Kristi Smedley, PhD.
Center for Regulatory Services, Inc.
5200 Wolf Run Shoals Rd
Woodbridge, Virginia 22192

Daniel Tusé, Ph.D.
DT/Consulting Group
2695 13th Street
Sacramento, CA 95818

Re: GRAS Notice No. GRN 000910

Dear Dr. Smedley and Dr. Tusé:

The Food and Drug Administration (FDA, we) completed our evaluation of the supplement to GRN 000910, dated December 11, 2020, that you submitted on behalf of Nomad Bioscience GmbH (Nomad). Nomad submitted an amendment to the supplement on June 9, 2021, providing additional information regarding the cumulative dietary exposure to the ingredient, thaumatin II. We previously evaluated GRN 000910 and responded in a letter dated September 9, 2020, that we had no questions at that time regarding Nomad's conclusion that thaumatin II is GRAS for use as a non-nutritive sweetener in a variety of food categories at levels ranging from 5 to 400 mg/kg or mg/L food or beverage.

The supplement expands the uses of thaumatin II as a non-nutritive sweetener to include those listed in Table 1.

Table 1. Food Categories and Intended Maximum Use Levels

Food Category	Use Level (mg/kg)
Beverages (water-based, non-alcoholic)	10
Beverages (carbonated, non-alcoholic)	10
Juice fruit drinks and ades	10
Flavored milks and milk drinks	10
Fruit juices/nectars/fruit-based smoothies	10
Fermented dairy products	10
Coffee and teas	10
Imitation dairy beverages	10
Vegetable juices	10

Thaumatin II is also the subject of GRN 000920[1] for use as a flavor modifier at a maximum use level of 7 mg/kg or mg/L in the categories listed in Table 1. The supplement to GRN 000910 is for the use of thaumatin II as a non-nutritive sweetener at a maximum use level of 10 mg/kg in the same food and beverage categories as GRN 000920. Nomad informs us of its view that this use of thaumatin II is GRAS, through scientific procedures.[2]

Our use of the term "thaumatin II" 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. The Office of Food Additive Safety did not consult with ONFL regarding the appropriate common or usual name for "thaumatin II."

In the supplement, Nomad estimates the mean and 90th percentile dietary exposures to thaumatin II from the expanded uses to be 82 µg/kg body weight (bw)/d and 172 µg/kg bw/d, respectively, for the U.S. population aged 2 years and older;[3] this was based on food consumption data from the 2013-2016 National Health and Nutrition Examination Survey.

Nomad states that it relies on safety information discussed in GRN 000910 to support the intended uses in the supplement. Nomad concludes that the estimated cumulative dietary exposure to thaumatin II is well below the levels at which no adverse effects were observed in experimental animals, thus the additional intended uses do not pose a safety concern. Nomad also states that based on an updated literature search as of December 2020, there are no new publications that would contradict their GRAS conclusion. Based on the available data and information, Nomad concludes that thaumatin II is GRAS under the intended conditions of use.

Standards of Identity

In the supplement, Nomad states its intention to use thaumatin II 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.

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[1] We responded to GRN 000920 in a letter dated November 24, 2020, stating that we had no questions at that time regarding Nomad's GRAS conclusion.

[2] Nomad states that the manufacturing process and specifications have not changed from that presented in GRN 000910.

[3] In GRN 000910, Nomad estimated the maximum dietary exposure to thaumatin II based on typical European diets to be 1.1 mg/kg bw/d. FDA estimated the cumulative dietary exposure to thaumatin II from the current and intended uses using food consumption data from the 2015-2018 National Health and Nutrition Examination Survey to be below that reported by Nomad.

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 Nomad's supplement concluding that thaumatin II is GRAS under their intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing thaumatin II. Accordingly, our response should not be construed to be a statement that foods containing thaumatin II, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Nomad provided, as well as other information available to FDA, we have no questions at this time regarding Nomad's conclusion that thaumatin II is GRAS under its intended conditions of use. This letter is not an affirmation that thaumatin II 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 the supplement to GRN 000910 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2022.02.17 17:13:57 -05'00'

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