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.
Konjac Flour
Handling/Processing

Identification of Petitioned Substance

Chemical Names:  
- Konjac Flour
- Konjac Mannan
- Amorphophallus Konjac Root Mannan

Other Names:  
- Konjac Glucomannan
- Konjac Gum
- Konnyaku
- Glucomannoglycan
- Konjac Jelly
- Trade Names
  - Amophol ® LG
  - Ticagel ® Konjac HV
  - Rheolex ® RX-H

CAS Numbers:  
- 37220-17-0

Other Codes:  
- INS No.: 425
- E No.: E 425
- UNII No.: 36W3E5TAMG
- ECHA No.: 253-404-6
- EINECS: 253-404-6
- RXCUI: 1429449
- MERCK INDEX: M6637

Summary of Petitioned Use

The National List of Allowed and Prohibited Substances (“National List”), a part of the U.S. Department of Agriculture (USDA) organic regulations (7 CFR Part 205), identifies a limited number of non-organic agricultural ingredients that may be used in or on processed organic products. USDA organic regulations require that processed products labeled as “organic” contain at least 95% organic ingredients (§ 205.301). Only the nonorganically produced agricultural products included at § 205.606 of the National List are permitted in products labeled as “organic” and only when the product is not commercially available in organic form.


Konjac flour is currently included on the National List as an allowed nonorganic ingredient in or on processed products labeled as “organic” when not commercially available in organic form (7 CFR 205.606). In August 2001, the National Organic Standards Board (NOSB) received a petition to add Konjac flour to the National List (FMC 2001). As the federal advisory board that provides recommendations to the USDA National Organic Program (NOP), the NOSB reviewed the petition and recommended konjac flour be added to the National List at their May 2002 meeting (NOSB 2007). The NOP subsequently added konjac flour to the National List in June 2007 (72 FR 35137). In November 2017, the NOSB recommended that konjac flour be removed from the National List (NOSB, 2017). This report intends to assist NOP in reviewing NOSB’s Fall 2017 recommendation.

Characterization of Petitioned Substance

Composition of the Substance:
Konjac flour is a hydrocolloid polysaccharide produced from the corms (a corm is an underground plant also referred to herein as a “tuber” or “rhizome”) of the *Amorphophallus konjac* plant. This plant, a tropical perennial root crop, is also known as the voodoo lily, elephant yam, devil’s tongue, and konnyaku potato (JECFA 2001, EPA 2018, Behera and Ray 2017). Glucomannan, the main component in konjac flour is a form of dietary fiber. Dietary fibers differ from other carbohydrates in that they can only be partially digested or broken down by human salivary or pancreatic enzymes.

The flour is made from the glucomannan found in specialized plant cells called idioblasts that are spread throughout the konjac corm, with concentrations becoming larger as distance increases from the epidermis of the corm (Chua et al. 2013). The molecular structure of konjac flour is composed mainly of high molecular weight, branched non-ionic glucomannan molecules that are composed of a backbone of β-1,4 linked D-glucopyranose and β-D-mannopyranose sugars, generally with a 1.0:1.6 ratio (Parry 2010, JECFA 2001). Acetyl group side chains are located every 9–19 units on the C2, C3, or C6 carbons of mannopyranose molecules (FMC 1998). These side chains contribute to solubility. The konjac mannan’s structure can be seen in Figure 1.


Source or Origin of the Substance:

*Amorphophallus konjac* is a major tuber crop grown in Asian countries and has been used as food in China and Japan for more than 1000 years (Behera and Ray 2017). While the konjac plant is not commercially grown in the United States, the majority of konjac flour used in the nation originates from China and Japan, though Thailand may be an emerging source of konjac flour from other varieties of the species (Orachorn et al. 2016). The Organic Integrity Database lists twenty-six suppliers of konjac flour and konjac products as of April 1, 2020. Twenty-one of these suppliers are located in China, one is located in Singapore, and four are located in the United States. However, the United States operators in USDA’s Organic Integrity Database are listed as “handlers” (OID 2020). Top suppliers in China include Hubei Yizhi Konjac Biotechnology Company and Baoji Konjac Chemical Company (HMI 2019). Detailed information about the quantity of organic konjac flour available from these suppliers could not be determined.

In terms of its global availability, konjac flour sales are forecasted to increase through 2023 in China, the United States, Japan, and Korea. The global market for hydrocolloids overall is expected to grow by 5.8%
Konjac flour is defined as a food additive by the Codex Alimentarius and considered GRAS (generally recognized as safe) by the Food and Drug Administration (FDA) (FAO/WHO 2019). The glucomannan contained within the flour acts as a hydrocolloid by absorbing and binding water, up to 100 g of water per 1 g of flour (Perry 2010). Absorbency is affected by acetylation (acetyl group substitution for a hydrogen). As acetylation of the glucomannan increases, the water absorbency of the flour will decrease, as will the viscosity of the resulting gel. Konjac flour will also absorb oil but only between one and two times its own weight, significantly less than the absorbency with water. Removal of acetyl groups, caused by the addition of an alkaline coagulant during heating of the product, will allow konjac flour to form a thermally irreversible gel (Ji et al. 2017).

The glucomannan within the flour will begin decomposing around 250 °C, with complete decomposition occurring at 350 °C. Gels will become less viscous above 80 °C. Konjac glucomannan is also affected by bacterial enzymes, such as β-d-glucanase and will undergo bacterial fermentation when exposed to them. Gels produced with konjac flour must be treated with preservatives to prevent degradation by airborne microorganisms that may start the bacterial fermentation process.

Konjac flour gels may be formed in several ways, based on the interactions of glucomannan with other chemical processes. Eliminating acetyl groups, as mentioned above, will allow the remaining structure to build random junction zones with hydrogen bonding. This forms an irreversible gel like polyacrylamide gels. The process of eliminating acetyl groups is typically performed with alkali reactions to limit hydrolysis during the process, but acidic deacetylation is also possible. Temperature stable gels may also be formed without removing acetyl groups, depending on other ingredients, pH of the solution, and presence of other polysaccharides, such as xanthan gum. The physical properties of the resulting gel, such as elasticity, melting characteristics, and heat sensitivity, will vary greatly between combinations. Konjac flour gels are currently not listed in any certified products on the Organic Integrity Database.

Konjac and carrageenan will form synergistic gels when blended. Maximum viscosity is achieved at a ratio of 75–90% konjac flour and 10–25% carrageenan. Adding konjac flour to xanthan gum will produce a very elastic gel that is thermally reversible. Maximum synergy is achieved by 50/50 blends of konjac flour and xanthan gum. Blending konjac flour with other starches can increase viscosity and improve the freeze-thaw stability of the resulting gel. This will reduce syneresis, or weeping, after the gel is thawed.
The flour itself is a white, cream, or light tan colored powder. It may have a fish-like smell if amines are present in the flour (Behera & Ray 2017). Hydrolyzed konjac has a chewy texture and greasy mouthfeel, which is why it can be used as a fat substitute (Parry 2010).

Selected properties are listed below in Table 1.

**Table 1: Properties of Konjac Flour**

<table>
<thead>
<tr>
<th>Property</th>
<th>Konjac Flour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>White or cream to light tan powder</td>
</tr>
<tr>
<td><strong>Functional Uses</strong></td>
<td></td>
</tr>
<tr>
<td>Gelling Agent</td>
<td></td>
</tr>
<tr>
<td>Thickener</td>
<td></td>
</tr>
<tr>
<td>Emulsifier</td>
<td></td>
</tr>
<tr>
<td>Stabilizer</td>
<td></td>
</tr>
<tr>
<td>Humectant</td>
<td></td>
</tr>
<tr>
<td>Film Former</td>
<td></td>
</tr>
<tr>
<td><strong>Formula Weight</strong></td>
<td></td>
</tr>
<tr>
<td>Glucomannan</td>
<td>Glucomannan has an average molecular weight of 200,000 to 2,000,000 Daltons</td>
</tr>
<tr>
<td><strong>Empirical Formula (Glucomannan)</strong></td>
<td>C$<em>{24}$H$</em>{42}$O$_{21}$</td>
</tr>
<tr>
<td><strong>Molecular Weight (Glucomannan)</strong></td>
<td>666.6 g/mol</td>
</tr>
<tr>
<td>Assay</td>
<td>Not less than 75% carbohydrate</td>
</tr>
<tr>
<td>Maximum level of protein permitted</td>
<td>8%</td>
</tr>
<tr>
<td><strong>Water Solubility</strong></td>
<td></td>
</tr>
<tr>
<td>Dispersible in hot or cold water;</td>
<td></td>
</tr>
<tr>
<td>forms a highly viscous solution;</td>
<td></td>
</tr>
<tr>
<td>pH between 4.0 and 7.0 7–10%</td>
<td></td>
</tr>
<tr>
<td>soluble by weight</td>
<td></td>
</tr>
<tr>
<td>CAS Number</td>
<td>37220-17-0</td>
</tr>
<tr>
<td>INS Number</td>
<td>425</td>
</tr>
<tr>
<td>E Number</td>
<td>E425</td>
</tr>
<tr>
<td>UNII</td>
<td>36W3E5TAMG</td>
</tr>
<tr>
<td><strong>Polymer Type</strong></td>
<td>Neutral; interrupted repeat</td>
</tr>
<tr>
<td><strong>Conformation Type</strong></td>
<td>Zone C-D (semi-flexible/random coil)</td>
</tr>
<tr>
<td><strong>Gelation Properties</strong></td>
<td>Needs alkaline conditions to remove acetyl groups; the gel formed is</td>
</tr>
<tr>
<td></td>
<td>thermally irreversible</td>
</tr>
<tr>
<td><strong>Key sites for biomodification</strong></td>
<td>Polymannan regions, binding by helical regions of other polysaccharides,</td>
</tr>
<tr>
<td></td>
<td>OH groups for esterification and etherification</td>
</tr>
</tbody>
</table>


**Specific Uses of the Substance:**

Because of its hydrocolloid nature, konjac glucomannan can form a highly viscous solution when dissolved in water (Nieto 2009). Adding alkali, heat, or other polysaccharides to the mixture can change the effect of konjac glucomannan on processed foods. Below are several ways in which Konjac flour is used in the food industry:

1. **Thickener:** Konjac flours solubilize in water, even at low temperatures (Parry 2010). As such, konjac flours can be used to thicken foods and cosmetics.
2. **Gelling Agent**: Konjac flour that has had the acetyl groups removed from the glucomannan backbone can be used to form a thermally irreversible gel (Harding et al. 2017). The hardness of the gel will depend on the concentration of glucomannan polymers present.

3. **Film Former**: Konjac glucomannan can form a strong film (Nieto 2009). The acetyl ester groups present give konjac glucomannan a slight negative charge and greater steric hindrance than would be produced by a hydroxyl group. Removing the acetyl groups can produce a stronger film if desired.

4. **Emulsifier and Stabilizer**: Emulsification is the process of dispersing one liquid within a second immiscible liquid, such as oil and water (Dickinson 2009). Hydrocolloids such as konjac glucomannan can act as emulsifiers in high concentrations by forming viscoelastic connections between the dispersed droplets. This essentially forms a weak, gel-like network, holding the droplets in place and preventing them from separating out of suspension.

5. **Humectant**: As mentioned above, konjac glucomannan acts as a hydrocolloid. This allows it to act as a humectant by binding to water molecules present in a substance and preventing them from evaporating out, thus maintaining the moisture of the substance.

**Approved Legal Uses of the Substance:**

The FDA defines konjac flour as a GRAS food additive. It is defined by the USDA NOP in 7 CFR 205.606 as a non-organically produced agricultural product allowed as an ingredient in or on processed products labeled as “organic.”

The USDA Food Safety and Inspection Service (FSIS) allows konjac flour to be used as a meat binder provided it does not exceed 3.5% of the product formulation individually or collectively with other binders (FSIS 2013). It is also listed in the USDA Food Standards and Labeling Policy Book as a food ingredient that provides the effects of thickening, gelling, texturizing, and water binding, like that of starch vegetable flours, such as potato flour (FSIS 2005). As such, it can be used in applications such as surimi, a compound fish paste often known in the United States as artificial crab (Iglesias-Otero et al. 2010).

The FDA has designated products containing glucomannan, a “water-soluble gum,” to require a choking warning at 21 CFR 201.319.

Konjac flour may be used in cosmetics. It is not listed in 21 CFR § 700, which deals with definitions of cosmetics and prohibited ingredients. Cosmetic ingredients that are not color additives do not require FDA approval to be used in the United States, though they may be affected by laws and regulations relating to interstate commerce (FDA 2018).

The Environmental Protection Agency (EPA) allows konjac flour to be used as a thickener in pesticide formulation not to exceed 1.0% by weight for inert ingredients used pre-harvest in 40 CFR 180.920 (EPA 2018).

**Action of the Substance:**

The activity of konjac flour is due to the glucomannan molecules contained in the idioblasts left in the flour after wind or cyclone sifting.

Konjac glucomannan acts as a hydrocolloid that can add desired properties to foods, such as thickening, gelling, and stabilizing. Hydrocolloids are heterogeneous long-chain polymers characterized by their ability to form gels or viscous dispersions in water (Saha and Bhattacharya 2010). Konjac glucomannan acts as the hydrocolloid in konjac flour. The presence of hydroxyl groups increases a hydrocolloid’s
affinity for binding water molecules, meaning the more hydroxyl groups present on a polymer, the more hydrophilic it is. Once water molecules are bound to a hydrocolloid, a dispersion that exhibits the properties of a colloid occurs, thus the name “hydrocolloid.”

Konjac flour can act as a thickener when added to water-containing solutions. The idioblasts containing glucomannan dissolve, releasing the hydrocolloid polymer into the liquid. As the concentration of glucomannan increases in the substance, it forms an entangled network, which restricts particle movement.

Gels are formed only when konjac glucomannans have been de-esterified (Harding et al. 2017). This is done through alkali treatment, which removes the acetyl groups from the glucomannan backbone. Once the acetyl groups have been removed, konjac glucomannan can form thermo irreversible gels. Unlike other gel forming agents, konjac flour does not form a gel due to the denaturation of its protein structure. Instead, gelation occurs when chemical changes occur on the polysaccharide chain, which in turn results in the structural changes needed to form a gel (Maekaji 1974). As mentioned above, this is usually done by treating the glucomannan with an alkaline substance, which promotes the hydrolysis of sugar linkages (Maekaji 1974, Timberlake 2015). Higher degrees of deacetylation will lead to faster gelation (Yang et al. 2017). This is caused by the konjac glucomannan chain changing from semi-crimping to a self-crimping structure, which leads to more connections between the glucomannan molecules.

Stronger gels may be produced when a helical polysaccharide, such as gellan gum, is added to the konjac glucomannan (Harding et al. 2017). Konjac flour exhibits a synergistic effect when combined with other gelation agents, such as xanthan gum, κ-carrageenan, agar, pectin, and gelatin, producing more robust gels due to its ability to promote cross-linking between the existing gelation networks (Akesowan 2002). Konjac flour derivatives, such as oligosaccharides, have been used as ingredients in skin care products and in wound healing applications (Bateni et al. 2013, Al-Ghazzewi et al. 2015). While the full mechanism of the immune support is still under investigation, the mannose-based oligosaccharides formed via glucomannan hydrolysis are have been shown to suppress Immunoglobulin E production in mice upon ingestion (Suzuki et al. 2010). The ingestion of mannose-rich konjac flour products continues the general trend in application of mannose sugars for wound-healing, with aloe vera applications being the most recognizable form (Hamman 2008, Al-Ghazzewi et al. 2015).

Konjac powder and glucomannan are used in nutritional supplements to promote weight loss (Birketvedt et al. 2005, Keithley et al. 2013, Ho et al. 2017). The β-1-4 linkages that extend the length of the polysaccharide chain are not digested by human enzymes or the microbiota in the human GI tract (Timberlake 2015). The combination of the inability to break down the glucomannan polysaccharide, along with the viscous solutions created when dissolved in water makes the substance among the most viscous sources of soluble fiber (Ho et al. 2017). This results in feelings of increased satiety after ingestion, which reduces food intake. This serves as the primary means for glucomannan supplements to promote weight loss (Akesowan 2002, Birketvedt et al. 2005, Keithley et al. 2013, Ho et al. 2017).

The primary medicinal use of konjac flour is treatment of cholesterol levels (Akesowan 2002, Keithley et al. 2013, Ho et al. 2017). The ability of glucomannan to lower cholesterol is tied to its efficacy as a source of soluble fiber (Ho et al. 2017). The precise mechanisms of action for decreased levels of low-density lipoprotein (LDL) are still being investigated, although the viscosity of glucomannan fiber within the gut is thought to shift the kinetics of nutrient uptake (Barsanti et al. 2011, Ho et al. 2017). The presence of the viscous fiber within the GI tract may reduce the reabsorption of cholesterol and bile acids and increase acetate production, both of which have been linked to reductions in LDL concentration (Wong et al. 2006, Keithley et al. 2013, Ho et al. 2017). Recent studies have suggested that the viscosity of the fiber may be more important than the quantity of fiber ingested, indicating that glucomannan may be a more effective source of fiber for cholesterol treatments than other dietary fibers. (Vuksan et al. 2011, Ho et al. 2017).
Combinations of the Substance:

Though formed directly from the corms of the Amorphophallus konjac plant, konjac flour may be combined with other gums, such as xanthan gum, to achieve a synergistic effect and form a stronger gel (Harding et al. 2017). As mentioned above, adding an alkaline solution, such as calcium hydroxide, to the konjac flour will strip the acetyl groups from the glucomannan backbone and enable it to form a thermally irreversible gel.

Status

Historic Use:

Historically, konjac has been used in China, Japan, and South East Asia as a traditional food (Chua et al. 2010). The flour can be processed into foods such as konjac curd and noodles, jellies, cakes, jams, and breads (FMC 2001). Chinese traditional medicine uses a gel prepared from konjac flour for detoxification, tumor suppression, and phlegm liquefaction (Chua et al. 2010). The flour has also been used for treatment of asthma, cough, pain, burns, and skin disorders.

Konjac flour is also used outside of food additives and traditional medicines. The glucomannan in it can be separated out for several purposes. Konjac glucomannan has been used in cosmetics as moisturizing agents, physical exfoliants, oil-in-water emulsifiers, and in disinfectant gels (Zhang et al. 2005). Due to its ability to form emulsions, gels and films, konjac glucomannan can also be applied to pharmaceutical applications, including drug-delivery systems such as films and drug capsules and bio-adhesives.

Konjac flour may be used as thickener in pesticides in traditional agricultural production at concentrations of 1% or below (EPA 2018).

Organic Foods Production Act, USDA Final Rule:

Konjac flour is not listed in the Organic Foods Production Act of 1990 (OFPA). It is listed in the USDA organic regulations, 7 CFR 205.606, as a non-organic ingredient allowed in foods labeled as organic.

International

The use of Konjac flour is permitted in varying forms in international markets. China, Japan, and other eastern Asian countries that have historically used konjac, classify it as a food (Parry 2010). Australia considers konjac flour to be a vegetable when used as a product’s key ingredient.

Canadian General Standards Board Permitted Substances List —

Konjac flour is not listed in the Canadian General Standards Board Permitted Substances List for organic production systems according to CAN/CGBS-32.12-2018. It is not included on the Lists of Official Food Additives kept by Health Canada’s official repository (HC 2017).

Konjac flour (listed as konjac mannan) is in the Natural Health Products Ingredients Database from Health Canada (HC 2007). It is an approved herbal substance and listed under Schedule 1: Plant and plant materials, as a film former, gelling agent, solubilizing agent, and thickening agent. Konjac glucomannan is listed as a non-medicinal ingredient in the database.


Konjac flour (INS No. 425) is not listed in Table 3.1 of the CODEX (GL 32-1999) as a food additive. (FAO/WHO 1999). However, konjac flour is listed in the CODEX (CXS 192-1995) in Table 3 as a food additive. It is considered acceptable in foods with the commodity standards (CS) 117-1981 and CS 309R-2011 and is in the carrier, emulsifier, gelling agent, glazing agent, humectant, stabilizer, and thickener functional classes (FAO/WHO 2019).
Konjac flour (E 425) is not listed as a permitted food additive in Annex VIII, section A of Commission Regulation (EC) No. 834/2007 and 889/2008. It is not listed in EC No. 834/2007. The use of Konjac flour (as E 425 i and E 425 ii) as a food additive was reevaluated by the EFSA Panel on Food Additives and Nutrient Sources in 2017 (Mortensen et al. 2017). The panel concluded that konjac flour was permitted as a food additive up to 10g/kg if total consumption from all sources was no more than 3 g per day.

In the European Union (EU), konjac must be at 1% concentration or below in end products or blends with other thickeners (Parry 2010). Konjac has an exemption to this rule in Belgium, which allows its use as a botanical material for weight control.

Konjac flour is not listed in the Japanese Agricultural Standard for Organic Production under the Standard for Organic Plants (Notification No. 1605/2005), Organic Processed Foods (Notification No. 1606/2005), Organic Feeds (Notification No. 1607/2005), or Organic Livestock Products (Notification No. 1608/2005). All standards were last revised in March 2012. It is not listed as a food additive in Table 1 of Article 4 of the Japanese Agriculture Standard for Organic Processed foods (MAFF 2012). However, in JAS Organic Production Notification No. 1606, wood ash as a permitted food additive in attached Table 1 in producing alimentary konjac products.

Konjac flour (INS 425) is not listed in the International Federation of Organic Agriculture Movements (IFOAM) norms (IFOAM 2018).

Evaluation Questions for Substances to Be Used in Organic Handling

Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Konjac flour is produced from the corms of the Amorphophallus konjac plant, a tropical perennial crop. The corms of the plant contain about 30–50% glucomannan gum. When the corms are dried and milled, the resulting powder is konjac flour (FMC 2001). The flour constitutes 60–80% of the dried root corm (JECFA 1993). The corms grow below ground and are harvested at 2 kg for commercial processing (Douglas et al. 2006). They are then washed and cut into thin slices, which are then dried and dry-milled into powder. The powder is separated, usually by cyclone or wind separation, producing crude konjac flour (Harding et al. 2017). The flour may contain fine oval sacs, which contain polymers (Pérols et al. 1997). When the flour is hydrated, the sacs will swell and rupture, releasing the glucomannan.

Konjac flour, konjac glucomannan, and konjac gum may be used interchangeably, as all refer to products from the dried Amorphophallus konjac corm (EPA 2018). The difference in naming typically refers to the processing that goes on after the crude konjac flour is dried and separated. Konjac flour is used to refer to the unpurified raw product. Konjac glucomannan is produced by washing the flour with water-containing ethanol to remove impurities. Konjac gum is the water-soluble hydrocolloid left over after aqueous extraction.

Glucomannan can be further processed to form differing types of gels. If heat or alkali treatment is used to remove the acetyl group from the glucomannan backbone in a process known as deacetylation, the resulting gel will be hard and thermally irreversible (Harding et al. 2017, Yang et al. 2017).
Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.

Since konjac flour is created from the corms of the Amorphophallus konjac plant, it is derived from an agricultural source. Crude konjac flour is created through a natural drying process. Konjac glucomannan forms in the corms of A. konjac during the growth process. As mentioned above, the konjac corm is about 60-80% flour. The flour is extracted from the corm through drying, milling, and wind or cyclone separation, which removes the remaining 40-20% of the corm, leaving only flour. As previously mentioned, aqueous extraction and ethanol washing can be used to further purify the flour, but this will not happen in a naturally occurring biological process (Xu et al. 2014).

Evaluation Question #3: If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

The Amorphophallus konjac K. Koch plant is the natural source of konjac flour (Maekaji 1974). Konjac flour is an agriculturally produced nonsynthetic substance. See Evaluation Question #12 for other nonsynthetic alternatives to konjac flour.

Evaluation Question #4: Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA’s good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.

Alcohol-washed konjac flour received GRAS status from the FDA in 1957 (Parry 2010). Konjac flour received FDA GRAS status in 1994 (FMC 2001, EPA 2018, Behera and Ray 2017). It is not listed in 21 CFR §182, 184, or 186 but is listed in 7 CFR 205.606 on the National List of Allowed and Prohibited Substances. Konjac flour (as konjac glucomannan) is also listed under 40 CFR 180.920 as a thickener not to exceed 1.0% by weight in pesticide formulation for inert ingredients used pre-harvest. 40 CFR 180 defines tolerances and exemptions for pesticide chemical residues in food. Moreover, deacetylated konjac flour does not have a separate GRAS status from konjac flour.

Konjac flour (as konjac glucomannan) appears in the GRAS Notice Inventory under GRN 328 and 407 as part of a polysaccharide complex of konjac glucomannan (konjac), sodium alginate, and xanthan gum (polysaccharide complex KAX). GRN 328 did not provide a determination for GRAS status. GRN 407 received a “FDA has no questions” status.

Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b)(4)).

The primary use of konjac flour is as a thickener or gelling agent, not as a preservative (Mortensen et al. 2017).

Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).

Konjac flour can be used to recreate the texture of fat in low fat foods, like iota-carrageenan (Pearson and Dutson 2013). However, this is not the primary purpose of the use of konjac flour as a food additive.
Instead, konjac flour is primarily used as a gelling agent, stabilizer, thickener, and film former in processed foods (FMC 2001).

Konjac flour may be used as a texturizing agent. This function is achieved by its ability to enhance water retention and in the formation of robust gels (Osburn and Keeton 1994, Akesowan 2002, Akesowan 2008, Chin et al. 2009, EFSA 2017). Gel formation and water retention have been used in meat products to introduce leaner cuts of meat, while maintaining the texture and cooking quality that are associated with cuts with higher fat content (Osburn and Keeton 1994, Chin et al. 2009). The incorporation of konjac flour helps to reduce water loss throughout the cooking process, alleviating “cooking loss” linked to sausages and other meat products made with lean meats (Chin et al. 2009). Moreover, there are documented synergistic effects of konjac flour with other gelling agents such as collagen and gelatin, which are naturally present in meats that increase gelation with increased temperature (Maekaji 1974, Osburn and Keeton 1994, Chin et al. 2009).

**Evaluation Question #7:** Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).

Konjac flour is a non-digestible polysaccharide (EPA 2018). This is due to the β-glycosidic linkages between the mannose and glucose molecules, which cannot be hydrolyzed by pancreatic amylase or salivary amylase. This means that it passes into the colon without being digested. Once in the colon, it is fermented by the native flora to produce glucomanno-oligosaccharides. Because it is not digested immediately, konjac glucomannan can increase feelings of satiety, leading the consumer to eat less (Behera and Ray 2017). This effect is present in concentrations typically used in food due to the ability of konjac glucomannan to absorb water in the gut and form a soluble gel. While this is not an effect on the nutritional quality of a food, it is a health effect and should be noted.

When used as a fat replacer in foods, konjac flour has been shown to lower the caloric content of the food. The incorporation of konjac flour has been reported to decrease the caloric content of meat products by an estimated 50% (Osburn and Keeton 1994). This is largely due to the negligible caloric value of the glucomannan protein based on the inability of humans to break down the β 1-4 linkages found throughout the polysaccharide (Timberlake 2015). This is primarily seen as an industry positive since konjac flour is primarily added to reduced-fat meat products (Osburn and Keeton 1994, Akesowan 2008, Chin et al. 2009). The caloric reduction in sausages incorporating konjac flour is typically coupled with a reduction in fat content, due the ability to use low-fat ingredients (Osburn and Keeton 1994, Akesowan 2008, Chin et al. 2009).

**Evaluation Question #8:** List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600 (b)(5)).

The Institute of Medicine Food and Nutrition Board Committee on Food Chemicals presents limits for heavy metals and contaminants in konjac flour in a monograph published in 1996 (IM 1996). The limits are the following:

- **Arsenic:** Not more than 3 mg/kg
- **Heavy Metals:** Not more than 10 mg/kg
- **Lead:** Not more than 5 mg/kg

The USDA has not reported any recalls of konjac flour for contamination or heavy metal residues since 1996. The USDA recall database posts notices of recalls from 1996 onward.

The EPA issued an exemption from the requirement of tolerance for konjac glucomannan as an inert ingredient under 40 CFR 180.920 in 2018 (EPA 2018).
**Evaluation Question #9:** Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

An EPA memorandum was published in 2018 to summarize the human health and ecological effects of exposure to konjac flour (EPA 2018). The memorandum was prepared in response to a request to use konjac glucomannan as an inert ingredient in a pesticide. The EPA found that konjac glucomannan is readily broken down through molecular degradation in the environment. The glucomannan has a negligible vapor pressure, meaning that it will not vaporize under normal conditions and will only exist as a particulate in the atmosphere. The polysaccharide nature of the glucomannan will allow it to absorb into sediment and soil, which should prevent it from moving into surface and groundwater via runoff from fields. Potential for bioaccumulation in soil is expected to be low. Based on the results of the human health and environmental studies on konjac glucomannan, the EPA approved konjac glucomannan as an inert ingredient under 40 CFR 180.920.

**Evaluation Question #10:** Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

Konjac glucomannan, the main component in konjac flour, exhibits low levels of acute toxicity (EPA 2018). Studies have been performed in rats and mice to produce oral LD$_{50}$ levels of >2800 mg/kg to >5000 mg/kg. It has not been shown to be a skin irritant or dermal sensitizer. Konjac flour may be an eye irritant (FMC 1998).

The main concern for human health from konjac flour is the development of asthmatic responses in workers exposed to airborne powders produced during the commercial manufacture of the flour from the konjac corms (EPA 2018). This form of occupational asthma is common in Japan. An inhalation exposure test was performed on guinea pigs and demonstrated that respiratory hypersensitivity could indeed be induced after repeated inhalation of konjac flour powder. Recent studies point to a protein called AG40D-2 as the respiratory sensitizer, not the glucomannan particles themselves.

No evidence has been found for damage to immune function in mammals. Neurotoxicity, carcinogenicity, genotoxicity, mutagenicity, and clastogenicity have not been found to stem from exposure to konjac flour. The EPA has not identified a toxicological endpoint of concern for konjac glucomannan and has indicated no concern for aggregate exposure. A review by the Food Science and Safety Section of the National Food Authority in Australia found no evidence of adverse effects attributable to konjac flour in animals and established an ADI “not specified” for the substance (JECFA 1996).

Konjac gum and konjac glucomannan were found in a review by the Nordic Council of Ministers to potentially cause diarrhea, flatulence, and abdominal pain if consumed in excess (Mortensen et al. 2017). Konjac flour may be considered a “functional food,” which is defined as a food with additional functions relating to health benefits (Behera and Ray 2017). Konjac flour swells in the human gut, which increases feelings of satiety, possibly leading to a reduction in calories consumed.

It has been claimed that adding konjac flour to the human diet may have many positive health effects, such as lowering serum cholesterol levels (Barrett et al. 2004); yet, these effects are not always supported by clinical research studies. Studies on the role of konjac glucomannan in weight reduction and carbohydrate metabolism modification have also been performed (Iglesias-Otero et al. 2019). However, despite konjac glucomannan being promoted as a weight loss supplement, results of these studies have
been inconclusive. For example, studies involving overweight and obese individuals with self-selected diets and no changes in exercise patterns have not supported the claim (Keithley et al. 2013).

**Evaluation Question #1:** Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

Other substances listed on the National List of Approved and Prohibited Substances could be used in place of konjac flour for thickening, gel-forming, film-forming, and emulsifying in processed foods. Since konjac flour is currently only listed as a non-organically produced agricultural product allowed in “organic” processed products, an organic version of it could be substituted. An organic konjac flour would possess similar properties as a non-organic one, which would allow for minimal differences in the finished product.

**Evaluation Question #12:** Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

Other polysaccharide hydrocolloids may provide possible alternatives for konjac flour in processed foods. Natural additives that may be successfully used in place of konjac flour include native starches, gums such as locust bean or guar gum, and pectin (Saha and Bhattacharya 2010). Gelatin, a protein hydrocolloid, may also be used.

Several substances can be found on the National List of Allowed and Prohibited Substances that may take the place of konjac flour (NOP 2016). These ingredients may provide similar functionality used alone or in combination with other substances.

Per 7 CFR 205.605 (a), the following nonagricultural, non-synthetics are allowed:

- Agar-agar
- Carrageenan
- Gellan gum

Per 7 CFR 205.605 (b), the following nonagricultural synthetics are allowed:

- Xanthan gum

Per 7 CFR 205.606, the following non-organically produced agricultural products are allowed only when organic forms are not commercially available (and only in accordance with the applicable restrictions specified in the section):

- Lecithin (de-oiled)
- Pectin (non-amidated forms only)
- Starches
- Native corn starch
- Tragacanth gum

**Evaluation Information #13:** Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b) (I)).

The most likely organic replacements for konjac flour (in addition to organic konjac flour) as a hydrocolloid are organic starches, such as cornstarch, tapioca starch, and arrowroot starch. Starch can act as a hydrocolloid without adding strange tastes or smells, like some gums may do (Saha and Bhattacharya 2010). However, the starches listed may not have the same gelling or thickening properties as konjac flour or konjac glucomannan, so caution must be used when making substitutions. Organic
gums, such as locust bean, guar, and tara could also be used; however, once again, these substances would not exactly mirror konjac flour’s hydrocolloid properties (NOP 2016).

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### Report Authorship

The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:

- Kylie White, MS, Savan Group
- Samantha Olsen, Technical Editor, Savan Group

All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11 – Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

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