



Donald F. Schmitt, M.P.H.  
ToxStrategies, Inc.  
23501 Cinco Ranch Blvd.  
Suite H210  
Katy, TX 77494

Re: GRAS Notice No. GRN 000926

Dear Mr. Schmitt:

The Food and Drug Administration (FDA, we) completed our evaluation of the supplement to GRN 000926 that you submitted on behalf of Cargill, Inc. (Cargill). We received the supplement on May 21, 2024. The supplement addresses additional uses and use levels for the subject of GRN 000926. Cargill submitted information on January 3, 2025, March 5, 2025, and April 2, 2025, that clarified the intended uses, specifications, dietary exposure, and literature search.

We previously responded to GRN 000926 on January 5, 2021. We stated that we had no questions at that time regarding Cargill's conclusion that soluble rice flour for use as a binder, bulking agent, carrier, texturizer, and film-former at levels up to 80% in bakery products; ready-to-drink beverages; flavor blends; reduced-sugar, ready-to-eat cereals and cereal bars; soft and hard candies; confectionary; dairy and imitation dairy products; dry mix seasonings and blends; instant soup and broth mixes; infant food, cereals, porridges, bakery products; powdered beverage mixes; instant and prepared sauces; reduced-fat salad dressings; reduced-sugar snack-based fillings; and reduced-fat or reduced-sugar condiments is GRAS for the intended uses.<sup>1</sup> In the supplement dated May 17, 2024, Cargill informs us of its view that soluble rice flour is GRAS, through scientific procedures, for use with the same technical effects as in GRN 000926 in comminuted meat at levels up to 22%; dried meat and poultry at levels up to 2.5%; dried vegetable products and plant-based imitation egg products at levels up to 10%; and as a carrier in flavor blends (to be used in seasonings, soups, broths, gravies, and dry prepared batter and breading mixes for meat and poultry) at levels up to 80%.<sup>2</sup>

Our use of the term, "soluble rice flour," 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

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<sup>1</sup> Cargill stated in GRN 000926 that soluble rice flour is not intended for use in infant formula or in products under the U.S. Department of Agriculture (USDA)'s jurisdiction.

<sup>2</sup> Cargill states that the expanded uses in this supplement do include products under USDA's jurisdiction.

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 Nutrition Center of Excellence. The Office of Pre-Market Additive Safety (OPMAS) did not consult with ONFL regarding the appropriate common or usual name for “soluble rice flour.”

In the supplement, Cargill revises the specification limit for arsenic from <0.5 mg/kg to <0.3 mg/kg and provides the results (including arsenic speciation) from three non-consecutive batch analyses to demonstrate that soluble rice flour meets the revised specification limit and is absent of *Cronobacter* spp. and *Listeria monocytogenes*.

Cargill states that the expanded uses of soluble rice flour exclude uses in foods intended for infants and young children aged <3 years. Cargill provides the updated cumulative dietary exposure to soluble rice flour from the current and expanded uses using food consumption data from the 2013-2016 National Health and Nutrition Examination Survey. Cargill estimates the eaters-only cumulative dietary exposure to soluble rice flour to be 88.3 g/person(p)/d or 1.44 g/kg body weight (bw)/d at the mean and 193 g/p/d or 3.24 g/kg bw/d at the 90<sup>th</sup> percentile for the U.S. population aged 2 years and older. Cargill also estimates the mean and 90<sup>th</sup> percentile eaters-only cumulative dietary exposure to soluble rice flour to be 47.2 g/p/d (3.72 g/p/d) and 112 g/p/d (8.65 g/p/d), respectively, for children aged 1-2 years, and 64.7 g/p/d (3.79 g/p/d) and 133 g/p/d (8.09 g/p/d), respectively, for children aged 2-5 years.

Cargill discusses the increase in dietary exposure to soluble rice flour due to the expanded intended uses and how this increase would not raise safety concerns. Cargill notes that soluble rice flour is composed of primarily carbohydrates, as well as moisture, protein, fiber, fat, and ash, which are typical components of the human diet. Cargill discusses that the 90<sup>th</sup> percentile dietary exposure to soluble rice flour would be within the Institute of Medicine’s recommended daily allowances for macronutrients.

Cargill conducted an updated literature search through January 2025, and discusses new published toxicity and clinical studies surrounding the safe use of soluble rice flour. Cargill did not identify any data or information that would contradict its safety conclusion from GRN 000926.

Based on the totality of the data and information described above, Cargill concludes that soluble rice flour is GRAS for its intended use.

### **Standards of Identity**

In the notice, Cargill states its intention to use soluble rice flour 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, & Cosmetic (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 soluble rice flour 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. OPMAS 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.

### **Use in Products under USDA Jurisdiction**

As provided under 21 CFR 170.270, during our evaluation of the GRN 000926 supplement, we coordinated with the Food Safety and Inspection Service (FSIS) of the USDA. Under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, FSIS determines the efficacy and suitability of ingredients used in meat, poultry, and egg products, and prescribes safe conditions of use. Suitability relates to the ingredient's effectiveness in performing its intended technical effect and the assurance that the ingredient's use will not result in products that are adulterated or misleading for consumers.

FSIS completed its review and has no objection to the use of soluble rice flour as a binder in comminuted red meat products at levels up to 22%, where the standard of identity permits, and beef jerky at levels up to 2.5%. Regarding labeling, soluble rice flour is required to be labeled in the ingredient statement of comminuted red meat products and beef jerky as "soluble modified rice flour." For beef jerky, the product name requires an additional qualifying statement, such as "Beef Jerky – Soluble Modified Rice Flour Added."

FSIS requested that we advise you to seek regulatory guidance from its Risk Management and Innovations Staff (RMIS) about the use of soluble rice flour in meat, poultry, and egg products. You should direct such an inquiry to Stevie Hretz, Director, RMIS, Office of Policy and Program Development, FSIS by email at [Stephanie.Hretz@usda.gov](mailto:Stephanie.Hretz@usda.gov).

### **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 Cargill's supplement concluding that soluble rice flour 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 soluble rice flour. Accordingly, our response should not be construed to be a statement that foods

containing soluble rice flour, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

## Conclusions

Based on the information that Cargill provided, as well as other information available to FDA, we have no questions at this time regarding Cargill's conclusion that soluble rice flour is GRAS under its intended conditions of use. This letter is not an affirmation that soluble rice flour 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 000926 is accessible to the public at [www.fda.gov/grasnoticeinventory](http://www.fda.gov/grasnoticeinventory).

Sincerely,

**Susan J.  
Carlson -S**

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Susan J. Carlson, Ph.D.  
Director  
Division of Food Ingredients  
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cc: Stevie Hretz, M.P.H., C.P.H.  
Director  
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