



April 5, 2021

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-20-0089

RE: Handling Subcommittee – Discussion Document on Zein (pronounced zee-uhn)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Handling Subcommittee’s Discussion Document on Zein (maize protein). The Subcommittee is asking a handful of questions to help determine if zein should be added to the National List at § 205.606 as an allowed non-organically produced agricultural ingredient. The petitioner is requesting that zein be allowed for use as a food coating and processing aid in organically processed products labeled as “organic.”

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 organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers’ associations, distributors, importers, exporters, consultants, retailers and others. OTA’s Board of Directors is democratically elected by its members. OTA’s mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Summary

- OTA is not taking a position on whether zein should be added to the National List for use in organic processing. Instead we are responding to the NOSB questions and providing additional insights on evaluation considerations and agricultural vs. non-agricultural determinations.
- OTA encourages NOSB to focus its energy on whether non-organic zein, as a food coating, is a **necessary** ingredient (or processing aid) in organic handling. Questions around its classification are important, particularly in deciding whether it would belong on § 205.605 or § 205.606 of the National List. However, classification questions could become a distraction to the first question to be asked – is the allowance of an additional non-organic food coating necessary or are there organic or natural alternatives?
- With respect to its classification, OTA encourages NOSB to first deliberate on whether Zein, a product derived from dent corn, is ‘agricultural’ or ‘non-agricultural,’ and to consider this question in the context of the existing regulatory definitions. To be allowed in products labeled as “organic,” it must be on the National List, period. The first determination is whether the substance is agricultural or non-agricultural. The ‘synthetic’ or ‘non-synthetic’ determination is arguably less significant when considering the structure of the National List for Handling Materials and the requirements of § 205.605 vs. § 205.606.

Questions for Stakeholders:

1. If zein is made from cornmeal that is wet-milled, how much (if any) sulfur residue is left in the final product?

OTA does not have data to answer this question. From a classification perspective, a material would be ‘non-synthetic’ if the synthetic material(s) used for separation/extraction/isolation are removed from the final substance (i.e. sulfur residues) such that they have no technical or functional effect in the final product. Given the specifications of zein and its labeling requirements, presumably any residue left in the final product would not have a technical or functional effect.

2. What are the hurdles to achieving organic zein?

Considering the manufacturing processes described in the Technical Report, the **commercial availability of organic corn gluten** is a major hurdle, and this is largely due to the predominant corn wet milling process, its reliance on sulfur dioxide (a prohibited input in organic processing) and the fact that this process appears to be the most cost-effective method (excluding the cost of externalities). The alternative wet milling methods that employ ‘ozone’ and ‘protease enzymes’ (both allowed on § 205.605) could conceivably yield organic corn gluten, provided the corn is certified organic and all other inputs and processes meet the handling requirements of the organic regulations. The same of course applies to the other methods described utilizing distillers dried grains and dry-milled corn, where the use of sulfur dioxide is not needed. Although supply issues are in play for organic ethanol given its high and growing demand, the regulations **do not** include ‘cost’ as a factor that justifies the allowance of a non-organic agricultural ingredient in organic processing. The real hurdle in the case of organic ethanol, or rather opportunity, is transitioning enough conventional acres to organic meet market demand.

If the alternative methods to the corn wet milling process are cost-prohibitive, and organic ethanol poses a cost challenge (at least at this time), adding zein to the National List could potentially create the greatest hurdle to achieving organic zein. Consider:

- If zein is classified as ‘non-agricultural’ and added to § 205.605 of the National List (synthetic or non-synthetic), there could be little to no incentive to develop organic zein because there would be no requirement to use it. Unfortunately, organic preference (the requirement to use organic if it exists) does not apply to § 205.605 of the National List. Given this regulatory impediment, exceptions have been made through the use of annotations (i.e. yeast, flavors).
- If zein is classified as ‘agricultural,’ and added to § 205.606, organic processors would be required to use organic zein when it is commercially available in the appropriate quality, quantity and form. Cost, however, is not a factor.

Until a cost-competitive alternative process becomes available in “normal times,” or until there is very strong demand for organic, the method utilizing sulfur dioxide will likely be favored by producers and suppliers. This leads to the subcommittee’s third question.

3. What sectors of the organic food market would benefit the most significantly from the addition of zein to the National List and how much will shelf-life be improved?

The Organic Trade Association is unaware of any members that are interested in or asking to use the petitioned substance. We appreciate the question though, because it gets to the heart of a fundamental consideration:

- Given the lack of an organic alternative, would allowing non-organic zein to be used in organic processing significantly expand the variety, supply and functionality of organic products and have an overall net positive impact on the expansion of organic acres and the growth of the organic sector? Would this in turn lead to the availability of organic zein?

OTA will continue our outreach and ensure that organic businesses and other stakeholders are aware of the petition and the potential opportunities. At this time, and to the best of our knowledge, carnauba wax serves as a viable and allowed alternative with equitable performance (edible, non-animal derived, vegan). Further, organic forms of carnauba are available, although not always in the quantity needed. Other alternatives include beeswax (also available in organic form), shellac, waxes, gums and alginates.

4. **Do we need to revisit the classification as a non-synthetic, or is the established precedence sufficient rationale?**

No, we believe NOSB should honor the decision of its previous Board members and view corn steep liquor as a non-synthetic substance. We suggest NOSB focus its evaluation on the use of zein as an ingredient intended for organic handling; the methods that can be used to make it; and the kinds of annotations that might be needed should it meet OFPA criteria and be proposed for addition to the National List.

We offer the following justifications for this view:

- The petitioner is requesting that zein be allowed as a non-organically produced **agricultural** product. In accordance with § 205.2 (Terms defined), an *agricultural product* is any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption.
- For products labeled as “organic,” any non-organic ingredient or processing aid, regardless of its classification, must be on the National List at either § 205.605 (nonagricultural) or § 205.606 (agricultural). It must go on the National List, period.
- For products labeled as “made with organic (specified ingredients or food group(s)),” non-organic agricultural ingredients may be used in the 30% non-organic allowed portion. They do not need to appear on the National List and organic forms do not need to be sourced. Therefore, zein is currently allowed for use as a food coating on products that are certified to the “made with...” labeling category, provided it is produced and handled without the use of the “prohibited big-three (excluded methods, sewage sludge and ionizing radiation).
- For the **organic** label, if NOSB determines that zein meets the OFPA criteria (no alternatives, safe for human health and the environment, compatible with organic handling) the first classification question is whether it be placed onto the National List at § 205.606 as a non-organic **agricultural** ingredient that may only be used when organic forms are commercially unavailable, or, whether it be placed on the National List at § 205.605 as an allowed **non-agricultural** ingredient (natural or synthetic). The non-agricultural list was designed for substances that are “not a product of agriculture.” The definition of ‘non-agricultural’ also includes substances that are “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.” While the latter half of the definition of non-agricultural is painfully ambiguous, we contend that zein *is a product of agriculture*, and it has not lost its agricultural identity (soft, yellow powder of simple proteins). Furthermore, as a product of agriculture, organic forms are possible.

- The NOSB recommendation on Corn Steep Liquor passed in spring 2011 was based on a compelling argument that the action of sulfur dioxide in the traditional corn wet milling process provides a buffering action to allow lactic acid fermentation to dominate over putrefaction. The conclusion was that the sulfur dioxide is added at the end of the process and its utility is in holding back a biological process (fermentation) and to prevent putrefaction, not to change the identity of the corn steep liquor. The majority considered that agricultural byproducts, food waste and products from food waste processing should not be considered a synthetic ingredient for the purposes of organic crop production. It is important to note that the information presented in the Technical Report does not capture all of the information that informed the spring 2011 decision. Furthermore, the questions in the TR focus entirely on ‘synthetic’ and ‘non-synthetic’ determinations. The TR does not deliberate on the agricultural vs. non-agricultural status of zein, or the corresponding regulatory definitions. This is problematic.
- Historically, synthetic processing aids used in food processing have not been determined to render the agricultural products synthetic. A long-standing example is corn starch (§ 205.606), which is made using the exact same steeping process as corn steep liquor. More recently, as a result of the NOP Classification of Materials Guidance on Agricultural vs. Non-agricultural (NOP 5033-2), if the substance being evaluated is a product of agriculture, but is processed to the extent that its chemical structure has been changed, then it becomes non-agricultural ...*unless* the chemical change is the result of naturally occurring biological processes or a result of a mechanical/physical/biological process described under § 205.270(a). Although we appreciate Guidance NOP 5033-2 and its goal of helping with consistent decision making, we believe there are some nuances that still need to be worked out to better align it with the definitions of agricultural and non-agricultural and the structure of § 205.605 and § 205.606. For example, according to the TR, the wet milling method that involves ozone (allowed on the National List at § 205.605), chemically changes the endosperm protein matrix. The corn gluten, as described in the TR and according to NOP 5033-2, would be classified as synthetic, and the resulting zein would also be classified synthetic (non-agricultural). Once placed on § 205.605 as a non-agricultural, there is no requirement to use organic, *even though* this same method could yield certified organic zein if the starting material was organic.

Our answer to question #4 demonstrates how revisiting the ‘non-synthetic’ classification of corn steep liquor in the context of a petition for zein can quickly become a distraction to more important question – should an exemption be made for an otherwise prohibited non-organic ingredient? If NOSB determines through the comment process that zein is: 1) necessary because of the lack of natural or organic alternatives; 2) not harmful to human health or the environment; and 3) is consistent with organic handling; then we suggest NOSB keep the following questions in mind when considering its classification and placement on the National List:

- The starting material for zein is dent corn, an agricultural product. The intermediate source for zein is corn gluten, also viewed as an agricultural product. The addition of zein to § 205.606 means that it is an agricultural ingredient for which organic forms are not commercially available. The working concept, however, is that organic forms can be commercially developed. The method that raises concern is the corn wet milling process utilizing sulfur dioxide. This is also the method that cannot be certified organic under the organic regulations. One option to consider is adding zein to the National List at § 205.606, but with an annotation restricting its use to forms that do not employ sulfur dioxide. Acknowledging this option is not what the petitioner is requesting, it would be more compatible with organic handling and would potentially create the most realistic on-ramp to an organic alternative.
- As we stated earlier, adding zein to § 205.605 could lock zein in as an allowed ‘non-agricultural’ substance, with no requirement to use organic, *unless* its listing included an annotation that requires the use of an organic form when commercially available. It is also important to note that classifying the

petitioned form of zein as ‘non-agricultural’ (synthetic or non-synthetic) would in turn prevent zein from being allowed in the “made with” labeling category as an allowed agricultural ingredient.

- If the development of an organic form is not in the interest of the petitioner, and/or it is realistically cost-prohibitive to produce organic corn gluten, then perhaps zein should not be added to the National List and non-organic agricultural zein can continue to be used in products that are NOP certified to the “made with” category. The advancement of organic forms of zein and/or other forms that do not employ sulfur dioxide can continue to develop according to market demand.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,



Gwendolyn Wyard
Vice President of Regulatory and Technical Affairs
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association