United States Department of Agriculture
Agricultural Marketing Service | National Organic Program
Document Cover Sheet
https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned

Document Type:

☒ **National List Petition or Petition Update**

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

☐ **Technical Report**

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

We are petitioning for inclusion as a **"**Nonorganic agricultural substance[s] allowed in or on processed products labeled as "organic" (§ 205.606)."

1. **Substance Name** "Zein". Sometimes labeled "confectioners glaze", "corn protein", "maize protein" or "vegetable protein". Zein is the hydrophobic protein water from corn (maize). Our nomenclature is: "Zein F4400C-FG". "FG"= "food grade" as opposed to our "pharma grade" (USP-NF) product.

## 2. Petitioner and Manufacturer Information

Flo Chemical Corporation PO Box 51 / 20 Puffer Street, Ashburnham, MA 01430 USA
978-827-5101

## 3. Intended or Current Use

To apply zein it is customarily solubilized at a 10% by weight concentration in a solution of 85% ethanol:15% water. The zein solution substance is then used as a dip, sprayed or panned (at a rate of approximately 1.5-3% by weight) on the substance. Dry time is typically 2-3 minutes.

Zein is utilized in many instances in the food industry both as a processing aid and as a coating (see below).

| | |
|---|---|
| Confections | glaze |
| Nuts | coating |
| Dried fruit | coating |
| Dried meats | coating / processing aid |
| Fresh fruit | coating |
| Fresh vegetables | coating |
| Nutraceuticals | micro / nano-encapsulation |
| Nutraceuticals | taste masker / processing aid |
| Baked goods | ingredient (substitute for wheat gluten) |
| Baked goods | coating |
| Poultry | processing aid |
| Frozen potatoes | coating |

## 4. Intended Activities and Application Rate

Zein has unique ability to create an edible film, which is used as a coating for food. Products are sprayed, dipped or panned. Customarily, 10% zein (by weight) is solubilized in a solvent. Depending on size, texture, temperature, moisture intended outcome and application method; application ranges by 0.5-6% (by weight) onto a product.

Flo Chemical Corp
Attn: Robert Zeif, Director of Business Development
robert@flochemicalcorp.com

## 5. Manufacturing Process

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. (See accompanying manufacturing flow chart).

The process is recognized as cGMP. The company is the application process for ISO 9001 certification. The OU Kosher certified plant is subject to frequent audits from food and pharmaceutical end-product manufacturers and complies with local, state and federal laws and certifications.

## 6. Ancillary Substances

Flo Chemical's Zein is a pure substance free of any ancillary substances.

The company does offer for sale the following commercial products, which use zein as an ingredient.

| | |
|---|---|
| Cozeen 303N | Palm oil (foreign origin / USA sourced) and ethanol / water added (a ready to use product). Coat porous and/or sticky foods, i.e, nutritional bars, nuts and gummies. A customer may order Cozeen 303NA,which is a paste to which the customer solubilizes in a water / ethanol solution. |
| VPP | Guar gum (foreign origin / USA sourced). Retains moisture in fresh and dried fruits and vegetables. Also reduces oil absorption of potatoes and chicken during frying. |
| AquaZein | Propylene glycol (USA origin). Coating and glazing nutraceutical single dose tablets. |

## 7. Previous Reviews

Zein, was first discovered (isolated) in the 1880's. Zein has been examined as a possible raw material for polymer application since the early part of the 20th Century. Gorham (1821) first described zein after isolating the protein from maize. He named the material "*zeine*". The description that Gorham gave to zein would easily be recognized today. It resembled bees' wax and to be soft, ductile, tenacious, and elastic (Lawton 2002). Since then it has had several stints being used in commercial applications. Early 20$^{th}$ century uses were in buttons, stockings and as binders. Currently it is used in food and

pharmaceutical production, as a flux for brazing sophisticated metal alloys used for turbine blades (Rolls Royce patents), as a binder to stabilize sand in an attempt to slow beach erosion, and in medicine to lubricate stents and nano-encapsulate new complex active ingredients in state-of-the-art drugs.

Hundreds of peer reviews have been written about zein by universities and research centers across the globe. The USDA has supported dozens of papers regarding zein, for example;

Sessa, David J USDA-ARS Plant Polymer Research Unit, National Center for Agricultural Utilization Research, "Zein- A Corn Compound With Diverse Valuable Uses" (2008) Research is part of Quality and Utilization of Agricultural Products, an ARS national program (#306)

Parris, Nicholas; Sykes, Marguerite; Dickey, Leland C.; Wiles, Jack L.; Urbanik, Thomas J.; Cooke, Peter H. 2002. Recyclable Zein-Coated Kraft Paper and Linerboard. Progress in paper recycling. Vol. 11, no. 3 (May 2002): Pages 24-29.

For more citations please refer to section 12 of this petition.

## 8. Regulatory Authority

Zein is considered GRAS by the FDA [CITE: 21CFR184.1984] Revised April 1, 2015. In accordance with 184.1(b)(1), [zein] is considered a food.

Commonwealth of Massachusetts - Department of Public Health, Bureau of Environmental Health No. MA-7340. In accordance with Massachusetts General Law Chapter 94 Section 305C, it is a license to "Process Or Distribute Food For Sale At Wholesale".

## 9. Chemical Abstracts Service (CAS) Number and Product Labels

CAS Re. No. 9010-66-6

Zein can be found on many food products and is labeled as: "zein," "confectioners glaze," "zein protein," "maize protein" or "vegetable protein."

(Please see accompanying specification sheet)

## 10. Physical and Chemical Properties

Zein is a plant protein isolated from corn with a molecular weight varies from 22 to 27 kDa and an isoelectric pH of 6.228. Zein belongs to a family of prolamines, which are composed of high amounts (> 50%) of hydrophobic amino acids, such as proline, glutamine, and asparagines (Elzoghby et al., 2012b). This water-insoluble but alcohol-soluble corn storage protein is one of the best-understood biomacromolecules and classified as GRAS by the US Food and Drug Administration. It is soluble in binary

solvents containing a lower aliphatic alcohol (ethanol, methanol, and isopropanol) and water at various concentrations of alcohols range from 55% to 90% (v/v). (Ahmed O. Elzoghby et al., 2015).

Zein films are transparent. Mechanical properties (tensile strength and puncture strength), gas permeability, and water vapor permeability (WVP) of the zein films can be measured. The tensile strengths of the zein films tend to be between 7 and 30 MPa and the puncture strengths between 37 and 191 MPa. Zein films tend to have higher oxygen permeability than carbon dioxide permeability. Differences have been found in the WVP between sides of the zein films; i.e., the air side of the zein film may have a higher WVP than the basal side of a zein film when the films are exposed to high humidity during testing. This indicates a relationship between the WVP of the zein film and the contact angle of the zein film. The mechanical properties of the zein film depended on the drying conditions during preparation. Zein films with various useful physical mechanical properties may be produced. (Yoshino, T., Isobe, S. & Maekawa, T. J Amer Oil Chem Soc (2002) 79: 345)

Zein is non-toxic, biodegradable, and recyclable. The environmental impact from its production is negligible. The corn gluten meal is recovered and re-sold. The ethanol and associated vapors are recovered and then recycled back into our manufacturing process. The water used is flushed from corn product and separated from the ethanol. Various US and international agencies, universities and commercial ventures have demonstrated zein's positive affects regarding the safeguarding of raw and processed foods for human, pet, aquaculture and livestock ingestion.

## 11. Safety Information

Zein is considered GRAS and is incorporated in numerous food and pharmaceutical products globally. The National Institute of Environmental Health Studies, nor any other government agency has issued reports regarding negative health effects from exposure or ingestion of zein.

## 12. Research Information

We are the only manufacturer of zein in North America, historically it has been impossible to source commercial or for that matter any quantity of organic corn gluten meal CGM. In the past 4 years we have had discussions with state and governmental agricultural boards to attempt to source organic CGM, to no avail. Those discussions either result in a flat "no" or referral to a entity which in fact does not produce, source, broker or import organic CGM. The Organic Integrity Database does have listings of companies stating that they have organic CGM. In the past 8 months we have exhaustively contacted every one of those entities, resulting in not one being able to deliver even 1 kg of product. In addition, none stated that they would be able to furnish organic CGM in the future.

We source our CGM from either of two companies. As of 1 February 2020 we have received the following updates.

> Supplier A is a Fortune 500 company with "44 locations, and customers in more than 60 markets in over 40 countries". Their VP Sales stated, "I have not heard of any domestic or foreign organic cgm so count us out as I think the mkt is too small".
>
> Supplier B is a 9 figure privately held company with production facilities and offices in US, Asia, Europe and Mexico. Their VP Global Co-Product Sales has stated "It is of my opinion there is no organic cgmeal produced in the USA and nor do we have any plan to EVER produce any. Our efforts to locate any quantity for you either US origin or off shore have come up nil."

*In conclusion, without a source of organic CGM we cannot produce an organic zein product.*

No organic alternatives to zein currently exist. Unbleached shellac (currently on the NOP list) is the closest product to zein in its ability to act as an edible coating on food. Zein captures market share from shellac as a result of the growing demand for vegan products.

Hundreds of papers have been written about zein, with new ones being circulated literally weekly. Below, please find an annotated bibliography, which includes what we consider to be a useful selection of the myriad of recognized applications both academically and commercially for zein as well as in depth information about this corn derived protein.


1. Lawton, John W. "Zein: A History of Processing and Use", November 1, 2002, American Association of Cereal Chemists
2. Momany, Frank A.; Sessa, David J.; Lawton, John C.; Selling, Gordon W.; Hamaker, Sharon A. H.; and Willett, Julious L. "Structural Characterization of A-Zein" December 27, 2005, American Chemical Society
3. Sessa, David J USDA-ARS Plant Polymer Research Unit, National Center for Agricultural Utilization Research, "Zein- A Corn Compound With Diverse Valuable Uses" (2008) Research is part of Quality and Utilization of Agricultural Products, an ARS national program (#306)
4. Gennadios, Aristippos "Protein-Based Films and Coatings" 2002
5. Selling, G., Biswas, A., Patel, A., Walls, D., Dunlap, C., Wei, Y. "Impact of Solvent on Electrospinning of Zein and Analysis of Resulting Fibers", *Macromolecular Chemistry and Physics* Vol. 208, no. 9, 2007
6. Bertrand, Kate, "Military packages put technology to the test," September 2005
7. McGowan B.A., Padua G.W., and Lee S-Y. "Formulation of Corn Zein Chewing Gum and Evaluation of Sensory Properties by the Time-Intensity Method", September, 2005, *Journal of Food Science*
8. Lawton Jr., J.W. "Plasticizers for Zein:their Effect on Tensile Properties and Water Absorption of Zein Films" January 12, 2004, *Cereal Chemistry*
9. Song R, Llaca V, Linton E, Messing J (November 2001). "Sequence, regulation, and evolution of the maize 22-kD alpha zein gene family". *Genome Res.* **11** (11): 1817–25. doi:10.1101/gr.197301
10. Garratt R, Oliva G, Caracelli I, Leite A, Arruda P (January 1993). "Studies of the zein-like alpha-prolamins based on an analysis of amino acid sequences: implications for their evolution and three-dimensional structure". *Proteins.* **15** (1): 88–99



Flo Chemical Corp
Attn: Robert Zeif, Director of Business Development
robert@flochemicalcorp.com

11. Qiangxian Wu, Hiroshi Sakabe and Seiichiro Isobe "Studies on the toughness and water resistance of zein-based polymers by modification" June, 2003, National Food Research Institute, Japan
12. H.J. Park, M.S. Chinnan, Gas and water vapor barrier properties of edible films from protein and cellulosic materials, J. Food Eng. 25 (1995) 497–507.
13. IU. Ünalan, I. Arcan, F. Korel, A. Yemenicioğlu, Application of active zein-based films with controlled release properties to control *Listeria monocytogenes* growth and lipid oxidation in fresh Kashar cheese. Innov. Food Sci. Emerg. Technol. Vol 20 October 2013 208-214.
14. Tajamul Rouf Shah, Kamlesh Prasad, Pradyuman Kumar & Fatih Yildiz (2016) Maize—A potential source of human nutrition and health: A review, Cogent Food & Agriculture, 2:1, DOI: 10.1080/23311932.2016.1166995

## 13. Petition Justification Statement

For several reasons we believe zein should be included on the National List [Nonorganically Produced Agricultural Substance (7 C.F.R. § 205.606)]. While there is an availability (limited) of organic corn; we, our suppliers, other suppliers as well as governmental agricultural and trade boards have not identified any source of organic CGM for our manufacturing needs. As earlier stated, without the organic CGM as feedstock it is impossible to manufacture organic zein.

For over 40 years Flo Chemical has been producing zein. Our customer base of small to global food, pharmaceutical and nutraceutical manufactures believe it is imperative for their products to incorporate zein as opposed to other coatings and encapsulation agents. Beside the functionality of our zein products, the two current ingredient drivers are: vegan and non-GMO. Weekly, we receive calls and emails inquiring if we offer "organic zein".

While there are alternative organic and non-organic products available on the market, zein's unique functional characteristics make it a product of choice for companies the world over. In Innovations in Food Packaging (Second Edition), 2014, zein is described as "one of the most thermoplastic proteins that can be extruded, molded, and cast into biodegradable films".

Organic products –
Organic oils, e.g., citrus oils, basil oils while valuable 'macro' coatings require a material for micro and *nano* encapsulation. Zein is a frequently used material for encapsulation of essential oils. Studies have shown it to be superior to natural materials and even cellulose-acetate.

Non-Organic products –
Shellac - An analogous, competing product on the NOP List, "orange (non-bleached) shellac" has historically been used interchangeably with zein. Besides differing nuances such as cost, dry time, thickness and country of origin, the principal difference is that zein is vegan. As we experience market share growth for coatings, there is a direct correlation with consumers growing awareness and demand for vegan products.

Following are several citations with regard to shellac not meeting vegan standards:

Animal derived ingredients to avoid – (www.peta.org) **Shellac. Resinous Glaze.** Resinous excretion of certain insects. Used as a candy glaze, in hair lacquer, and on jewelry. Alternatives: plant waxes, Zein (from corn).

The Vegetarian Society does consider shellac to be vegetarian, but not vegan. The female lac insect produces a resin to cocoon the eggs she lays. (Vegsoc.org)

Shellac is not only animal unfriendly and not vegan, its production is also bad for humans. Reports by NGOs have shown that people working at shellac plantations and shellac processing factories are often underpaid, exploited and treated badly and child labour is not uncommon. Another reason why it's good to avoid shellac. (www.thegreenvegans.com)

Carnauba wax & Beeswax – The melting point of carnauba wax is 82°C. The melting point of zein is 266°-283°C. Zein's ability to "assemble with each other and form a meshwork structure during the film casting process, has been proposed to contribute to the high strength and low gas permeability of the film together with the high hydrophobicity"… Zein films can also be produced by compression molding or extrusion of zein resin at an elevated temperature, which generally results in an increased plasticization efficiency". The result is a stronger less permeable product than carnauba wax or for that matter beeswax with a melting point range of 62 to 64 °C. If beeswax is heated above 85 °C discoloration occurs. In addition, zein being completely biodegradable and recyclable has opened up opportunities coating food packaging. Because the coted packaging material comes in contact with the food product, we are often asked if we have an organic coating.

Alginates – unlike zein, alginate coated beads are affected by acetone and ethanol solvents. The alcohols interact between the beads, which may cause agglomeration. In addition, in some instances because of wall thickness, alginate derived beads may collapse from water / moisture pore volume. Given Zein's superior geometry, cell walls self-assemble into chains and layers or films and the resulting beads have demonstrated thicker bead walls resulting in less likely to collapse.

Carrageenan – doesn't really share Zein's space. Carrageenan is mostly used for thickening and stabilizing primarily in food. While zein is used by a number of cosmetics companies for thickening lotions and mascara it represents a small percentage of our business.

As previously mentioned, Zein, was first discovered (isolated) in the 1880's. The long-standing interest in zein has been it's wide-ranging uses: from food and drugs to coating batteries to protect from environmental conditions, all the way to terrestrial oil recovery. For all these applications there is one common theme: zein completely quickly biodegrades to plant protein molecules. Flo Chemical's manufacturing is a cGMP process utilizing clean / green products. In over 125 years of being a known substance, none of the countless papers or commercial applications has ever cited any ill effects on

human or animal health or adverse reactions in soil or water. Intriguingly, if water was delivered to developing nations in zein polymer containers, not only would the empty containers completely degrade to harmless maize protein, the containers would be safe for ruminants to consume and in fact deliver a modicum of ingestible protein.
In light of Zein's attributes of being GRAS, clean label, non-GMO, an effective moisture barrier and having a modicum of antibacterial properties, we often field requests from US, Canadian and European (confectionery) food manufacturers for zein to coat their organic products. Some examples follow:

> A CT based distributor of polishes, glazes and anti-sticking agents for the food and confectionery industries. These products are formulations compounded to perform specific tasks within the production. As manufacturers continue to expand their lines and produce organic products, they are in need of these formulations that are either organic or acceptable to be utilized in their organic production. Our objective is to have these manufactured by Flo Chemical Corporation. We have discussed the utilization of these products with our customer base and there is an interest in their use.
>
> A CA based grower of several varieties of citrus. In email and in-person discussions based on consumer input for an organic coating for their citrus they expressed an interest in zein. 'Zein's several unique properties would be an ideal product for us to consider as a replacement [coating]. Moving forward a vegan alternative is important as well. We will field test as soon as you have samples for us.'
>
> A MA based fruit growers cooperative and food manufacturer. The company presently uses shellac and stated in a meeting that they are "looking for alternatives to shellac". They asked for samples of zein to test as soon as possible. They inquired if it is organic because they would prefer an organic coating. One of the company's major products is susceptible to moisture migration problems when included in cereals, bars or covered in chocolate.
>
> A small NH based confectionery company that is developing a new line of product with the goal of it being organic. They have "successfully tested 24,000 lbs. of new product using zein, we are looking for organic options though none work as well in our formulation as your zein."
>
> The world's largest kosher certification agency, OU, (our products are OU kosher) has inquired, "When will you be able to supply a vegan kosher alternative to shellac".

We are the only manufacturer of zein in North America; no organic zein is available for sale globally. Based the conversations with current & perspective customers, as well as marketing partners based in the US and UK who create zein based coatings, we would anticipate shipping 2,000 kg of organic zein the first year.

*There are a myriad of companies large and small looking for a vegan / organic alternative confectioners glaze, coating / encapsulation agent. The availability of a proven vegan glaze and coating on the National List would be a great service to manufacturers and to the consumer public.*

Flo Chemical Corp
Attn: Robert Zeif, Director of Business Development
robert@flochemicalcorp.com

FLO CHEMICAL CORPORATION
*World Leading Producer of ZEIN*

# SPECIFICATION SHEET

## ZEIN F4400C - FOOD GRADE
**Extracted from NON-GMO IP Corn Gluten Meal**
**For Food & Cosmetic Use**

**ZEIN** is the water-insoluble prolamine protein found only in corn gluten

| | |
|---|---|
| **Description:** | Straw to yellow colored granular powder, bland in taste and aroma |
| **CAS Number:** | 9010.66.6 |
| **Bulk Density Range:** | 1.25 – 2.1 gm/10ml |
| **Identification Tests:** | Positive for USP/NF Tests (A) and (B) and Test (C), which is also the Solubility Test in an alcohol/water solution below. |
| **Solubility in Water:** | Insoluble |
| **ZEIN (Protein):** | 81.88-100% calculated on a dry basis |
| **Nitrogen:** | 13.10 – 16.00% |
| **Loss on Drying:** | 8% maximum (drying for 2 hrs at 105˚C) |
| **Total Ash:** | 2% maximum |
| **Heavy Metals:** | 20ppm maximum |
| **Mesh Size:** | Minimum 95% through 20 mesh |
| **Standard Packaging:** | 25 kilo poly bag inside double walled corrugated carton (55.12lbs net) |

20 Puffer Street | PO Box 51 | Ashburnham, MA 01430 | Tel 978.827.5101 | Fax 978.827.6429
flochemicalcorp@verizon.net | www.zeinproducts.com

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# SPECIFICATION SHEET

## ZEIN F4400C - FOOD GRADE
**Extracted from NON-GMO IP Corn Gluten Meal**
**For Food & Cosmetic Use**

## ASSAY METHODS FOR ZEIN

### Identification Tests

A. Add a few drops of nitric acid t.s. to an aqueous **ZEIN** suspension – heat it. The solution will be a light yellow color. After adding ammonia t.s., an orange color develops.

B. Add a few drops of copper sulfate t.s. to an alkaline **ZEIN** solution and warm it in a warm bath. A purple color will develop.

C. Solubility in alcohol: Insoluble in aqueous alcohol. Dissolve 1gm in 10ml of 75-80% alcohol with water at 37˚C gives a clear to cloudy solution.

### Assay
Proceed as directed under "Nitrogen Determination" (461) USP, ZEIN % $N_2$X 6.25.

### Loss on Drying
Accurately weigh 2gm of sample into a tared weighing dish. Dry at 105˚C for 2 hrs. Cool to room temperature in a desiccator. Weigh and calculate the percent loss on drying as follows:

$$\text{LOD\%} = \frac{\text{Wt. Sample wet} - \text{Wt. Dry}}{\text{Wt. Sample Wet}} \times 100$$

### Total Ash
Weigh accurately 2gm of sample into a large tared crucible. Ignite the contents gently, then heat to a dull red. Cool to room temperature in a desiccator and add 1ml concentrated sulfuric acid. Slowly heat to 800-850˚C. Hold at that temperature for 2 hrs. Cool to room temperature in a desiccator. Weigh and calculate the total ash as follows:

$$\text{Total Ash \%} = \frac{\text{Sample wt.} - \text{Wt. Residue}}{\text{Weigh Sample}} \times 100$$

### Heavy Metals
Proceed as directed under "Heavy Metals" (231) USP, Method II

Rev: 05/2014

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flochemicalcorp@verizon.net | www.zeinproducts.com

FLO CHEMICAL CORPORATION
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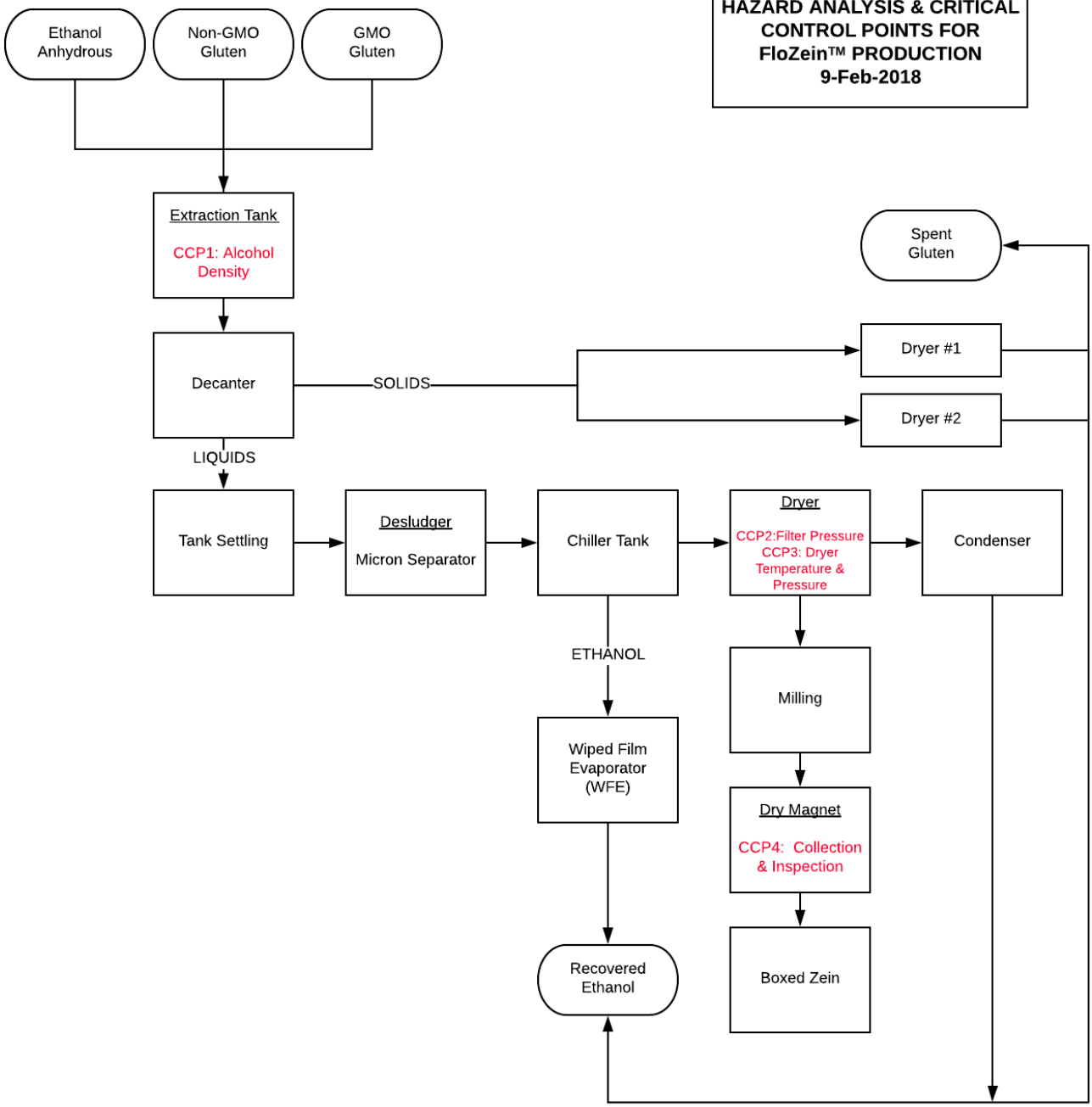
**HAZARD ANALYSIS & CRITICAL CONTROL POINTS FOR FloZein™ PRODUCTION**
**9-Feb-2018**

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