Susan Cho, Ph.D.
AceOneRS, Inc.
5903 Hampton Forest Way
Fairfax, VA 22030

Re: GRAS Notice No. GRN 001133

Dear Dr. Cho:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001133. We received the notice that you submitted on behalf of Anderson Global Group (AGG) on October 28, 2022, and filed it on June 16, 2023. AGG submitted amendments to the notice on October 20, 2023, November 8, 2023, November 18, 2023, December 11, 2023, and December 12, 2023 that provided clarification on the specifications, analytical methods, intended uses, dietary exposure, and elements of the safety narrative.

The subject of the notice is resistant dextrin from corn for use as a texturizer, bulking agent, and a source of dietary fiber in various foods at the maximum use levels specified in Table 1.[1] This notice informs us of AGG's view that these uses of resistant dextrin from corn are GRAS through scientific procedures.

Table 1. Intended food categories and maximum use levels for resistant dextrin from corn

Food Category	**Maximum use level, g/serving[2] (Powder)**	**Maximum use level, g/serving[2] (Syrup)**
Baked goods	3	3.9
Beverages, non-dairy, non-alcoholic, ready-to-drink	3	3.9
Cereals	6	7.8
Granola bars	6	7.8
Nutrition bars	10	13
Condiments and dressings	3	13
Confections	1.2-3	1.56-3.9
Dairy, beverages	3	3.9
Dairy, non-beverages	3	3.9
Dry beverage powder	1.2-9	1.56-11.7

[1] AGG states that resistant dextrin from corn is not intended for use in infant formula and in products under the jurisdiction of the United States Department of Agriculture.
[2] Based on the Reference Amounts Customarily Consumed (RACC) per eating occasion.

Food Category	Maximum use level, g/serving[2] (Powder)	Maximum use level, g/serving[2] (Syrup)
Frozen desserts	3	3.9
Gravies and sauces	3	3.9
Meal replacements	3	3.9
Pasta and grain products	3	3.9
Prepared meals and soups	3	3.9
Processed fruits	3	3.9
Shelf-stable desserts	3	3.9
Snacks and crackers	3	3.9

Our use of the term, "resistant dextrin from corn," 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 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 (CFSAN). The Office of Food Additive Safety (OFAS) did not consult with ONFL regarding the appropriate common or usual name for "resistant dextrin from corn."

AGG describes resistant dextrin from corn as a white to light yellow powder or light yellow syrup obtained by hydrolysis of corn starch followed by transglucosidation and repolymerization. AGG states that the resistant dextrin from corn contains non-digestible α-1,2 (65%) and β-1,6, β-1,4, and β-1,2 glycosidic (35%) linkages. It is designated by CAS Registry No. 9004-53-9 and has a weight average molecular weight of 1.5 kDa, an average molecular degree of polymerization of 9.2, and a molecular formula of $C_{6n}H_{10n+2}O_{5n+1}$.

AGG describes the manufacturing process of resistant dextrin from corn that begins with roasting dry corn starch under acidic conditions, which results in the hydrolysis of the α-1,4 and α-1,6 glycosidic bonds and a breakdown of the starch into shorter chains. The free glucose linkages then undergo transglycosylation and repolymerization to create random β-1,4, β-1,6, and β-1,2 glycosidic linkages. The resulting resistant dextrin is then purified by decolorization with activated carbon, filtration, and ion exchange chromatography, and then concentrated. Following this, the concentrate is subjected to partitioning chromatography, another decolorization, ion exchange chromatography, and further concentration. The resulting concentrate is sterilized and filtered to yield the syrup that may be spray dried to obtain the powder form. AGG states that all raw materials and processing aids are used in accordance with applicable U.S. regulations, are GRAS for their intended use, or are the subject of an effective food contact notification, and that the manufacturing method follows current good manufacturing practices.

AGG provides specifications for resistant dextrin from corn that include total dietary fiber (>80% for powder and >61% for syrup) and limits for lead, mercury, arsenic, and cadmium (each <0.05 mg/kg), and microorganisms. AGG provides the results from the analyses of three non-consecutive batches each for the powder and syrup forms to demonstrate that resistant dextrin from corn can be manufactured to meet these specifications. AGG states that resistant dextrin from corn is stable for a minimum of 1 year as a syrup and 2 years as a powder under ambient conditions.

AGG estimates the dietary exposure to resistant dextrin from corn from the intended uses using food consumption data from the 2017-2018 National Health and Nutrition Examination Survey (NHANES). AGG estimates the eaters-only dietary exposure to resistant dextrin from corn in the powder form to be 14.4 g/person (p)/d (228 mg/kg body weight (bw)/d) at the mean and 26.5 g/p/d (447 mg/kg bw/d) at the 90th percentile for the U.S. population aged 2 years and older. The corresponding dietary exposure to the resistant dextrin from corn in the syrup form is estimated to be 18.6 g/p/d (295 mg/kg bw/d) at the mean and 34.3 g/p/d (578 mg/kg bw/d) at the 90th percentile. AGG states that the intended uses of resistant dextrin from corn are the same as those for resistant dextrin from tapioca described in GRN 001045[3] and substitutional for other resistant dextrins. Therefore, the cumulative dietary exposure to resistant dextrin is not expected to increase as a result of the intended uses of resistant dextrin from corn.

AGG describes the absorption, distribution, metabolism, and excretion of resistant dextrin and states that this dietary fiber is resistant to hydrolysis in the small intestine and reaches the colon where it is fermented by microflora. AGG references the FDA definition and dietary reference value for total dietary fiber in its assessment of the safety of consumption of resistant dextrin from corn. AGG indicates that dietary exposure to resistant dextrin, including that from corn, is not associated with mutagenic or genotoxic effects. AGG discusses a published oral subchronic toxicology study in rats that administered resistant dextrin and reported no significant adverse effects. AGG also reviews published oral human studies that administered resistant dextrin including cases where this ingredient was derived from corn. These studies assessed gastrointestinal tolerance responses and/or a range of other clinical parameters. AGG concludes that the dietary exposure to resistant dextrin from corn from its intended uses is not associated with any type of dietary fiber-related adverse events or effects.

Based on the totality of evidence, AGG concludes that resistant dextrin from corn is GRAS for its intended use.

Standards of Identity

In the notice, AGG states its intention to use resistant dextrin from corn 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.

[3] Resistant dextrin from tapioca was the subject of GRN 001045. We evaluated GRN 001045 and responded in a letter dated August 26, 2022, stating that we had no questions at that time regarding the notifier's GRAS conclusion.

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 corn 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 in CFSAN. 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.

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 corn 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 corn. Accordingly, our response should not be construed to be a statement that foods containing resistant dextrin from corn, 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 corn is GRAS under its intended conditions of use. This letter is not an affirmation that resistant dextrin from corn 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

001133 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

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Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
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