U.S. FOOD & DRUG ADMINISTRATION
Human Foods Program

Dr. Ashley Roberts
AR Toxicology
12692 Loyalist Parkway
Picton, ON, K0K 2T0
CANADA

Re: GRAS Notice No. GRN 001333

Dear Dr. Roberts:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001333. We received the notice that you submitted on behalf of Pfeifer & Langen UK Limited (Pfeifer & Langen) on December 19, 2025, and filed it on June 9, 2026. Pfeifer & Langen submitted an amendment to the notice on August 24, 2026, clarifying the identity, analytical methods, stability, and tolerability of maize cob extract.

The subject of the notice is maize cob extract for use as an ingredient at levels up to 40% in various foods as shown in Table 1, excluding use in infant formula, infant foods, and products under the jurisdiction of the United States Department of Agriculture. The notice informs us of Pfeifer & Langen's view that these uses of maize cob extract are GRAS through scientific procedures.

Table 1. Proposed uses for maize cob extract

Food Category	Food Subcategory	Maximum Use Level (%)
Baked goods and baking mixes	Cakes, muffins, cheesecakes	20
	Whole grain cakes and muffins	20
	Cookies, brownies	25
	Danish, breakfast pastries, doughnuts	7
	Pancakes, waffles	10
	Grain based bars (including nongrain-based snack bars)	20
	Nutrition bars such as meal replacement bars, protein bars, energy bars (including non-baked)	15
Breakfast cereals	Ready-to-eat cereals plain/ whole grain (lower sugar)	15

Food Category	Food Subcategory	Maximum Use Level (%)
	Ready-to-eat cereals frosted/ flavored (higher sugar)	25
Frozen dairy desserts and mixes	Frozen milk desserts including non-dairy equivalents	15
	Water-based popsicles	15
Jams and jellies	Jams, jellies, sweet spreads dairy/non-dairy alternatives, cacao, and chocolate based	20
Milk products	Yogurts, yogurt-based beverages, and non-dairy alternatives	5
Nutritional beverages and powders	Nutritional and protein beverages and powder mixes, including meal replacements, protein and other sports or weight management drinks	5
Processed fruit or vegetable drinks	Fruit and/or vegetable-based drinks and smoothies	2
Puddings and fillings	Puddings and custards fillings, frostings, and desserts	15
Soft candy	Chocolate and chocolate products, candy bars, fudge, nougat candies, meringue	40
Sweet sauces, toppings, and syrups	Chocolate, cocoa and caramel-based toppings, sweet sauces, and syrups	20

Our use of the term, “maize cob extract,” 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 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 “maize cob extract.”

Pfeifer & Langen provides information on the identity and composition of maize cob extract. Pfeifer & Langen states that maize cob extract is an off-white powder produced by the enzymatic breakdown of milled maize cob and is composed of a mixture of non-digestible oligosaccharides and cellulose. Pfeifer & Langen notes that maize cob extract has a degree of polymerization (DP) of 2 – 9 and consists primarily of arabinoxylo-oligosaccharides (AXOS), xylo-oligosaccharides (XOS), cello-oligosaccharides (COS), and cellulose.

Pfeifer & Langen states that the manufacturing process starts with treatment of milled maize cob using heat, sulfuric acid, and/or sodium hydroxide to disrupt the cell walls and remove impurities, followed by hydrolysis with xylanase and cellulase and solid-liquid separation. The solid fraction is washed and decolorized to inactivate and remove the enzymes and then dried, milled and sieved to obtain the cellulose fraction of the final product. The soluble oligosaccharide liquid fraction is decolorized and purified using filtration and ion exchange chromatography, followed by drying, milling and sieving. The oligosaccharide and cellulose products are then mixed to obtain the final maize cob extract. Pfeifer & Langen states that maize cob extract is manufactured in accordance with current good manufacturing practices and that all raw materials and processing aids are food grade and are approved for their respective uses in accordance with an appropriate U.S. regulation, are GRAS for their intended use, or are the subject of an effective food contact notification.

Pfeifer & Langen provides specifications for maize cob extract that include total oligosaccharide DP 2-9 content (40 – 90%), total polymeric saccharide content (10 – 50%), and limits for total monosaccharides (≤ 15%), moisture (≤ 6%), ash (≤ 8%), heavy metals, including lead (≤ 0.2 mg/kg), and microorganisms. Pfeifer & Langen provides the results from the analyses of six non-consecutive batches to demonstrate that maize cob extract can be manufactured to meet the specifications. Pfeifer & Langen states that maize cob extract has a shelf-life of 24 months at ambient conditions (20-25 °C, 60% relative humidity).

Using food consumption data from the 2021-2023 National Health and Nutrition Examination Survey (NHANES), Pfeifer & Langen estimates the eaters-only dietary exposure to maize cob extract from the intended uses to be 19.1 g/person (p)/d at the mean and 39.1 g/p/d at the 90th percentile for the U.S. population aged 2 years and older. Pfeifer & Langen states that maize cob extract is intended to substitute for other oligo- and polysaccharides currently consumed in the U.S., and thus, the dietary exposure to these saccharides will not increase from the intended uses of maize cob extract. Moreover, Pfeifer & Langen notes that due to the physiochemical nature of non-digestible fiber, dietary intake is generally considered self-limiting.

Pfeifer & Langen discusses publicly available data and information supporting the safety of maize cob extract. Pfeifer & Langen characterizes maize cob extract as a corn-cob derived mixture of soluble and insoluble non-digestible saccharides composed primarily of AXOS, XOS, cello-COS, and cellulose. Pfeifer & Langen notes that these oligosaccharides are common components of the human diet, are non-digestible, and are therefore not absorbed intact. Pfeifer & Langen states that soluble fibers may be

subject to metabolism/fermentation by the gut microbiota in the large intestines into innocuous monosaccharides and short chain fatty acids. Pfeifer & Langen states the safety of maize cob extract is supported by previous GRAS conclusions for wheat-bran extract and XOS, and incorporates relevant safety information from GRNs 000343 and 000458[1]. Additionally, to further support the safety of maize cob extract, Pfeifer & Langen notes that analogue non-digestible oligo- and polysaccharide substances are commonly consumed ingredients. Pfeifer & Langen summarizes the results of a current literature search to identify available safety information relevant to maize cob extract and does not identify any safety concerns or information that would contradict its GRAS conclusion. Pfeifer & Langen summarizes numerous published studies, including genotoxicity, animal toxicity, and clinical studies relevant to the safety of the individual components of maize cob extract (AXOS, XOS, COS, and cellulose). Furthermore, Pfeifer & Langen notes that the tolerability of maize cob extract is supported by the results of a published, randomized, double-blind, placebo-controlled, cross-over study in which no significant findings on assessed safety and tolerability parameters were reported. Pfeifer & Langen describes the opinion of the National Academy of Medicine (formerly Institute of Medicine) regarding adequate intakes of fiber in the diet to support the safety of maize cobb extract.

Based on the totality of information, Pfeifer & Langen concludes that maize cob extract is GRAS for its intended use.

Standards of Identity

In the notice, Pfeifer & Langen states its intention to use maize cob extract 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 maize cob extract 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.

[1] Wheat bran extract composed primarily of XOS and AXOS, and XOS, is the subject of GRNs 000343 and 000458, respectively. We evaluated these notices and responded in letters dated November 22, 2010, and August 23, 2013, stating that we had no questions at the time regarding the notifiers' GRAS conclusions.

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 Pfeifer & Langen's notice concluding that maize cob extract 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 maize cob extract. Accordingly, our response should not be construed to be a statement that foods containing maize cob extract, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Pfeifer & Langen provided, as well as other information available to FDA, we have no questions at this time regarding Pfeifer & Langen's conclusion that maize cob extract is GRAS under its intended conditions of use. This letter is not an affirmation that maize cob extract 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 001333 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

SUSAN J. CARLSON -S

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