

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.

Konjac Flour

Handling/Processing

Identification of Petitioned Substance

Chemical Names:	19	Propol ® Phoenix 2A
Konjac Flour	20	Nutricol ® GP 6220
Konjac Mannan	21	Rheolex ® LM
Amorphophallus Konjac Root Mannan		
		CAS Numbers:
		37220-17-0
Other Names:		
Konjac Glucomannan		
Konjac Gum		Other Codes:
Konnyaku		INS No.: 425
Glucomannoglycan		E No.: E 425
Konjac Jelly		UNII No.: 36W3E5TAMG
Trade Names		ECHA No.: 253-404-6
Amophol ® LG		EINECS: 253-404-6
Ticagel ® Konjac HV		RXCUI: 1429449
Rheolex ® RX-H		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 and its derivative substances have been used in several industries, including medicine, nutritional supplements, and weight loss products (Birketvedt et al. 2005, Bateni et al. 2013, Keithley et al. 2013, Al-Ghazzewi et al. 2015, Ho et al. 2017). The focus of this technical report will be on the food uses of konjac flour, which are primarily as a stabilizer, gelling, and thickening agent (Maekaji 1974, Osburn and Keeton 1994, JECFA 1996, Kurakake and Komaki 2001, Akesowan 2008, Chin et al. 2009, Zhang et al. 2009, EFSA 2017).

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.

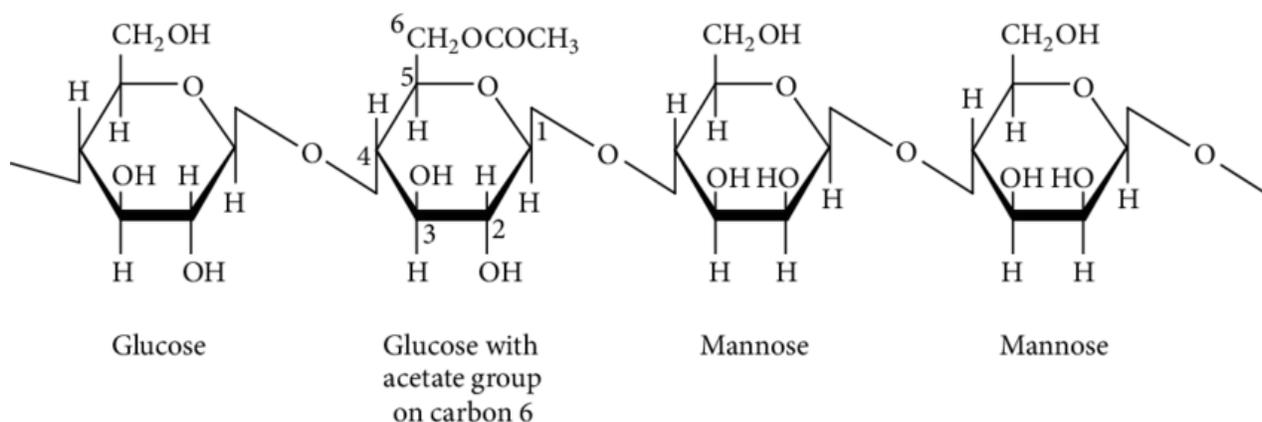
Characterization of Petitioned Substance

Composition of the Substance:

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

59
60 The flour is made from the glucomannan found in specialized plant cells called idioblasts that are spread
61 throughout the konjac corm, with concentrations becoming larger as distance increases from the epidermis of
62 the corm (Chua et al. 2013). The molecular structure of konjac flour is composed mainly of high molecular
63 weight, branched non-ionic glucomannan molecules that are composed of a backbone of β -1,4 linked
64 D-glucopyranose and β -D-mannopyranose sugars, generally with a 1.0:1.6 ratio (Parry 2010, JECFA 2001).
65 Acetyl group side chains are located every 9–19 units on the C2, C3, or C6 carbons of mannopyranose molecules
66 (FMC 1998). These side chains contribute to solubility. The konjac mannan’s structure can be seen in Figure 1.
67

68 Konjac flour is commercially available as an off-white to brown powder with $\geq 96\%$ purity (JECFA 1996,
69 Aromantic 2016, EFSA 2017). The substance readily absorbs water, with reports of absorption of 200 times its
70 weight in water (PubChem 24892726, Flomenbaum et al. 2006, EFSA 2017).
71
72
73



74
75
76 **Figure 1: Structure of Konjac Mannan (Keithley et al. 2013)**
77

78 **Source or Origin of the Substance:**

79 *Amorphophallus konjac* is a major tuber crop grown in Asian countries and has been used as food in China
80 and Japan for more than 1000 years (Behera and Ray 2017). While the konjac plant is not commercially
81 grown in the United States, the majority of konjac flour used in the nation originates from China and
82 Japan, though Thailand may be an emerging source of konjac flour from other varieties of the species
83 (Orachorn et al. 2016). The Organic Integrity Database lists twenty-six suppliers of konjac flour and
84 konjac products as of April 1, 2020. Twenty-one of these suppliers are located in China, one is located in
85 Singapore, and four are located in the United States. However, the United States operators in USDA’s
86 Organic Integrity Database are listed as “handlers” (OID 2020). Top suppliers in China include Hubei
87 Yizhi Konjac Biotechnology Company and Baoji Konjac Chemical Company (HMI 2019). Detailed
88 information about the quantity of organic konjac flour available from these suppliers could not be
89 determined.
90

91 In terms of its global availability, konjac flour sales are forecasted to increase through 2023 in China, the
92 United States, Japan, and Korea. The global market for hydrocolloids overall is expected to grow by 5.8%

93 annually through 2022 (Bizzozero 2018). Additionally, FDA announced that it intends to expand the
94 definition of “dietary fiber” to include several new sources of non-digestible carbohydrates (FDA 2020b).
95 Glucomannan, including konjac glucomannan, is one of the non-digestible carbohydrates (FDA 2020a)
96 listed. Until the rule is finalized, FDA will allow manufacturers to use glucomannan in their dietary fiber
97 declarations on a case-by-case basis. As such, supply may be limited as increasing demand could affect
98 the availability for production needs.

99
100 Konjac plants typically grow in shady environments and need well-draining soil with a pH between 6.5
101 and 7.5 to thrive. The optimal temperature for growth is between 68–77 °F (20–25°C), but the plant can be
102 grown at temperatures as low as 41°F. Konjac corms, which form underground, may grow up to 10 kg if
103 left unharvested (Douglas et al. 2006). The plants reproduce by sloughing off rhizomatous offsets. Once
104 the rhizome has been disconnected from the mother plant, it can grow into another one.

105
106 Konjac flour is created by slicing and drying the corms of the *Amorphophallus konjac* plant, then milling
107 the dried result. The powder produced from the milling process is then wind or cyclone separated to
108 form konjac flour. The wind or cyclone separation process removes impurities, such as ash, from the
109 flour. The resulting flour is composed of approximately 75% carbohydrates, 2–8% protein, <1% fat, and
110 3–5% ash (JECFA 1993).

111 112 **Properties of the Substance:**

113 Konjac flour is defined as a food additive by the Codex Alimentarius and considered GRAS (generally
114 recognized as safe) by the Food and Drug Administration (FDA) (FAO/WHO 2019). The glucomannan
115 contained within the flour acts as a hydrocolloid by absorbing and binding water, up to 100 g of water
116 per 1 g of flour (Perry 2010). Absorbency is affected by acetylation (acetyl group substitution for a
117 hydrogen). As acetylation of the glucomannan increases, the water absorbency of the flour will decrease,
118 as will the viscosity of the resulting gel. Konjac flour will also absorb oil but only between one and two
119 times its own weight, significantly less than the absorbency with water. Removal of acetyl groups, caused
120 by the addition of an alkaline coagulant during heating of the product, will allow konjac flour to form a
121 thermally irreversible gel (Ji et al. 2017).

122
123 The glucomannan within the flour will begin decomposing around 250 °C, with complete decomposition
124 occurring at 350 °C. Gels will become less viscous above 80 °C. Konjac glucomannan is also affected by
125 bacterial enzymes, such as β -d-glucanase and will undergo bacterial fermentation when exposed to them.
126 Gels produced with konjac flour must be treated with preservatives to prevent degradation by airborne
127 microorganisms that may start the bacterial fermentation process.

128
129 Konjac flour gels may be formed in several ways, based on the interactions of glucomannan with other
130 chemical processes. Eliminating acetyl groups, as mentioned above, will allow the remaining structure to
131 build random junction zones with hydrogen bonding. This forms an irreversible gel like polyacrylamide
132 gels. The process of eliminating acetyl groups is typically performed with alkali reactions to limit
133 hydrolysis during the process, but acidic deacetylation is also possible. Temperature stable gels may also
134 be formed without removing acetyl groups, depending on other ingredients, pH of the solution, and
135 presence of other polysaccharides, such as xanthan gum. The physical properties of the resulting gel, such
136 as elasticity, melting characteristics, and heat sensitivity, will vary greatly between combinations. Konjac
137 flour gels are currently not listed in any certified products on the Organic Integrity Database.

138
139 Konjac and carrageenan will form synergistic gels when blended. Maximum viscosity is achieved at a
140 ratio of 75–90% konjac flour and 10–25% carrageenan. Adding konjac flour to xanthan gum will produce
141 a very elastic gel that is thermally reversible. Maximum synergy is achieved by 50/50 blends of konjac
142 flour and xanthan gum. Blending konjac flour with other starches can increase viscosity and improve the
143 freeze-thaw stability of the resulting gel. This will reduce syneresis, or weeping, after the gel is thawed.

144

145 The flour itself is a white, cream, or light tan colored powder. It may have a fish-like smell if amines are
 146 present in the flour (Behera & Ray 2017). Hydrolyzed konjac has a chewy texture and greasy mouthfeel,
 147 which is why it can be used as a fat substitute (Parry 2010).

148

149 Selected properties are listed below in Table 1.

150

151

152

Table 1: Properties of Konjac Flour

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

153 Sources: PubChem 24892726, Mortensen et al. 2017, FMC 1998, Parry 2010, Harding et al. 2017

154

155 **Specific Uses of the Substance:**

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

160

161

162

163

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.

- 164 2. **Gelling Agent:** Konjac flour that has had the acetyl groups removed from the glucomannan
165 backbone can be used to form a thermally irreversible gel (Harding et al. 2017). The hardness of
166 the gel will depend on the concentration of glucomannan polymers present.
167
- 168 3. **Film Former:** Konjac glucomannan can form a strong film (Nieto 2009). The acetyl ester groups
169 present give konjac glucomannan a slight negative charge and greater steric hindrance than
170 would be produced by a hydroxyl group. Removing the acetyl groups can produce a stronger
171 film if desired.
172
- 173 4. **Emulsifier and Stabilizer:** Emulsification is the process of dispersing one liquid within a second
174 immiscible liquid, such as oil and water (Dickinson 2009). Hydrocolloids such as konjac
175 glucomannan can act as emulsifiers in high concentrations by forming viscoelastic connections
176 between the dispersed droplets. This essentially forms a weak, gel-like network, holding the
177 droplets in place and preventing them from separating out of suspension.
178
- 179 5. **Humectant:** As mentioned above, konjac glucomannan acts as a hydrocolloid. This allows it to
180 act as a humectant by binding to water molecules present in a substance and preventing them
181 from evaporating out, thus maintaining the moisture of the substance.
182

183 **Approved Legal Uses of the Substance:**

184 The FDA defines konjac flour as a GRAS food additive.
185

186 It is defined by the USDA NOP in 7 CFR 205.606 as a non-organically produced agricultural product
187 allowed as an ingredient in or on processed products labeled as “organic.”

188 The USDA Food Safety and Inspection Service (FSIS) allows konjac flour to be used as a meat binder
189 provided it does not exceed 3.5% of the product formulation individually or collectively with other
190 binders (FSIS 2013). It is also listed in the USDA Food Standards and Labeling Policy Book as a food
191 ingredient that provides the effects of thickening, gelling, texturizing, and water binding, like that of
192 starch vegetable flours, such as potato flour (FSIS 2005). As such, it can be used in applications such as
193 surimi, a compound fish paste often known in the United States as artificial crab (Iglesias-Otero et al.
194 2010).
195

196 The FDA has designated products containing glucomannan, a “water-soluble gum,” to require a choking
197 warning at 21 CFR 201.319.
198

199 Konjac flour may be used in cosmetics. It is not listed in 21 CFR § 700, which deals with definitions of
200 cosmetics and prohibited ingredients. Cosmetic ingredients that are not color additives do not require
201 FDA approval to be used in the United States, though they may be affected by laws and regulations
202 relating to interstate commerce (FDA 2018).
203

204 The Environmental Protection Agency (EPA) allows konjac flour to be used as a thickener in pesticide
205 formulation not to exceed 1.0% by weight for inert ingredients used pre-harvest in 40 CFR 180.920 (EPA
206 2018).
207

208 **Action of the Substance:**

209 The activity of konjac flour is due to the glucomannan molecules contained in the idioblasts left in the
210 flour after wind or cyclone sifting.
211

212 Konjac glucomannan acts as a hydrocolloid that can add desired properties to foods, such as thickening,
213 gelling, and stabilizing. Hydrocolloids are heterogeneous long-chain polymers characterized by their
214 ability to form gels or viscous dispersions in water (Saha and Bhattacharya 2010). Konjac glucomannan
215 acts as the hydrocolloid in konjac flour. The presence of hydroxyl groups increases a hydrocolloid’s

216 affinity for binding water molecules, meaning the more hydroxyl groups present on a polymer, the more
217 hydrophilic it is. Once water molecules are bound to a hydrocolloid, a dispersion that exhibits the
218 properties of a colloid occurs, thus the name “hydrocolloid.”
219

220 Konjac flour can act as a thickener when added to water-containing solutions. The dioblasts containing
221 glucomannan dissolve, releasing the hydrocolloid polymer into the liquid. As the concentration of
222 glucomannan increases in the substance, it forms an entangled network, which restricts particle
223 movement.
224

225 Gels are formed only when konjac glucomannans have been de-esterified (Harding et al. 2017). This is
226 done through alkali treatment, which removes the acetyl groups from the glucomannan backbone. Once
227 the acetyl groups have been removed, konjac glucomannan can form thermo irreversible gels. Unlike
228 other gel forming agents, konjac flour does not form a gel due to the denaturation of its protein structure.
229 Instead, gelation occurs when chemical changes occur on the polysaccharide chain, which in turn results
230 in the structural changes needed to form a gel (Maekaji 1974). As mentioned above, this is usually done
231 by treating the glucomannan with an alkaline substance, which promotes the hydrolysis of sugar linkages
232 (Maekaji 1974, Timberlake 2015). Higher degrees of deacetylation will lead to faster gelation (Yang et al.
233 2017). This is caused by the konjac glucomannan chain changing from semi-crimping to a self-crimping
234 structure, which leads to more connections between the glucomannan molecules.
235

236 Stronger gels may be produced when a helical polysaccharide, such as gellan gum, is added to the konjac
237 glucomannan (Harding et al. 2017). Konjac flour exhibits a synergistic effect when combined with other
238 gelation agents, such as xanthan gum, κ -carrageenan, agar, pectin, and gelatin, producing more robust
239 gels due to its ability to promote cross-linking between the existing gelation networks (Akesowan 2002).
240 Konjac flour derivatives, such as oligosaccharides, have been used as ingredients in skin care products
241 and in wound healing applications (Batani et al. 2013, Al-Ghazzewi et al. 2015). While the full mechanism
242 of the immune support is still under investigation, the mannose-based oligosaccharides formed via
243 glucomannan hydrolysis are have been shown to suppress Immunoglobulin E production in mice upon
244 ingestion (Suzuki et al. 2010). The ingestion of mannose-rich konjac flour products continues the general
245 trend in application of mannose sugars for wound-healing, with aloe vera applications being the most
246 recognizable form (Hamman 2008, Al-Ghazzewi et al. 2015).
247

248 Konjac powder and glucomannan are used in nutritional supplements to promote weight loss (Birketvedt
249 et al. 2005, Keithley et al. 2013, Ho et al. 2017). The β -1-4 linkages that extend the length of the
250 polysaccharide chain are not digested by human enzymes or the microbiota in the human GI tract
251 (Timberlake 2015). The combination of the inability to break down the glucomannan polysaccharide,
252 along with the viscous solutions created when dissolved in water makes the substance among the most
253 viscous sources of soluble fiber (Ho et al. 2017). This results in feelings of increased satiety after ingestion,
254 which reduces food intake. This serves as the primary means for glucomannan supplements to promote
255 weight loss (Akesowan 2002, Birketvedt et al. 2005, Keithley et al. 2013, Ho et al. 2017).
256

257 The primary medicinal use of konjac flour is treatment of cholesterol levels (Akesowan 2002, Keithley et
258 al 2013, Ho et al. 2017). The ability of glucomannan to lower cholesterol is tied to its efficacy as a source of
259 soluble fiber (Ho et al. 2017). The precise mechanisms of action for decreased levels of low-density
260 lipoprotein (LDL) are still being investigated, although the viscosity of glucomannan fiber within the gut
261 is thought to shift the kinetics of nutrient uptake (Barsanti et al. 2011, Ho et al. 2017). The presence of the
262 viscous fiber within the GI tract may reduce the reabsorption of cholesterol and bile acids and increase
263 acetate production, both of which have been linked to reductions in LDL concentration (Wong et al. 2006,
264 Keithley et al. 2013, Ho et al. 2017). Recent studies have suggested that the viscosity of the fiber may be
265 more important than the quantity of fiber ingested, indicating that glucomannan may be a more effective
266 source of fiber for cholesterol treatments than other dietary fibers. (Vuksan et al. 2011, Ho et al. 2017).
267

268 **Combinations of the Substance:**

269 Though formed directly from the corms of the *Amorphophallus konjac* plant, konjac flour may be combined
270 with other gums, such as xanthan gum, to achieve a synergistic effect and form a stronger gel (Harding et
271 al. 2017). As mentioned above, adding an alkaline solution, such as calcium hydroxide, to the konjac flour
272 will strip the acetyl groups from the glucomannan backbone and enable it to form a thermally irreversible
273 gel.
274

275 **Status**

276
277 **Historic Use:**

278 Historically, konjac has been used in China, Japan, and South East Asia as a traditional food (Chua et al.
279 2010). The flour can be processed into foods such as konjac curd and noodles, jellies, cakes, jams, and
280 breads (FMC 2001). Chinese traditional medicine uses a gel prepared from konjac flour for detoxification,
281 tumor suppression, and phlegm liquefaction (Chua et al. 2010). The flour has also been used for treatment
282 of asthma, cough, pain, burns, and skin disorders.
283

284 Konjac flour is also used outside of food additives and traditional medicines. The glucomannan in it can
285 be separated out for several purposes. Konjac glucomannan has been used in cosmetics as moisturizing
286 agents, physical exfoliants, oil-in-water emulsifiers, and in disinfectant gels (Zhang et al. 2005). Due to its
287 ability to form emulsions, gels and films, konjac glucomannan can also be applied to pharmaceutical
288 applications, including drug-delivery systems such as films and drug capsules and bio-adhesives.
289

290 Konjac flour may be used as thickener in pesticides in traditional agricultural production at
291 concentrations of 1% or below (EPA 2018).
292

293 **Organic Foods Production Act, USDA Final Rule:**

294 Konjac flour is not listed in the Organic Foods Production Act of 1990 (OFPA). It is listed in the USDA
295 organic regulations, 7 CFR 205.606, as a non-organic ingredient allowed in foods labeled as organic.
296

297 **International**

298 The use of Konjac flour is permitted in varying forms in international markets. China, Japan, and other
299 eastern Asian countries that have historically used konjac, classify it as a food (Parry 2010). Australia
300 considers konjac flour to be a vegetable when used as a product's key ingredient.
301

302 **Canadian General Standards Board Permitted Substances List –**

303 Konjac flour is not listed in the Canadian General Standards Board Permitted Substances List for organic
304 production systems according to CAN/CGSB-32.12-2018). It is not included on the Lists of Official Food
305 Additives kept by Health Canada's official repository (HC 2017).
306

307 Konjac flour (listed as konjac mannan) is in the Natural Health Products Ingredients Database from
308 Health Canada (HC 2007). It is an approved herbal substance and listed under Schedule 1: Plant and
309 plant materials, as a film former, gelling agent, solubilizing agent, and thickening agent. Konjac
310 glucomannan is listed as a non-medicinal ingredient in the database.
311

312 **CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and**
313 **Marketing of Organically Produced Foods (GL 32-1999) –**

314 Konjac flour (INS No. 425) is not listed in Table 3.1 of the CODEX (GL 32-1999) as a food additive.
315 (FAO/WHO 1999). However, konjac flour is listed in the CODEX (CXS 192-1995) in Table 3 as a food
316 additive. It is considered acceptable in foods with the commodity standards (CS) 117-1981 and CS
317 309R-2011 and is in the carrier, emulsifier, gelling agent, glazing agent, humectant, stabilizer, and
318 thickener functional classes (FAO/WHO 2019).

319
320 **European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 –**
321 Konjac flour (E 425) is not listed as a permitted food additive in Annex VIII, section A of Commission
322 Regulation (EC) No. 889/2008. It is not listed in EC No. 834/2007. The use of Konjac flour (as E 425 i and
323 E 425 ii) as a food additive was reevaluated by the EFSA Panel on Food Additives and Nutrient Sources
324 in 2017 (Mortensen et al. 2017). The panel concluded that konjac flour was permitted as a food additive
325 up to 10g/kg if total consumption from all sources was no more than 3 g per day.

326
327 In the European Union (EU), konjac must be at 1% concentration or below in end products or blends with
328 other thickeners (Parry 2010). Konjac has an exemption to this rule in Belgium, which allows its use as a
329 botanical material for weight control.

330
331 **Japan Agricultural Standard (JAS) for Organic Production –**

332 Konjac flour is not listed in the Japanese Agricultural Standard for Organic Production under the
333 Standard for Organic Plants (Notification No. 1605/2005), Organic Processed Foods (Notification No.
334 1606/2005), Organic Feeds (Notification No. 1607/2005), or Organic Livestock Products (Notification No.
335 1608/2005). All standards were last revised in March 2012. It is not listed as a food additive in Table 1 of
336 Article 4 of the Japanese Agriculture Standard for Organic Processed foods (MAFF 2012). However, in
337 JAS Organic Production Notification No. 1606, wood ash as a permitted food additive in attached Table 1
338 in producing alimentary konjac products.

339
340 **International Federation of Organic Agriculture Movements (IFOAM) –**

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

343

344 **Evaluation Questions for Substances to Be Used in Organic Handling**

345

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

350

351 Konjac flour is produced from the corms of the *Amorphophallus konjac* plant, a tropical perennial crop. The
352 corms of the plant contain about 30–50% glucomannan gum. When the corms are dried and milled, the
353 resulting powder is konjac flour (FMC 2001). The flour constitutes 60–80% of the dried root corm (JECFA
354 1993). The corms grow below ground and are harvested at 2 kg for commercial processing (Douglas et al.
355 2006). They are then washed and cut into thin slices, which are then dried and dry-milled into powder.
356 The powder is separated, usually by cyclone or wind separation, producing crude konjac flour (Harding
357 et al. 2017). The flour may contain fine oval sacs, which contain polymers (Pérols et al. 1997). When the
358 flour is hydrated, the sacs will swell and rupture, releasing the glucomannan.

359

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

366

367 Glucomannan can be further processed to form differing types of gels. If heat or alkali treatment is used
368 to remove the acetyl group from the glucomannan backbone in a process known as deacetylation, the
369 resulting gel will be hard and thermally irreversible (Harding et al. 2017, Yang et al. 2017).

370
371 **Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a**
372 **chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss**
373 **whether the petitioned substance is derived from an agricultural source.**
374

375 Since konjac flour is created from the corms of the *Amorphophallus konjac* plant, it is derived from an
376 agricultural source. Crude konjac flour is created through a natural drying process. Konjac glucomannan
377 forms in the corms of *A. konjac* during the growth process. As mentioned above, the konjac corm is about
378 60–80% flour. The flour is extracted from the corm through drying, milling, and wind or cyclone
379 separation, which removes the remaining 40–20% of the corm, leaving only flour. As previously
380 mentioned, aqueous extraction and ethanol washing can be used to further purify the flour, but this will
381 not happen in a naturally occurring biological process (Xu et al. 2014).

382
383 **Evaluation Question #3: If the substance is a synthetic substance, provide a list of nonsynthetic or**
384 **natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).**
385

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

389
390 **Evaluation Question #4: Specify whether the petitioned substance is categorized as generally**
391 **recognized as safe (GRAS) when used according to FDA’s good manufacturing practices (7 CFR §**
392 **205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.**
393

394 Alcohol-washed konjac flour received GRAS status from the FDA in 1957 (Parry 2010). Konjac flour
395 received FDA GRAS status in 1994 (FMC 2001, EPA 2018, Behera and Ray 2017). It is not listed in 21 CFR
396 §182, 184, or 186 but is listed in 7 CFR 205.606 on the National List of Allowed and Prohibited Substances.
397 Konjac flour (as konjac glucomannan) is also listed under 40 CFR 180.920 as a thickener not to exceed
398 1.0% by weight in pesticide formulation for inert ingredients used pre-harvest. 40 CFR 180 defines
399 tolerances and exemptions for pesticide chemical residues in food. Moreover, deacetylated konjac flour
400 does not have a separate GRAS status from konjac flour.

401
402 Konjac flour (as konjac glucomannan) appears in the GRAS Notice Inventory under GRN 328 and 407 as
403 part of a polysaccharide complex of konjac glucomannan (konjac), sodium alginate, and xanthan gum
404 (polysaccharide complex KAX). GRN 328 did not provide a determination for GRAS status. GRN 407
405 received a “FDA has no questions” status.

406
407 **Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned**
408 **substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7**
409 **CFR § 205.600 (b)(4)).**
410

411 The primary use of konjac flour is as a thickener or gelling agent, not as a preservative (Mortensen et al.
412 2017).

413
414 **Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate**
415 **or improve flavors, colors, textures, or nutritive values lost in processing (except when required by**
416 **law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR §**
417 **205.600 (b)(4)).**
418

419 Konjac flour can be used to recreate the texture of fat in low fat foods, like iota-carrageenan (Pearson and
420 Dutson 2013). However, this is not the primary purpose of the use of konjac flour as a food additive.

421 Instead, konjac flour is primarily used as a gelling agent, stabilizer, thickener, and film former in
422 processed foods (FMC 2001).

423
424 Konjac flour may be used as a texturizing agent. This function is achieved by its ability to enhance water
425 retention and in the formation of robust gels (Osburn and Keeton 1994, Akesowan 2002, Akesowan 2008,
426 Chin et al. 2009, EFSA 2017). Gel formation and water retention have been used in meat products to
427 introduce leaner cuts of meat, while maintaining the texture and cooking quality that are associated with
428 cuts with higher fat content (Osburn and Keeton 1994, Chin et al. 2009). The incorporation of konjac flour
429 helps to reduce water loss throughout the cooking process, alleviating “cooking loss” linked to sausages
430 and other meat products made with lean meats (Chin et al. 2009). Moreover, there are documented
431 synergistic effects of konjac flour with other gelling agents such as collagen and gelatin, which are
432 naturally present in meats that increase gelation with increased temperature (Maekaji 1974, Osburn and
433 Keeton 1994, Chin et al. 2009).

434
435 **Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or**
436 **feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).**

437
438 Konjac flour is a non-digestible polysaccharide (EPA 2018). This is due to the β -glycosidic linkages
439 between the mannose and glucose molecules, which cannot be hydrolyzed by pancreatic amylase or
440 salivary amylase. This means that it passes into the colon without being digested. Once in the colon, it is
441 fermented by the native flora to produce glucomanno-oligosaccharides. Because it is not digested
442 immediately, konjac glucomannan can increase feelings of satiety, leading the consumer to eat less
443 (Behera and Ray 2017). This effect is present in concentrations typically used in food due to the ability of
444 konjac glucomannan to absorb water in the gut and form a soluble gel. While this is not an effect on the
445 nutritional quality of a food, it is a health effect and should be noted.

446
447 When used as a fat replacer in foods, konjac flour has been shown to lower the caloric content of the food.
448 The incorporation of konjac flour has been reported to decrease the caloric content of meat products by an
449 estimated 50% (Osburn and Keeton 1994). This is largely due to the negligible caloric value of the
450 glucomannan protein based on the inability of humans to break down the β 1-4 linkages found
451 throughout the polysaccharide (Timberlake 2015). This is primarily seen as an industry positive since
452 konjac flour is primarily added to reduced-fat meat products (Osburn and Keeton 1994, Akesowan 2008,
453 Chin et al. 2009). The caloric reduction in sausages incorporating konjac flour is typically coupled with a
454 reduction in fat content, due the ability to use low-fat ingredients (Osburn and Keeton 1994, Akesowan
455 2008, Chin et al. 2009).

456
457 **Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of**
458 **FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600**
459 **(b)(5)).**

460
461 The Institute of Medicine Food and Nutrition Board Committee on Food Chemicals presents limits for
462 heavy metals and contaminants in konjac flour in a monograph published in 1996 (IM 1996). The limits
463 are the following:

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

467
468 The USDA has not reported any recalls of konjac flour for contamination or heavy metal residues since
469 1996. The USDA recall database posts notices of recalls from 1996 onward.

470
471 The EPA issued an exemption from the requirement of tolerance for konjac glucomannan as an inert
472 ingredient under 40 CFR 180.920 in 2018 (EPA 2018).

473
474 **Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the**
475 **petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i)**
476 **and 7 U.S.C. § 6517 (c) (2) (A) (i)).**
477

478 An EPA memorandum was published in 2018 to summarize the human health and ecological effects of
479 exposure to konjac flour (EPA 2018). The memorandum was prepared in response to a request to use
480 konjac glucomannan as an inert ingredient in a pesticide. The EPA found that konjac glucomannan is
481 readily broken down through molecular degradation in the environment. The glucomannan has a
482 negligible vapor pressure, meaning that it will not vaporize under normal conditions and will only exist
483 as a particulate in the atmosphere. The polysaccharide nature of the glucomannan will allow it to absorb
484 into sediment and soil, which should prevent it from moving into surface and groundwater via runoff
485 from fields. Potential for bioaccumulation in soil is expected to be low. Based on the results of the human
486 health and environmental studies on konjac glucomannan, the EPA approved konjac glucomannan as an
487 inert ingredient under 40 CFR 180.920.
488

489 **Evaluation Question #10: Describe and summarize any reported effects upon human health from use**
490 **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. §**
491 **6518 (m) (4)).**
492

493 Konjac glucomannan, the main component in konjac flour, exhibits low levels of acute toxicity (EPA
494 2018). Studies have been performed in rats and mice to produce oral LD₅₀ levels of >2800 mg/kg to >5000
495 mg/kg. It has not been shown to be a skin irritant or dermal sensitizer. Konjac flour may be an eye
496 irritant (FMC 1998).
497

498 The main concern for human health from konjac flour is the development of asthmatic responses in
499 workers exposed to airborne powders produced during the commercial manufacture of the flour from the
500 konjac corms (EPA 2018). This form of occupational asthma is common in Japan. An inhalation exposure
501 test was performed on guinea pigs and demonstrated that respiratory hypersensitivity could indeed be
502 induced after repeated inhalation of konjac flour powder. Recent studies point to a protein called AG40D-
503 2 as the respiratory sensitizer, not the glucomannan particles themselves.
504

505 No evidence has been found for damage to immune function in mammals. Neurotoxicity, carcinogenicity,
506 genotoxicity, mutagenicity, and clastogenicity have not been found to stem from exposure to konjac flour.
507 The EPA has not identified a toxicological endpoint of concern for konjac glucomannan and has indicated
508 no concern for aggregate exposure. A review by the Food Science and Safety Section of the National Food
509 Authority in Australia found no evidence of adverse effects attributable to konjac flour in animals and
510 established an ADI “not specified” for the substance (JECFA 1996).
511

512 Konjac gum and konjac glucomannan were found in a review by the Nordic Council of Ministers to
513 potentially cause diarrhea, flatulence, and abdominal pain if consumed in excess (Mortensen et al. 2017).
514

515 Konjac flour may be considered a “functional food,” which is defined as a food with additional functions
516 relating to health benefits (Behera and Ray 2017). Konjac flour swells in the human gut, which increases
517 feelings of satiety, possibly leading to a reduction in calories consumed.
518

519 It has been claimed that adding konjac flour to the human diet may have many positive health effects,
520 such as lowering serum cholesterol levels (Barrett et al. 2004); yet, these effects are not always supported
521 by clinical research studies. Studies on the role of konjac glucomannan in weight reduction and
522 carbohydrate metabolism modification have also been performed (Iglesias-Otero et al. 2019). However,
523 despite konjac glucomannan being promoted as a weight loss supplement, results of these studies have

524 been inconclusive. For example, studies involving overweight and obese individuals with self-selected
525 diets and no changes in exercise patterns have not supported the claim (Keithley et al. 2013).
526

527 **Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned**
528 **substance unnecessary (7 U.S.C. § 6518 (m) (6)).**
529

530 Other substances listed on the National List of Approved and Prohibited Substances could be used in
531 place of konjac flour for thickening, gel-forming, film-forming, and emulsifying in processed foods. Since
532 konjac flour is currently only listed as a non-organically produced agricultural product allowed in
533 “organic” processed products, an organic version of it could be substituted. An organic konjac flour
534 would possess similar properties as a non-organic one, which would allow for minimal differences in the
535 finished product.
536

537 **Evaluation Question #12: Describe all natural (non-synthetic) substances or products which may be**
538 **used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed**
539 **substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).**
540

541 Other polysaccharide hydrocolloids may provide possible alternatives for konjac flour in processed
542 foods. Natural additives that may be successfully used in place of konjac flour include native starches,
543 gums such as locust bean or guar gum, and pectin (Saha and Bhattacharya 2010). Gelatin, a protein
544 hydrocolloid, may also be used.
545

546 Several substances can be found on the National List of Allowed and Prohibited Substances that may take
547 the place of konjac flour (NOP 2016). These ingredients may provide similar functionality used alone or
548 in combination with other substances.
549

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

- 551 • Agar-agar
 - 552 • Carrageenan
 - 553 • Gellan gum
- 554

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

- 556 • Xanthan gum
- 557

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

- 561 • Lecithin (de-oiled)
 - 562 • Pectin (non-amidated forms only)
 - 563 • Starches
 - 564 • Native corn starch
 - 565 • Tragacanth gum
- 566

567 **Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives**
568 **for the petitioned substance (7 CFR § 205.600 (b) (1)).**
569

570 The most likely organic replacements for konjac flour (in addition to organic konjac flour) as a
571 hydrocolloid are organic starches, such as cornstarch, tapioca starch, and arrowroot starch. Starch can act
572 as a hydrocolloid without adding strange tastes or smells, like some gums may do (Saha and
573 Bhattacharya 2010). However, the starches listed may not have the same gelling or thickening properties
574 as konjac flour or konjac glucomannan, so caution must be used when making substitutions. Organic

575 gums, such as locust bean, guar, and tara could also be used; however, once again, these substances
576 would not exactly mirror konjac flour's hydrocolloid properties (NOP 2016).
577

578 Report Authorship

579 The following individuals were involved in research, data collection, writing, editing, and/or final
580 approval of this report:
581

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586 All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11 – Preventing
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588

589 References

- 590
591 Akesowan A. 2002. Viscosity and gel formation of a konjac flour from *amorphophallus oncophyllus*. AU
592 Journal of Technology. 5(3).
593
- 594 Akesowan A. 2008. Effect of combined stabilizers containing konjac flour and κ -carrageenan on ice cream.
595 AU Journal of Technology. 12(2): 81-85.
596
- 597 Al-Ghazzewi F, Elamir A, Tester R, Elzagoze. 2015. Effect of depolymerized konjac glucomannan on
598 wound healing. Bioactive Carbohydrates and Dietary Fibre. 5(2): 125-128.
599
- 600 Aromantic Ltd. 2016. Konjac glucomannan powder safety data sheet. [accessed Dec 2019].
601 [https://www.aromantic.co.uk/technical-documents/sds/konjac-glucomannan-powder-sds-
602 aro.aspx](https://www.aromantic.co.uk/technical-documents/sds/konjac-glucomannan-powder-sds-aro.aspx)
- 603 Barrett DM, Somogyi L, Ramaswamy HS. 2004. Direct food additives in fruit processing. In: Processing
604 Fruits: Science and Technology. 2nd ed. 311. Boca Raton (FL): CRC Press.
- 605 Barsanti L, Passarelli V, Evangelista V, Frassanito AM, Gualtieri P. 2011. Chemistry, physico-chemistry
606 and applications linked to biological activities of beta-glucans. Natural Product Reports. 28(3):
607 457-466.
608
- 609 Bateni E, Tester R, Al-Ghazzewi F, Bateni S, Alvani K, Piggot J. 2013. The use of konjac glucomannan
610 hydrolysates (GMH) to improve the health of the skin and reduce acne vulgaris. American
611 Journal of Dermatology and Venereology. 2(2): 10-14.
- 612 Behera SS, Ray RC. 2017. Nutritional and potential health benefits of konjac glucomannan, a promising
613 polysaccharide of elephant foot yam, *amorphophallus konjac k. koch*: a review. Food Reviews
614 International. 33(1): 22-43.
- 615 Birketvedt GS, Shimshi M, Erling T, Florholmen J. 2005. Experiences with three different fiber
616 supplements in weight reduction. Medical Science Monitor. 11(1): 15-18.
- 617 Bizzozero J. 2018. Market opportunities for clean label gums & starches. Food Insider Journal. 2(1): 5.
618 Informa Exhibitions, LLC. [accessed 1 April 2020]. [https://www.publicity.com/wp-
619 content/uploads/2018/03/Food-Insider-Journal-Clean-Label-GumsStarches_pdf-article-link.pdf](https://www.publicity.com/wp-content/uploads/2018/03/Food-Insider-Journal-Clean-Label-GumsStarches_pdf-article-link.pdf).

- 620 Chin KB, Go MY, Xiong YL. 2009. Konjac flour improved textural and water retention properties of
621 transglutaminase-mediated, heat-induced porcine myofibrillar protein gel: Effect of salt level and
622 transglutaminase incubation. *Meat Science*. 81(3): 565-572.
- 623 Chua M, Baldwin TC, Hocking TJ, Chan K. 2010. Traditional uses and potential health benefits of
624 *amorphophallus konjac k. koch ex N.E.Br.* *Journal of Ethnopharmacology*. 128(2): 268-278.
- 625 Chua M, Hocking TJ, Chan K, Baldwin TC. 2013. Temporal and spatial regulation of glucomannan
626 deposition and mobilization in corms of *amorphophallus konjac* (araceae). *American Journal of*
627 *Botany*. 100(2): 337-345.
- 628 Dickinson E. 2009. Hydrocolloids as emulsifiers and emulsion stabilizers. *Food Hydrocolloids*. 23(6):
629 1473-82.
- 630 Douglas JA, Follett JM, Waller JE. 2006. Effect of three plant densities on the corm yield of konjac
631 (*amorphophallus konjac*) grown for 1 or 2 years. *New Zealand Journal of Crop and Horticultural*
632 *Science*. 34(2): 139-44.
- 633 [EFSA] European Food Safety Authority (EU). 2017. Re-evaluation of konjac gum (E 425 i) and konjac
634 glucomannan (E 425 ii) as food additives. *EFSA Journal*. 15(6): 4864.
- 635 [EPA] Environmental Protection Agency (US). 2018 May. Konjac glucomannan; exemption from the
636 requirement of a tolerance. Washington (DC): Environmental Protection Agency. [accessed 2019
637 November 11]. 40 CFR Part 180. [https://www.federalregister.gov/documents/
638 2018/05/07/2018-09649/konjac-glucomannan-exemption-from-the-requirement-of-a-
639 tolerance#print](https://www.federalregister.gov/documents/2018/05/07/2018-09649/konjac-glucomannan-exemption-from-the-requirement-of-a-tolerance#print).
- 640 [FAO/WHO] Food and Agriculture Organization of the United Nations/World Health Organization
641 (UN). 2019. Konjac Flour (425). General Standard for Food Additives Database. [accessed 11
642 November 2019]. <http://www.fao.org/gsfaonline/additives/details.html?id=10>.
- 643 [FDA] Food and Drug Administration (US). 2010. GRAS Notices - GRN No. 328. [accessed 11 November
644 2019].
645 [https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=328&sort=GRN_No&
646 order=DESC&startrow=1&type=basic&search=konjac](https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=328&sort=GRN_No&order=DESC&startrow=1&type=basic&search=konjac).
- 647 [FDA] Food and Drug Administration (US). 2011. GRAS Notices - GRN No. 407. [accessed 11 November
648 2019].
649 [https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=407&sort=GRN_No&
650 order=DESC&startrow=1&type=basic&search=konjac](https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=407&sort=GRN_No&order=DESC&startrow=1&type=basic&search=konjac).
- 651 [FDA] Food and Drug Administration (US). 2018. FDA authority over cosmetics: how cosmetics are not
652 FDA-approved but are FDA-regulated. [accessed 11 November 2019].
653 [https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-
654 how-cosmetics-are-not-fda-approved-are-fda-regulated](https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated)
- 655 [FDA] Food and Drug Administration (US). 2018. Import alert 33-15. [Accessed Dec 2019].
656 https://www.accessdata.fda.gov/cms_ia/importalert_105.html
- 657 [FDA] Food and Drug Administration (US). 2020a. FDA grants citizen petition on glucomannan as a
658 dietary fiber. [accessed 14 April 2020]. [https://www.fda.gov/food/cfsan-constituent-
659 updates/fda-grants-citizen-petition-glucomannan-dietary-fiber](https://www.fda.gov/food/cfsan-constituent-updates/fda-grants-citizen-petition-glucomannan-dietary-fiber).

- 660 [FDA] Food and Drug Administration (US). 2020b. Questions and answers on dietary fiber. [accessed 14
661 April 2020]. [https://www.fda.gov/food/food-labeling-nutrition/questions-and-answers-](https://www.fda.gov/food/food-labeling-nutrition/questions-and-answers-dietary-fiber)
662 [dietary-fiber](https://www.fda.gov/food/food-labeling-nutrition/questions-and-answers-dietary-fiber).
- 663 [FDA] Food and Drug Administration (US). Konjac mannan, UNII 36W3E5TAMG. U.S. National Library
664 of Medicine, National Institutes of Health. [accessed 12 November 2019]. Substance Registration
665 System. <https://fdasis.nlm.nih.gov/srs/unii/36w3e5tamg>.
- 666 [FDA] Food and Drug Administration (US). Konjac mannan, UNII 36W3E5TAMG. U.S. National Library
667 of Medicine, National Institutes of Health. [accessed 12 November 2019]. Substance Registration
668 System. <https://fdasis.nlm.nih.gov/srs/unii/36w3e5tamg>.
- 669 Flomenbaum NE, Howland MA, Goldfrank LR, Lewin NA, Hoffman RS, Nelson LS, editors. 2006.
670 Goldfrank's Toxicological Emergencies, 8th ed. New York (NY): McGraw Hill.
- 671 [FMC] FMC Biopolymer. 2001. Resubmission request to revise 7 CFR 205.605 to include konjac flour.
672 FMC Biopolymer. [accessed 11 November 2019].
673 <https://www.ams.usda.gov/sites/default/files/media/Konjac%20Flour%20Petition.pdf>.
- 674 [FMC] FMC Corporation. 1998. Konjac flour, material safety data sheet. Philadelphia (PA): FMC
675 Corporation. [accessed 11 November 2019]. MSDS No. 37220-17-0.
676 <https://www.ams.usda.gov/sites/default/files/media/Konjac%20Flour%20Petition.pdf>.
- 677 [FSA] Food Standards Agency (UK). 2018. Approved additives and E numbers. Business Guidance.
678 [accessed 11 November 2019]. [https://www.food.gov.uk/business-guidance/approved-](https://www.food.gov.uk/business-guidance/approved-additives-and-e-numbers)
679 [additives-and-e-numbers](https://www.food.gov.uk/business-guidance/approved-additives-and-e-numbers).
- 680 [FSIS] Food Safety Inspection Service (US). 2005. Food standards and labeling policy book. Washington
681 (DC): United States Department of Agriculture, FSIS, Office of Policy, Program Development and
682 Evaluation.
- 683 [FSIS] Food Safety and Inspection Service (US). 2013. FSIS Directive 7120.1 Revision 15: safe and suitable
684 ingredients used in the production of meat, poultry, and egg products. Washington (DC);
685 [accessed 12 November 2019]. United States Department of Agriculture.
686 [https://www.fsis.usda.gov/wps/wcm/connect/7f981741-94f1-468c-b60d-](https://www.fsis.usda.gov/wps/wcm/connect/7f981741-94f1-468c-b60d-b428c971152d/7120_68.pdf?MOD=AJPERES)
687 [b428c971152d/7120_68.pdf?MOD=AJPERES](https://www.fsis.usda.gov/wps/wcm/connect/7f981741-94f1-468c-b60d-b428c971152d/7120_68.pdf?MOD=AJPERES).
- 688 Guo, R 2018. Memorandum to the national organic standards board: Response to National Organic
689 Standards Board Recommendations (Fall 2017 Meeting).
690 <https://www.ams.usda.gov/sites/default/files/media/NOPResponsetoNOSBFall2017.pdf>
- 691 Hamman JH. 2008. Composition and applications of *aloe vera* leaf gel. *Molecules*. 13(8): 1599-1616.
- 692 Harding, SE, Tombs MP, Adams GG, Paulsen BS, Inngjerdigen KT, Barsett H, editors. 2017. Structural
693 polysaccharides. In *An introduction to polysaccharide biotechnology*, 2nd ed. Boca Raton (FL):
694 CRC Press; p. 47-98.
- 695 [HC] Health Canada (CA). 2007. Defined organism substance - konjac flour. Natural Health Products
696 Ingredients Database. Government of Canada, Health Canada, Health Products and Food Branch,
697 and Natural Health Products Directorate. [accessed 11 November 2019].
698 <http://webprod.hcsc.gc.ca/nhpdbdipsn/ingredReq.do?id=3974&lang=eng>.

- 699 [HC] Health Canada (CA). 2017. Lists of Permitted Food Additives. Government of Canada. [accessed 11
700 November 2019]. [https://www.canada.ca/en/health-canada/services/food-nutrition/food-
701 safety/food-additives/lists-permitted.html#a4](https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted.html#a4).
- 702 [HMI] Huddle Market Insights. 2019. Global konjac flour sales market report 2018 by manufacturer,
703 Region, type and application. XYZ Research. [accessed 1 April 2020].
704 [https://www.huddlemarketinsights.com/report/food-and-
705 beverages/global%20konjac%20flour%20sales%20market%20report%202018%20by%20manufact
706 urer,%20region,%20type%20and%20application%20/60300](https://www.huddlemarketinsights.com/report/food-and-beverages/global%20konjac%20flour%20sales%20market%20report%202018%20by%20manufacturer,%20region,%20type%20and%20application%20/60300).
- 707 Ho HVT, Javonovski E, Zurbau A, Mejia SB, Sievenpiper JL, Au-Yeung F, Jenkins AL, Duvnjak L, Leiter
708 L, Vuksan V. 2017. A systematic review and meta-analysis of randomized controlled trials of the
709 effect of konjac glucomannan, a viscous soluble fiber, on LDL cholesterol and the new lipid
710 targets non-HDL cholesterol and apolipoprotein B. *American Journal of Clinical Nutrition*.
711 105(5): 1239-1247.
- 712 [IFOAM] The IFOAM NORMS for organic production and processing, version 2014. Updated October
713 2018. https://www.ifoam.bio/sites/default/files/ifoam_norms_version_july_2014.pdf
- 714 Iglesias-Otero MA, Borderías J, Tovar CA. 2010. Use of Konjac Glucomannan as Additive to Reinforce the
715 Gels from Low-Quality Squid Surimi. *Journal of Food Engineering*. 101(3): 281–288.
- 716 [IM] Institute of Medicine (US). 1996. Revised Monograph - Konjac Flour. In: *Food Chemicals Codex*.
717 Washington (DC): The National Academies Press.
718 <https://www.nap.edu/resource/fcc/konjac.pdf>.
- 719 [JECFA] Joint Food and Agriculture Organization/World Health Organization Expert Committee on
720 Food Additives (UN/WHO). 1993. Konjac flour. [accessed 11 November 2019]. WHO Food
721 Additives Series 32. <http://www.inchem.org/documents/jecfa/jecmono/v37je04.htm>.
- 722 [JECFA] Joint Food and Agriculture Organization/World Health Organization Expert Committee on
723 Food Additives (UN/WHO). 1996. Konjac flour. [accessed 11 November 2019]. WHO Food
724 Additives Series 37. <http://www.inchem.org/documents/jecfa/jecmono/v37je04.htm>.
- 725 [JECFA] Joint Food and Agriculture Organization/World Health Organization Expert Committee on
726 Food Additives (UN/WHO). 2001. Konjac flour. [accessed 11 November 2019].
727 [http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/Monograph1/additive-245-
m1.pdf](http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/Monograph1/additive-245-
728 m1.pdf)
- 729 Ji L, Xue Y, Feng D, Li Z, & Xue, C (2017). Morphology and gelation properties of konjac glucomannan:
730 effect of microwave processing. *International Journal of Food Properties*, 20(12): 3023–3032, DOI:
731 10.1080/10952912.2016.1270962.
- 732 Keithley JK, Swanson B, Mikolaitis SL, Demeo M, Zeller JM, Fogg L, Adamji J. 2013. Safety and efficacy of
733 glucomannan for weight loss in overweight and moderately obese adults. *Journal of Obesity*.
734 (December 2013): 1–7. <https://doi.org/10.1155/2013/610908>.
- 735 Kian K. 2015. *Phoenix claws and jade trees: essential techniques of authentic Chinese cooking*. New York
736 (NY): Clarkson Potter.
- 737 Kurakake M, Komaki T. 2001. Production of β -mannanase and β -mannosidase from *Aspergillus*
738 *awamori* K4 and their properties. *Current Microbiology*. 42: 377-380.

- 739 Maekaji K. 1974. The mechanism of gelation of konjac mannan. *Agricultural and Biological Chemistry*.
740 38(2): 315–321.
- 741 [MAFF] Ministry of Agriculture, Forestry, and Fisheries (JP). 2012. Japanese Agriculture Standard for
742 Organic Processed Foods. http://www.maff.go.jp/e/jas/specific/pdf/834_2012-3.pdf.
- 743 Mortensen A, Aguilar F, Crebelli R, Di Domenico A, Frutos MJ, Galtier P, Gott D, et al. 2017. Re-
744 evaluation of konjac gum (e 425 i) and konjac glucomannan (e 425 ii) as food additives. *EFSA*
745 *Journal*. 15(6), no. 6 (2017). <https://doi.org/10.2903/j.efsa.2017.4864>.
- 746 [NOP] National Organic Program (US). 2016. Xanthan Gum. Washington (DC): United States Department
747 of Agriculture, Agricultural Marketing Service. [accessed 19 November 2019].
748 <https://www.ams.usda.gov/sites/default/files/media/TRXanthanGumHandling042216.pdf>.
- 749 [NOSB] National Organic Standards Board 2007. National Organic Program (NOP) – amendments to the
750 National List of Allowed and Prohibited Substances (Processing). *Federal Register*, 72(123), 35137
751 – 35141. <https://www.govinfo.gov/content/pkg/FR-2007-06-27/pdf/07-3142.pdf>.
- 752 [NOSB] National Organic Standards Board. 2017. Sunset 2019 NOSB final review: handling substances
753 205.605(a), 205.605(b), 205.606 November 2017.
754 <https://www.ams.usda.gov/sites/default/files/media/HS2019SunsetsFinalRec.pdf>.
- 755 Nieto MB. 2009. Structure and Function of Starch-Based Edible Films and Coatings. In: Embuscado ME,
756 Huber KC, editors. *Edible Films and Coatings for Food Applications*. New York (NY): Springer
757 Science Business Media; p. 57–112.
- 758 [OID] Organic Integrity Database. 2020. Search results: konjac. USDA. [accessed 29 March 2020].
759 <https://organic.ams.usda.gov/Integrity/Search.aspx>
- 760 Orachorn M, Borompichaichartkul C, Perrigo A, Srzednicki G, Prakitchaiwattana C, and Antonelli A.
761 2016. Tracing the evolution and economic potential of konjac glucomannan in *amorphophallus*
762 species (Araneae) using molecular phylogeny and RAPD markers. *Phytotaxa*. 282(2): 081–106.
763 [accessed 1 April 2020]. <https://doi.org/http://dx.doi.org/10.11646/phytotaxa.282.2.1>.
- 764 Osburn WN, Keeton JT. 1994. Konjac flour gel as fat substitute in low-fat prerigor fresh pork sausage.
765 *Journal of Food Science*. 59(3): 484–489.
- 766 Parry, JM. 2010. Konjac Glucomannan. In: Imeson A, editor. *Food stabilisers, thickeners, and gelling*
767 *agents*. West Sussex (UK): Blackwell Publishing, Ltd; p. 198–214.
- 768 Pearson, A. M., and T R Dutson. *Production and Processing of Healthy Meat, Poultry and Fish Products*.
769 Springer Science and Business Media, 2013.
- 770 Pérols C, Piffaut B, Scher J, Ramet JP, Poncelet D. 1997. The potential of enzyme entrapment in konjac
771 cold-melting gel beads. *Enzyme and Microbial Technology*. 20(1): 57–60.
- 772 [PubChem] PubChem Database. Glucomannan, CID=24892726. National Center for Biotechnology
773 Information. [accessed 11 November 2019]. [https://pubchem.ncbi.nlm.nih.gov/](https://pubchem.ncbi.nlm.nih.gov/compound/Glucomannan)
774 [compound/Glucomannan](https://pubchem.ncbi.nlm.nih.gov/compound/Glucomannan).
- 775 Saha D, Bhattacharya S. 2010. Hydrocolloids as thickening and gelling agents in food: a critical review.
776 *Journal of Food Science and Technology*. 47(6): 587–597.

- 777 Suzuki H, Oomizu S, Yanase Y, Onishi N, Unchida K, Mihara S. 2010. Hydrolysed konjac glucomannan
778 suppresses IgE production in mice B cells. *International Archives of Allergy and Immunology*.
779 152(2): 122-130.
780
- 781 Timberlake KC. 2015. *General, organic, and biological chemistry: structures of life*. 5th ed. Hoboken (NJ):
782 Pearson Education Inc.
- 783 [USDA] United States Department of Agriculture. 2019. Collagen gel, gelatin, and casings technical
784 evaluation report. [accessed Dec 2019].
785 [https://www.ams.usda.gov/sites/default/files/media/CollagenGelGelatinCasingsTechnicalRe](https://www.ams.usda.gov/sites/default/files/media/CollagenGelGelatinCasingsTechnicalReport01282019.pdf)
786 [port01282019.pdf](https://www.ams.usda.gov/sites/default/files/media/CollagenGelGelatinCasingsTechnicalReport01282019.pdf).
- 787 Vuksan V, Jenkins AL, Rogovik AL, Fairgrieve CD, Jovanovski E, Leiter LA. 2011. Viscosity rather than
788 quantity of dietary fibre predicts cholesterol-lowering effect in healthy individuals. *British*
789 *Journal of Nutrition*. 106(9): 1349-1352.
- 790 Wong JM, de Souza R, Kendall CW, Emam A, Jenkins DJ. 2006. Colonic health: fermentation and short
791 chain fatty acids. *Journal of Clinical Gastroenterology*. 40(3): 235-243.
- 792 Xu W, Wang S, Ting Y, Jin W, Liu J, Lei J, Li B, Wang C. 2014. A simple and feasible approach to purify
793 konjac glucomannan from konjac flour – temperature effect. *Food Chemistry*. 158: 171-176.
- 794 Yang D, Yuan Y, Wang L, Wang X, Mu R, Pang J, Xiao J, Zheng Y. 2017. A review on konjac glucomannan
795 gels: microstructure and application. *International Journal of Molecular Sciences*. 18(11) (2017):
796 2250.
- 797 Yee, MCF. 2011. An investigation of the biology and chemistry of the Chinese medicinal plant,
798 *amorphophallus konjac*. Wolverhampton Intellectual Repository and E-theses. [accessed 1 April
799 2020]. <https://core.ac.uk/display/9054010>.
- 800 Zhang M, Chen XL, Zhang ZH, Sun CY, Chen LL, He HL, Zhou BC, Zhang YZ. 2009. Purification and
801 functional characterization of endo- β -mannanase MAN5 and its application in oligosaccharide
802 production from konjac flour. *Applied Microbiology and Biotechnology*. 83(5): 865-873.
- 803 Zhang Y, Xie B, Gan X. 2005. Advance in the applications of konjac glucomannan and its derivatives.
804 *Carbohydrate Polymers*. 60(1): 27-31.