



October 25, 2021

Jared Clark
Standards Division
USDA-AMS-NOP

Docket: AMS-NOP-19-0106

RE: Proposed Rule; National List of Allowed and Prohibited Substances (2022 Sunset)

Dear Mr. Clark:

Thank you for this opportunity to provide comment on several proposed amendments to the National List of Allowed and Prohibited Substances (National List) based on recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB).

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

This proposed rule, if accepted as written, would amend the National List by removing the following substances in organic crop and livestock production (§§ **205.601 and 205.603**): Vitamin B1 (Crops); Oxytocin (Livestock); Procain (Livestock); Sucrose Octanoate Esters (Crops and Livestock).

It would also remove the following nonorganic ingredients currently allowed in organic handling (§§ **205.605 and 205.606**): Alginic acid; Colors (black currant juice color, blueberry juice color, carrot juice color, cherry juice color, grape juice color, paprika color, pumpkin juice color, turmeric extract color); Kelp; Konjac flour; Sweet potato starch; Turkish bay leaves; and Whey protein concentrate.

All of the substances/ingredients included in this rule have a “sunset date” of March 15, 2022, except for Turkish bay leaves and whey protein concentrate (sunset date of June 27, 2022).

Summary

Scope	Material	OTA Position
Crops	Vitamin B1	No objection to removal; 12-month implementation.
Livestock	Oxytocin & Procaine	No objection to removal; 12-month implementation.
Crops & Livestock	Sucrose Octanoate Esters	No position; New information and regulatory dynamics may impact determinations about necessity.
Handling	Alginic Acid	No objection to removal; 24-month implementation.
Handling	Colors (black currant juice color, blueberry juice color, carrot juice color, cherry juice color, grape juice color,	No objection to removal, <i>provided</i> the comments received from organic businesses during this comment period clearly demonstrate these materials are no longer necessary because of the commercial

	paprika color, pumpkin juice color, turmeric extract color)	availability of organic alternatives (quality, quantity and form); 24-month implementation.
Handling	Sweet Potato Starch	No objection to removal; 24-month implementation.
Handling	Konjac Flour.	No objection to removal, <i>provided</i> the comments received from organic businesses during this comment period clearly demonstrate that konjac flour is no longer necessary because of the commercial availability of an organic alternative (quality, quantity and form); 24-month implementation.
Handling	Turkish Bay Leaves	No objection to removal; 24-month implementation.
Handling	Whey Protein Concentrate	No objection to removal; 24-month implementation.

We offer the following more detailed comments.

OTA supports the judicious use of materials that have been added to the National List due to their necessity in a certain organic production system or due to their essential function in an organic processed product or organic handling system. We also strongly support the critical role of NOSB and its responsibility to ensure that materials added to or removed from the National List meet the criteria of the Organic Foods Production Act (OFPA) and USDA’s organic regulations (7 CFR 205). Specifically, materials should be added or remain on the National List if: 1) they are necessary and compatible with organic production and handling practices; 2) there are no commercially available alternative materials (natural, organic) or practices; and 3) no new information has been submitted demonstrating adverse impacts on humans or the environment (OFPA SEC. 2118 [7 U.S.C. 6517 and 6518] National List).

OTA’s comments to NOSB on its Sunset Review process are shaped through a survey process we conduct whereas an electronic survey is created for each material under review. The surveys are made available to every NOP certificate holder and include 7-10 questions addressing the necessity (farm and livestock) or essentiality (handling) of the National List substances under review. The names of the companies submitting the information are confidential (not disclosed to OTA). To ensure wide distribution of the surveys beyond OTA membership, OTA works with Accredited Certifying Agencies (ACAs) and OMRI to distribute the survey links to all of their clients as well as to targeted clients they know are using the inputs under review. OTA also works through its Farmers Advisory Council (FAC¹) to help assist in distribution to NOP certified farmers.

NOP’s proposal to remove the following substances from National List, in most cases, supports the information OTA collected during the NOSB Sunset Review process and during this comment period. Below is a summary of the information we have gathered with special attention given to materials where we have concerns because either suitable alternatives may not be available and/or new information and regulatory dynamics may impact determinations about necessity.

¹ OTA’s Farmers Advisory Council was established in 2013 to formalize two-way communication between OTA and member producers as well as regional organic producer organizations across the United States. Through dialog and input, FAC gives organic farmers a voice to directly influence OTA’s policy, and provides an avenue for OTA to share information and advocacy work with this stakeholder group.

Vitamin B1 (Crops)

Background: Vitamin B1 (thiamine) has been on the National List for use in organic production since the NOP regulations were first implemented. NOSB voted to remove it from the National List in fall 2017 (2019 Sunset Review) on the basis that it is not essential for crop production because its originally intended use for root growth and reduction of transplant shock are unsubstantiated by technical information. Yeast, various meals (e.g., soybean meal, cottonseed meal), and other crop waste or residues are cited as suitable alternatives. OTA did not take a position on this material when it was being reviewed by NOSB in 2017. We received 0 responses for this substance on 2019 Sunset Surveys. The NOP is proposing to remove (prohibit) Vitamin B1 from the National List in accordance with NOSB's recommendation on the basis that it is not essential for organic crop production.

OTA Position: OTA **does not take objection** to NOP's implementation of the NOSB recommendation to remove Vitamin B1 from the National List. We also request an implementation period of 12 months be included to allow industry time to comply.

Oxytocin (Livestock)

Background: Oxytocin is a hormone used to treat post-partum conditions that are associated with the birthing of a calf, such as retained placenta. It has been on the National List for use in organic production since the NOP regulations were first implemented. NOSB voted to remove oxytocin from the National List in fall 2017 (2019 Sunset Review) on the basis that it is not essential for organic livestock production. NOP is proposing to remove (prohibit) oxytocin from the National List in accordance with NOSB's recommendation on the basis that it is not essential for organic livestock production.

OTA's comments at the fall 2017 NOSB meeting supported the NOSB's proposal to remove oxytocin. We recognized that there are multiple natural alternatives available to address many of the post-parturition complications that can arise in organic dairy cattle. We also recognized that the allowance of Oxytocin prevents some organic producers from claiming that their products are "hormone free" despite the fact that Oxytocin is not a growth hormone.

OTA Position: OTA **does not take objection** to NOP's implementation of the NOSB recommendation to remove oxytocin from the National List. We also request an implementation period of 12 months be included to allow industry time to comply.

Procaine (Livestock)

Background: Procaine is a local anesthetic used when performing minor surgeries or physical alternations on livestock. It has been on the National List for use in organic production since the NOP regulations were first implemented. NOSB voted to remove procaine from the National List in fall 2017 (2019 Sunset Review) on the basis that it is not essential for organic livestock production. All known procaine products are already prohibited because they are formulated with antibiotics that are prohibited in organic. Lidocaine is cited as an effective and widely available suitable alternative. NOP is proposing to remove (prohibit) procaine from the National List in accordance with NOSB's recommendation on the basis that it is not essential for organic livestock production.

OTA's comments at the fall 2017 NOSB meeting did not take exception to the proposal to prohibit procaine unless new information was submitted to NOSB in this public comment period that highlighted specific conditions that necessitate its use. NOSB's subsequent recommendation to remove indicated that no such information was provided.

OTA Position: OTA **does not take objection** to NOP's implementation of the NOSB recommendation to remove procaine from the National List. We also request an implementation period of 12 months be included to allow industry time to comply.

Sucrose Octanoate Esters (Crops & Livestock)

Background: Sucrose Octanoate Esters (SOE) were originally petitioned for use in organic crop and livestock production as an insecticide/miticide, specifically as a miticide for use on honeybees (apiculture). They have been permitted on the National List for use in organic production since 2007. NOSB voted to remove SOE from the National List in fall 2018 (2020 Sunset Review) on the basis that they are not essential for organic production because there were no EPA registrations for SOE and therefore no legally approved SOE products available for use. OTA did not take a position on these materials when they were being reviewed by NOSB in 2018. We received 0 responses for this substance on 2020 Sunset Surveys (both crops and livestock.)

NOP is proposing to remove (prohibit) Sucrose Octanoate Esters from the National List in accordance with NOSB's recommendation on the basis that they are not essential for organic production. However, since the NOSB's recommendation in 2018, there have been two new EPA registration for products with this active ingredient: OrganiShield (manufacturing use product), EPA Reg. # 94424-2, and OrganiShield (end use product), EPA Reg. # 94424-1 with sublabels for sciarid fly control in mushroom growing media; insecticide/miticide (foliar use) for greenhouse, nursery, and field crops; and *varroa* mite control on honey bees.

OTA Position: OTA **has not taken a position** on the proposed prohibition of SOE. While we do not take issue with NOSB's 2018 recommendation to remove (prohibit), we also recognize new information and regulatory dynamics may impact determinations of necessity and commercial availability of the products. First, we recognize that EPA registrations of these products are just recently being approved which suggests that commercial availability of these products is growing. Second, we recognize that these materials are intended for use in apiculture and the NOP regulations do not have standards for apiculture production. If USDA were to implement the NOSB recommendation for organic apiculture standards, it could expand the market opportunity for organic apiculture products and the number of organic apiculture producers needing to use these products.

Alginic Acid (Handling)

Background: Alginic acid has been on the National List for use in organic handling since the regulations were first implemented. It was reclassified to its current listing at § 205.605(b) as a 'synthetic' in 2018. It is used as a stabilizer in many products such as beverages, cheese and dressings, and it is also used as a defoaming agent. Based on the 2015 Technical Review, allowed alternatives include agar agar, carrageenan, gellan gum and xanthan gum. NOSB voted to remove alginic acid from the National List in fall 2019 (2021 Sunset Review) on the basis that no comments in support of its allowance were received

and alternatives are available. NOP is proposing to remove (prohibit) alginic acid from the National List in agreement with NOSB’s recommendation that it no longer meets OFPA criteria.

OTA did not take a position on alginic acid when it was being reviewed by NOSB in 2019. We received zero responses for this substance to our 2021 Sunset Surveys.

OTA Position: OTA **does not take objection** to NOP’s implementation of the NOSB recommendation to remove alginic acid from the National List. We request an implementation period of 24 months be included to allow industry time to comply.

Colors (Handling)

Background: NOP is proposing to remove eight nonorganic colors from the National List at § 205.606 (see table below). These colors have been on the National List since 2007 as allowed nonorganic agricultural ingredients in organic products when organic versions are not commercially available. NOSB recommended the removal of these colors at its fall 2020 meeting. A number of organic handlers reported that while one or more of these colors are available in organic form, they are not available in the same form or quality as the nonorganic version. Some comments from color manufacturers stated that they have sufficient quantity of these colors in organic form. NOP is proposing to remove these colors from the National List, as recommended by NOSB. The effect of this action is that only organic forms would be allowed in organic handling. NOP is welcoming comments that provide more information on whether there are sufficient amounts of organic versions to meet demand and on the availability of organic colors in suitable form and quality.

During the NOSB Sunset review, OTA received a total of 48 responses to our Sunset Survey for the eight colors under review. Several of the comments, as summarized below, indicate that the supply of organic colors is fragile and removal from the National List may be premature, especially without a substantial implementation period.

Color and # of responses	Products the colors are being used in:	*Example statements about organic alternatives not being available:
Black Current Juice (2) Blueberry Juice (3)* Carrot Juice (3)* Cherry Juice (2) Grape Juice (2) Paprika (2)* Pumpkin Juice (2) Turmeric Extract (3)*	-Fruit snacks & Candy -Energy chews for athletes -Juices -Cereals and cereal snacks -Plant-based ice cream and yogurt -Baby teether crackers -Gummy dietary supplements -Certified organic flavors	<ul style="list-style-type: none"> - Organic forms are not available in the quality needed. If removed from the NL, we would lose organic status of this product, resulting in not purchasing organic for the other 95% organic ingredients. - Routinely search for organic alternatives (multiple suppliers) but there is limited to no availability. If removed, it would likely result in loss of organic choice and loss of revenue and customers. - If removed from the National List, we would lose the ability to keep trying to source organic and develop organic colors while the market grows because we would need to discontinue organic. - If removed from the National List, it may not result in the development of organic colors but instead the loss of organic products.

OTA Position: OTA does not take objection to NOP's implementation of the NOSB recommendation to remove the above eight nonorganic **Colors** from the National List at § 205.606, **provided** the comments received from organic stakeholders during this comment period clearly demonstrate that organic versions are available in the suitable quantity, quality and form. Based on the feedback we received during the NOSB Sunset review as well as during this comment period, we are particularly concerned there may not be a sufficient supply of the following colors: **blueberry juice; carrot juice; paprika; and turmeric extract**. Should NOP decide to remove one or more of the colors, we request an implementation period of 24 months to allow industry time to comply.

Kelp (Handling)

Background: Kelp has been on the National List at § 205.606 since the regulations were first implemented, for use only as a thickener and dietary supplement and only when an organic version is not commercially available. NOSB voted to remove it from the National List at the Fall 2020 meeting (2022 Sunset Review) on the basis that organic kelp is commercially available and that there are alternatives to kelp on the National List (kombu and wakame). NOP is proposing to remove kelp from the National List in agreement with NOSB's recommendation that it no longer meets OFPA criteria. The effect of this action is that only organic forms of kelp would be allowed in organic handling.

OTA did not take a position on kelp when it was being reviewed by NOSB in 2020. We received two responses to our Sunset Survey. One operation was using non-organic kelp as a flavor in an organic seasoning blend and the other was using it as a thickener and supplement in plant-based protein supplements. No further information was provided regarding the availability of organic kelp or attempts to source or use organic or other natural alternatives.

OTA Position: OTA **does not take objection** to NOP's implementation of the NOSB recommendation to remove kelp from the National List. We request an implementation period of 24 months be included to allow industry time to comply.

Konjac Flour (Handling)

Background: Konjac flour has been on the National List at § 205.606 since 2007, for use in organic handling only when an organic version is not commercially available. NOSB received little feedback from industry during the Fall 2017 (Sunset 2019) meeting and voted in favor of its removal (11 remove; 4 relist) because there appeared to be some availability of an organic form. NOP is proposing to remove konjac flour from the National List in agreement with NOSB's recommendation that it no longer meets OFPA criteria. The effect of this action is that only organic forms of konjac flour would be allowed in organic handling.

OTA did not take a position on konjac flour when it was being reviewed by NOSB in 2017. We did, however, convey in our comments the one response we received to our Sunset Survey saying the non-organic form is in use. The survey respondent clarified that konjac flour (vs. powder) is used as a primary ingredient, not a thickener, and they are not aware of a commercially available organic alternative.

OTA Position: OTA **does not take objection** to NOP's implementation of the NOSB recommendation to remove konjac flour from the National List provided it no longer meets OFPA criteria. We request an implementation period of 24 months be included to allow industry time to comply.

Sweet Potato Starch (Handling)

Background: Sweet potato starch has been on the National List at § 205.606 since 2007, for use in bean thread production only when an organic version is not commercially available. NOSB received little feedback when they reviewed sweet potato starch in 2017 (Sunset 2019). The comments received indicated very little use and the availability of organic forms. NOP is proposing to remove sweet potato starch from the National List in agreement with NOSB's recommendation that it no longer meets OFPA criteria. The effect of this action is that only organic forms of sweet potato starch would be allowed in organic handling.

OTA did not take a position on sweet potato starch when it was being reviewed by NOSB in 2017. No survey responses were received.

OTA Position: OTA **does not take objection** to NOP's implementation of the NOSB recommendation to remove sweet potato starch from the National List. We request an implementation period of 24 months be included to allow industry time to comply.

Turkish Bay Leaves (Handling)

Background: Turkish bay leaves have been on the National List at § 205.606 since 2007, for use in organic handling only when an organic version is not commercially available. After the fall 2015 meeting, NOSB recommended the removal of Turkish bay leaves from the National List. However, the recommendation was not finalized because during the NOP rulemaking, public commenters requested continued allowance due to the unavailability of organic whole Turkish bay leaves. During the 2020 Sunset Review, NOSB received many comments supporting the removal. NOP is proposing to remove Turkish bay leaves from the National List in agreement with NOSB's recommendation that it no longer meets OFPA criteria. The effect of this action is that only organic forms of Turkish bay leaves would be allowed in organic handling.

OTA did not take a position on Turkish bay leaves when it was being reviewed by NOSB in 2020. We received one response to our Sunset Survey stating the ingredient is being used for flavor in a wide range of canned soup and there is full availability of organic forms.

OTA Position: OTA **does not take objection** to NOP's implementation of the NOSB recommendation to remove Turkish Bay Leaves from the National List. We request an implementation period of 24 months be included to allow industry time to comply.

Whey Protein Concentrate (Handling)

Background: Whey Protein Concentrate (WPC) has been on the National List at § 205.606 since 2007, for use in organic handling only when an organic version is not commercially available. After the fall 2015 meeting, NOSB recommended the removal of WPC from the National List. However, the

recommendation was not finalized because during NOP rulemaking, public commenters asserted that WPC was essential to organic processed products and organic versions were not commercially available. During the 2020 Sunset Review, NOSB received many comments supporting the removal of WPC, including several manufacturers who demonstrated they produce a robust supply of organic WPC in several forms and sell excess to the conventional market. NOP is proposing to remove WPC from the National List in agreement with NOSB's recommendation that it no longer meets OFPA criteria. The effect of this action is that only organic forms of whey protein concentrate would be allowed in organic handling.

OTA received three responses to our Sunset Survey. Two respondents reported whey protein concentrate is being used for nutrition in organic baby food and in organic cereals, baked goods/snacks, frozen breakfasts, and frozen meats as a protein source, flavor and thickener. The survey responses indicated that some organic processors are not able to find enough organic supply, while others do not have a problem finding this ingredient in organic form. One manufacturer said that organic alternatives are available and will meet the requirements needed. However, leaving it on the list would support any interruption in supply continuity. One certified operator said there is a search done annually as there is not always organic supply available and/or the supply is not consistent. At least one processor reported they would have to continually change formulas of products to deal with inconsistent supply or organic form. A manufacturer of organic WPC responded to the survey stating they produce WPC from organic cheese whey which yields lactose and whey protein concentrate. The respondent said that, "Lactose is a very popular offering, whereas the whey protein concentrate is in less demand. We believe this is due to use of non-organic whey protein concentrate. If we utilized all our whey stream (which we are working on), we do not feel organic availability will be an issue."

OTA Position: OTA **does not take objection** to NOP's implementation of the NOSB recommendation to remove whey protein from the National List. A commercial supply of organic whey protein concentrate appears to be readily available. Sunsetting the allowance to use a nonorganic form will help support organic cheese manufacturers and advance the development and use of the organic whey protein concentrate. We request an implementation period of 24 months be included to allow industry time to comply.

Implementation Period – Crops, Livestock and Handling

OTA requests a **12-month implementation period** be provided, from the scheduled sunset date for each crop and livestock input under review (§§ 205.601 and 205.603). For the handling ingredients under review (§§ 205.605 and 205.606), we request a **24-month implementation period** be provided, from the scheduled sunset date.

Regardless of the extensive review and public comment period the National List items underwent, OTA remains realistic about the ability to reach every single organic certificate holder during the NOSB Sunset Review process as well as during this proposed rule comment period. Many certified operators may be unaware of the proposed rule, and they will not become aware of the changes until a final rule is released and they are notified of the change by their certifier.

As it relates to the handling ingredients, at a minimum, reformulating a processed product typically



includes sourcing and testing alternative ingredients, establishing product specifications, research and development on the reformulated product, NOP certification review and approval, quality and cost analysis, consumer product trials, market analysis, and product launch. Relabeling, at a minimum, includes label design, nutritional analysis and food nutrition facts development, regulatory compliance review, and approval. This process typically takes one to two years.

We strongly believe our requested implementation periods are necessary and will provide industry with the time needed to comply with the changes once they are notified of a final ruling.

Conclusion

In closing, OTA supports NOP’s process of carefully considering all of the comments received from organic stakeholders during this comment period and its final decision to implement NOSB’s recommendation if the material no longer meets the requirements for inclusion on the National List at 7 U.S.C. 6517(c)(1)(A)(ii).

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Program for the opportunity to comment and for carefully considering our comments.

Respectfully submitted,

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Farm Policy Director

cc: Laura Batcha
Executive Director/CEO
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