

Mr. Thom King
Icon Foods, Inc.
19250 NE Portal Way
Portland, OR 97230

Re: GRAS Notice No. GRN 001170

Dear Mr. King:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001170. We received Icon Foods, Inc. (Icon)'s notice on October 10, 2023, and filed it on February 12, 2024. Icon submitted amendments to the notice on May 22, 2024; May 24, 2024; June 24, 2024; August 22, 2024; and August 26, 2024, providing clarifying information on the intended uses, analytical methods, batch analyses, and specifications.

The subject of the notice is resistant dextrin from tapioca for use as a source of dietary fiber, bulking agent, humectant, texturizer, and formulation aid in various foods at the maximum use levels specified in Table 1.¹ The notice informs us of Icon's view that these uses of resistant dextrin from tapioca are GRAS through scientific procedures.

Table 1. Intended food uses of resistant dextrin from tapioca and corresponding maximum use levels.

Intended food uses	Maximum use level, g (on dry basis) ² /serving ³
Baked goods	3
Beverages, non-alcoholic excluding carbonated soft drinks	3
Beverages, reduced calorie and diet carbonated soft drinks	10
Breakfast cereals	6
Cereal bars and granola bars	6
Nutrition bars	15

¹ Icon states that resistant dextrin from tapioca is not intended for use in infant formula and infant food products, or in products that are under the jurisdiction of the United States Department of Agriculture.

² Icon describes two forms of resistant dextrin from tapioca that include a syrup and a powder. The intended use levels for the syrup form will be higher than for the powder form to account for the difference in the solids content.

³ Based on the Reference Amounts Customarily Consumed (RACC) per eating occasion.

Intended food uses	Maximum use level, g (on dry basis)²/serving³
Condiments and dressings	3
Confections	1.2-3
Non-beverage dairy products	3
Dry beverage powders	1.2-9
Frozen desserts	3
Gravies and sauces	3
Meal replacements	3
Pasta and grain products	3
Prepared meals and soups	3
Processed fruits	3
Shelf-stable desserts	3
Snacks and crackers	3
Coffee creamers	3
Plant based protein products (meat substitutes)	3

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 non-standardized foods. Issues associated with labeling and the common or usual name of a food ingredient are under the purview of the Office of Nutrition and Food Labeling (ONFL) in the Nutrition Center of Excellence. The Office of Pre-Market Additive Safety (OPMAS) did not consult with ONFL regarding the appropriate common or usual name for “resistant dextrin from tapioca.”

Icon describes resistant dextrin from tapioca as a white powder or slightly yellow syrup obtained from tapioca starch. Icon states that resistant dextrin from tapioca contains non-digestible α -1,2 and β -1,6, β -1,4, and β -1,2 glycosidic linkages. It is designated by CAS Registry No. 9004-53-9, has an average degree of polymerization of 11, and a molecular formula of $(C_6H_{10}O_5)_n$.

Icon describes the manufacturing process for resistant dextrin from tapioca that begins with the hydrolysis of the α -1,4 and α -1,6 glycosidic bonds in tapioca starch under acidic conditions. The free glucose linkages then undergo trans-glycosylation and repolymerization. The resulting product may be enzyme treated with food grade α -amylases to lower the content of the α -1,4 and α -1,6 glycosidic bonds. The product is then purified by decolorization with activated carbon, filtered, and subjected to ion exchange chromatography to reduce ash and optional further purification using chromatography. Following sterilization and evaporative concentration to remove excess water, the resulting product is then either packaged as a syrup or further dried to a powder by any of the typical drying methods used in food manufacturing. Icon states that the specific order and number of purification steps may be altered to ensure that

resistant dextrin from tapioca meets the specifications. Icon states that all raw materials and processing aids are food grade and are used in accordance with applicable U.S. regulations or are GRAS for their intended uses, and that the manufacturing method follows current good manufacturing practices.

Icon provides specifications for resistant dextrin from tapioca that include total dietary fiber ($\geq 80\%$ for powder and $\geq 60\%$ for syrup on a dry basis), moisture ($\leq 6\%$ for powder and $\leq 28\%$ for syrup), and limits for lead, mercury, arsenic, cadmium (each < 0.1 mg/kg), and microorganisms. Icon provides the results from the analyses of three non-consecutive batches each for the powder and syrup to demonstrate that resistant dextrin from tapioca can be manufactured to meet these specifications. Icon states that resistant dextrin from tapioca is stable for at least 2 years under ambient conditions.

Icon estimates the dietary exposure to resistant dextrin from tapioca from the intended uses using food consumption data from the 2017-2020 National Health and Nutrition Examination Survey. Icon estimates the eaters-only dietary exposure to tapioca fiber to be 16 g/person (p)/d (271 mg/kg body weight (bw)/d) at the mean and 29.9 g/p/d (553 mg/kg bw/d) at the 90th percentile for the U.S. population aged 2 years and older. Icon states that the intended uses of resistant dextrin from tapioca will be substitutional for other current sources of fiber; therefore, there will be no increase in the dietary exposure to fiber.

Icon describes the absorption, distribution, metabolism, and excretion properties of resistant dextrin from tapioca. Icon states that resistant dextrin from tapioca follows the general metabolic fate of dietary fiber. Resistant dextrin from tapioca is not readily hydrolyzed by enzymes in the upper gastrointestinal tract. Instead, when it reaches the colon, it is fermented by gut microflora and produces short-chain fatty acids that are absorbed, and the fermented fiber is excreted. Icon discusses several sources of information on the effects of oral exposure to resistant dextrin from tapioca in addition to other resistant dextrin dietary fibers. Icon also conducted a literature review through August 2023 and did not identify any new data that would contradict its GRAS conclusion. The weight of evidence suggests that the proposed consumption of resistant dextrin from tapioca in humans is not associated with adverse health effects.

Based on the totality of the data and information described above, Icon concludes that resistant dextrin from tapioca is GRAS for its intended uses.

Standards of Identity

In the notice, Icon 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 CFR. 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

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. OPMAS 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.

Section 301(ll) of the Federal Food, Drug, and Cosmetic Act (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 Icon'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 Icon provided, as well as other information available to FDA, we have no questions at this time regarding Icon'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

001170 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

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for Susan J. Carlson, Ph.D.

Director

Division of Food Ingredients

Office of Pre-Market Additive Safety

Office of Food Chemical Safety, Dietary

Supplements, and Innovation

Human Foods Program