



Donald Schmitt, MPH
ToxStrategies, Inc.
931 W. 75th St., Suite 137, PMB 255
Naperville, IL 60565

Re: GRAS Notice No. GRN 000926

Dear Mr. Schmitt:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000926. We received the notice that you submitted on behalf of Cargill, Inc. (Cargill) on March 27, 2020 and filed it on June 15, 2020. Cargill submitted an amendment to the notice on September 23, 2020, providing additional information on the identity of the ingredient, enzymes used during the manufacturing process, revised dietary exposure estimates, and the safety narrative.

The subject of the notice is 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.¹ The notice informs us of Cargill's view that these uses of soluble rice flour are GRAS through scientific procedures.

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 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 (OFAS) did not consult with ONFL regarding the appropriate common or usual name for "soluble rice flour."

Cargill describes soluble rice flour as a white powder with a characteristic odor, a

¹ Cargill states that soluble rice flour is not intended for use in infant formula or in products under the U.S. Department of Agriculture's jurisdiction.

solubility of >80% in water at 5% solids, and a viscosity of 0.001-1.0 Pa·s in water at 10% solids. Cargill provides the composition of soluble rice flour that includes carbohydrate (85-89%), fat (<0.50-0.80%), fiber (1-3%), and protein (5-7%) content. Cargill states that the composition of soluble rice flour is similar to native rice flour, except for the higher dextrose equivalent value.

Cargill provides a description of the manufacturing process for soluble rice flour from food-grade rice flour. Cargill states that water and food-grade enzymes (namely α -amylase and protease) are added to food-grade rice flour, followed by the adjustment of the pH. The resulting slurry is heated to 100-150 °C multiple times to gelatinize and solubilize starch granules, and additional α -amylase may be added to hydrolyze remaining starch granules to achieve the desired dextrose equivalent level. Cargill states that the enzyme is deactivated by pH and temperature adjustment. The resulting product is subjected to an evaporation step, an optional filtration step, and is then dried to the powdered product. Cargill states that sodium bisulfite may be optionally added to the initial slurry as an antimicrobial agent, followed by the aforementioned treatment, and that the final product is analyzed to ensure that the SO₂ level is <10 ppm. Cargill states that the manufacture of soluble rice flour is consistent with current good manufacturing practices. Cargill also provides the regulatory status of the reagents and processing aids used in the manufacturing process and notes that enzymes used in the manufacture of soluble rice flour are from non-toxicogenic and non-pathogenic sources and are permitted for their intended uses.

Cargill provides the following specifications for soluble rice flour: moisture (\leq 10%), dextrose equivalent (5-18), pH (4-7; 25% w/w solution), total arsenic (<0.5 mg/kg), cadmium (<0.1 mg/kg), lead (<0.1 mg/kg), mercury (<0.1 mg/kg), and limits for microorganisms. Cargill provides results from three non-consecutive lots to demonstrate that soluble rice flour can be made to meet these specifications. Cargill provides results of stability testing to demonstrate that soluble rice flour is stable up to 5 months when stored in dry conditions and at room temperature.

Cargill provides an estimate of the dietary exposure to soluble rice flour based on the intended uses in food and dietary intake data from the What We Eat in America-Food Commodity Intake Database (WWEIA-FCID, 2003-2016) and National Health and Nutrition Examination Survey (NHANES, 2003-2016). Cargill reports that the per-user mean and 90th percentile estimated dietary exposures to soluble rice flour for the U.S. population ages 1 year and older are 74.8 and 175 grams/day (g/d) (i.e., 1.24 and 2.97 g/kg body weight/d (g/kg bw/d)), respectively. Cargill reports that the highest per-user 90th percentile estimated dietary exposure to soluble rice flour is for those aged 19 years and older (187 g/d (2.44 g/kg bw/d)) and lowest for children ages 1-5 years (110 g/d (7.03 g/kg bw/d)). According to estimates provided by Cargill, consumers aged 1-5 years have the highest per-user mean and 90th percentile dietary exposure based on body weight (3.06 and 7.03 g/kg bw/d, respectively). Cargill states that, based on the specifications and analysis of three non-consecutive lots of soluble rice flour, the intended uses of soluble rice flour are not expected to contribute to the dietary exposure

of total and inorganic arsenic.² Cargill states that the use of soluble rice flour is self-limiting for technological reasons which could affect consumer acceptance.

Cargill states that the safe use of soluble rice flour in foods for human consumption is supported by the widespread use of rice and its derivatives such as rice flour, as a source of human food. Rice also serves as a dietary staple for more than 50% of the global population. Cargill states that the composition of soluble rice flour is similar to that of conventional rice flour, with the exception of carbohydrates, which is slightly higher, and also protein and moisture, which are generally lower in soluble rice flour compared to the conventional rice flour. Cargill states that the increase in carbohydrates is mainly due to an increase in sugars as reflected by a dextrose equivalent of approximately 9-12. Cargill discusses several published safety studies, including animal toxicology, mutagenicity, genotoxicity, and human studies, conducted using different conventional rice flours as controls. No toxicologically relevant effects were reported by the authors. Cargill states that rice is not a major allergen and the data relevant to oral exposure in a cosmetic ingredient review (CIR) panel report concluded that rice and its derivatives lacked allergenic potential. Cargill notes that FDA had no questions about GRAS conclusions for the use of other rice-based ingredients in food.³

Cargill includes the report of a panel of individuals (Cargill's GRAS panel). Based on its review, Cargill's GRAS panel concluded that soluble rice flour is safe under the conditions of its intended use.

Based on the totality of the data and information presented in its GRAS notice, Cargill concludes that soluble rice flour is GRAS under its intended conditions of 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 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 Federal Food, Drug, and 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

² Cargill lists the specification for total arsenic for soluble rice flour (<0.5 mg/kg) and states that analyzed batches of soluble rice flour were observed to be approximately 0.2 mg/kg total arsenic. Cargill does not provide information on arsenic speciation. However, Cargill notes that inorganic arsenic is water soluble and is expected to be removed during the manufacture of soluble rice flour.

³ Cargill references GRNs 000373, 000478, 000609, 000720 for various uses of rice-derived ingredients in food; we evaluated these GRAS notices and responded in letters dated August 19, 2011, September 14, 2015, June 6, 2016, and January 16, 2018, stating that we had no questions at those times regarding the notifiers' GRAS conclusions.

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 in the Center for Food Safety and Applied Nutrition. 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 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 notice 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 GRN

000926 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

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J. Carlson -S
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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition