Susan Cho, Ph.D.
AceOne RS
6309 Morning Dew Ct., Suite 101,
Clarksville, MD 21029

Re: GRAS Notice No. GRN 001045

Dear Dr. Cho:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001045. We received the notice that you submitted on behalf of Anderson Global Group (AGG) on December 20, 2021 and filed it on March 21, 2022. AGG submitted amendments to the notice on February 9, 2022, May 27, 2022, and August 15, 2022, clarifying the status of information marked confidential, providing an updated signature page, and providing additional information on the intended use, composition, specifications, stability, and potential allergenicity of the ingredient.

The subject of the notice is resistant dextrin from tapioca for use as a source of dietary fiber at maximum levels ranging from 1.2 to 10 g per serving[1] in baked goods; non-alcoholic beverages; cereals and granola bars; condiments and dressings; confections; dairy products; frozen desserts; gravies and sauces; meal replacements; pasta and grain products; prepared meals and soups; processed fruits; shelf-stable desserts; snacks and crackers; and nutrition bars.[2] The notice informs us of AGG's view that these uses of resistant dextrin from tapioca are GRAS through scientific procedures.

Our use of the term, "resistant dextrin from tapioca" in this letter is not our recommendation of that term as an appropriate common or usual name for declaring the substance in accordance with FDA's labeling requirements. Under 21 CFR 101.4, each ingredient must be declared by its common or usual name. In addition, 21 CFR 102.5 outlines general principles to use when establishing common or usual names for nonstandardized foods. Issues associated with labeling and the common or usual name

[1] AGG describes two forms of resistant dextrin that include a syrup and a spray-dried powder and states that the intended use levels are approximately 30% higher for the syrup form (1.56 to 13 g/serving).

[2] AGG does not intend to use the ingredient in infant formula or in foods under the jurisdiction of the United States Department of Agriculture. AGG also states that the intended uses are similar to those described in GRN 000436 with an additional use in nutrition bars at up 10 g/serving. The subject of GRN 000436 is enzyme-modified dextrin. We evaluated GRN 000436 and responded in a letter dated January 18, 2013, stating that we had no questions at that time regarding the notifier's GRAS conclusion.

of a food ingredient are under the purview of the Office of Nutrition and Food Labeling (ONFL) in the Center for Food Safety and Applied Nutrition.

AGG provides information about the identity and composition of resistant dextrin from tapioca (CAS Registry No. 9004-53-9).[3] AGG describes two forms of resistant dextrin from tapioca; a yellow syrup and a white powder. AGG describes resistant dextrin from tapioca as a specialty dextrin produced by acid hydrolysis of dry starch followed by its transglucosidation and repolymerization; the product of these reactions is low molecular weight pyrodextrins and the introduction of nondigestible glucoside linkages. AGG notes that resistant dextrin from tapioca is composed of α-1,2, β-1,6, β-1,4, and β-1,2 glycosidic linkages. AGG states that their resistant dextrin from tapioca consists of 67.7% α-linkages and 32.3% β-linkages. AGG also states that resistant dextrin from tapioca has a number average molecular weight (M_n) of 767, a weight average molecular weight (M_w) of 1732, and an average degree of polymerization (DP) of 10.6.

AGG describes the manufacturing process for resistant dextrin from tapioca. Dry tapioca starch is roasted under acidic conditions, which results in the hydrolysis of α-1,4 and α-1,6 glycosidic bonds. AGG states that these linkages recombine in the absence of sufficient water resulting in random glycosidic linkages, such as β-1,4, β-1,6, and β-1,2. The resulting resistant dextrin is then subjected to the following purification steps: treatment with activated carbon, filtration, ion exchange chromatography, concentration, partition chromatography, and sterilization. The resulting product is a syrup that may be spray dried to obtain the powder form. AGG states that all raw materials and processing aids used in the manufacture of resistant dextrin are food grade and the processes are consistent with current Good Manufacturing Practices.

AGG provides specifications for the liquid and powder forms of resistant dextrin from tapioca. They include total fiber (≥ 80% on a dry basis for powder and ≥ 60% for syrup) and limits for moisture (≤ 6% for powder and ≤ 28% for syrup). Specifications also include limits for lead (< 0.2 mg/kg), arsenic (< 0.2 mg/kg), cadmium (< 0.2 mg/kg) as well as for microorganisms. AGG provides the results of analyses of three non-consecutive batches of both the powder and syrup forms of resistant dextrin from tapioca to demonstrate that the ingredient can be manufactured to meet these specifications.

AGG provides estimates of dietary exposure to resistant dextrin from tapioca based on food consumption data from the 2017-2018 National Health and Nutrition Examination Survey (NHANES). AGG estimates the mean and 90th percentile eaters-only dietary exposures to resistant dextrin from tapioca for the U.S. population aged 2 years and older from the intended uses to be 14.4 g/person/day (228 mg/kg body weight

[3] The CAS registry number provided by AGG (i.e., 9004-53-9) corresponds to dextrin. Dextrin is the subject of 21 CFR 184.1277 and is defined as an incompletely hydrolyzed starch. Under this regulation, dextrin may be prepared by dry heating corn, waxy maize, waxy milo, potato, arrowroot, wheat, rice, tapioca, or sago starches, or by dry heating the starches after: (1) treatment with safe and suitable alkalis, acids, or pH control agents and (2) drying the acid or alkali treated starch. Under 184.1277, dextrin must meet the specifications of the Food Chemicals Codex (FCC).

(bw)/day) and 26.5 g/person/day (447 mg/kg bw/day). AGG states that the 90th percentile dietary exposures to resistant dextrin from tapioca ranged from 17.2 g/person/day for children aged 2 to 5 years to 31.5 g/person/day for males aged 19 years and older.

AGG discusses the safety of resistant dextrin from tapioca. AGG notes that resistant dextrin is a non-digestible carbohydrate that meets FDA's definition of a dietary fiber.[4] AGG states that the intended uses and dietary fiber content of its resistant dextrin from tapioca is similar to enzyme-modified dextrin, the subject of GRN 000436.[2] As such, AGG incorporates the safety data and information from GRN 000436 into this notice. AGG reports that a comprehensive literature search for resistant dextrin was conducted through October 2021.

AGG states that like other dietary fibers, resistant dextrin from tapioca is not digested by enzymes within the gastrointestinal (GI) tract, but instead, is fermented into short chain fatty acids by the colonic microbiota. AGG summarizes published studies assessing the mutagenicity and toxicity of resistant dextrin from tapioca, corn, and wheat. AGG states that regardless of the starch source, resistant dextrin is not mutagenic. AGG reports that no toxicologically significant effects were found in a 90-day oral subchronic toxicity study with resistant dextrin from tapioca. AGG also discusses published tolerability studies with resistant dextrin to support safety and concludes that resistant dextrin was well-tolerated with no major adverse events reported. Citing their literature review, AGG states that the risk of an allergic reaction to resistant dextrin from tapioca is low.

AGG notes that the Institute for Medicine (IOM, 2005) has not established a tolerable upper limit for dietary fiber and concludes that serious and chronic adverse effects are not expected from consuming excess dietary fiber. Based on the totality of the data and information, AGG concludes that resistant dextrin from tapioca is GRAS for its intended use.

Standards of Identity

In the notice, AGG states its intention to use resistant dextrin from tapioca in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity.

Potential Labeling Issues

Under section 403(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a food is

[4] The definition of "dietary fiber" in 21 CFR 101.9(c)(6)(i) was added by FDA's final rule revising the nutrition and supplement facts labels (81 FR 33742, May 27, 2016). This final rule, among other things, defines dietary fiber as non-digestible soluble and insoluble carbohydrates (with three or more monomeric units), and lignin that are intrinsic and intact in plants; isolated or synthetic non-digestible carbohydrates (with three or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health.

misbranded if its labeling is false or misleading in any way. Section 403(r) of the FD&C Act lays out the statutory framework for labeling claims characterizing a nutrient level in a food or the relationship of a nutrient to a disease or health-related condition (also referred to as nutrient content claims and health claims). If products containing resistant dextrin from tapioca bear any nutrient content or health claims on the label or in labeling, such claims are subject to the applicable requirements and are under the purview of ONFL. OFAS did not consult with ONFL on this issue or evaluate any information in terms of labeling claims. Questions related to food labeling should be directed to ONFL.[4]

Potential Requirement for a Color Additive Petition

There is no GRAS provision for color additives. AGG notes that the syrup form of resistant dextrin from tapioca is yellow in color. As such, the use of resistant dextrin from tapioca syrup in food products may constitute a color additive use under section 201(t)(1) of the FD&C Act and FDA's implementing regulations in 21 CFR Part 70. Under section 201(t)(1) and 21 CFR 70.3(f), a color additive is a material that is a dye, pigment, or other substance made by a synthetic process or similar artifice, or is extracted, isolated, or otherwise derived from a vegetable, animal, mineral, or other source. Under 21 CFR 70.3(g), a material that otherwise meets the definition of a color additive can be exempt from that definition if it is used (or is intended to be used) solely for a purpose or purposes other than coloring. Our response to GRN 001045 is not an approval for use as a color additive nor is it a finding of the Secretary of the Department of Health and Human Services within the meaning of section 721(b)(4) of the FD&C Act. Questions about color additives should be directed to the Division of Food Ingredients in the OFAS.

Section 301(ll) of the FD&C Act

Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In our evaluation of AGG's notice concluding that resistant dextrin from tapioca is GRAS under its intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing resistant dextrin from tapioca. Accordingly, our response should not be construed to be a statement that foods containing resistant dextrin from tapioca, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that AGG provided, as well as other information available to FDA, we have no questions at this time regarding AGG's conclusion that resistant dextrin from tapioca is GRAS under its intended conditions of use. This letter is not an affirmation that resistant dextrin from tapioca is GRAS under 21 CFR 170.35. Unless

noted above, our review did not address other provisions of the FD&C Act. Food ingredient manufacturers and food producers are responsible for ensuring that marketed products are safe and compliant with all applicable legal and regulatory requirements.

In accordance with 21 CFR 170.275(b)(2), the text of this letter responding to GRN 001045 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2022.08.26 15:09:15 -04'00'

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