Mr. Donald F. Schmitt M.P.H.
ToxStrategies, Inc.
23501 Cinco Ranch Blvd.
Suite B226
Katy, TX 77494

Re: GRAS Notice No. GRN 001151

Dear Mr. Schmitt:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001151. We received the notice you submitted on behalf of Cooperative Koninklijke Cosun, U.A. (Cosun) on July 18, 2023, and filed it on November 1, 2023. Cosun submitted amendments to the notice on January 25, 2024, January 31, 2024, and February 26, 2024, that revised the intended uses and clarified manufacturing details, specifications, analytical methods used, and the dietary exposure.

The subject of the notice is fava bean protein for use as a source of protein in dry-blend protein powders at levels up to 90%; non-alcoholic beverages, soups, and nutritional beverages at levels up to 50%; meat alternatives at levels up to 30%; meal replacement and nutritional bars at levels up to 20%; imitation dairy products, snack foods, and bakery products at levels up to 10% by weight in the food as consumed.[1] The notice informs us of Cosun's view that these uses of fava bean protein are GRAS through scientific procedures.

Our use of the term, "fava bean protein," 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 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 "fava bean protein."

Cosun describes fava bean protein as an extract of fava (*Vicia faba* L.) beans consisting of ≥83% protein. Cosun states that the typical nutritional composition for fava bean protein is protein (85%), carbohydrates (6.5%), fat (0.5%), and ash (4%). Cosun

[1] Cosun states that fava bean protein is not intended for use in infant formula and in products under the jurisdiction of the United States Department of Agriculture.

presents the amino acid profile of fava bean protein and compares it to the amino acid profile of other common food-derived proteins.

Cosun provides a description of the manufacturing process for fava bean protein. Cosun states that fava bean flour (obtained by milling commercially available fava beans) is soaked in water and the pH is adjusted to 7.5 using sodium hydroxide. The resulting slurry is then separated by centrifugation, concentrated by filtration, and washed to remove sodium hydroxide. The resulting product is subsequently evaporated, pasteurized, passed through a filter, and spray dried to yield fava bean protein. Cosun states that fava bean protein is manufactured according to current good manufacturing practices and that all raw materials, processing aids and food contact substances used in the manufacturing process are used in accordance with existing U.S. regulations, were concluded to be GRAS for the intended use, or are the subject of an effective food contact notification.

Cosun provides the specifications for fava bean protein that include protein (≥83% dry basis), carbohydrate (≤10%, dry basis), ash (≤6%), fat (≤2%, dry basis), moisture (≤9%), pH (7-8), lead (≤0.1 mg/kg), arsenic (≤0.1 mg/kg), cadmium (≤0.1 mg/kg), mercury (≤0.1 mg/kg), and limits for microorganisms. Cosun provides the results from the analyses of three non-consecutive batches to demonstrate that fava bean protein can be manufactured to meet these specifications. Based on the results from stability testing, Cosun concludes that fava bean protein is stable for 12 months at below 20°C.

Cosun also determines the levels of the anti-nutrient alkaloid components, vicine and convicine, in three batches of fava bean protein. Results ranged from 870-1540 mg/kg for vicine and 330-560 mg/kg for convicine. Cosun also notes that L-3,4-dihydroxyphenylalanine (L-DOPA) naturally occurs in fava beans and stated that the level of L-DOPA in the fava bean protein was approximately 54-76 mg/kg.

Cosun states that fava bean protein is intended to be used in the same food categories and at the same use levels as those described in GRN 000879[2]. Given that the intended uses of fava bean protein are substitutional for those in GRN 000879, Cosun states that an increase in the overall consumption of protein is not expected.

Cosun states that safety of fava bean protein is supported by the historical safe consumption of appropriately treated fava beans as a food and general lack of toxicity. Cosun conducted a literature search to identify relevant safety information and did not identify any information that was not already identified in GRN 000879. Cosun summarizes published animal toxicity studies on fava beans and fava bean protein and concludes that these studies demonstrate that there are not any safety-related concerns for these ingredients. Cosun notes that fava beans naturally contain L-DOPA, a precursor to dopamine and used as a drug to treat Parkinson's disease. However, Cosun

[2] Fava bean protein isolate was the subject of GRN 000879. We evaluated this notice and responded in a letter dated March 23, 2020, stating that we had no questions at that time regarding the notifier's GRAS conclusion.

states that based on the levels of L-DOPA detected in fava bean protein and recommended daily allowance for proteins, the maximum estimated exposure is not a safety concern. Cosun also includes a discussion of the anti-nutrients, vicine and convicine, found in fava beans, and their metabolism by β-glucosidase to the aglycones divicine and isouramil, which can produce "favism" in certain glucose-6-phosphate dehydrogenase deficient consumers. Cosun states that the process of soaking and cooking in water reduces the level of anti-nutritional factors by up to 100%, thus limiting any safety concerns. Further, Cosun states that dietary exposure levels of anti-nutrients, estimated based on their analytical data and the level of consumption of fava bean protein per day, would not elicit the effects observed in people prone to favism. Cosun discusses the potential for fava bean protein to produce allergenicity in humans. Based on an assessment of the literature, Cosun concludes that the potential for fava bean proteins to cause an immune response is rare but consistent with similar, known allergic response to other legumes.

Based on the totality of evidence, Cosun concludes that fava bean protein is generally recognized as safe under the conditions of its intended use.

Standards of Identity

In the notice, Cosun states its intention to use fava bean protein 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 fava bean 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 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 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 Cosun's notice concluding that fava bean 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 fava bean protein.

Accordingly, our response should not be construed to be a statement that foods containing fava bean protein, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Cosun provided, as well as other information available to FDA, we have no questions at this time regarding Cosun's conclusion that fava bean protein is GRAS under its intended conditions of use. This letter is not an affirmation that fava bean 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 GRN 001151 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2024.06.12 13:39:16 -04'00'

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