



September 30, 2024

National Organic Standards Board
Handling Subcommittee
USDA-AMS-NOP

Docket: # AMS-NOP- 24-0023

RE: Sunset 2026 for Handling Substances Listed on § 205.605 and § 205.606 of the National List

Dear NOSB Handling Subcommittee,

Strengthening Organic Systems (SOS) greatly appreciates the crucial role of NOSB in reviewing the National List of Allowed and Prohibited Substances. Under the rigorous Sunset process, NOSB and stakeholders work together to make sure that organic's allowed "toolkit" continues to be safe for humans, safe for the environment, and necessary because of the lack of natural or organic alternatives.

As a preface to our comments, SOS would like to emphasize the importance of the National List in organic production and handling, and the Sunset process that encourages a shift towards more sustainable and organic compliant alternatives. The National List represents the best and most heavily vetted technology our food system has developed. It provides a relatively limited set of critical tools that organic producers and handlers may use when organic practices and/or alternatives are not effective and/or available. By regularly reviewing and updating the National List, the organic sector can adapt to evolving knowledge and technology, promoting continuous improvement and upholding the principles of organic production. There is no other regulation like this in the world, and SOS is proud to be part of the process.

With respect to the Sunset 2026 Handling Substances, in all cases, we agree with the Handling Subcommittee's assessment and recommendation to renew or delist, pending any new information that may be brought forward during this comment period. We emphasize that with any decision to Sunset a material from the National List, substantial evidence is needed to demonstrate that it no longer meets the criteria for listing.

§ 205.605(a) - Nonorganic, nonagricultural (nonsynthetic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

SOS agrees with the Handling Subcommittee's recommendation to renew the listing of the following substances on § 205.605(a) of the National List:

- Acids -Citric Acids -Lactic
- Calcium chloride
- Enzymes
- L-Malic acid
- Magnesium sulfate
- Microorganisms
- Perlite
- Potassium iodide
- Pullulan
- Yeast

We offer additional food for thought on Pullulan and Yeast in consideration of nuanced regulatory “irregularities” that may warrant future NOSB discussion.

Pullulan:

- USDA certified organic pullulan is marketed and sold in the United States. It appears to be commercially available (See Organic Integrity Database and associated websites), however we defer to other commenters (users of pullulan capsules) to weigh in specifically on any known quantity, quality and/or form issues.
- Many encapsulated supplement products utilizing USDA certified organic pullulan (clearly listed in the ingredient statement) are available in the marketplace. It is great to see so many organic businesses choosing to use certified organic pullulan capsules. This demonstrates demand, consumer preference, and market response at its best.
- Dietary supplements encapsulated in a non-organic capsule will not qualify for the “organic 95%+” (USDA organic seal) label claim because the weight of the capsule exceeds the 5% non-organic allowance. We are unaware of any exceptions. The product may however qualify for the “made with 70%+ organic” label claim provided all composition and processing requirements are met.
- If ‘nonagricultural’ Pullulan is removed from the National List, the option to continue using non-organic pullulan caps for encapsulated supplements certified to the “made with” label category would not be possible. This is an atypical “commercial availability” situation. Typically, when an **agricultural** ingredient becomes available in organic form, the ingredient would be removed from § 205.606 and an organic form (with no exception) would be required for products labeled as “organic.” A company would still have the option however to use a non-organic Pullulan (in the 30% non-organic allowance) and get certified to the “made with” label category. The “**non-agricultural**”¹ classification requires Pullulan to be on the National List to be approved for use in “organic” and “made with” products.

The regulatory irregularity is that a non-agricultural substance (aka pullulan) may be certified organic (therefore arguably an agricultural ingredient) if it meets all composition and processing requirements, but the non-organic pullulan cannot be used in the 30% of a “made with” product. The irregularity results from the imperfection of the Classification of Materials Decision Tree for Agricultural vs. Non-agricultural (particularly for fermentation byproducts) as well as the NOP definition of ‘nonagricultural.’

While SOS does not view this issue as a pressing priority, it is worth noting, if NOSB is considering a future removal of Pullulan, either via Sunset or a petition. The questions we ask:

1. Given the “made with” label claim restriction on the allowance of Pullulan, and the option and availability to use organic pullulan, does it ever need to be removed from the National List?
2. If substantial evidence points to the commercial availability of organic pullulan, and it is removed from § 205.605 of the National List, should non-organic Pullulan continue to be allowed in “made with” products only? Should it be classified as “agricultural” since it has been demonstrated to be certifiable under the USDA National Organic Program?

¹ **Nonagricultural.** 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.

Yeast:

- Yeast falls into a similar situation as Pullulan, although its listing does not include a “made with” label use restriction and we do not believe organic yeast (all forms and uses) is commercially available. Further, yeast (as a microorganism vs. the product of fermentation), better fits the definition of “non-agricultural.”

Products such as Pullulan on the other hand, are created through a fermentation process utilizing agricultural substrate and can arguably be categorized or defined as an agricultural product, especially if they are certified organic. The similarity to note is that if Yeast were ever removed from § 205.605 of the National List, only organic forms would be allowed in “organic” AND “made with” products (e.g. Bread, “made with organic flour”).

§ 205.605(b) - Nonorganic, nonagricultural (synthetic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

SOS agrees with the Handling Subcommittee’s recommendation to renew the listing of the following substances on § 205.605(b) of the National List:

- Ascorbic acid
- Calcium citrate
- Collagen gel
- Ferrous sulfate
- Hydrogen peroxide
- Nutrient vitamins and minerals
- Peracetic acid/Peroxyacetic acid
- Potassium citrate
- Potassium phosphate
- Sodium acid pyrophosphate
- Sodium citrate
- Tocopherols

We offer additional comments on the allowance of Nutrient Vitamins and Minerals and areas where clarification may be needed to support consistent interpretation and enforcement of the listing.

Nutrient vitamins and minerals

SOS supports the rational and safe fortification of organic foods and we support the relisting of vitamins and minerals on § 205.605(b) of the National List. However, going forward, we believe there is room for updating the annotation to reflect more appropriate FDA references and/or NOP Guidance to clarify the nutrients that may be added to organic products.

There is a long and complicated history around the listing of vitamins and minerals that has never been fully resolved. In short, the outcome is an annotation referencing a CFR that is not maintained by FDA (21 CFR 104.20). The annotation and reference is problematic because it does not reflect the nutrients and vitamins that were reviewed and approved by NOSB in 1995, it does not contain several of the essential vitamins and minerals required in food products today, and it does not reflect the annotation proposed by NOP in 2012. Instead, we have a NOP Interim Rule that continues the allowance of vitamins and minerals that are not listed under 104.20, with no further clarification on which nutrients may be added to organic products. SOS understands that the Interim Rule functions as a final rule for all legal and practical purposes, it provides flexibility, and certifiers have been living with the situation for many years (the Interim Rule was published in 2012). Our observation however is that the

situation lends itself to certifier inconsistencies, certifier shopping, and unlevel playing field for organic businesses.

Simply put, it is messy.

SOS is committed to supporting consistent implementation of the organic regulations and creating a level playing field for all organic businesses. We believe this is an area that could use some clean-up work, and it could start with some simple guidance and/or training.

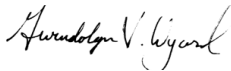
§ 205.606 - Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.” (in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form)

SOS agrees with the Handling Subcommittee’s assessment and recommendation on the following § 205.606 ingredients, with additional comments noted below on celery powder and dried orange pulp:

- Fish oil
- Gelatin
- Dried Seaweed
- Pacific kombu
- Wakame seaweed (*Undaria pinnatifida*)
- Celery powder
 - SOS is highly aware of the substantial amount of time and research invested in the development of commercially available organic celery powder. We have seen no evidence that there is a commercially available supply of organic currently. We encourage NOSB to relist Celery Powder for another Sunset cycle and support the completion of the work/research being conducted by The Organic Center and the University of Wisconsin. SOS also encourages industry to continue to be proactive in its work to develop an organic alternative.
- Orange pulp, dried
 - SOS does not have conclusive information on the commercial supply of organic orange pulp. We support the delisting of this ingredient provided evidence concerning viable alternatives supporting its removal is provided during the comment period.

In closing, SOS thanks NOSB again for its important and obligatory role in ensuring that allowed substances in organic production and handling meet the criteria of the law and align with organic principles. The National List continues to be powered and driven by stakeholders throughout the supply chain and the organic community. The National List criteria are tough, the process is rigorous, the discussion and decisions are thoughtful and transparent, and everyone is welcome. Thank you for upholding this standard and carrying out the process with respect and integrity. We thank you immensely for your volunteer service and for carefully considering public feedback.

Respectfully Submitted,



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