

**Formal Recommendation**  
**From: National Organic Standards Board (NOSB)**  
**To: National Organic Program (NOP)**

**Date:** November 15, 2021

**Subject:** Zein - petitioned

**NOSB Chair:** Steve Ela

**The NOSB hereby recommends to the NOP the following:**

Rulemaking Action: None

**Statement of the Recommendation:**

The NOSB recommends that zein NOT be added to the National List.

**Rationale Supporting Recommendation**

The NOSB recommends not adding zein to the National List. The petitioner requested that zein be added at §205.606 and allowed for use as a food coating and processing aid. While there was limited comment from the stakeholder community, not one comment was in favor of putting zein on the National List. During Subcommittee review the essentiality of zein was challenged and gained little support until it was narrowly annotated for nutraceutical and pharmaceutical industries. Despite the narrowed scope the NOSB voted to not add zein to the National List, based on essentiality and the availability of alternatives.

**NOSB Vote:**

**Listing Motion:**

Motion to add zein at 205.605, annotated as : “Only for use in nutraceuticals and pharmaceuticals as a micro encapsulation acting as a moisture barrier and taste masker”.

Motioned by: Jerry D’Amore

Seconded by: Steve Ela

Yes: 3 No: 10 Abstain: 1 Absent: 0 Recuse: 0

Motion Failed

**Classification Motion:**

Motion to classify zein was not taken based on NOSB discussion and NOP concurrence that items on 205.605 do not have to be classified first.

See recommendation below

**National Organic Standards Board  
Handling Subcommittee  
Petitioned Material Proposal  
Zein  
August 3, 2021**

**Summary:**

This document reviews the petitioned use of zein, or corn protein, as a “Nonorganic agricultural substance[s] allowed in or on processed products labelled as organic,” as well as the recently submitted 2021 technical review. While the petitioner asked for the material to be allowed as a nonorganic agricultural substance, the NOSB disagrees with this classification. In reviewing the petition, TR, NOP Classification of Materials guidance decision tree ([NOP 5033](#)), and past NOSB decisions, it was determined that this is a nonagricultural substance and that it should be classified as non-synthetic.

**Introduction:**

The NOSB was petitioned in February of 2020 to consider zein, otherwise known as “maize protein”, “protein coating” or “confectioner’s glaze”, as an addition to the National List. The full petition may be found [here](#). The petitioner, Flo Chemical Corporation, asked for inclusion of zein under “Nonorganic agricultural substance[s] allowed in or on processed products labeled as “organic” (§ 205.606).” The NOSB asked for a [technical report](#) which was produced in January 2021 and deemed sufficient in February 2021.

**Regulatory background:**

This is the first time that zein has been petitioned for inclusion on the National List.

*The TR states, “Zein is a food substance generally recognized as safe (GRAS) by FDA [[21 CFR 184.1984](#)] as a direct human food ingredient, for use as a surface-finishing agent, and for technical effects (i.e., as an anticaking agent or free-flow agent, a drying agent, and a humectant). Zein also is allowed as an indirect food additive used as a component of adhesives [[21 CFR 175.105](#)]. A major use of zein is for coating foods and pharmaceutical products. The most common production process for zein uses corn gluten, also known as corn gluten meal, as the starting material. Corn gluten itself is a GRAS food ingredient [[21 CFR 184.1321](#)].”*

As zein has not been previously considered for addition to the National List, there are no current NOP policy memos that relate to zein or its category of proposed use. Despite this, the rulings that have been made on corn steep liquor (CSL) are directly relevant to any review of zein. The corn gluten meal (CGM) that zein is made from is a different product created during the same wet-milling process used to make CSL. The bulk of the corn gluten meal is produced via wet-milling with sulfur dioxide. Dry-milling produces very little of the desired zein protein in the end product.

In determining whether or not to allow corn steep liquor as a non-synthetic product, OMRI reported the following decision-making process:

*“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."

In a memo on November 12, 2009, the NOP asked the organic industry to consider CSL nonsynthetic and allowed for use in organic agriculture until the NOSB can discuss it at the Spring 2010 meeting. Although the OMRI Advisory Council voted twice that CSL is synthetic, OMRI has followed the NOP directive and currently lists products with CSL."

In 2011, the NOSB reviewed corn steep liquor and through a similar rationale, came to the same conclusion.

**“Recommendation:** *The Crops Committee recommends that Corn Steep Liquor produced via the traditional countercurrent corn wet milling process be considered as non-synthetic and allowed for use in organic crop production.*

**Committee Vote Motion:** *Consider CSL to be non-synthetic when produced via the traditional countercurrent corn wet milling process only.*

**Motion:** *Jeff Moyer Second: Tina Ellor Yes: 4 No: 3 Abstain: 0 Absent: 0”*

**Use:**

Zein is the protein component of corn, which has the useful quality of being hydrophobic, but easily dissolved in an alcohol solution. This allows zein to be dissolved into the solution and then sprayed or otherwise applied on the food item. The alcohol then evaporates and leaves behind a thin layer of zein that acts as a protective coating. This zein layer serves as a moisture barrier and effectively extends the shelf life of dried nuts and fruits, candies, and fresh fruits and vegetables much in the same way plastic wrap would. In contrast to plastic sheeting, the zein layer is fully edible and adds nothing but a small amount of protein of poor nutritional quality to the consumed product.

**Manufacture:**

According to the petitioner, "Flo Chemical Corporation manufactures (isolates) zein utilizing a proprietary process (Freeman Process), which was developed in 1976 by the company's founders. The process starts with the following raw materials: non-GMO CGM, water and ethanol."

While it would be possible to manufacture organic zein with organic starting products, the manufacturer states that sourcing certified organic corn gluten meal for the production of organic zein is not currently possible.

**International use:**[Canadian General Standards Board Permitted Substances List](#)

Zein is not included in the Canadian General Standards Board—CAN/CGSB-32.311-2020, Organic Production Systems Permitted Substances List.

[CODEX Alimentarius Commission](#)

Zein does not appear in the CODEX Alimentarius Commission—Guidelines for the Production, Processing, 130 Labelling and Marketing of Organically Produced Foods (GL 32-1999). 131 132

[European Economic Community \(EEC\) Council Regulation](#)

Zein does not appear in the European Economic Community (EEC) Council Regulation—EC No. 834/2007 135 and 889/2008.

[Japan Agricultural Standard \(JAS\) for Organic Production](#)

Zein is not listed in Table 1 “Additives” of the JAS for Organic Processed Foods Notification No. 1606.

[International Federation of Organic Agriculture Movements \(IFOAM\) Norms](#) Zein is not included in the IFOAM Norms

**Summary of review:**

As this is the first time zein has been considered, there are no previous public comments or reviews to draw upon. For questions of whether or not the product should be allowed and/or how to classify it, referencing the relevant discussions surrounding corn steep liquor is useful. The NOSB determination on how to categorize corn steep liquor can be found [here](#).

Combining both written and oral stakeholder comments from the 2021 Spring Meeting, there were about ten total responses with none in favor of adding zein to the National List. With that said, there were only two comments against the material itself with the remainder simply challenging the need of “another coating” or “preservatives” on fresh fruits and vegetables. During three subsequent Handling Subcommittee meetings this question of “need” was thoroughly debated with the eventual consensus being that the petitioned substance should be limited to very specific uses where its “unique” hydrophobic properties appear to be “preferred”. The petition is therefore annotated as follows:

Annotation of zein for inclusion on the National List at §205.606: “Only for use in nutraceuticals or pharmaceuticals as a micro encapsulation acting as a moisture barrier and taste masker.”

**Category 1: Classification**

1. Substance is for:  **Handling**  **Livestock**
2. For HANDLING and LIVESTOCK use:
  - a. Is the substance  **Agricultural** or  **Non-Agricultural**?
  - b. If the substance is **Non-agricultural**, is the substance  **Non-synthetic** or  **Synthetic**?

There has been ongoing debate about whether the end products of the corn wet-milling process can be considered non-synthetic. Wet-milling steeps the corn for 24-48 hours in a hot water solution that is 0.1% - 0.2% sulfur dioxide, allowing the sulfur dioxide to break protein bonds and add itself to the resulting molecule. This means that a chemical reaction has occurred.

According to the Decision Tree for Classification of Agricultural and Nonagricultural Materials for Organic Livestock Production or Handling ([NOP 5033-2](#)), an agricultural substance that undergoes a chemical change becomes non-agricultural. This then brings up the question as to whether zein should be considered nonsynthetic or a synthetic. As the NOSB has evaluated this question previously for corn steep liquor, the precedent has been established to consider these end products non-synthetics.

3. For **LIVESTOCK**: Reference to appropriate OFPA category  
Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

N/A

## Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

The substance will be used solely as a coating for nutraceutical and pharmaceutical capsules and as an inert, hydrophobic substance, will have no potential for detrimental chemical reactions.

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]

Zein has been deemed GRAS since 1960 and is fully biodegradable and edible. It contributes no toxicity or detrimental breakdown products to the environment.

3. Describe the probability of environmental contamination during manufacture, use, misuse, or disposal of such substance? [§6518(m)(3)]

There are legitimate concerns regarding the environmental impacts of the corn wet-milling process. Corn wet-milling is the primary means used to create the corn gluten meal that is the starting product for zein. As evidence that it is a concern to the regulatory agencies, from 1999-2004 the Agricultural Research Service Southern Regional Research Center received a grant from the USDA titled, "Development of environmentally acceptable technologies for processing corn." A specific aim of the research was to reduce the use of sulfur dioxide in wet-milling of corn as it was determined to be environmentally detrimental. (Full text of the grant report can be found [here](#).) If and when sulfur dioxide is released into the air through the drying process, it reacts with air and water to form sulfuric acid and becomes one of the major contributors to acid rain. While there are steps that can be taken to remove the sulfur dioxide before exhaust is released into the environment, the potential for negative environmental effects exists.

The previous decision-making on that point is outlined above. Having summarized that, it 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 out of 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. 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.

4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].

Zein is a fully edible protein layer that contributes an incomplete amino acid profile to the consumer. While it therefore should not be a major protein source in the human diet, its proposed use as a coating for pills represents no impact to human health.

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt and solubility of the soil), crops and livestock. [§6518(m)(5)]

In its proposed role as a coating in organic nutraceuticals and pharmaceuticals, zein will have no role in the agroecosystem. As previously mentioned, the only environmental concerns come from the corn-wet milling process that is used to create the corn gluten meal that is the starting material for zein production.

6. Are there any adverse impacts on biodiversity? (§205.200)

The TR states: “ Zein is extracted from CGM. In its evaluation of CGM as an herbicide ((Office of Pesticide Programs 2003)), stated:

*“All required toxicology data for this biochemical pesticide are waived. No additional toxicological data are needed. The decision to waive these data are based on: 1) the product is naturally occurring, 2) possesses a non-toxic mode of action, 3) corn gluten meal is considered GRAS (Generally Recognized As Safe) by FDA under 21 CFR §184.1321, and can be used without limitations, other than current Good Manufacturing Practices, and 4) under 40 CFR §180.1164, corn gluten is exempted from the requirements of a tolerance on food when used as a herbicide; and under 40 CFR §180.1001 (d), corn gluten meal is exempted from the requirement of a tolerance when used as an attractant on crops. Further, the registrant’s request for data waivers was appended with abstracts from scientific journals discussing the use of corn gluten meal as a food and/or feed for dairy and beef cattle, cats, minks, foxes, sheep, horses, swine, poultry, trout, salmon, catfish, guinea pigs, hamsters, monkeys, mice, rats, rabbits, and dogs.”*

Zein itself has been considered GRAS (generally recognized as safe) since about 1960 and this status was confirmed in 1981 (Select Committee of GRAS Substances (SCOGS) 1981).

Zein is a fully biodegradable, edible protein extracted from corn milling byproducts (primarily corn gluten, a GRAS substance) with an alcohol and applied to food as an alcoholic solution. The alcohols involved are isopropyl alcohol (a major ingredient in hand sanitizers) and ethyl alcohol (grain alcohol). Zein manufacturing processes are designed to recover and reuse the alcohol for both economic and environmental reasons. An analogous substance is the purified protein gelatin, extracted from animal processing waste products.

### Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

There are products currently on the National List that can serve a similar role to zein in forming a protective coating around foodstuffs. Examples of this include beeswax, shellac, vegetable proteins, and carnauba wax. Zein's unique functionality comes in because it offers a vegan/vegetarian option to replace shellac and beeswax as coatings. As opposed to other vegetable proteins (such as wheat), zein is a hypoallergenic option. The final other option, carnauba wax, can be sourced and grown only in Brazil, making it outside of the US jurisdiction for regulating how its grown and produced. However, for the annotated use in micro-encapsulation for pharmaceuticals and nutraceuticals, it appears to be the preferred option.

2. **For Livestock substances, and Nonsynthetic substances used in Handling:** In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

The substance is compatible with a system of sustainable agriculture, as it would serve solely as an encapsulation method for organically produced substances being made into pills. It would therefore have no impact on the sustainability of the agriculture that produced the substance. Zein itself would be both created and applied in a laboratory setting.

Zein is created from a renewable resource (corn gluten meal), it is fully biodegradable, and it presents no threat to human health. As the substance is created and applied in the laboratory, it has no impact on the agroecosystem beyond serving as a vehicle for ingesting organic pharmaceutical and nutraceutical products.

#### **Classification Motion:**

Motion to classify zein as nonsynthetic

Motion by: Jerry D'Amore

Seconded by: Steve Ela

Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

#### **National List Motion:**

Motion to add zein at §205.605(a), annotated as: "Only for use in nutraceuticals or pharmaceuticals as a micro encapsulation acting as a moisture barrier and taste masker."

Motion by: Jerry D'Amore

Seconded by: Steve Ela

Yes: 4 No: 3 Abstain: 0 Absent: 0 Recuse: 0

**Approved by Jerry D'Amore, Handling Subcommittee Chair, to transmit to NOP August 18, 2021.**