

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Discussion Document
Zein
February 16, 2021**

SUMMARY

This document includes a brief review of 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 technical review.

INTRODUCTION

The NOSB was petitioned in February of 2020 to consider zein, otherwise known as “maize protein”, “protein coating” or “confectioner’s glaze”, for 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.

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 off 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.

BACKGROUND

This is the first time that zein has been petitioned for inclusion on the National List. It was first designated as GRAS (generally recognized as safe) by the FDA in 1984. The petitioner states that there is currently only one North American manufacturer of zein, the petitioner - Flo Corporation. Their stated manufacturing process is:

“Zein is derived from dent corn gluten meal. All of our zein production for the food industry comes from USA sourced, non-GMO corn. In addition, all of our production is certified OU Kosher.

Manufacturing: Flo Chemical Corporation manufactures (isolates) zein utilizing a proprietary process (Freeman Process), which was developed in 1976 by the company’s founders. 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. In addition, organic ethanol is reported by the petitioner to be prohibitively expensive.

RELEVANT AREAS OF THE RULE, NOP GUIDANCE, NOP POLICY MEMO, and OMRI

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].”

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 as they are different products created during the same wet-milling process. The bulk of the corn gluten meal is produced via wet-milling with sulfur dioxide as the alternative wet milling strategies are not cost-competitive and 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 agricultural product, The Organic Materials Review Institute (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”

PREVIOUS PUBLIC COMMENT AND TECHNICAL REPORT 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](#).

DISCUSSION

The potentially contentious areas for understanding zein’s suitability for inclusion on the National List fall under three main categories: a) the environmental impacts of the corn wet-milling process used to create the corn gluten meal, b) whether the zein product can be considered non-synthetic and c) whether zein fills a unique functionality not already filled by currently allowed substances.

Corn wet-milling

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 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 (see questions regarding expense of organic ethanol.)

Classification as a non-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, raising debate as to whether the zein should be considered an agricultural product 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 as non-synthetics.

Alternatives

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 functionality is unique 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 not a major food allergen. The final other option, carnauba wax, can be sourced and grown only in Brazil.

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?
2. What are the hurdles to achieving organic zein?
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?
4. Do we need to revisit the classification as a non-synthetic, or is the established precedence sufficient rationale?

Subcommittee vote:

Motion to accept the petition discussion document on zein

Motion by: Jerry D'Amore

Seconded by: Steve Ela

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Jerry D'Amore, Handling Subcommittee Chair, to transmit to NOP February 17, 2021.