



Dr. Madhu Soni
Soni and Associates Inc.
749 46th Square
Vero Beach, FL, 32968

Re: GRAS Notice No. GRN 000609

Dear Dr. Soni:

The Food and Drug Administration (FDA, we) completed our evaluation of the second supplement to GRN 000609 that you submitted on behalf of Axiom Foods and SPRIM Strategy and Intelligent Innovation (Axiom). We received this supplement on October 13, 2020. It addresses changes to the specifications for arsenic, dietary fiber, ash, *E. coli* and *S. aureus* compared to the first supplement (dated December 8, 2017). Axiom submitted clarifying information on April 30, 2021 regarding: 1) the rationale for changes to the specifications; 2) the effect of the revised specification for total arsenic on dietary exposure; and 3) safety data cited in the updated literature search.

We previously responded to GRN 000609 on June 5, 2016. We stated that we had no questions at that time regarding Axiom's conclusion that rice protein is GRAS for use as an ingredient, formulation aid, and texturizer at levels ranging from 0.96% to 34.3% in baked goods and baking mixes, beverages and beverage bases, breakfast cereals, dairy product analogs, fats and oils, grain products and pastas, milk products, plant protein products, processed fruits and fruit juices, processed vegetables and vegetable juices, and soups and soup mixes. We responded to the first supplement to GRN 000609 on June 14, 2018. We stated that we had no questions regarding Axiom's conclusion that rice protein was GRAS under the intended conditions of use described in the first supplement.

In this supplement, Axiom informs us that compared to the first supplement, the specification for total arsenic was increased from 0.12 to 0.20 mg/kg, reinstating the total arsenic specification of 0.20 mg/kg as per the original GRAS notice. Axiom describes that the specification for total arsenic has been revised to accommodate batches of rice protein that tested above the arsenic specification set in the first supplement (0.12 mg/kg), but below that set in GRN 000609 (0.20 mg/kg). Axiom presents data from three batches to demonstrate that rice protein meets the total arsenic specification set in the second supplement. Axiom also provided information on additional changes to specifications for dietary fiber (decreased from 18% to 10%), ash (increased from 3.5% to 5%), *E. coli* and *S. aureus* (from 10 CFU/10 g to negative/25 g). The specifications for dietary fiber and ash were revised because batch data were consistently below 10% for dietary fiber and <5% for ash content. The specifications for

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E. coli and *S. aureus* were revised due to changes to the analytical methods validated for these analyses.

Axiom indicates that the first supplement to GRN 000609 resulted in a change in the specification for protein from $\geq 80\text{-}90\%$ to $\geq 75\%$, and a decrease in the total arsenic specification from 0.2 mg/kg to 0.12 mg/kg . In this supplement, the specification for total arsenic is increased to that in the original GRN 000609, but the protein specification is not changed from $\geq 75\%$. Axiom states that this could result in an increase in the use level of rice protein and therefore, a slight increase in the dietary exposure to total arsenic. Axiom estimates the dietary exposure to inorganic arsenic to be $1.34\text{ }\mu\text{g/p/d}$ based on the highest level of inorganic arsenic analyzed in three batches of rice protein ($77.5\text{ }\mu\text{g/kg}$) and the 90th percentile dietary exposure to rice protein from the intended uses (17.3 g/p/d). Axiom concludes that the increase in dietary exposure to inorganic arsenic is negligible based on these estimations.

Axiom provides an updated review of the literature regarding the safety of rice protein through August 2020, stating that no new publications that would contradict their GRAS conclusion were found. Based on the totality of evidence, Axiom concludes that rice protein is GRAS under the intended conditions of use described in the second supplement.

Standards of Identity

In the second supplement, Axiom states the intended use of rice protein in several food categories, includes 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 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 or health claims). If products containing rice protein 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 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 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 Axiom's second supplement concluding that rice protein 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 rice protein. Accordingly, our response should not be construed to be a statement that foods containing rice protein, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Axiom provided, as well as other information available to FDA, we have no questions at this time regarding Axiom's conclusion that rice protein is GRAS under its intended conditions of use. This letter is not an affirmation that rice protein 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 second supplement to GRN 000609 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Susan J.
Carlson -S**

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