Alan B. Richards, Ph.D.
Vanguard Regulatory Services, Inc.
1311 Iris Circle
Broomfield, CO 80020

Re: GRAS Notice No. GRN 000610

Dear Dr. Richards:

The Food and Drug Administration (FDA, we) completed our evaluation of the supplement that you submitted on behalf of Hayashibara Co. Ltd. (Hayashibara) to GRN 000610. We received the supplement on May 8, 2023. The supplement addresses changes to the manufacturing method for the subject of GRN 000610. Hayashibara submitted clarifying information on November 20, 2023, regarding the manufacturing and batch analyses.

We previously responded to GRN 000610 on June 6, 2016. We stated that we had no questions at that time regarding Hayashibara's conclusion that isomaltodextrin is GRAS for use as an ingredient and as a dietary fiber in milk and milk products; fish and fish mixtures; legumes; meat substitutes, mainly legume protein and cereal protein products; baked products; crackers and salty snacks from grain products; pancakes, waffles, French toast, and other grain products; pastas, cooked cereals, and rice; cereals; grain mixtures, frozen plate meals, sauces, and soups; fruits and fruit products; vegetable products; salad dressings; sugars, sweets, and beverages, selected waters; and in formulated nutrition beverages, "energy" drinks, sports drinks, and functional beverages at a level of 3.2 to 6.3 g/serving. In the supplement dated April 28, 2023, Hayashibara informs us of its view that isomaltodextrin is GRAS, through scientific procedures, for the same uses described in GRN 000610.[1]

In GRN 000610, Hayashibara states that isomaltodextrin is enzymatically produced from food-grade starch. Prior to treatment with α-amylase and α-glucosyltransferase, the pH of the liquified starch is adjusted using calcium carbonate, sodium carbonate, sodium hydroxide, and hydrochloric acid. In this supplement, calcium hydroxide and oxalic acid replace the pH control agents listed in the original notice. Additionally, Hayashibara discusses changes to the manufacturing. The modified method employs one decolorization step instead of two and includes an additional heat sterilization step. Hayashibara states that good manufacturing practices are followed and that all raw

[1] Hayashibara states that isomaltodextrin is not intended for use in products under the U.S. Department of Agriculture's jurisdiction or in foods intended for infants or young children >12 months of age.

materials, processing aids, and ion exchange resins are used in accordance with applicable U.S. regulations or are GRAS for the intended use.[2]

Hayashibara provides the results of three non-consecutive batch analyses using the modified method to demonstrate that isomaltodextrin can be manufactured to meet the specifications described in GRN 000610. Additionally, Hayashibara concludes that the stability of isomaltodextrin manufactured with this modified method is the same as that reported in the original notice.

Hayashibara conducted an updated literature search through March 2023 and discusses new published studies surrounding the safety of the enzymes used. Hayashibara did not identify any data or information that would contradict its safety conclusion from GRN 000610.

Based on the totality of the data and information described above, Hayashibara concludes that isomaltodextrin is GRAS for its intended use.

Standards of Identity

In the notice, Hayashibara states its intention to use isomaltodextrin 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.

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 Hayashibara's supplement concluding that isomaltodextrin 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 isomaltodextrin. Accordingly, our response should not be construed to be a statement that foods containing isomaltodextrin, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

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

[2] Hayashibara states that the oxalic acid used in the manufacture of isomaltodextrin is largely removed during the purification and provides the results from three non-consecutive batch analyses to demonstrate that the levels of oxalic acid in isomaltodextrin are below the limit of quantitation (0.1 g/kg).

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 the supplement to GRN 000610 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2024.01.17 16:46:03 -05'00'

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