



BILLING CODE 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2017-0249; FRL-9976-60]**

### **Konjac glucomannan; Exemption from the Requirement of a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of konjac glucomannan (CAS Reg. No. 37220-17-0) when used as an inert ingredient on growing crops only at a concentration not to exceed 1% by weight in a pesticide formulation. Technology Services Group, on behalf of, Attune Agriculture, LLC, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of konjac glucomannan resulting from use in accordance with the terms of this exemption.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2017-0249, is available at <http://www.regulations.gov> or at the Office of Pesticide

Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDFRNotices@epa.gov](mailto:RDFRNotices@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCFA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2017-0249 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2017-0249, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Petition for Exemption**

In the **Federal Register** of September 15, 2017 (82 FR 43352) (FRL-9965-43), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11048) by Technology Services Group, on behalf of, Attune Agriculture, LLC, 10552 Philadelphia Road, White Marsh, MD 21162. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of konjac glucomannan (also referred to as konjac mannan) (CAS Reg. No. 37220-17-0) when used as an inert ingredient (thickener) in pesticide formulations applied to growing crops only at a maximum use level of 1.0%. That document referenced a summary of the petition prepared by Technology Services Group, on behalf of, Attune Agriculture, LLC, the petitioner, which is available in the docket, <http://www.regulations.gov>. A comment was received on the notice of filing. EPA's response is discussed in Unit V.C.

## **III. Inert Ingredient Definition**

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may

not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

#### **IV. Aggregate Risk Assessment and Determination of Safety**

Section 408(c)(2)(A)(i) of FFDCFA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCFA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCFA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for konjac glucomannan including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with konjac glucomannan follows.

*A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by konjac glucomannan as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Konjac glucomannan is a non-digestible polysaccharide with a large molecular weight (i.e., 200,000-2,000,000 daltons). A substance of this size would be unlikely to penetrate intact human skin or gastrointestinal tract. Because of its large molecular weight and the body's inability to digest it, it is unlikely that the body will absorb konjac glucomannan. This is supported by the studies below.

Often in the literature, konjac flour and konjac glucomannan are used interchangeably. The European Commission defines konjac flour as the unpurified raw product from the root of the perennial plant *Amorphophallus konjac*, and konjac glucomannan refers to the product that has been washed and extracted using water-containing ethanol. The majority of the studies refer to the use of konjac flour as the test substance. EPA has concluded that it is appropriate to

rely on those studies since the two substances are essentially the same in molecular weight and origin thus expected to present the same toxicological profile.

Konjac glucomannan exhibits low levels of acute toxicity. Acute studies in rats and mice show oral LD<sub>50s</sub> of >2,800 mg/kg to >5,000 mg/kg. The dermal LD<sub>50</sub> in rabbits is > 2,000 mg/kg. Konjac glucomannan was not shown to be a skin irritant or dermal sensitizer and shows minimal eye irritation.

Asthmatic responses in humans (e.g., Konjac asthma or *konnyaku* asthma) exposed to airborne powders produced during commercial manufacture of konjac flour from konjac tubers has been reported. It has been associated with the inhalation of dust produced during the production of konjac flour to make konnyaku, a traditional jelly-like Asian food prepared from glucomannan. An inhalation exposure study with guinea pigs demonstrated that respiratory hypersensitivity to food grade konjac flour can be induced following repeated inhalation exposures. According to a more recent study, however, the antigen in konjac flour responsible for respiratory sensitization is actually a protein and not glucomannan.

Several repeat-dose toxicity studies conducted on Sprague-Dawley rats are available for konjac flour: a four-week dietary study, a twelve-week feeding study, an 18-month dietary study, and an 8-week oral study with pregnant cats. Two carcinogenicity studies are also available.

A four-week dietary exposure study was conducted with Sprague-Dawley rats. Groups of four male rats were fed either 5 % cellulose (control), 10% cellulose, 10% pectin or 10% konjac (~5,000 mg/kg/day) for 28 days. Compared to the control group, consumption of 10% konjac in the diet decreased the digestion and absorption of protein in the large intestine which resulted in a decrease in body weight gain. Because of the high dosing it is not certain if the effect seen is the result of excessive dosing or from the toxicity of chemical.

In a twelve-week feeding study, groups of 12/sex, five week old Sprague-Dawley rats received the basal diet (a 1% cholesterol) or konjac meal supplementation at 2.5, 5.0 or 10% of the diet (~1,250, 2,500, or 5,000 mg/kg/day). Changes were seen on gross examination of the liver. The full study report was not available but according to the Food and Agriculture Organization/World Health Organization (FAO/WHO) Joint Expert Committee on Food Additives (JECFA) report, the author suggests the reason for this is that konjac flour binds with bile acids and depresses reabsorption in the intestines which consequently reduces the accumulation of lipids in the liver. All treated groups had reduced total cholesterol in comparison with the high-cholesterol control group. Body-weight gain was slightly but statistically significantly lower in males fed 10% refined konjac meal than in the other groups during the first eight weeks. Food intake was also reduced in this group. Therefore, the NOAEL is 5% of the diet (~2,500 mg/kg/day) with a LOAEL of 10% (~5,000 mg/kg/day) based on decreased body weight gain in males.

An 18-month dietary study assessed groups of 15 Sprague-Dawley rats fed a basal diet or a diet with 1.0% konjac flour (~ 500 mg/kg/day). There was no difference in body weight gain, absolute or relative organ weights or femur weights and no evidence of treatment-related pathological changes or effects on calcium and phosphorus metabolism. Treated male rats had significantly lower serum cholesterol levels at 9 and 18 months and lower triglycerides at 3 and 9 weeks but not 12 months. In female rats, the only difference from the control was a lower triglyceride level at 18 months. The liver of treated rats had smaller more lightly stained nuclei and reduced bile duct proliferation in the portal area. Certain cells (not specified) of treated rats displayed fewer signs of senescence compared to controls. There was no evidence that 1% konjac flour in the diet (~ 500 mg/kg/day) was toxic to rats.

Two groups of 15 adult pregnant British short-hair cats were fed diets containing either 2% carob gum or 2% konjac flour (0.98 to 3.08 mg/kg/day prior to parturition) for eight weeks. There were no significant changes in body weight between controls and treated animals. Biochemical and hematological parameters were reported to be within normal ranges throughout the study. Mean birth weight of kittens born to control cats was statistically significantly lower ( $p > 0.01$ ) than kittens born to konjac fed cats; however, the standard deviation was within the range of controls and therefore, these effects are not considered adverse. All cats in the study completed lactation and reared successfully.

There is no evidence that konjac glucomannan suppresses or otherwise harms immune function in mammalian systems. No signs of neurotoxicity were reported in the studies of acute or repeat-dose oral exposure to konjac glucomannan.

Genotoxicity tests of konjac flour include an Ames test, a mouse lymphoma assay, and an *in vivo* mouse micronucleus test. All genotoxicity assays were negative. Konjac was not mutagenic in the Ames test and did not induce mutations in cultured mouse lymphoma cells or cause clastogenicity in the *in vivo* micronucleus study in the presence or absence of S-9 activation.

Konjac glucomannan is not expected to be carcinogenic. In addition to showing negative results in genotoxicity and mutagenicity tests, a 20-week and a 1-year feeding study were conducted and no evidenced of carcinogenicity was observed. In fact, the incidence of colon tumors in 1,2-dimethylhydrazine DMH treated animals was significantly reduced with konjac glucomannan consumption. Similarly, spontaneous liver tumors in C3H/He mice were inhibited by maintaining the mice on a diet containing 10 % glucomannan.

*B. Toxicological Points of Departure/Levels of Concern*

No toxicological endpoint of concern has been identified for konjac glucomannan. Based on the available information as discussed in Unit IV.A., it is concluded that there is no end point of concern identified and therefore, quantitative risk assessment is not warranted.

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to konjac glucomannan, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from konjac glucomannan in food as follows:

Dietary exposure (food and drinking water) to konjac glucomannan may occur following ingestion of foods with residues from treated crops. Additional dietary exposure may result from the use of konjac glucomannan as a food additive; it has been used as a thickener, texture stabilizer, emulsifier, and gelling agent in foods and beverages, as well as agriculture and animal feed. However, a quantitative dietary exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

2. *Dietary exposure from drinking water.* Since a hazard endpoint of concern was not identified for the acute and chronic dietary assessment, a quantitative dietary exposure risk assessment for drinking water was not conducted, although exposures may be expected from use on food crops.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). Although currently, there are no uses for konjac glucomannan in products that might result in residential exposure, it is possible that some may be requested in the future. Additional non-dietary exposure may occur from use of konjac glucomannan in pharmaceutical products and cosmetics. Based on the

discussion above, a quantitative residential exposure assessment for konjac glucomannan was not conducted.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found konjac glucomannan to share a common mechanism of toxicity with any other substances, and konjac glucomannan does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that konjac glucomannan does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### *D. Safety Factor for Infants and Children*

Section 408(b)(2)(C) requires EPA to retain an additional tenfold margin of safety in the case of threshold effects to ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. As noted in Unit IV.B., there is no indication of threshold effects being caused by konjac glucomannan. Therefore, this requirement does not apply to the present analysis. Moreover, due to the lack of any toxicological endpoints of concern, EPA is conducting a qualitative assessment of konjac glucomannan, which does not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

#### *E. Aggregate Risks and Determination of Safety*

Taking into consideration all available information on konjac glucomannan, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to konjac glucomannan. Therefore, EPA concludes that the exemption from the requirement of a tolerance as requested by the petitioner—for residues of konjac glucomannan on growing crops when used as an inert ingredient (thickener), in pesticide formulations at a concentration not to exceed 1.0% by weight of the pesticide formulation is safe under FFDCA section 408.

## **V. Other Considerations**

### *A. Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of konjac glucomannan in or on any food commodities. EPA is establishing limitations on the amount of konjac glucomannan that may be used in pesticide formulations applied to growing crops. These limitations will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for use on growing crops for sale or distribution that exceeds 1% by weight of konjac glucomannan.

### *B. Response to Comments*

One comment was received in response to the Notice of Filing. The comment was received from a private citizen who opposed the authorization to sell any pesticide that leaves a residue on food. The Agency recognizes that some individuals believe that no residue of pesticides should be allowed. However, under the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by the statute. EPA has

evaluated all the available data and concluded that there is a reasonable certainty of no harm from the limited use of konjac glucomannan as inert ingredients in pesticide formulations. The commenter has not provided any information supporting a conclusion that this exemption would not be safe.

## **VI. Conclusions**

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for konjac glucomannan (CAS Reg. No. 37220-17-0) when used as an inert ingredient (thickener) in pesticide formulations applied to growing crops only at a concentration not to exceed 1.0% by weight of the pesticide formulation.

## **VII. Statutory and Executive Order Reviews**

This action establishes an exemption from the requirement of a tolerance under FFDC section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001); Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCa section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCa section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

#### **VIII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 12, 2018.

Donna Davis,  
*Acting Division Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In §180.920, add alphabetically the inert ingredient “Konjac glucomannan (CAS Reg.

No. 37220-17-0)” to the table to read as follows:

**§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

Inert ingredients	Limits	Uses
* * *	* *	* *
Konjac glucomannan (CAS Reg. No. 37220-17-0)	Not to exceed 1.0% by weight in pesticide formulation.	Thickener
* * *	* *	* *

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