



September 30, 2021

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

**Docket:** AMS-NOP-21-0038

**RE: Handling Subcommittee – Proposal on Zein**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Handling Subcommittee's Proposal on Zein (maize protein). The Subcommittee is proposing to classify zein as a non-agricultural, non-synthetic substance, and to add it to § 205.605(a) of the National List, annotated as, "Only for use in nutraceuticals or pharmaceuticals as a micro encapsulation acting as a moisture barrier and taste masker."

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 continues to be unaware of any member companies that are in need of or interested in using zein. We do not support adding a material to the National List unless there is a clear need, as expressed by organic certificate holders.
- If NOSB intends to keep with the precedent established for end products of the corn wet milling process (e.g. corn steep liquor) and classify zein as 'nonsynthetic,' then the material must also be classified as 'agricultural' and with a listing motion to § 205.606 of the National List.
- OTA does not support the addition of zein to the National List at § 205.605 (nonagricultural) because: 1) it is *agricultural*; and 2) the development of organic zein is possible. Although certified organic zein is not currently available, the Technical Review describes processes and materials that could comply with the organic product composition and processing standards. Adding zein to the National List at § 205.605 would discourage the development of organic zein because there would be no requirement to use it. Organic preference does not apply to § 205.605 of the National List.
- OTA does not support the allowance of zein in products that are NOP certified organic (95%+). Organic nutraceutical and pharmaceutical companies currently have the option to use non-organic agricultural ingredients in products certified to the "made with" (70%+ organic) label category. OTA would like to maintain the current course and let the USDA Organic seal and consumer demand drive the development and use of organic zein.

**We offer the following more detailed comments:**

**Zein is not necessary in organic handling**

The Organic Trade Association continues to be unaware of any member companies that are interested in or asking to use the petitioned substance. We have carried out extensive outreach to our [Dietary Supplements Council](#) and our membership as a whole, and we have not received a single response or comment in favor of adding zein to the National List.

To be clear, we do not support adding zein to the National List. We do however want to see an accurate classification for the record.

**Zein should be classified as agricultural (nonsynthetic)**

The petitioner is requesting that zein be allowed as a non-organically produced **agricultural** product. If NOSB intends to keep with the precedent that has been established for end products of the corn wet milling process (e.g. corn steep liquor) and classify zein as ‘nonsynthetic,’ then according to NOP Guidance 5033-2 (*Classification of Agricultural and Non-agricultural Materials*), the correct classification should be agricultural (non-synthetic).

When making classification decisions, it is important to start with the regulations before moving to guidance. 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. Zein meets this definition.

The definition of ‘*nonagricultural*’ is “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.”

Zein is not a mineral and it is not a bacterial culture. The definition goes on to include 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 ‘*nonagricultural*’ is painfully ambiguous, we contend that corn gluten **is a product of agriculture**, and it has not lost its agricultural identity. Furthermore, because it is a product of agriculture and alternative methods that do not employ sulfur dioxide may be used (e.g. enzymatic corn wet milling, ozone wet milling), organic forms are possible.

With the regulation front and center, we can now turn to guidance. The classification tree for agricultural vs. non-agricultural addresses the second half of the ‘*nonagricultural*’ definition by saying that an *agricultural* product becomes *nonagricultural* if it is chemically changed via processes other than mechanical/physical/biological processes described under § 205.270. **In other words, if the substance is synthetic, then it is non-agricultural.**

In the case of Corn Steep Liquor, the precedent (and NOP directive) established is a ‘non-synthetic’ classification. A chemical reaction occurs, however, the non-synthetic determination was made on the argument “that lactic acid (fermentation) is the driving force behind the chemical change rather than the sulfurous acid.” This same argument must be applied to the agricultural vs. nonagricultural classification of zein, since it is also a product of corn, and the wet milling process.

Use of the **Agricultural vs. Non-agricultural Decision Tree** demonstrates the point:

1. Is the substance a mineral or bacterial culture as included in the definition of non-agricultural substance at section 205.2 of the USDA organic regulations? **NO** (*next question*)

2. Is the substance a microorganism (e.g., yeast, bacteria, fungi) or enzyme?

*NO, it is a class of proteins found in the corn kernel (next question)*

3. Is the substance a crop or livestock product or derived from crops or livestock?

*YES, derived from corn /corn gluten meal (next question)*

4. Has the substance been processed to the extent that its chemical structure has been changed?

*YES, during the wet milling process disulfide bonds are broken, reducing the molecular weight of the resulting proteins (next question to determine how the chemical change was brought about)*

5. Is the chemical change a result of a naturally occurring biological processes such as fermentation or use of enzymes; or a result of mechanical/physical/biological processes described under 205.270(a)?

*YES, based on the analysis that informed the 2011 NOSB subcommittee recommendation, lactic acid (fermentation, biological process) is the driving force of the chemical change. Sulfur dioxide is added at the end of the process to stop the fermentation and prevent putrefaction. Therefore, consistent with the NOP Directive, zein should be classified as nonsynthetic. Although corn steep liquor and corn gluten meal are two separate byproducts of wet milling, both undergo a steeping step where the chemical change occurs. If chemical change is the result of a biological process, then both materials are nonsynthetic. If a material is classified as nonsynthetic, then it must also be classified as **agricultural**.*

#### **Adding zein to § 205.605(a) would be technically incorrect and would stifle organic innovation**

In addition to being technically incorrect as described above, if zein is classified as nonagricultural and added to § 205.605 of the National List (synthetic or non-synthetic), there would be little to no incentive to develop organic zein. Unfortunately, organic preference does not apply to nonagricultural substances listed on § 205.605 of the National List. Commercial availability requirements apply only to § 205.606, unless the 205.605 substance is annotated otherwise (e.g. yeast). Therefore, if zein is placed on § 205.605 and organic zein were to become commercially available, certified operations would not be required to use it. The National List at § 205.606 was created to house agricultural ingredients that are commercially unavailable in organic form. As organic forms develop and become commercially available, the ingredient can sunset or be petitioned off the National List. Again, OTA does not support adding zein to the National List because there does not appear to be a need for it. However, from a classification perspective, if it is classified as nonsynthetic and added to the National List, it should be placed on § 205.606 where commercial availability would appropriately apply to an agricultural ingredient.

#### **Zein may be used in NOP certified products labeled as “made with organic ingredients.”**

Organic nutraceutical and pharmaceutical companies that would like to utilize zein for microencapsulation currently have a certification option under the National Organic Program in the “made with (70%+)” labeling category.

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. For the “made with” label, agricultural ingredients 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 in or 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).”



If the development of an organic zein is not in the interest of the petitioner, because it cost-prohibitive to produce, then we suggest that zein not be added to the National List. Instead, it can continue to be allowed only in the 30% of 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,

A handwritten signature in black ink, appearing to read "Gwendolyn V. Wyard".

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

cc: Laura Batcha  
Executive Director/CEO  
Organic Trade Association