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National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW.,
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Docket ID # AMS-NOP-20-0089

Re. HS: Zein

These comments to the National Organic Standards Board (NOSB) on its Spring 2021 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

The NOSB has received a petition to list zein, a product of nonorganic corn protein, on §606 of the National List. New materials should not be added to §606. Everything that is produced nonorganically can be produced organically. Although the specific petitioned use is as a food coating, the petition identifies a number of uses for zein: as an ingredient and as a processing aid, including as a glaze, coating, taste masker, wheat gluten substitute, and for use in micro- or nano-encapsulation.

Zein is synthetic if made with corn gluten meal from wet corn milling.

Corn steep liquor

The classification of zein is tied back to the classification of corn steep liquor (CSL), which is produced by a similar process. As petitioned, the manufacture of zein begins with corn gluten meal, a product of the same counter-current corn wet milling process that produces CSL. The classification of CSL was controversial, as is evident from the description in the HS discussion document. We repeat, because of its importance, the description of the decision process of Organic Materials Review Institute (OMRI):

> For technical questions such as these, OMRI relies on our Advisory Council, an independent body made up of experts in their fields, to determine the status of a

substance. The Advisory Council was provided with peer-reviewed literature, patents, manufacturing processes and a copy of the 2006 NOSB synthetic/nonsynthetic decision tree catered to CSL to help inform their votes. In May 2009, the Advisory Council voted 8-2 that corn steep liquor is synthetic.

Later, OMRI received additional information that lent to the argument that it was not synthetic; mainly that lactic acid is the driving force for the chemical change rather than sulfurous acid. Lactic acid is produced naturally in the steeping process through the conversion of dissolved sugars. The Advisory Council was asked to vote again, taking into account the new information. Again, the council voted that CSL was synthetic, 7-3. This comment from an Advisory Council member summarizes the prevailing argument: "As long as any of the active species [Sulfurous acid] is present, it can react with the proteins. Breaking of disulfide bonds is an irreversible reaction that goes to completion. Once the sulfite ion reacts, more of it is produced by the ionization process to maintain equilibrium conditions. The suboptimal pH of the industrial process does not stop breaking of disulfide bonds by sulfite ion. It only slows it down. In the industrial process some of the bonds are probably broken by lactic acid, but it is unreasonable to assume that the entire degradation process is due to unilateral action of lactic acid produced in the fermentation reaction."

The NOSB's vote on a motion to classify CSL as nonsynthetic was 5 yes, 6 no, 1 abstention, 2 recusals, with no absences. This vote count did not meet the required 2/3's decisive vote required by law, but the NOP decided to regard CSL as nonsynthetic:

> Corn Steep Liquor (CSL), a byproduct of the corn wet milling process and other corn processing techniques, has been considered a non-synthetic input for liquid fertilizer formulations for organic crop production. The NOSB was asked to classify CSL using the classification of materials parameters that they voted to accept at the November 2009 meeting. At the April 2011 meeting, the NOSB motion to classify CSL failed, not reaching the necessary two-thirds majority for a decisive vote. The NOP appreciates the NOSB's extensive deliberation on the classification of this substance and will consider additional means to address this issue. The NOP notes that CSL continues to be allowed in organic crop production.[1]

The HS discussion document says, "As the NOSB has evaluated this question previously for corn steep liquor, the precedent has been established to consider these end products as non-synthetics." This is a misstatement. A simple majority of the board voted that CSL was synthetic. There was no decisive vote on classification.

[1] Miles McEvoy, 2011. Memorandum for the chairperson of the National Organic Standards Board, re. NOSB recommendations of April 2011. August 11, 2011.

Zein is made from the solids, not the liquid fraction.

It is relevant to the application of the CSL history to the classification of zein that those in the Crops Committee voting to classify CSL as nonsynthetic used as a justification findings that chemical change was occurring in the nonsoluble fraction, rather than the liquid fraction: "Furthermore, the proposal that CSL should be considered to be non-synthetic is attributed to the fact that the SO2 action occurs in the endosperm protein matrix of the corn kernel, not in the steep water. There is compelling evidence that the proteins that the SO2 may alter are insoluble, thus are not a part of the CSL." As noted in the Technical Review (TR), zein is hydrophobic and insoluble in water.[2]

The NOSB has not voted on the classification of either zein or the corn gluten meal from which it is made. Although NOP has treated corn gluten meal as nonsynthetic, it does not base that opinion on NOSB recommendations: "We have retained classification as nonsynthetic due to the historical consideration of corn gluten as nonsynthetic; however, further consideration of this issue may be warranted by the NOSB. Parties interested in further consideration of corn gluten are encouraged to submit a petition to the NOSB according to the National List petition guidelines."[3]

The Technical Review states that zein made from corn gluten meal produced by wet corn milling is synthetic, unless the corn gluten meal is made by an enzymatic process.

The TR states,[4]

> In the corn wet milling process, sulfur dioxide reacts with disulfide bonds in insoluble proteins, severing them and reducing the molecular weight of the resulting proteins. When a molecule of sulfur dioxide reacts with a disulfide bond, it "adds" itself to the new bond, artificially increasing the sulfur content of the protein. Chemical analyses of the corn protein zein isolated from the CGM byproduct of the corn wet milling process show two measurable anomalies compared to "zein" isolated from corn gluten derived from untreated corn. The first anomaly is a lower molecular weight (Parris and Dickey 2001) and the second anomaly is a sulfur content that is greater than the sum of the contributions of the sulfur-containing amino acids in zein (Boundy et al. 1967). Both anomalies indicate that sulfur dioxide has chemically changed the protein in corn gluten meal and consequently in the extracted zein.

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[2] Zein TR, 2021. Lines 58-59.
[3] Response to comments, as quoted in TR, lines 267-271.
[4] Zein TR. Lines 194-215.

> A method for wet milling corn that does not employ sulfur dioxide uses ozone (O_3) instead (Ruan et al. 2004). Using ozone to replace sulfur dioxide avoids sulfur dioxide discharge to the environment. Ozone is a strong oxidant and disinfectant that controls the growth of putrefactive microorganisms in steeping systems. However, like sulfur dioxide, ozone chemically changes the endosperm protein matrix to achieve starch release. The protein content of ozone-treated corn is lower than that of untreated corn, indicating that protein is being destroyed in the ozonation process (Wang 2005).
>
> Another alternative method that does not employ sulfur dioxide steeping is enzymatic corn wet milling (E-milling) (Ramírez et al. 2009). This process uses protease (protein hydrolyzing) enzymes to eliminate the need for sulfites and decrease the steeping time. During periods of high corn feedstock costs, this process is cost-competitive with the conventional sulfur dioxide steeping process, but it is not cost-competitive in normal times.

Since zein as petitioned is synthetic, it does not belong on §606, the listing for "nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as 'organic.'"

Zein can be produced organically by an alternative process.

Although the HS states, "The petitioner states that there is currently only one North American manufacturer of zein, the petitioner - Flo Corporation," it also says:

> [I]t is important to note that there does seem to be an effective pathway to avoiding the wet-milling process entirely in the production of zein. Researchers from the University of Illinois have developed another zein product that is created directly from whole corn. They plan to market this product under the name Amazein and point to the fact that direct production from corn bypasses need for sulfur dioxide or the other caustic chemicals that are used during the wet milling process that creates much of the corn gluten meal on the market. This method of direct extraction from whole organic corn may also allow for the creation of a truly organic zein product as organic ethanol is available in the US, though perhaps prohibitively expensive.

Cost is not a criterion for listing on the NL, so the fact that organic zein may be "prohibitively expensive" is not a reason for allowing zein as petitioned to be used in organic food. On the contrary, the difference in cost may be largely due to the ability to externalize the adverse environmental and health costs of producing zein from nonorganic corn in the conventional manner.

Zein does not satisfy OFPA criteria.

As a product of chemical-intensive corn, zein causes environmental and health impacts.

The following information is extracted from Beyond Pesticides' *Eating with a Conscience* database.[5]

Pesticide Tolerances —Health and Environmental Effects: The database shows that while field corn products grown with toxic chemicals show low pesticide residues on the finished commodity, there are 109 pesticides with established tolerance for field corn products, 39 are acutely toxic creating a hazardous environment for farmworkers, 96 are linked to chronic health problems (such as cancer), 34 contaminate streams or groundwater, and 88 are poisonous to wildlife.

Pollinator Impacts: In addition to habitat loss due to the expansion of agricultural and urban areas, the database shows that there are 37 pesticides used on field corn products that are considered toxic to honey bees and other insect pollinators. For more information on how to protect pollinators from pesticides, see Beyond Pesticides' BEE Protective webpage.

- This crop is foraged by pollinators.

*(**A** = acute health effects, **C** = chronic health effects, **SW** = surface water contaminant, **GW** = ground water contaminant, **W** = wildlife poison, **B** = bee poison, **LT** = long-range transport)*

2,4-D (C, SW, GW, W, B)
Acetochlor (C, SW, W, B)
Alachlor (SW, GW, W)
Ametryn (C, W)
Aminopyralid (A, SW, GW, W)
Atrazine (C, SW, GW, W)
Azoxystrobin (A, SW, GW, W)
Bentazon (C, SW, GW)
Bifenthrin (A, C, SW, W, B)
Boscalid (C, W)
Bromoxynil (A, C, GW, W)
Butylate (C, W)
Captan (A, C, W)
Carbaryl (A, C, SW, GW, W, B)
Carboxin (C, W)
Carfentrazone-ethyl (W)
Chlorantraniliprole (C, GW, W, B)
Chlorpyrifos (A, C, SW, GW, W, B, LT)
Clethodim (A, C)
Clopyralid (A, C, GW, W)
Diflufenzopyr (C)
Dimethenamid (A, C, W)
Dimethoate (A, C, GW, W, B)
Diquat Dibromide (A, C, W)
Diuron (C, SW, W, B)
Endothall (A, C, W)
EPTC (C, SW, W)
Esfenvalerate (A, C, W, B)
Ethoprop (ethoprophos) (A, C, W, B)
Etoxazole (C)
Fenamidone (C, W)
Fipronil (A, C, W, B)
Flubendiamide (C)
Fludioxonil (C, W, B)
Flufenacet (C, W)
Flumioxazin (C, W)
Fluometuron (C, W, B)
Fluoxastrobin (C, W)
Fluridone (C, W)
Fluroxypyr (C, W)
Fluthiacet-methyl (C, W)
Ipconazole (C)
Isoxadifen-ethyl
Lambda-cyhalothrin (A, C, W, B)
Linuron (C, W)
Malathion (A, C, SW-URBAN, GW, W, B)
Mancozeb (C, W, B)
Mesotrione (C, GW, W, B, LT)
Metalaxyl (A, C, W)
Metconazole (C, W)
Methomyl (A, C, W, B)
Methoxyfenozide (W)
Metolachlor (C, SW, GW, W)
Metribuzin (A, C, SW, W)
Myclobutanil (C, W)
Nicosulfuron (C, W)
Nitrapyrin (A, C, GW, W)
Oxyfluorfen (C, W)
Paraquat/Paraquat dichloride (A, C, SW, GW, W, B)
Pendimethalin (C, GW, W)
Permethrin (A, C, GW, W, B)
Phorate (A, C, GW, W, B)
Phosphine (A, C)
Piperonyl butoxide (PBO) (C, W)
Pyraflufen-ethyl (C, W, B)
Pyrethrins (C, W, B)
Pyridate (C, W)
Pyriproxyfen (C, W)
Rimsulfuron (C)
Sethoxydim (C, B)
Simazine (C, SW, GW, W)
Spinetoram (C, B)
Spinosad (C, W, B)
Spiromesifen (W)
Sulfentrazone (C, W)
Sulfuryl fluoride (A, C)
Tebuconazole (A, C)
Tebufenozide (W)
Tefluthrin (A, C, W, B)
Tembotrione (C)
Terbufos (A, C, W, B)
Terrazole (C, W)
Tetraconazole
Thiabendazole (C, W)
Thiamethoxam (C, B)
Topramezone (C)

[5] https://www.beyondpesticides.org/resources/eating-with-a-conscience/choose-a-crop.

Clothianidin (A, C, SW-URBAN, W, B)
Cryolite (C)
Cyfluthrin (A, C, W, B)
Cypermethrin (A, C, W, B)
Cyprosulfamide
Dacthal (DCPA) (C, SW, GW, W, B, LT)
Deltamethrin (A, C, W, B)
Dicamba (A, C, GW, W)
Glufosinate ammonium (C, SW, W)
Glyphosate (C, SW-URBAN, GW, W, B)
Halosulfuron-methyl (C)
Hexythiazox (C)
Imazapyr (SW, GW, W, B)
Imazethapyr
Imidacloprid (A, C, SW, W, B)
Propargite (A, C, W)
Propiconazole (A, C, W)
Propyzamide (C, W)
Prosulfuron
Pyraclostrobin (C, W)
Triadimenol (A, C)
Trifloxystrobin (C, W)
Trifluralin (C, SW, GW, W, LT)

All tolerance data is based on the Environmental Protection Agency's *Tolerances by Commodity, Crop Group, or Crop Subgroup Index* (last updated July 2009). For more information, see our Methodology page.

Corn wet milling poses environmental hazards.

As pointed out in the HS discussion document, "There are legitimate concerns regarding the environmental impacts of the corn wet-milling process." The concerns include the release of sufur dioxide, contributing to acid rain; particulate matter air pollution, a contributor to respiratory illness; and volatile organic compounds (VOCs) and combustion products from drying.[6]

Zein is not essential for organic production and processing.

Zein is not currently used in organic products. The TR describes alternative materials: shellac, waxes, gums, alginates, and proteins.[7] "Organic beeswax and organic carnauba wax are two commercially available alternatives."[8]

Barriers to organic production must be identified.

Nonorganic agricultural products carry with them the negative impacts—to the food and the environment—of chemical-intensive production practices. It is important, in making a case for inclusion on §606 that the petitioner and the HS identify barriers to organic production that cannot be overcome, taking into account the fact that incorporation into the regulations may take years.

If zein is listed, the NOSB must explicitly prohibit use for nano-encapsulation.

All substances on the NL must be listed "by specific use or application." Since one use of zein is nano-encapsulation[9] and the NOP has failed to codify the recommendation of the NOSB prohibiting engineered nanomaterials in organic products, the NOSB must make clear that zein may not be produced with nano-encapsulation.

[6] EPA, 2021. AP-42: Compilation of Air Pollution Factors, Section 9.9.7 Wet Corn Milling. https://www3.epa.gov/ttnchie1/ap42/ch09/final/c9s09-7.pdf.
[7] TR lines 411-511.
[8] TR line 516.
[9] TR line 28.

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors