



Fred Lozy, Ph.D.
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2233 Argentia Rd.
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CANADA

Re: GRAS Notice No. GRN 000943

Dear Dr. Lozy:

The Food and Drug Administration (FDA, we) completed our evaluation of the supplement that you submitted on behalf of CP Kelco U.S., Inc. (CPK) to GRN 000943. We received the supplement on July 1, 2022. The supplement addresses expanded uses for fiber from citrus peel (citrus fiber) in processed meat and poultry products and increased use levels in baked goods and baking mixes, non-milk-based meal replacement beverages and protein drinks, and ready-to-eat breakfast cereals. CPK submitted clarifying information on September 14, 2023, September 21, 2023, and November 30, 2023, on the expanded food uses, the adjusted use levels used in the dietary exposure assessment, and provided a material safety data sheet.

We previously responded to GRN 000943 on April 9, 2021. We stated that we had no questions at that time regarding CPK's conclusion that citrus fiber is GRAS for use as an ingredient, binder, gelling aid, thickening aid, bulking aid, emulsion stabilizer, or cloud stabilizer in baked goods and baking mixes; alcoholic beverages (cocktail drinks); beverage and beverage bases (sport or electrolyte drinks, fluid replacement drinks, non-milk-based meal replacement beverages, protein drinks); breakfast cereals (excluding instant); cheeses; specialty coffee drinks and ready-to-drink tea beverages; ketchup and relish; confections and frostings (excluding raw sugars); dairy product analogs; egg substitutes; fats and oils (fat-based sauces, salad dressings, margarine and margarine-like spreads, mayonnaise and mayonnaise-type dressings); fish products (excluding catfish); frozen dairy desserts; fruit and water ices; gelatins, puddings, and fillings; grain products and pastas; gravies and sauces; jams and jellies; milk products; nuts and nut products; plant protein products; processed fruits and fruit juices; processed vegetables and vegetable juices; soft candy; soups and soup mixes; and sweet sauces, toppings, and syrups at levels up to 3%.¹

In the supplement dated June 3, 2022, CPK informs us of its view that citrus fiber is GRAS, through scientific procedures, for additional uses as a binder in beef hot dogs and

¹ CPK states that citrus fiber is not intended for use in infant formula, or in products that have standards of identity that do not permit the addition of citrus fiber.

turkey sausages at levels up to 3.5% and in other processed meat and poultry products at levels up to 3%, and as an ingredient, binder, gelling aid, thickening aid, bulking aid, emulsion stabilizer, or cloud stabilizer in baked goods and baking mixes at levels up to 5%, non-milk-based meal replacement beverages and protein drinks at levels up to 3%, and ready-to-eat breakfast cereals at levels up to 6%.

CPK states that the identity, method of manufacture, and specifications are the same as discussed in GRN 000943. CPK estimates the cumulative dietary exposure to citrus fiber from the intended uses in this supplement, current uses, and all other sources in the diet based on food consumption data from the 2017-2018 National Health and Nutrition Examination Survey (NHANES). CPK estimates the eaters-only cumulative dietary exposure to citrus fiber to be 20.8 g/person (p)/d at the mean and 34.7 g/p/d at the 90th percentile for the U.S. population aged 2 years and older.

CPK states that based on an updated literature search through May 2022, there are no new publications that would contradict its safety conclusion from GRN 000943.

Based on the available data and information, CPK concludes that citrus fiber is GRAS under the intended conditions of use.

Standards of Identity

In the notice, CPK states its intention to use citrus fiber in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations (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 citrus fiber 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.

Use in Products under United States Department of Agriculture (USDA) Jurisdiction

As provided under 21 CFR 170.270, during our evaluation of GRN 000943, 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.

This substance requires an additional review by FSIS outside the GRAS evaluation for inclusion into the FSIS Directive 7120.1 Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products.

FSIS requested that we advise you to seek regulatory guidance from its Risk Management and Innovations Staff (RMIS) about the use of citrus fiber in meat, poultry, and egg products. You should direct such an inquiry to Stephanie Hretz, Director, RMIS, Office of Policy and Program Development, FSIS by email at 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 CPK's supplement concluding that citrus fiber 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 citrus fiber. Accordingly, our response should not be construed to be a statement that foods containing citrus fiber, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that CPK provided, as well as other information available to FDA, we have no questions at this time regarding CPK's conclusion that citrus fiber is GRAS under its intended conditions of use. This letter is not an affirmation that citrus fiber 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 000943 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

Digitally signed by Susan J.
Carlson -S
Date: 2024.07.26 10:24:18
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Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
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cc: Stephanie Hretz, M.P.H.
Director
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