of Organic Certification in the Face of Social Distancing Requirements

As part of the organic certification process, organic operations must undergo an annual on-site inspection. This process has been challenging for organic farmers, handlers, certification agencies, and organic inspectors in the face of the social distancing requirements needed to slow the spread of COVID-19.

All organic stakeholders are seeking to protect human health, but also to maintain the integrity of the organic seal. The two goals may seem in conflict, but they don't need to be. Organic accredited certification agencies (ACAs) have been in communication with USDA's National Organic Program (NOP) to develop mechanisms to maintain the integrity of the organic certification process while also protecting the safety of farmers, handlers, certifiers, and inspectors. In some cases, this has involved performing the

record review aspects of an organic inspection virtually. In other cases, the on-farm inspections have been delayed somewhat. In other cases, inspectors have performed on-site inspections in person, but using social distancing protocols, or have used virtual techniques to do some of the actual site inspections.

Therefore, we are urging you to provide technical and financial assistance to organic operations so they can maintain their certifications during the pandemic by providing required records to certification agencies through virtual platforms. Smaller organic ACAs could also benefit from financial assistance in this regard.

Relaxing USDA Nutrition Program Rules to Give Low Income Consumers Greater Access to Nutritious Food During the Pandemic

- Allow Supplemental Nutrition Assistance Program (SNAP) payments to be made online directly to farms and CSAs.

- Provide waivers and direction to States to broaden their WIC-approved food lists to allow WIC participants to purchase organic foods.

- Issue an emergency waiver to all States to allow food banks to skip the normal paperwork and recordkeeping requirements for gathering information from each customer. These paperwork procedures are greatly slowing down the food distribution process at already overburdened food banks, making it difficult to maintain social distancing protocols.

- Support the ability of food banks and other emergency feeding programs to purchase organic products directly from farmers at market prices.

Move Critical Rulemaking Forward to Protect Organic Integrity

Two rulemakings that are critical to the organic sector are in the final stages of clearance. In your communications with the Office of Management and Budget, we urge you to underscore the importance of moving these Congressionally mandated rulemakings along without delay.

- The rulemaking to improve organic enforcement, both domestically and internationally, (aka the "strengthening organic enforcement" rule) is critical for the economic viability of the U.S. organic sector. The 2018 Farm Bill required USDA to complete the rulemaking by December 19, 2019, but the proposed rule is still under review by OMB. This rulemaking must move forward.

- The final rule on Origin of Livestock (OOL), to close loopholes with regards to the organic standards related to the transitioning of conventional dairy cows into organic dairy operations, is another critical regulation for the organic sector. Through the Fiscal Year 2020 appropriations process, Congress mandated that USDA complete OOL final rule by June 17, 2020.

We acknowledge that some of the following recommendations overlap with policy issues in other federal agencies, as well as the White House. As the chief advocate for U.S. agriculture in the Administration, we want to make you aware of our multi-faceted concerns and to urge your inter-agency advocacy on these matters.

Farms, Farmers Markets, Farm Stands, and Community Support Agriculture (CSA) Operations Should be Deemed as Essential

Our country's ability to produce food for its citizens has not been in question anytime in recent history. But the decision by some States to deem traditional retail grocery stores as essential, but to declare non-traditional food marketing venues as non-essential undermines thousands of farmers who market through those channels. As consumers turn more to local sources of food during the pandemic crisis, it is critical that these marketing channels be deemed essential. For many parts of the country spring and summer are critical marketing seasons for farmers who serve local markets, and for consumer desiring the fresh and healthy produce. To cut off consumers from these markets, by allowing local and state governments to deem them as non-essential, is counterproductive. Of course, these marketing venues should be required to institute social distancing protocols, just as retail grocery stores are doing. In fact, farmers markets across the country have already established these procedures and are sharing best practices with each other.

We realize that at the Department of Homeland Security has issued some general recommendations about what should be considered essential industries and that food and agriculture are on that list. However, we are concerned that that DHS advisory does not explicitly include local marketing venues, such as farmers markets, farm stands, and community supported agriculture (CSA) operations. As a result, many local and state governments are shutting down those venue. We urge you to advocate for a revision to the DHS recommendation with your colleagues at the DHS. In addition, we urge you to advocate with the President, to urge that the federal declarations of essentiality of all food production and marketing venues be enforced with more rigor.

Farm Labor Accommodations Are Critical to Continuing Production of Organic Food During the Pandemic

- Establish a program to provide relief workers for sick farmers and farmworkers.

- In order to ensure uninterrupted food, crop, and commodity production, recognize all H-2A, as well as any other non-immigrant visa petitions involving an agricultural worker, visa consular processing functions as "essential" and direct the U.S. Consulates to treat all agricultural worker appointments as emergency visa services.

- Provide farmworkers who are currently employed on a farm with the same payments as any other workers without questions about their status as citizens, and make farmworkers eligible for paid sick leave, SNAP, health coverage, childcare, and workmen's compensation.

The New Emergency Response Program Administered by the Small Business Administration (SBA) Should Include Farmers and Agricultural and Food Cooperatives

- The Small Business Administration (SBA) is maintaining that farms and agricultural businesses are ineligible for emergency Economic Injury Disaster Loan (EIDL) programs. They are maintaining that only aquaculture enterprises, agricultural cooperatives, and nurseries are eligible for SBA disaster assistance. It is imperative that farmers be able to access SBA disaster assistance as these programs can help fill the void that many farm businesses are currently feeling due to COVID-19.

- In addition, the SBA should clarify that agricultural cooperatives and consumer food cooperatives are eligible for the Paycheck Protection Program (PPP) during the pandemic emergency. Many of

these cooperatives are under a great deal of economic stress as result of the pandemic and short-term access to the PPP will allow these cooperatives to maintain their staff so that they are able to serve their farmer and consumer owners during the emergency.

We thank you in advance for your efforts to respond quickly to the needs of organic farmers and businesses in light of the COVID-19 pandemic.

Sincerely,

Abby Youngblood, Executive Director, National Organic Coalition
Kate Mendenhall, Executive Director, Organic Farmers Association
Brise Tencer, Executive Director, Organic Farming Research Foundation

Appendix B

NOC Fall 2019 NOSB Comments

Peer Review

NOC urges the NOSB to call on the USDA National Organic Program to make public the results of the 2018 peer review audit, which contains information about the NOP's oversight and accreditation process for certifiers. The NOSB has a responsibility to review these findings in full in assessing the health of the NOP's accreditation program. NOC recommends that the CACS request and review the full panel report results on an annual basis.

The peer review process under the Organic Foods Production Act (OFPA), National Organic Program (NOP) procedures, and the Federal Advisory Committee Act (FACA) requires disclosure of the full peer review report.

As a part of the NOP's "commitment to continuous improvement," and its obligations under OFPA and its implementing regulations,[96] NOP established a new peer review process in 2016. While peer reviews had been conducted prior to that by third party review organizations, it was the finding of a 2010 Office of Inspector General audit that these third-party reviews were inadequate and did not satisfy the requirements as set for by OFPA and its regulations.[97]

According to OFPA regulations, the "Administrator shall establish a peer review panel pursuant to the Federal Advisory Committee Act (FACA)(5 U.S.C. App. 2 et seq.)"[98] and that panel "shall annually evaluate the [NOP's] adherence to the accreditation of certification/registration bodies and the [NOP's] accreditation decisions."[99]

As part of its revised peer review procedures, NOP released a detailed document in 2016, outlining the new procedural requirements for the peer review process.[100]

Within those procedural requirements, explicit instructions are provided concerning the development, review, and release of the annual report produced by the peer review panel. In particular, the NOP's procedures state under sections 3.12 and 3.13:

> 12. Presentation. The peer review panel report, along with any NOP response, will be presented at the next NOSB public meeting.
>
> 13. Publication. After the public meeting, the NOP will post a copy of the peer review panel report and the NOP response, on the NOP Web site. A USDA Organic Insider notice will announce the availability of the report.

NOP procedures also reiterate the requirement that "all final peer review panel reports will be posted on the NOP website. . . ."[101] under section four, which address the NOP's obligations concerning records retention.

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[96] *See* 7 U.S.C. §6516 and 7 C.F.R. §205.509.
[97] OIG Report
[98] 7 CFR § 205.509.
[99] 7 CFR § 205.509.
[100] U.S. Dept. of Ag., National Organic Program, Procedure: Peer Review of National Organic Program (NOP) Accreditation, May 12, 2016, at 4 https://www.ams.usda.gov/sites/default/files/media/NOP%201031%20Peer%20Review%20Process%20v2.pdf
[101] Id.

Because OFPA's regulations establish the peer review panel as a federal advisory committee, these public disclosure provisions are rooted in the mandated transparency requirements established under FACA.[102]

Since implementing its peer review procedures in 2016, NOP has yet to adhere to its internal procedures. In 2016, the peer review panel report was initially released in full to the public, but is no longer available in full on the USDA website. For 2017 and 2018, only executive summaries of the ANSI reports were released.

NOC has repeatedly requested that the NOP release the 2018 peer review panel report in full, and we urge the NOSB to join us in requesting that the results of this and future reports be made accessible to the NOSB and public stakeholders.

According to the executive summary for the 2018 peer review audit:

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

These are just a few of the serious problems identified by the peer review audit, but a complete understanding of the scope of the problem and the adequacy of the NOP's response is not possible without access to the full report.

NOC requests the NOSB to actively engage in reviewing the NOP's response to the problems identified through annual peer review audits, as well as identifying areas of risk that warrant further investigation through future peer review audits. A current area of risk is the proliferation of certified hydroponic and container production operations. NOC calls on the NOSB to request that a future peer review audit examine the accreditation process for certifying agencies that certify operations in the absence of clear standards, including hydroponic and container operations.

For the peer review audit process to be effective, the peer review entity must have the ability to track the NOP's corrective actions and compliance with issues that have arisen in previous peer review audits. The NOP's compliance with recommendations from the 2016, 2017, and 2018[103] peer review audits should be considered as a part of the 2019 peer review audit. The peer review panel membership should be determined by an outside entity, which might include members of the NOSB, and it should have the authority to request any files and look at any certifiers that it judges to be appropriate.

[102] 5 U.S.C. App. 2 §8(2) and §10(b)-(c).

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

Appendix C

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 sustainable agriculture 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 D

NOC Fall 2019 NOSB Comments

Clarify products of fermentation

NOC was pleased to see the Handling Subcommittee request for the work agenda request of fermentation products noted in the May 13, 2019, Executive Committee notes.[104] Our Spring 2019 comments are again included here as a reference for several of our other comments.

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

Fermentation processes produce foods or food ingredients in several ways:

1. **Foods and ingredients that are organisms grown by fermentation—that is, the biomass produced by the fermentation process.** These include nutritional yeast and baking yeast. Yeast may be certified organic when produced in compliance with an approved organic systems plan.[105] Marroquin International petitioned to have yeast reclassified as agricultural and listed on §205.606. It made the argument that yeast, like mushrooms, should be considered livestock under OFPA. "Microorganisms" are listed on §205.605(a).

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

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

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

1. Food organisms: yeast*.

[104] https://www.ams.usda.gov/sites/default/files/media/ESNotes2019July.pdf

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

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

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

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

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

Classification: agricultural vs. nonagricultural

The fact that products of fermentation are included on three different lists for processing is a sign that the classification of products of fermentation needs to be clarified. In particular, the Handling Subcommittee (HS) stated, "Glycerin, produced organically by fermentation is an agricultural product as defined in 7 CFR 205.2, since it is a processed product produced from an agricultural commodity, e.g. cornstarch."[106] This is also consistent with the NOP classification decision tree, which preserves the nonagricultural classification through fermentation. However, it is not consistent with the definition of a "nonagricultural substance" in the regulations.

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

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

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

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

[106] NOSB Handling Subcommittee proposal for glycerin, October 14, 2014.

fermentation or extracted from fermentation products would be easier to resolve if fermentation processes were regarded as agricultural production systems. It may be argued that defining what organic production means in the context of vat fermentation is no more difficult than defining organic aquaculture.

However, the NOSB has been clear that soil-less systems are not organic.[107] Organic agriculture is premised on a belief that the foundation of healthy plants and animals is healthy soil. This, indeed, is a problem in defining organic aquaculture.

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

Classification: Synthetic vs. Nonsynthetic

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

Other issues

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

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

Therefore, in addition to the material-specific comments below, we support the request that the development of criteria for evaluating products of fermentation processes be added to the NOSB work plan.

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