

OrganicEye Comments pursuant to October 2024 National Organic Standards Board Meeting Agenda

Preamble

OrganicEye is a tax-exempt farm policy research group best known for its role as an organic industry watchdog.

We steward our funding and resources carefully. Therefore, with the exception of celery powder (a documented probable carcinogen), and the Compost Production for Organic Agriculture proposal to legalize bio-based plastics — including those with synthetic compounds in their composition — for use in organics, we will be addressing a minimal number of agenda items in a very succinct manner.

Why not divert more of our resources to collaborating with the NOSB? One of the materials reviewed at the last meeting would serve as a good example.

The lead member presenting the background on genetically mutated algal oil (up for review for use as an "essential" nutraceutical added to organic food) referenced, without any further elaboration, that thousands of comments had come in during the board's initial debate before voting to add the material to the national list in 2011.

The presentation failed to present any explanation as to why organic stakeholders would have been motivated to comment in such high numbers.

Here's some of the missing history:

Algae-based DHA oil, created through mutagenesis, with some variations extracted with volatile solvents (depending on whether it is intended for use in infant formula, fluid milk, or other products) was first manufactured by Martek Biosciences (since acquired by the giant Dutch conglomerate, DSM). In 2023, DSM merged with the Swiss company Firmenich to form a new entity named <u>dsm-firmenich</u>¹. These enterprises, consisting of a network of R&D, creation, and application facilities, and employing more than 2,000 colleagues in science and research, are light years away from any organic farm.

¹ https://www.dsm-firmenich.com/en/home.html

Rather than producing higher levels of omega-3 fatty acids in livestock through pasturing under organic management, some giant pharmaceutical companies, as well as the multibillion-dollar dairy conglomerate, Dean Foods (then-owner of the Horizon dairy label), had been using these products prior to their review and addition to the National List.

What motivated thousands of responses from stakeholders? What motivated large agribusinesses to spend thousands hiring surrogates (attorneys, scientists, and at least one doctor who operated a major pediatric website and had licensed his likeness to a supplement company selling a Martek DHA product) to testify in front of the board?

At the time, there were serious questions about the efficacy of humans ingesting algae (something that had traditionally not been part of the human food chain) as a nutritional supplement. The only data presented to substantiate the health claims came from studies conducted by the company itself.

More importantly, there had been numerous adverse reaction reports submitted to the US Food and Drug Administration by medical professionals and parents, indicating serious reactions were being experienced by, at the very least, a subset of infants ingesting the supplement in formula.

On a close split vote, the material was added to the list. But at the last "Sunset" review, <u>none</u> of this background was shared, and it wasn't apparent if a more current literature review had taken place.

When the NOSB was first seated in the early 1990s, and during the following couple decades, a large percentage of nominees had been actively engaged over many years in both the creation of the Organic Foods Production Act and promulgating the associated regulations. Many had attended numerous NOSB meetings before ever being appointed to the board.

That prior engagement in organic regulatory oversight and rulemaking now seems to be a rare exception. Many nominees may have strong academic or experiential skills, but no context for their background within the organic movement.

In recent years, there has been less and less institutional knowledge on this board — which serves the corporate lobby very well. But it doesn't serve consumers/eaters who don't want their families turned into lab rats. And it doesn't serve certified organic agricultural practitioners who comply with both the spirit and letter of the law and are, in innumerable ways, being placed at a competitive disadvantage.

Therefore, we are choosing to limit our investment and the focus of our participation. However, as always, we stand willing to field questions from board members at any time.

Residue Testing

There's nothing inherently wrong with most of the recommendations and discussion in the document submitted to the public by the Certification, Accreditation, and Compliance Subcommittee. However, without fundamental changes in both requiring testing for imports or domestic production reaching specified benchmarks and taking away discretion, in terms of implementation, from certifiers who have a direct conflict of interest in overseeing their clients, they do not hold much more promise than the proverbial effort to rearrange the deck chairs on the Titanic.

Organic industry stakeholders have been victims of massive domestic and international fraud — the scale of which, in many instances, has been large enough to be a market mover, materially injuring hard-working organic farmers and their ethical marketing partners.

At the same time, those of us who eat organic food have been defrauded. I've sometimes asked livestock producers, "Are your milk, meat, or eggs organic if what you are feeding the animals is conventional?"

OrganicEye has long suggested that the USDA implement universal mandatory testing on imports. The cost is inconsequential compared to the billions of dollars of commerce flowing into the US, including from countries with endemic levels of fraud (intellectual property theft, counterfeit name-brand consumer products, adulteration of food, Internet fraud, and the list goes on). Why would the statutory protectors of the organic label trust that smart criminals would be incapable of deceiving certifiers (even if these for-profit international certifiers were all working on the up and up).

When one bulk cargo ship might hold the equivalent annual output of 40-50 certified organic farms in the US, with tens of thousands of dollars spent on domestic certification in aggregate, the cost to test the cargo becomes inconsequential.

A few points of feedback on the discussion document:

1. In the case of imports, the cost of testing should be passed along to the exporting business enterprise. Otherwise, US organic operations will bear the cost of overseeing the process.

- 2. Domestic operations producing over a pre-prescribed volume of commodities should also be subject to mandatory testing and bear all associated costs.
- 3. Based on our staff's experience successfully testing for hexane contamination, it would be important to have airtight containers since these solvents volatilize.
- 4. Unless we missed it, we did not see reference to whether testing would take place on an unannounced basis or by appointment.

Risk-Based Certification

For the last few years, OrganicEye has advocated for an upgraded inspection process. Based on historical experience, the best organic farm operations should be exempted from annual inspections (along with handlers with solid track records and low risk enterprises).

The problem with the current system is that it depends on lots of modestly trained inspectors without professional experience in production agriculture or forensic accounting.

Shifting to inspections once every five years would free up resources so veteran inspectors can be well compensated and have the time to do thorough audits along with a much more aggressive unannounced inspection program.

The current "busywork" of annual inspections accounts for cracking very few of the major fraud scandals that have become public.

This proposal would have to be widely discussed by organic industry participants, and well-refined before being taken to Congress, as it would require an amendment to the Organic Foods Production Act.

A few points of feedback on the discussion document:

- 1. Again, our concern at OrganicEye is that the cost of upgraded scrutiny of highrisk operations will be borne by low-risk organic farmers and handlers.
- 2. Depending on certifiers to make the determination as to which operations are going to receive extra scrutiny is subject to the inherent conflict of interest that universally exists in these relationships.

Despite the flowery rhetoric about how committed certifiers are, though some certainly are, there is a tremendous economic disincentive to find problems with their existing "clients." Not only would that jeopardize the relationship, but the

added paperwork, additional scrutiny, potential for mediation, and potential for litigation would all erode the bottom line of the certifier.

The USDA has to have influence and control on targeting operations for special scrutiny. (It's likely that artificial intelligence will make this determination easier going forward.)

3. "It just makes good business sense to evaluate risk and vulnerabilities to one's business." So states the discussion document.

This might be true for wise and ethical business managers and investors. But it's sure as hell not true of bad actors attempting to game the system. Although the vast majority of organic industry participants, in our opinion, operate in compliance with the law, that cannot be depended upon. And we cannot trust the judgment of for-profit certifiers (and all of them are for-profit unless they are operating illegally as part of a nonprofit organization — even then, in terms of IRS law, they should be separate profit centers and taxable).

Petition to permit synthetic packaging materials and approved commercial composted fertilizers for use on organic farms

- Commercially blended fertilizers, used in organic production, are not allowed to contain any prohibited or synthetic materials
- Compostable plastics cannot be made without the use of prohibited and synthetic materials. It would be illegal to permit their incorporation into organic farm production.
- Synthetic compost feedstock" is a euphemism for compostable plastic.
- A farm that uses compost made from compostable plastic, aka synthetic compost feedstock, "shall not" be certified under SEC. 2109. ø7 U.S.C. 6508.
- Certain plants are very adept at uptaking contaminates from the soil and incorporating them into their tissue.

The Organic Food Production Act of 1990 (OFPA):

"SEC. 2109. Ø7 U.S.C. 6508; PROHIBITED CROP PRODUCTION PRACTICES AND MATERIALS. (b) SOIL AMENDMENTS.—**For a farm to be certified under this title, producers on**

such farm shall not—

(1) **use** any fertilizers containing synthetic ingredients or **any commercially blended** *fertilizers containing materials prohibited under this title* or under the applicable State organic certification program." [emphasis added]

The BPI petition and Subcommittee report are severely lacking in credible analysis of compostable bioplastics, aka synthetic compost feedstock. The only issue addressed was pathogenic content.

OFPA and USDA regulations specific requirements for commercially blended fertilizers, including the required zero tolerance of prohibited materials and synthetic ingredients, are currently being ignored. Nothing in the Crops Subcommittee speaks to the possible contamination of the soil, water, and/or air by prohibited or synthetic substances in compostable packaging.

The Crops Subcommittee has treated the composting of bioplastics the same as the composting of organic material a farmer would do on their farm rather than as commercially blended fertilizer. By ignoring the proven presence of toxins and other prohibited materials in the synthetic compost feedstock (aka bioplastics) and recommending the use of compostable bioplastics in commercial blended fertilizers, the Subcommittee, and by extension, the NOSB, NOP, and USDA, would be in violation of both the letter and intent of OFPA.

The motion to add synthetic compost feedstocks does not define what is acceptable under OFPA and the regulations. Rather, the American National Standards Institute (ANSI) is allowed to define "synthetic compost feedstock" for use by the NOP: "...to have the materials and products that meet the American Society for Testing Materials ("ASTM") standards for compostability."

ANSI standards for compostability do not align with OFPA regulations. ANSI standards permit the presence of, and the release of, heavy metals and/or potentially thousands of other toxic compounds into the environment and potentially into the tissue of organically-produced foodstuffs.

The Organic Foods Production Act and the regulations for commercially blended fertilizers do not allow the presence of synthetic and/or prohibited substances, whether they are released or not. The ANSI requirement that the compost derived from synthetic compost feedstock not "*introduce unacceptable levels of heavy metals or other toxic substances into the environment, upon same decomposition*" is not relevant; these composts are not allowed to be used if a farm wants to be certified organic.

All ANSI testing is lab based and not in vivo; ANSI does not require any field testing in composting facilities nor productive fields. We don't know what the effects will be on the

soil, water, or air on certified farms. Farms on which compost made from synthetic compost feedstock is used would effectively become large scale lab experiments. The use of ANSI standards for compostability would therefore threaten farmers' certification.

Being compostable is not the same as meeting USDA Organic requirements. It is the responsibility of the USDA to meet the stringent requirements set forth in OFPA and the regulations. The agency cannot ignore the statutory language/intent of Congress by the use of less stringent outside guidelines. The proposal to use ANSI standards for compostability, would amount to the agency abdicating their responsibilities in enforcing OFPA and the current regulations.

The <u>NOSB Crops Subcommittee discussion document: Compost February 13,</u> <u>2024</u> (see page 137 of the linked document) states "Given the efforts to address climate change through waste reduction and recycling, and to continuously improve and provide clarity of the organic standards and rules, the NOSB and NOP have been discussing ways to update organic definitions and regulations regarding organic compost production."

This may be a laudable goal; however the recommended changes do not improve clarity or aid in addressing climate change. Rather, the recommended changes serve to muddy the waters on which commercially blended fertilizers are allowed to be imported and used on certified organic farms. The enabling statute is quite specific and crystal clear on fertilizers: OFPA makes a specific point to distinguish between "*commercially blended fertilizers*" and fertilizers that farmers produce themselves.

Organic farming is all about restoring, improving, and sustaining the soil. The authors of OFPA understood the dangers that importing fertilizers – especially commercial fertilizers – bring to the goal of organic farming. With the specific goal of healthy and toxin-free soil, OFPA, states, in no uncertain terms, that there is a zero tolerance of any and all prohibited substances in a commercially blended fertilizer and a zero tolerance of synthetic ingredients in any fertilizer used on organic farms: a farm "SHALL NOT" be certified if these two conditions are not met as required by OFPA. Wisely, the door is shut on using commercial fertilizers that may contaminate a certified farm. [emphasis added]

For the sake of clarity, the USDA should make clear that, for any farm to be certified, commercial fertilizers must meet the higher standards required by OFPA. And as proven in Center for Environmental Health v. Vilsack, the USDA should clearly state that <u>UREC is not applicable to commercially produced fertilizers</u>.

Whether the NOP changes the definition of compost, the way compost is made, or what is considered acceptable feedstock, *SEC. 2109. ø7 U.S.C. 6508 (1)* must be adhered to. A rule change does not take the place of legislative law.

There are documentation requirements for commercial fertilizers. Approving a commercial fertilizer is defined as a "Certification activity," as per 7 CFR 205.2 and must be "conducted by a certifying agent, or by a person acting on behalf of a certifying agent."

As such, a commercial fertilizer manufacturer is required, under 7 CFR 205.201(a,) to document how all requirements are met. These documents should be public, as called for in OFPA, to assure the public of the integrity of the USDA Organic seal.

These requirements apply to any feedstock, including the synthetic compost feedstock being petitioned for allowance. How would these requirements be met? Would the manufacturers of the materials, including the plastics and chemical and material additives maintain these records and share them with the certifier to ascertain that no prohibited materials or synthetics were used? Would it be the composters' responsibility to maintain these required records or would the plastic producers themselves be required? Are there commercial composters willing to meet these statutory requirements? Is the required documentation for the synthetic compost feedstock that BPI is petitioning to be approved available? Does BPI have a certifying agent or someone acting on the behalf of a certifying agent ensuring that their synthetic compost feedstocks and composts will be devoid of prohibited materials? Has the NOSB spoken with any certifiers to see if they are willing to assume responsibilities for approving "synthetic compost feedstock" since the term is not being defined under 7 CFR 202.2?

The BPI petition makes the claim:

"The packaging materials that meet the ASTM compostability standard are presently allowed as food contact substances in packaging for organic food but anomalously are disallowed as a compost feedstock."

7 CFR 205.272 (a) and (b)(2) require the handler to protect organic products from contact with prohibited substances. As shown in numerous studies, such as <u>Evidence</u> for widespread human exposure to food contact chemicals, there are thousands of food contact chemicals such as **phthalates and novel plasticizers present in plastic packaging**.

Over 1800 of these substances are known to migrate from the packaging to the food. According to USDA Organic regulations, 205.201(a(5), for these products to be certified as USDA Organic, there must be "management practices and physical barriers established ... to prevent contact of organic production and handling operations and products with prohibited substances"

As evidenced by testing by Consumer Reports and others, this requirement is not being met. How is BPI stating they will meet the "no contact" with prohibited substances and

zero tolerance of prohibited substances in the production and handling requirement for commercially blended fertilizers? Meeting the ANSI standards cited would <u>not</u> meet OFPA and regulatory requirements.

BPI's claims that packaging materials that meet the ASTM compostability standard meet OFPA and USDA Organic regulations for use as packaging materials for organic food are without any merit.

BPI has cited no records substantiating their claim that the packaging materials actually meet USDA Organic regulations for packaging materials. The fact that a product is being used does not constitute proof that it meets the required standards. Neither BPI nor the Crop Subcommittee have provided a side-by-side comparison of the ASTM standard to the NOP compost feedstock to show how the ASTM standard meets NOP compost feedstock requirements. Such a comparison would show that the two standards differ, with the required NOP standard being much stricter.

If there is no documented proof of approval by the NOSB, NOP, and an accredited certifying agent (ACA), then the petition is moot, as the basis upon which it was requested is false. Therefore the petition must be denied.

According to the National Organic Standards Board Crops Subcommittee Compost Proposal August 13, 2024, Appendix A – Redline of Proposed Changes Definition and 205.203, all "synthetic compost feedstocks" will be permitted. As per Figure 1 below, "Compostable plastics," aka "synthetic compost feedstocks" is a generic term. "Synthetic compost feedstock" is non-specific as to the materials used to create the synthetic compost, whether it be the polymer or the added chemicals to make the plastic usable.

As per Figure 1, **not all compostable polymers are natural**. Biodegradable polymers can be divided into two classes: synthetic biodegradable polymers and natural biodegradable polymers. Does the recommendation to permit "synthetic compost feedstocks" allow both synthetic and natural biodegradable polymers to be treated the same? Would biodegradable plastics made from GMO corn and/or fossil fuels be allowed as compost on certified Organic fields? How could it realistically be screened out?



Figure 1: Classification of biodegradable polymers. From: Recent advances in biodegradable polymers for sustainable applications

Polymers are not the only inputs to the manufacture of compostable bioplastics. Toxic chemicals and other prohibited substances are customarily added to make the compostable plastic usable. This is true when the compostable packaging is designed to be water and/or grease resistant, as in the case of most food packaging. In one <u>study done, "Are bioplastics and plant-based materials safer than conventional plastic? In vitro toxicity and chemical composition," [see citations below] emerging research shows that plant-based plastics are not that different from petroleum-based plastics, in that both contain thousands of synthetic chemicals, with large numbers being highly toxic. In this study, widespread presence of toxic materials was found in most bioplastics. The presence of these materials is not allowed in commercially blended fertilizers.</u>

Other materials, such as fibers, may be added for strength or other required properties. All these additional chemicals and materials become the feedstocks without their being approved for inclusion on the National List. "Synthetic compost feedstock" is a generic term that ignores USDA Organic regulations. In November 2018, the State of Oregon Department of Environmental Quality issued a summary report on <u>compostable plastic products</u>. From the report:

"Over 1,200 comparisons involving compostable packaging and over 360 comparisons for food service ware were found. In the majority of these comparisons, making and using compostable materials (and composting them) was found to result in higher environmental impacts than either using non-compostable materials, or using compostable materials and treating them via recycling, landfilling or incineration. One primary reason for this is the potential for higher burdens associated with producing the feedstocks used to make different types of compostable packaging. Another is that composting, unlike other end-of-life waste management alternatives such as recycling, is a relatively poor method of recovering nutrients or value embedded in human-made materials such as packaging."

In addition, the report noted other problems:

- Not all certified compostable packaging fully composts in all compost facilities due to operational variations. Some compostable packaging may burden compost facility operators with higher costs and generate finished compost product that is contaminated with pieces of uncomposted waste.
- The acceptance of compostable packaging may increase contamination from "look-alike" materials that further pollute compost, soils and waterways.
- Some paper based compostable food service ware is treated with toxic materials such as perfluorinated compounds that are known to accumulate in body tissues and the larger environment.
- Further, most compostable plastic packaging does not degrade in marine environments

The report also speaks to the effect on climate change of biobased content:

"In general, biobased packaging materials exhibit significant environmental tradeoffs compared to non-biobased counterparts. Biobased materials are made from renewable feedstocks that can be replenished as they are used or within short- or midterm timeframes. For example, a biobased material may have lower GHG profile compared against alternatives, yet it may also increase other impacts such as acidification (acid rain), eutrophication (nutrient loading into waterways), and human and ecotoxicity from the use of chemicals (e.g., pesticides). Agricultural production drives a great deal of the burdens due to the processes being largely powered by fossil fuels. Research suggests that the biobased attribute is consistently unreliable for selecting lower impact packaging across all traditional packaging materials."

BPI claims that their proposed amendments:

"Refresh the outdated organic regulations based on scientific advancements and innovation in materials science;"

BPI fails to acknowledge that these "*advancements and innovations in material sciences*" are still undergoing evaluation, with many independent researchers finding them highly problematic and, in some cases, worse than the materials they are supposed to replace. BPI is arguing to use farm fields as test labs for thousands of novel chemicals and unproven materials rather than respect the laws and intent behind organic farming.

"Expressly align with the de minimis presence doctrine that restricts the presence of synthetic substances in finished organic compost;"

Commercially blended compost has a "de minimis" defined. As per OFPA, there is a zero tolerance for prohibited materials and synthetic materials in commercially blended fertilizers. The proposed amendments by BPI would allow for levels of contamination by thousands of novel chemicals that currently are not allowed.

"Lower or eliminate the waste stream segregation costs of organic compost manufacturers;"

This is not a goal of organic farming. A goal of organic farming is to improve and regenerate the soil so a constant stream of fertilizers need not be imported. Organic farms are not sewerage pathways for composters.

"Improve the quantity, quality and availability of compost for organic farming"

Changing the requirements to allow prohibited substances, both natural and synthetic, as is being requested, can only degrade the quality of the compost. This is why OFPA specifically requires zero tolerances for prohibited substances and synthetic substances in commercially blended composts.

"Support the NOP's work agenda request for Climate-Smart Agriculture,"

The manufacture and production of compostable plastic has shown that it can have a deleterious effect on the climate.

"Reduce the administrative burdens on AMS, the NOSB and Accredited Certifying agents regarding compost feedstocks and traces of synthetic substances therein"

Manufacturing compostable plastics is far more complicated than growing green matter for compost.

Allowing synthetic compost feedstock will significantly add to the administrative burdens, as requirements will not extend to all the materials, methods, and facilities used to produce the biopolymers and all other chemicals and materials used in the production of compostable plastics.

The biopolymers would have to be documented as to how they are grown or how they are synthesized. Every chemical used in making the compostable plastic will have to be documented and approved. Certifying agents will have to become organic chemists, or hire expensive consultants as their agents, to examine and verify that the production facilities and materials used all meet Organic standards. The administrative burdens would be magnified by a magnitude and the knowledge requirements by multiple magnitudes.

The claims by BPI that the use of compostable plastics is good for the environment and is "climate-smart" are consistently shown to be false. Bioplastics can be just as bad, or worse, for the environment than regular plastics. The claims that compostable plastics are "climate-smart" are unprovable and are potentially misleading and/or false in many instances.

Conclusion

In summary, it would be impossible for "synthetic compost feedstocks" to meet OFPA requirements and current USDA Organic regulations. The ANSI standards cited for approval of synthetic compost feedstocks would violate OFPA requirements for zero tolerance of prohibited materials in commercially blended compost. The allowance of synthetic compost feedstock, aka compostable plastic, would turn certified Organic land into giant experiments where thousands of novel chemicals, heavy metals, and other unknown prohibited materials would be applied on a regular basis.

Citations:

Zimmermann, L., Dombrowski, A., Völker, C., & Wagner, M. (2020). Are bioplastics and plant-based materials safer than conventional plastics? In vitro toxicity and chemical composition. *Environment International*, 145, 106066. doi:<u>10.1016/j.envint.2020.106066</u> Carney Almroth, B., Carle, A., Blanchard, M., Molinari, F., Bour, A. (2023). Single-use take-away cups of paper are as toxic to aquatic midge larvae as plastic cups. *Environ Pollut.* 1;330:121836. doi:<u>10.1016/j.envpol.2023.121836</u>

Wicker, Alden, Bioplastics as toxic as regular plastics; both need regulation, say researchers 22 Apr 2024 <u>Global Circular economy</u>

Samir, A., Ashour, F.H., Hakim, A.A.A. *et al.* Recent advances in biodegradable polymers for sustainable applications. *npj Mater Degrad* **6**, 68 (2022). https://doi.org/10.1038/s41529-022-00277-7

State of Oregon, Department of Environmental Quality, Material Attribute: Compostable. How well does it predict the life cycle environmental impacts of packaging and food service ware. Nov. 2018 Geueke, B., Parkinson, L.V., Groh, K.J. *et al.* Evidence for widespread human exposure to food contact chemicals. *J Expo Sci Environ Epidemiol* (2024). https://doi.org/10.1038/s41370-024-00718-2

Celery Powder

According to Consumers Union/Consumer Reports, substituting celery powder for synthetic forms of sodium nitrate as a preservative in processed meat is a sham.

Celery powder delivers as much or more of a suspected carcinogenic compound, targeted by authoritative medical researchers, as the synthetic versions.

When celery powder was initially petitioned to be added to the National List in 2007, no mention of a connection with cancer was ever presented to the NOSB.

Present efforts to develop a "certified organic carcinogen" (celery powder produced under organic management) is one of the most profoundly cynical efforts in the history of this industry.

Who are you going to believe, the corporate lobbyists who work aggressively in the organic industry or:

Norld Health Organization

- International Agency for Research on Cancer
- American Cancer Institute
- American Cancer Society
- Consumers Union
- OrganicEye

Unless this material is recommended for delisting, our organization fully intends to file the petition below requesting it be reclassified as a *prohibited natural*. If successful, the only outstanding question will be how many people will contract intestinal lymphoma in the interim.

Organic Eye believes that the use of celery powder as a preservative in foods that are labeled as "uncured" — with a practically microscopic disclaimer that states "except for nitrates naturally occurring in celery powder" — is not only misleading and confusing but

also exposes the consumer to the potential carcinogenic effects of the high levels of nitrates and nitrites present in celery powder and should therefore be added to the List of Prohibited Naturals.

Pursuant to the document entitled <u>*Procedure: National List Petition Guidelines*</u> the following are responses to the items listed therein:

4. B.1 Celery Powder has been listed as an ingredient on the NOSB (National Organic Standards Board) <u>National List</u> (§205.606) since 2007. It has never been included on the list of Prohibited Naturals.

4. B.2 The Petitioner is Organic Eye, PO Box 8, La Farge, WI 54639.

4. B.3 The intended or current use of celery powder is as a preservative for meats that are labeled as organic and "uncured".

4. B.4 Intended activities and application rate. Again, the intended use of celery salt is as a preservative for meats and cheeses that are labeled as organic and "uncured."
4. B.5 The manufacturing process for celery powder is as follows: According to the Organic Materials Review Institute, the manufacturing process for celery powder is fairly simple. Celery is harvested, cleaned, macerated and blanched. The insoluble solids are separated from the liquid and then concentrated, heated and dried. Celery powder is not typically formulated with any ancillary substances.

7 U.S.C. § 6517 (C) (2) provides the following guidelines on what should be included on the List of Prohibited Naturals:

The <u>National List</u> may prohibit the use of specific natural substances in an <u>organic</u> farming or <u>handling operation</u> that are otherwise allowed under this chapter only if— (A) the <u>Secretary</u> 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 be harmful to human health or the environment; and

(ii) is inconsistent with organic farming or handling, and the purposes of this chapter

Procedural History of Celery Powder on the National List and on the List of Prohibited Naturals.

In 2007, Jerry Brown of Florida Food Products, Inc. and Jim Bacus of Jim Bacus Consulting filed a <u>petition</u> for the inclusion of celery powder on the National List. <u>The</u> <u>NOSB approved the petition in that same year by a vote of 8-4, with 2 absent and</u> <u>1recused.</u>

Subsequent NOSB actions on celery powder include a 9-5 vote to retain Celery Powder on the List in October of 2015 and, in 2017, a <u>notice of renewal</u> was published in the Federal Register

Celery powder has never been on the List of Prohibited Naturals.

As this petition will illustrate, several research studies have shown that nitrates and nitrites are likely carcinogens. Furthermore, the labeling of food products as "uncured" when in fact, due to the use of celery powder as a curing agent, they may contain nitrates and nitrites in higher levels than conventionally preserved foods is not only inherently false and misleading but may also expose the organic food consumer to the various health risks that have been associated with the ingestion of these compounds. This is particularly egregious given that many consumers are choosing organic foods because they perceive them as being safer and trust that all synthetic and non-organic compounds and ingredients are thoroughly vetted by the NOSB.

It also seems significant that the original petition to add celery powder to the National List submitted by Brown and Bacus in 2007, which the NOSB appeared to have been persuaded by when it made its initial decision to include celery powder on the National List, made no mention of the attendant cancer risks associated with celery powder. Furthermore, two of the three articles cited in support of the petition appear to have been written by the petitioner, Bacus, himself.

Other trade associations have submitted petitions in favor of the continuation of celery powder on the National List. See. e.g. the draft <u>comment</u> dated 9/6/2019 prepared by the Organic Trade Association (OTA), the primary focus of which was on the need to keep the nonorganic celery powder on the National List pending the development of an organic form of the same and which did not address the potential health risks associated with the high levels of nitrates and nitrites found in celery powder.

An earlier <u>OTA document</u>, prepared as a response to questions received from the NOSB, similarly focused on the need to develop an organic form of celery powder and gave scant attention to the attendant health risks of celery powder in either conventional or organic form. In response to the NOSB's question re the latest information on the human health risks of nitrate and nitrites present in processed meats from either synthetic or plant-based sources, the OTA stated that "To the best of our knowledge, the source of the nitrate/nitrate (synthetic vs. plant-based) does not make a difference" and referred the NOSB to the "expert panel" for further information.

I. Nitrates, Nitrites, and Cancer

Many research studies and independent public interest organizations have found that nitrates and nitrites are likely carcinogens. *See*, e.g., the Agency for Toxic Substance and Disease Registry (ATSDR) <u>Case Studies in Environmental Medicine Nitrate/Nitrite</u> <u>Toxicity (2013)</u> which raises the concerns that excessive ingestion of nitrates and nitrites

increases the risks of developing methemoglobinemia, hypotension, pregnancy complications, a number of reproductive effects, and cancer, among others. In this report the ATSDR states:

...Some study results have raised concern about the cancer-causing potential of nitrates and nitrites used as preservatives and color-enhancing agents in meats [Norat et al. 2005; Tricker and Preussmann 1991]. Nitrates can react with amino acids to form nitrosamines, which have been reported to cause cancer in animals [Bruning-Fann and Kaneene 1993]. Elevated risk of non-Hodgkin's lymphoma [Ward et al. 1996] and cancers of the esophagus, nasopharynx, bladder, colon, prostate and thyroid have been reported [Cantor 1997; Eichholzer and Gutzwiller 1998; Barrett et al. 1998; Ward et al. 2010].

An increased incidence of stomach cancer was observed in one group of workers with occupational exposures to nitrate fertilizer The International Agency for Research on Cancer (IARC) classifies nitrates and nitrites as "probably carcinogenic to humans" (Group 2A) under certain conditions (i.e., ingested nitrate or nitrite under conditions that result in endogenous nitrosation) which could lead to the formation of known carcinogens such as N-nitroso compounds [IARC 2010].

• <u>ATSDR Case Studies in Environmental Medicine Nitrate/Nitrite Toxicity</u> at page 56.

See Also the <u>Citizen Petition submitted by Consumer Reports to the Food Safety and</u> <u>Inspection Services (FSIS)</u> that cited numerous studies that have come to similar conclusions regarding the carcinogenic properties of nitrates and nitrites. The following is an excerpt from an International Agency for Research on Cancer (IARC) study quoted in the Citizen Petition:

The International Agency for Research on Cancer (IARC), an agency of the World Health Organization (WHO), has evaluated the carcinogenicity of nitrate and nitrite,¹⁹ as well as consumption of processed meat.²⁰ IARC classifies ingested nitrate or nitrite under conditions that result in endogenous nitrosation—the formation of N-nitroso compounds in the body—as probably carcinogenic to humans (Group 2A), and classifies processed meat as carcinogenic to humans (Group 1). In its overall evaluation of nitrate and nitrite, IARC noted that there is an active endogenous nitrogen cycle in humans that involves nitrate and nitrite, which are interconvertible in the body.²¹ Ingested nitrate is excreted in the saliva and reduced to nitrite, mainly by oral bacteria.²² Under acidic conditions in the stomach, nitrite then reacts readily with nitrosatable compounds, especially secondary amines and alkyl amides (present in meat and other foods), to generate N-nitroso compounds. These nitrosating conditions are enhanced following ingestion of additional nitrate, nitrite, or nitrosatable compounds. Some of the N-nitroso compounds that could be formed in humans under these conditions are known carcinogens.²³

The IARC has published other monographs on the carcinogenic effects of Nitrates and Nitrites. See, e.g. IARC report *IARC Monographs on the Evaluation of Carcinogenic* <u>Risks to Humans VOLUME 94 Ingested Nitrate and Nitrite, and Cyanobacterial Peptide</u> <u>Toxins</u>. See Also the article by the American Institute for Cancer Research entitled, <u>Hot</u> <u>Dogs, Bacon, Celery Powder and Cancer Risk</u> that states as follows:

...Although natural ingredients like celery powder may make processed meats sound much safer than conventional options, we don't have evidence to support that. Even small amounts of processed meats eaten regularly – such as having a daily hot dog — increase the risk of colorectal and stomach cancers. Whether you choose conventional or "natural" processed meats, until research becomes clearer, the best advice from many medical authorities is to minimize them all.

Clearly, based on the foregoing discussion, under the provisions of 7 U.S. Code § 6517 (C)(2), celery powder's presence as an ingredient in preserved foods "would be harmful to human health or the environment and is inconsistent with organic farming or handling, and the purposes of this chapter".

II. Foods preserved with celery powder may contain higher levels of nitrates and nitrites than those preserved with artificially manufactured nitrates and nitrites.

In addition to being a likely carcinogen, celery powder may contain even more nitrates and nitrites than foods preserved with synthetically manufactured versions of the same preservatives, thus increasing the attendant risks of developing the various diseases discussed in the above referenced ATSDR report and Consumer Reports Citizen petition. See, e.g., *Ingredients in Meat Products: Properties, Functionality and Applications*, pp 398-399:

...Celery powder prepared from celery juice has been shown to have a nitrate content of approximately 2.75%. When using juice powder added at 0.2%, 0.35%, or 0.4% (on a total formulation basis), and assuming 100% nitrate-to-nitrite conversion, ingoing nitrite concentrations of approximately 69, 120, and 139 ppm (based on meat block), respectively, could be expected. As the amount of celery juice powder in the formulation increases, higher amounts of generated nitrite can be expected. ...From these results it was determined an uncured product with nitrite replaced with a source containing naturally occurring nitrate could result in a product with higher levels of residual nitrite than one in which nitrite was originally and intentionally added. (*Hyperlink unavailable. Copies to be furnished on request.*)

III. Labeling processed foods as "uncured" when in fact they contain celery powder with the same, if not more, amounts of nitrates and nitrites than conventionally preserved food is inherently false and misleading.

The above cited *Consumer Reports* petition was directed at the Food Safety and Inspection Service (FSIS), urging them to change the labeling requirements, pointing

out that labeling practices as they then existed allowed processed meat manufacturers to state that their products are uncured when in fact, due to the addition of celery salt, they may have more nitrates and nitrites than processed meats that are cured with synthetic nitrites. Current regulations now permit an item to be labeled as uncured, even when celery powder is used as the curing agent, as long as there is a disclaimer in fine print stating that nitrates and nitrites may nonetheless be present due to the use of celery powder.

In the words of the Consumer Reports petition,

...Both synthetic and non-synthetic nitrates and nitrites may cause cancer, and product testing results released today by Consumer Reports show that processed meats made with celery powder and other non-synthetic sources of nitrates and nitrites can contain residues of these substances, just as do meats that use synthetic sources.² Consumer Reports is also releasing survey data today showing that consumers are confused by the "No Nitrate or Nitrite Added*" statements, which are currently accompanied by a fine-print disclaimer on product labels identifying the non-synthetic source of nitrates or nitrites (e.g., "* Except those naturally occurring in celery powder").

We therefore urge the agency to stop requiring, and instead prohibit, the "No Nitrate or Nitrite Added" claim on processed meat, except when no nitrate or nitrite is added from any source. In its place, we ask that the agency require a front-of-package declaration and clear ingredient labeling whenever nitrates or nitrites are used in meats, regardless of the source. We also urge the agency to take additional steps to minimize levels of residual nitrates, nitrites, and nitrosamines in these products.

It appears as though the FSIS agreed with the arguments made by Consumer Reports.

An article Dated December 17, 2020 in <u>Food Safety News</u>, states: "After careful consideration of your petition and the 17 public comments submitted to regulations.gov in response to your petition, we have decided to partially grant your request," FSIS said in its response posted Tuesday on the agency's website.

"FSIS intends to conduct a rulemaking to propose to prohibit the statements, "No Nitrate or Nitrite Added" and "Uncured," on products that have been processed using any source of nitrates or nitrites," it continued. "FSIS also intends to approve non-synthetic sources of nitrates or nitrites as curing agents. However, rather than requiring disclosure statements about the use of nitrate or nitrites on labels of meat and poultry products, as requested in the petition, FSIS intends to propose to amend and clarify its meat and poultry labeling regulations to establish new definitions for "Cured" and "Uncured." The basis for these proposed changes would be discussed in detail in the proposed rule, which is listed in the Fall 2020 Semiannual Regulatory Agenda,1 with a tentative publication date of May 2021."

Shortly after the Consumer Reports petition was filed, several public interest organizations and individuals filed 17 comments with the FSIS, as located here: <u>https://www.regulations.gov/docket/FSIS-2019-0022/comments</u>. These commenters included the American Cancer Society Cancer Action Network (ACS CAN), the Public Justice Food Project (PJ Food Project), and the Animal Legal Defense Fund (ALDF). (*Hyperlinks are unavailable. Copies to be furnished on request.*)

An excerpt from the ACS CAN comment states as follows:

"...Concerns with synthetic nitrites arose approximately fifty years ago now, and, as a result, celery powder and other non-synthetic sources of nitrate or nitrite were developed in the 1990s to cure meats. Under current federal rules, meats processed with non-synthetic nitrates and nitrites must be labeled "uncured" and "no nitrates or nitrites added," despite the fact that these meats contain nitrates and nitrites.

Consequently, these rules give consumers the false impression that these meats are not processed. ACS CAN objects to this misleading information, especially given that there is no science to demonstrate a lesser risk from non-synthetic nitrates and nitrites. ACS CAN believes that consumers cannot reduce their cancer risk if they are not fully informed about whether or not meats are processed and calls for accurate labeling of meats processed with all nitrates or nitrites, natural or synthetic."

OrganicEye believes that the weight of the evidence supports the conclusion that the use of nitrite- and nitrate-laden celery powder poses the same risks of cancer to the consumer as the use of artificially created and potentially carcinogenic nitrates and nitrites.

For this reason, celery powder should be added to the List of Prohibited Naturals because, under the provisions of 7 U.S.C. § 6517 (C) (2) subparts i and ii, it *is* "harmful to human health or the environment" and it *is* "inconsistent with organic farming or handling, and the purposes of this chapter."

Furthermore, the FSIS' acknowledgement that labeling meats as uncured, when in fact celery powder is added as a curative agent, is misleading constitutes an implicit recognition that celery powder poses health risks that must be clearly disclosed to the consumer.

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