The Cornucopia Institute

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National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Docket # AMS-NOP-24-0023

The Cornucopia Institute uncovers the truth behind organic food and advocates for an organic label you can trust. Through research and investigations into agriculture and food issues, we provide needed information to family farmers, consumers, and other stakeholders in the organic agriculture community.

CROPS SUBCOMMITTEE (CS)

PROPOSAL: COMPOST

First and foremost, Cornucopia has a process concern with this proposal. The NOSB included permitted synthetic feedstocks in the definition as a response to the Biodegradable Products Institute (BPI) petition to the United States Department of Agriculture (USDA) to allow synthetic compostable packaging as an organic compost feedstock. That petition sought to subvert the NOSB process by going directly to the USDA and claiming the NOSB did not need to be involved because they were "simply" changing the definition of compost and it wasn't a National List issue. This petition was a transparent attempt to bypass the NOSB process that protects the integrity of the organic standards, including the National List. Fortunately, the NOP did defer that discussion to the NOSB for a recommendation.

CS in this proposal recommends new language for the definition of "compost" at 7 CFR 205.2, and for the composting requirements outlined at 7 CFR 205.203, with the understanding that the NOP will need to incorporate any recommendations made by NOSB into its rulemaking process already underway in the Market Development for Mushrooms and Pet Food.

Proposal Language

Currently, organic regulations define compost as:
205.2 Terms Defined

Compost. The product of a managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil. Compost must be produced through a process that combines plant and animal materials
1. with an initial C:N ratio of between 25:1 and 40:1.
2. Producers using an in-vessel or static aerated pile system must maintain the composting materials at a temperature between 131 °F and 170 °F for 3 days.
3. Producers using a windrow system must maintain the composting materials at a temperature between 131 °F and 170 °F for 15 days, during which time, the materials must be turned a minimum of five times.

The CS proposes the following new definition for compost:

Compost – the product of managed aerobic, biological decomposition of plant and/or animal materials, and/or permitted synthetic compost feedstocks at § 205.601(c). The product will have undergone mesophilic and thermophilic temperatures, which significantly reduce the viability of pathogens and weed seeds, and stabilize the carbon such that it is beneficial to plant growth.

This proposed definition is similar to the American Association of Plant and Food Control Officials from 2018, which has also been adopted by the US Composting Council:

Compost – is the product manufactured through the controlled aerobic, biological decomposition of biodegradable materials. The product has undergone mesophilic and thermophilic temperatures, which significantly reduces the viability of pathogens and weed seeds, and stabilizes the carbon such that it is beneficial to plant growth. Compost is typically used as a soil amendment, but may also contribute plant nutrients.

The primary difference between the proposed definition and the definition from the American Association of Plant and Food Control Officials is the specificity of "*biological decomposition of plant and/or animal materials, and/or permitted synthetic compost feedstocks…"* Cornucopia agrees that specificity is needed in this area because the organic standards are applicable to a narrower range of practices than conventional farming. Importantly, however, the proposed definition would open the door to synthetic feedstocks being allowed in organic compost.

Criticisms of the Proposed Definition Changes

One concern with opening the door to synthetic compost feedstocks it that it is nearly impossible to remove substances from the National List once they are enshrined there, due to changes in the sunset review process. Previously, the Sunset process required a "motion to re-list" with majority support rather than a "motion to remove." The National Organic Program (NOP) instituted changes to the sunset review process in the fall of 2013 so that the NOSB now votes on a motion to remove a substance.[1] It has been suggested that this majority control of National List sunsets would add stability to the entire material review process, preventing marketplace disruptions.

[1] National Organic Program, Agricultural Marketing Service, U.S. Department of Agriculture. "Review of Allowed and Prohibited Substances in Organic Production and Handling. Questions and Answers." https://www.ams.usda.gov/sites/default/files/media/NOP%20Q%26A%20Sunset%20Process.pdf

Cornucopia disagrees with the 2013 change to the sunset process on principle, since one of the previous strengths of the National List was that substances would naturally "fall off" the list once they no longer met the requirements for necessity in the marketplace. The organic marketplace is centered around using natural substances and management practices to tackle problems that arise in organic production and handling, rather than relying on synthetic substances and input-intensive management. The argument that the marketplace requires substances to be available in perpetuity once they are listed appears to be made only by producers and handlers that seek to do away with continuous improvement in the organic industry. The five-year review process allows ample time for the public to engage, and there is significant notice before substances are de-listed. Any change to the National List also requires USDA to complete rulemaking, a process which includes yet another public comment opportunity.

Compost is already a potential source of contamination from synthetic substances not allowed in organic production and toxins that have a profound impact on the land. Due to the risks involved, Cornucopia supports clear standards that will discourage the use of compost as a "dumping ground" for industrial waste, and will encourage the uses that foster soil health and ecosystem services.[2]

Cornucopia requests that the National List process will explicitly protect organic farms from so-called "forever chemicals" and remove products expediently if synthetic compost feedstock is found to contaminate the soil. If this compost proposal is finalized, Cornucopia asks that the NOSB and the NOP use the precautionary principle[3] when substances receive environmental and human health reviews, being especially cautious of the risks of soil contamination from microplastics, forever chemicals, and other potential toxins.

Finally, Cornucopia is concerned about how this proposed definition will impact an existing schism in organic terrestrial plant production. Though the proposal to amend § 205.203(c) (the soil fertility and crop nutrient management practice standard) addresses many commenters' concerns, such as food safety, it's not clear whether this section would apply to crops grown to maturity in soilless production, including hydroponic and container production.

Soilless organic production currently exists in a kind of regulatory limbo; terrestrial plants in soilless production systems are allowed to be certified organic, despite the soil fertility requirements in the regulations clearly requiring soil-based production. Because of this loophole or lack of clarity, it's unclear whether soilless production would need to meet the proposed changes in § 205.203(c) — or even whether these operations are meeting these requirements now. This opens up food safety and organic integrity concerns because the proposed definition at

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[2] This scrutiny of compost materials is required by OFPA and the regulations because contamination is a real threat to soil health, the environment, and human health on a macro scale. §205.203(c) of NOP regulations requires that "The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances."

[3] The precautionary principle enables decision-makers to adopt precautionary measures when scientific evidence about an environmental or human health hazard is uncertain and the stakes are high.

§ 205.2 removes temperature and timing requirements that were initially added for food safety considerations.

It remains unclear which provisions of the organic regulations apply to soilless operations. This serious flaw in the system is highlighted by the compost proposal. Cornucopia maintains that organic agriculture is soil-based. (A full breakdown of this position can be found in the Soil Position Statement.)

Many of these criticisms of the compost proposal could be addressed by policy changes either in the regulations themselves, in guidance, or in some other process standard (such as the Policy and Procedure Manual).

Benefits to the Compost Proposal

Cornucopia is happy to see that the NOSB proposal rejects adding a blanket definition for "compost feedstocks" which could allow the inclusion of synthetic substances that have never been reviewed by the NOSB and are not included in the National List. We also support rejecting the concept of "de minimus" contamination in compost. With the continuing evolution of research into pesticides, insecticides, fungicides, and other chemicals, including synthetic nitrites and plastics, we are finding impacts on human health and the environment at lower and lower concentrations. It is anathema to organic practices to allow a baseline of contamination in compost, and organic consumers will not tolerate this kind of compromise to our future soil and health.

The NOSB must be included in any decision about synthetic compost feedstocks by requiring National List evaluation to ensure the organic community can give input. A blanket allowance of this array of synthetics would subvert the public process and set a truly troubling precedent.

Conclusions and recommendations for applying the compost proposal

Overall, Cornucopia supports the proposal because it would make it explicit that all synthetic compost feedstocks must be evaluated for addition to the National List now and in the future.

Cornucopia understands that the strict disallowance of synthetic compost feedstocks is challenging in practice. For example, inputs including newspaper are already allowed, even though they may contain some synthetic components (because newspaper is not entirely cellulose). Cornucopia strongly recommends further clarification in the compost proposal to ensure that the NOP in particular understands the intent is to minimize the existence of prohibited substances in compost as much as possible.

Cornucopia champions the "precautionary principle" [4] in organic agriculture, which supports an easier path toward removing substances more easily from the National List. A relevant example of why the precautionary principle is so important is the devastation caused by PFAS contamination. PFAS are widely used, long-lasting chemicals, and are considered highly toxic to humans and the environment. Because of their widespread use since the 1940s and their

[4] The precautionary principle enables decision-makers to adopt precautionary measures when scientific evidence about an environmental or human health hazard is uncertain and the stakes are high.

persistence in the environment, organic farms are now facing devastating economic losses when they find their soil contaminated by PFAS – often applied decades before, and without the knowledge of the current farm family.

Synthetic feedstocks could pose similar risks. Even unintentionally, we may be adding forever pollutants to our soil. To avoid this risk, Cornucopia recommends that any substances that have even the potential to contaminate crops or soil should be disallowed. This recommendation is based on the existing regulation at §205.203(c), which requires that:

> *The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances.*

To dovetail with this compost proposal, Cornucopia recommends that the NOSB develop an explicit strategy for keeping contaminated inputs out of organic production. Addressing contamination from inputs like conventional manure, produce, and even grass clippings is needed to ensure we are meeting the requirements of §205.203(c).

We hope that the Crops Subcommittee will add this issue back to their work agenda.

CERTIFICATION, ACCREDITATION, COMPLIANCE SUBCOMMITTEE (CACS)

PROPOSAL: CLIMATE INDUCED FARMING RISK AND CROP INSURANCE

Cornucopia applauds the efforts of the NOSB thus far on the important topic of improving crop insurance for organic farmers in light of the challenges posed by climate change. We hope this work can continue to level the playing field for organic producers and eventually *incentivize* transition from conventional production to organic. The updates to Risk Management Agency (RMA) are especially hopeful and we agree with the CACS identification of areas that could still use work. Cornucopia sees that the deck is often stacked against organic farmers when it comes to crop insurance. These problems need to be cured to fuel growth in the organic sector.

As recognized by the CACS, issues with crop insurance must be addressed to avoid disincentivizing organic transition. Many of the practices the global agricultural community needs to support in order to address climate change – including utilizing diverse crop rotations and practices supporting soil health – are specifically disincentivized by crop insurance programs. Also, transitioning farmers should not be treated as beginning farmers when they have other farming experience.

Alongside improvements to crop insurance systems, the organic community should also find ways to *incentivize* more farmers to transition to organic methods, thereby promoting long-term ecological sustainability. Organic farming, at its best, safeguards environmentally responsible farming practices, ensures a stable supply of organic food, and provides a crucial safety net for

organic farmers who face unique challenges. These benefits could be worked into crop insurance and other federal and state benefits going forward.

The CAC Subcommittee's continued efforts to discern what organic producers need from crop insurance programs continue to be relevant, and we hope that both national and state programs will increase their efforts to improve this issue soon.

DISCUSSION DOCUMENT: RESIDUE TESTING IN A GLOBAL SUPPLY CHAIN

Cornucopia supports continuous improvement in testing to ensure integrity in the organic supply chain.

Cornucopia has long advocated for enhanced residue testing protocols, most recently in the context of organic grain imports which were shown to be fraudulently labeled, interfering with the domestic grain market. As the CAC Subcommittee is aware, this large-scale fraud was a primary driver of the Strengthening Organic Enforcement Rule. As was the case during the height of Cornucopia's grain import fraud investigation, Cornucopia maintains that bulk shipments of organic product should all be tested at the port of origin and upon arrival in the United States. By conducting rigorous testing, we can ensure organic products genuinely meet these organic standards, thereby safeguarding consumer health and trust.[5]

Maritime shipments of organic feedstuffs continue to be imports of concern, given the prevalence of transshipments through third countries and often inconsistent mass/balance data whereby import volume and acreage cannot be reconciled. Cornucopia commends and supports efforts to include enhanced testing protocols of maritime shipments in the Farm Bill. Specifically, we support proposals requiring testing of, at a minimum, every bulk shipment of organic feedstuffs arriving on maritime vessels. Cornucopia supports expanding this proposal to include imports arriving by land from Mexico and Canada, given increasing concerns regarding transshipments through these countries for commodities grown overseas.

Testing protocols should be broad enough to be flexible and specific to the commodity, and consideration should be given to the country of origin. Residue testing beyond this could be done using a risk-based approach.

In this way, residue testing in organic products can be used as an enforcement tool. Since organic certification is a practice-based standard, this testing can be used to ensure that practices in an organic systems plan are being used properly.

With the increased occurrence and complexity of sampling in the processing/handling environment, there also needs to be a discussion of who bears the cost of this sampling.

[5] Residue testing is also required by the regulations. §205.671 states, "When residue testing detects prohibited substances at levels that are greater than 5 percent of the Environmental Protection Agency's tolerance for the specific residue detected or unavoidable residual environmental contamination, the agricultural product must not be sold, labeled, or represented as organically produced." Other sections of the regulations relate to the testing for residues.

Currently, certifiers calculate the cost of crop residue sampling as part of their up-front costs of doing business, and incorporate those costs into certification fees. Unfortunately, this practice results in an inherent conflict of interest: certifiers must essentially invest in the products they should be certifying. In the case of bulk shipments, costs of residue testing should fall directly on the importer.

DISCUSSION DOCUMENT: RISK-BASED CERTIFICATION

We appreciate the continued work of the CACS on this topic. Risk-based certification has many benefits and risk-based assessments should remain flexible enough to address the changing marketplace going forward. To that end, there are some areas that pose greater risks, which should be taken into account during the certification process.

We agree with the CACS conclusions that the "one size fits all" model does not work for the current status of the marketplace. A low-risk operation's certification process should likely not be identical to the process for a higher-risk operation – and yet Cornucopia often hears of small, diversified operations receiving much more rigorous inspections and higher paperwork burdens than larger businesses.

Supply chain transparency and antitrust concerns

To ensure markets are fair, vigorous enforcement of the organic regulations is critical, including enhanced oversight of imports. The Strengthening Organic Enforcement (SOE) final rule has codified much of this risk-based approach in the supply chain; Cornucopia hopes that we soon will see a decrease in organic import fraud.

In addition to the question of domestic and import fraud, monopolization is a serious concern in the organic marketplace. Free markets are the foundation of a vibrant economy, and competition among sellers in an open marketplace gives consumers many benefits, including lower prices, higher quality products and services, more choices, and greater innovation. However, when a major economic player controls a large percentage of the market, they can easily push out smaller competitors. The risk of fraud and conflicts of interest also increase as the marketplace becomes less competitive.

Addressing fraud and antitrust issues in the organic marketplace will also help encourage transition. Domestic producers must be confident that competition is fair in order for benefits of organic production to outweigh the risks of competing with imported product. Clearly, there is a domestic market for organic grain production. The testing protocols noted above can help level the playing field. Addressing potential fraud through testing can incentivize more producers to make the transition, thereby benefiting producers and consumers alike.

Cornucopia's consumer-focused mission aims to promote consumer confidence in organic through transparency in the marketplace. Education about the production of organic food allows consumers to make informed decisions and ensures that consumers are getting what they pay for when purchasing organic products. Transparency in the supply chain also allows consumers to support producers who do adhere to the organic standards, thus promoting confidence in

purchasing decisions and in the overall organic marketplace. Ultimately, a transparent marketplace is the essential ingredient in driving continuous improvement and ensuring the organic sector continues to thrive.

Risk inherent in allowing "organic" hydroponics and container production

As already discussed briefly in this comment, there is an inherent risk in allowing soilless production in organic because those practices fall into a vacuum within the standards. The Cornucopia Institute continues to support the Organic Agriculture is Soil-Based: Position Statement:[6] organic farming is soil-based, and hydroponic and container production should not be allowed.

The allowance of soilless production under the organic label is misaligned with the existing rules. The issue of organic hydroponics is not settled: organic products *cannot* meet a consistent standard while soilless production exists alongside the requirements for soil. This schism must be resolved to move forward with risk-based certification.

Consistent and uniform standards require that unintended consequences, misalignment, and "holes" in rulemaking be cured as soon as possible.[7] The fractures in the organic marketplace can only be resolved by issuing noncompliances to existing certifiers and operators allowing soilless production, thereby ending the certification of these operations, *or* by immediate rulemaking to clarify when and how soilless production can be employed.

Curing the problem would also require a moratorium on the certification of new "organic" hydroponic operations until rulemaking can settle the issue.

Cornucopia urges the NOSB to call for a moratorium on the certification of new aeroponic operations, hydroponic operations, and crops grown to maturity in containers until we can utilize our existing NOSB and rulemaking process to move forward with greater consistency.

Questions from CACS:

- *How does your organization define risk?*

Cornucopia defines risk based on the utilization of the "precautionary principle" as already discussed in this comment. Cornucopia considers risk-based approaches to have three main stages:

1. Risk identification and assessment. Identifying risk can be done using a straightforward set of triggers. Cornucopia believes that scale, a history of violations, and attention to certain commodities that have been identified as high risk are all factors that should be taken into account.

[6] Note that where Cornucopia refers to soilless production or "hydroponics", we mean any soilless production where the plants are grown to maturity. This includes traditional aeroponic and hydroponic systems, and systems where plants are grown in an inert media (like coconut choir) in containers.

[7] Summary of the Final Rule Establishing the National Organic Program National Organic Program. Docket Number: TMD–00–02–FR, Effective: February 20, 2001. https://www.ams.usda.gov/rules-regulations/establishing-national-organic-program

2. Risk control. This stage requires proactive measures used to mitigate identified risks. These could include targeted on-site visits (especially unannounced visits), remote monitoring, or enhanced training for certifiers or inspectors.
3. Risk review and reporting. Risks should be continuously monitored and reassessed so that timely interventions can be made when necessary.

A risk-based approach to certification and inspections does not suggest any less vigilance in oversight of standard organic certification protocol. Rather, it focuses oversight activities on preventing or mitigating important and likely risks. Moreover, a risk-based approach should be dynamic, utilizing the concept of "continual improvement" that should be such an essential part of the organic program. For example, monitoring findings should be evaluated to determine whether additional actions (including training or clarification of protocol requirements) are necessary to ensure human subject protection and data quality across sites.

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

Yes, having explicit language in the regulations would benefit the organic marketplace, in part by making it defensible that risk-based oversight is the accepted strategy. This approach would help streamline the application of risk-based oversight for certifiers and administrators as well.

- *Are there other definitions that would be beneficial to include at §205.2 Terms Defined besides those listed above? Is it important that all certifiers use the same risk criteria to evaluate certifier operations? Why or why not?*

All certifiers must use the same risk criteria, because inconsistency could lead to "certifier shopping" and lead to conflicts of interest within the accreditation system. Consistency is also required by OFPA, and it's what allows the organic marketplace to grow.

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

One burden we consistently hear from producers is that diversified operations receive longer and more laborious inspection and review processes. We understand that diversified operations are often more complex, with multiple commodities, seasonal differences, and methodologies to account for. However, it's these operations that embody the spirit and integrity of the organic label. Cornucopia will engage with community members in this area to see if there are any themes on how burdens could be reduced for these kinds of producers and handlers. Currently, the primary complaint is that the cost is proportionally higher for these small diversified operations. Improvements to cost share and other cost reduction programs would be of immediate benefit.

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

While Cornucopia appreciates the current complaint structure, it's not clear how complaints about operations affect the risk-based approach discussed in this document. More clarity in that arena would be helpful.

Cornucopia believes a risk-based approach would benefit from cooperation with other agencies. Other agencies can provide information that is valuable for determining level of risk for certain sections of the organic rules and regulations. Of particular concern are the requirements that organic production and handling not damage the environment or its natural resources.

For example, the definition of "organic production" in the regulations requires that the production system "…foster cycling of resources, promote ecological balance, and conserve biodiversity."[8] The natural resources and biodiversity conservation requirement of the USDA organic regulations at 7 C.F.R. § 205.200 requires operations to "maintain or improve the natural resources of the operation, including soil and water quality." Section 205.2 of the regulations also defines "natural resources of the operation" as the "physical, hydrological and biological features of a production operation, including soil, water, wetlands, woodlands, and wildlife."

To this end, certifiers and the USDA should consider actions by the Environmental Protection Agency, Army Corps of Engineers, State and Tribal agencies, and the U.S. Fish and Wildlife Service. Local soil and water conservation districts may also have valuable insight into topics, including erosion, that would be helpful. Data concerning pollution of air and water, changes to hydrologic features, NPDES permitting, endangered species tracking, and impacts on local wildlife are all relevant to risk in organic production.

MATERIALS SUBCOMMITTEE (MS)

PROPOSAL: INERT INGREDIENTS IN PESTICIDE PRODUCTS

The NOSB should ensure that all individual synthetic "inerts" used in organic pesticide formulations meet OFPA criteria – that they are not harmful to human health and the environment, that they are necessary, and that they are compatible with organic systems of production. This being understood, Option 1, as presented in the NOSB proposal, is the best option. The Organic Foods Production Act (OFPA) requires this level of scrutiny when assessing inputs.[9]

Option 2 has serious flaws. Option 2 would reference a subset of EPA regulations, such as inerts exempt from the requirements of a tolerance. However, these EPA categories do not mesh with OFPA criteria or the intent of the certified Organic label. Organic integrity requires a level of transparency that may not be present in other industries, but that transparency is necessary for the functioning of the organic marketplace. Also, the information that the NOSB would compile to review inert ingredients would be primarily from the public sphere, in terms of environmental and human health concerns. Because inert ingredients so often compose the majority of the products applied to organic crops, it is not acceptable to give a blanket allowance to thousands of

[8] *See* CFR § 205.2. Organic production. A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.

[9] For example, section 2118(b) of OFPA specifically states that the National List "shall contain an itemization, by specific use or application, of each synthetic substance permitted under subsection (c)(1) or each natural substance prohibited under subsection (c)(2).

inerts over which organic stakeholders have no control. The lack of clarity surrounding inerts undermines organic integrity, consistency under the label, and challenges consumer trust.

Option 2 is not ideal because the EPA "exempt from tolerance" and other categorizations only look at the aggregate, non-occupational exposure from the pesticide. A material that is exempt from tolerance could have problematic worker exposure effects or detrimental environmental effects. In addition, the EPA is slow to update its chemical classifications, even when new research shows a substance may have serious deleterious impacts. The Organic Program should go its own way and not rely on the EPA.

We sympathize with the NOSB that Option 1 is more burdensome in terms of workload. Cornucopia urges the NOP give more support to the NOSB to lessen that burden. Personnel hired by the NOP could perform much of the work of data searches, compilation of health and environmental data, and basic OFPA reviews of the inerts used in organic production. This will help support the NOSB in conducting their review process.

We agree that listings should also be prioritized by current usage and need. The list of products that would be applicable for the National List is not in the hundreds or thousands, but rather a clear subset. Most inert substances on EPA List 3 and 4 are not in *common* use, even if they are occasionally used. No efforts should be made to include these low-or-no-use products on the National List, because the use of those substances can be *petitioned*, should a distinct need arise for them in the future.

Cornucopia does agree with the MS proposal to immediately prohibit alkylphenol ethoxylate substances and per- and polyfluoroalkyl (PFAS) substances.

Addressing concerns about inert ingredients is an essential inquiry into the integrity of the USDA organic program. Cornucopia is concerned that inerts could be allowed under a blanket allowance that would quickly become out of date and nonsensical. Many inerts may be more toxic and compose a greater portion of an applied material than the active ingredients. These products should have never been allowed without a review in the first place. Even though synthetic inerts were previously allowed as ingredients in product formulations as long as they were not of toxicological concern for the Environmental Protection Agency (EPA), the general review requirements of the National List still apply.[10]

Further, the NOP and NOSB must retain authority to determine which pesticide products align with the Organic Foods Production Act (OFPA) and National List Criteria. While the NOP and NOSB should use available EPA data when reviewing substances before they are placed on the National List (or at Sunset), the authority of deciding which products belong in organic production and handling should solely lie with the NOSB and NOP.

[10] As stated in the Advanced Notice of Public Rulemaking (ANPR) on 'inerts', OFPA allows the use of synthetic inert ingredients in a product formulation if the inerts are "not classified as 'inerts' of toxicological concern by the EPA, in addition to the general considerations for National List substances at 7 U.S.C. 6517 (c)(1)(a) and 6518(m)."

DISCUSSION DOCUMENT: INDUCED MUTAGENESIS

Cornucopia appreciates the Materials Subcommittee (MS) for its clear analysis of induced mutagenesis, by clarifying existing definitions and previous NOSB recommendations as they pertain to induced mutagenesis and excluded methods in general.

In the discussion document, the MS highlighted that the definition of excluded method refers to means, not results that are "not possible under natural conditions or processes and are not considered compatible with organic production."

It seems clear from the information produced and the MS discussion itself that induced mutagenesis should qualify as an excluded method.

We understand that the MS is reluctant to classify as excluded because there are some organic growers in the US who currently use cultivars developed using induced mutagenesis. It's not clear to Cornucopia whether, or to what extent, organic production is reliant on cultivars developed using induced mutagenesis. This information would need to be clarified before the NOSB could determine whether certain cultivars might be "grandfathered in."

LIVESTOCK SUBCOMMITTEE (LS)

PETITIONED MATERIAL PROPOSAL: MELOXICAM

Cornucopia supports National Organic Coalition's (NOC) stance and comments on the petitioned material proposal for meloxicam.

While Cornucopia supports the desire to respond to animal welfare concerns, this proposal has several significant flaws that must be cured before meloxicam is listed. The NOSB must address these concerns and then put forth a new proposal for meloxicam in Spring, 2025.

A Technical Review (TR) is needed

Cornucopia Agrees with NOC that a TR is needed. A TR provides a reference for all future NOSB reviews and puts the information available in the public record. The NOSB should continue to ask for a TR on all petitions, so that we all are assured the Program will act on the best available information. Cornucopia asks that the NOSB request a TR for meloxicam before approving its use.

The human health and environmental review is not complete

Related to the need for a TR, Cornucopia finds the NOSB's review of the impacts of use on humans and the environment are also incomplete.

The review seemed to disregard risks to human health because "[m]eloxicam is an approved drug for human use…" without ever addressing the risk residues may pose to sensitive consumers. It is making a judgment concerning possible exposure *to uninformed consumers* based on FDA's approval of the drug *by prescription*. While it is approved for human use, its prescription is

limited to instances where there are no other good alternatives, such as extreme pain cases (due in part to its effects on the liver).

Nonsteroidal anti-inflammatory drugs (NSAIDs), including meloxicam, are widely used for their analgesic, antipyretic, and anti-inflammatory properties. However, they are also associated with a broad spectrum of hypersensitivity reactions, ranging from mild cutaneous manifestations to severe systemic responses.[11] For example, Cornucopia is aware of individuals where even a miniscule exposure to certain NSAID medications – including exposure through livestock products – can cause anaphylaxis, which is life-threatening. Cornucopia knows of many consumers who choose organic livestock products *because* the limits on livestock medications makes them personally safer.

We must ensure that the use of this material in organic animals does not jeopardize the health of our organic consumers.

On the environmental review, the Subcommittee determined that there are "no known effects on soil organisms, crops, or livestock" and "no reported adverse impacts on biodiversity…". A TR would provide references for these statements that would provide more assurance to the community and allow future NOSB reviews to build on the existing record (if new research findings were developed).

Withdrawal time concerns

The motion proposes only a meat withdrawal period of two times FDA recommendations. Cornucopia sees no evidence concerning data on the residues of meloxicam remaining in the meat. We also do not know for certain whether residue times varies by species, or if residues can be present in other animal products (like milk products). It's not clear whether the FDA has approved meloxicam for use in food producing animals. Given this baseline of information, the stipulation of a withdrawal period that is two times FDA recommendations has no valid basis.

The petition also notes withdrawal periods for milk but without specificity for each species. With the current wording of the motion there is no withdrawal period, and milk could be immediately sold after administration of the drug. This poses an unknown risk that *must* be addressed.

This is another area where a TR could be helpful, and Cornucopia recommends that the TR address withdrawal concerns for all potential uses.

The listing should limit meloxicam only for pain control specifically for disbudding and dehorning in mammals

The petition is mostly focused on pain management during disbudding or dehorning (in mammals). Cornucopia does recognize the need for better pain management and supports listing of meloxicam for disbudding and dehorning *specifically*.

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[11] *See* Review of NSAID Hypersensitivity Reactions Based on Clinical Phenotyping. 2024. DOI: 10.1142/S2661341724300015.
https://www.worldscientific.com/doi/full/10.1142/S2661341724300015

Unfortunately, the motion does not restrict meloxicam to only this use but rather allows for its widespread use on *any* species at any time. Given the specificity in the petition and the review the NOSB has done so far, this allowance is too broad. We do not have any information about other industry uses for meloxicam or even how it is used in different species.

The restriction that meloxicam is only to be used in mammals should also be explicitly stated in the future listing, rather than assumed. The current motion could allow for its use in any livestock species, including poultry. There may be potential uses for meloxicam in other species, but those uses should be petitioned for separately. The NOSB should look at the narrow application of this petition when building out their proposal.

The meloxicam petition also states that the medication should not be used during the third trimester of pregnancy, but the proposed motion would allow for the medication's use during pregnancy.

These considerations must be cured before meloxicam is accepted into the organic program.

PROPOSAL: ANNOTATION CHANGE - DL-METHIONINE

Cornucopia *strongly opposes* the proposal to remove the methionine use limits.

Methionine is required for proper cell development and feathering in poultry and has been added in synthetic form to organic poultry feed since the inception of the organic rules and regulations. Synthetic methionine is currently allowed in organic production at a set rate of a certain number pounds of synthetic 100 percent methionine per ton of feed in the diet, depending on the poultry type. Cornucopia recommends this allowance remain in place and limits on synthetic methionine not be removed.

Cornucopia has consistently commented that we would like to see a natural source of methionine developed and to move away from the use of synthetic methionine as soon as possible. With the proper incentive, natural alternatives (including management changes and dietary additions) can be substituted for synthetic methionine. There has been research in recent years that suggests natural alternatives to DL-methionine are on the horizon. For example, current research into black soldier fly larvae seems a promising source of methionine in poultry diets. As a bonus, omnivorous birds like chickens and turkeys consume insects as part of their historical diets.

While Cornucopia agrees that methionine is essential for animal welfare, moving to unrestricted use of synthetic methionine should not be a forgone conclusion. Cornucopia hears from both producers and inspectors which have seen the current methionine levels as pushing the limits of sound poultry management. Several certifiers from NOC have also noted that it is problematic to keep track of total methionine use when flocks go through multiple people's hands.

Looking at the natural behavior and biology of poultry, it's clear that high animal welfare is predicated on a natural diet and fostering natural behaviors. Since the organic standards require outdoor access and the promotion of natural behavior, it's not a large leap to suggest that poultry should be spending more time outdoors performing natural behaviors (which should include

foraging). All these production practices that should be standard in organic production *should* lessen the need for large amounts of synthetic methionine.

Organic farmers that are dedicated to organic ideals routinely raise their meat chickens and egg-laying hens on pasture, in compliance with the organic rules that require them to spend time outdoors. Pasture-raised poultry are likely to forage, acquiring more natural methionine from their diet. Instead, it's confinement indoors and a limited diet that are responsible for limiting the natural availability of methionine and increasing the need for synthetic supplementation.