



Andrey Nikiforov, Ph.D.
Toxicology Regulatory Services, Inc.
154 Hansen Road, Suite 201
Charlottesville, VA 22911

Re: GRAS Notice No. GRN 000719

Dear Dr. Nikiforov:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000719. We received the notice that you submitted on behalf of PepsiCo, Inc. (PepsiCo) on July 14, 2017, and filed it on August 7, 2017. We received an amendment to the notice on December 4, 2017, that contains additional safety information, clarification regarding the intended uses and public availability of data and information considered by PepsiCo's GRAS panel, and identification of a literature search timeframe.

The subjects of the notice are orange pomace and enzyme-treated orange pomace for use as an ingredient, stabilizer, thickener, and texturizing agent in orange juice, fruit juice blends, juice drinks, smoothies, grain-based bars, hot cereals, pastries, pie fillings, salad dressings, sauces and dips, condiments, pastes, fruit butters, and fruit leathers at levels up to 50%.¹ The notice informs us of PepsiCo's view that these uses of orange pomace and enzyme-treated orange pomace are GRAS through scientific procedures.

Our use of the terms, "orange pomace" or "enzyme-treated orange pomace" 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 "orange pomace" or "enzyme-treated orange pomace."

PepsiCo provides information about the identity and composition of orange pomace and enzyme-treated orange pomace. PepsiCo describes orange pomace and enzyme-treated orange pomace as a mixture of pulp and membranes that remain after peels, seeds, and juice are removed from orange fruit. PepsiCo states that orange pomace and enzyme-treated orange pomace are composed primarily of water, carbohydrates, fiber, protein,

¹ PepsiCo states that orange pomace and enzyme-treated orange pomace are not intended for use in food products regulated by the U.S. Department of Agriculture.

and fat, with minor constituents including limonin and hesperidin, as well as related polyphenolic flavonoids and polymethoxylated flavones.

PepsiCo describes the method of manufacture for orange pomace and enzyme-treated orange pomace. Sweet oranges (*Citrus sinensis*) are processed to remove peels and seeds, and then pressed to remove juice. The remaining mixture of pulp and membranes is pasteurized to obtain the finished orange pomace product. PepsiCo states that orange pomace may then be diluted with orange juice and treated with food grade polygalacturonase in combination or alternately with pectin lyase to reduce viscosity. PepsiCo notes that both enzymes are obtained from *Aspergillus niger* and are GRAS for this use. The mixture is processed to reduce particle size and pasteurized to deactivate remaining enzymes. PepsiCo states that the composition of orange pomace and enzyme-treated orange pomace are the same.

PepsiCo provides specifications for orange pomace and notes that specifications for enzyme-treated orange pomace are the same. Specifications include ranges for Brix value (9–15°), moisture (70–85%), protein (1–2%), carbohydrates (9–14%), total sugars (4–9%), total dietary fiber (4–13%),² vitamin C (20–50 mg/100g), Scott oil (0.006–0.025%)³, fat (< 0.5%), as well as limits for limonin (≤ 25 mg/L), hesperidin (≤ 3000 mg/L), and lead (≤ 0.1 mg/kg)⁴. PepsiCo provides the results of nonconsecutive batch analyses to demonstrate that orange pomace and enzyme-treated orange pomace can be manufactured to meet specifications.

PepsiCo provides estimates of dietary exposure to orange pomace and enzyme-treated orange pomace based on the maximum intended use levels and food consumption data from the National Health and Nutrition Examination Survey (NHANES 2009-2012). PepsiCo notes that the intended uses of orange pomace and enzyme-treated orange pomace are substitutional, however, maximum use levels are higher for enzyme-treated orange pomace in some food categories and, as such, these levels are used to estimate exposure. PepsiCo reports that the dietary exposure to enzyme-treated orange pomace in consumers is 62 g/person (p)/day (d) (1.1 g/kg body weight (bw)/d) at the mean and 132 g/p/d (2.5 g/kg bw/d) at the 90th percentile.

PepsiCo states that there are no published toxicity studies on either orange pomace or enzyme-treated orange pomace itself. PepsiCo states that the cumulative estimated daily intake for oranges and orange products (including orange pomace and enzyme-treated orange pomace) is 175 g/p/d, which is less than consuming a large orange/d. PepsiCo considers that the macronutrients of orange pomace and enzyme-treated orange

² AOAC 991.43 Total, Soluble, and Insoluble Fibre in Foods and AOAC 2009.01 Total Dietary Fiber in Foods. FDA understands that PepsiCo's use of the term "dietary fiber" is for the purpose of the specifications for orange pomace and enzyme-treated orange pomace.

³ The Scott oil specification refers to method AOAC 968.20 for recoverable oil in fruits, including oranges, by distillation.

⁴ PepsiCo provides the results of batch analyses conducted with orange pomace and enzyme-treated orange pomace and notes that lead was not detected with a limit of detection of 0.005 mg/kg and cadmium, arsenic, and mercury were not detected with a detection limit of 0.01 mg/kg.

pomace do not pose safety concerns, and as such PepsiCo evaluated the safety of the most prominent minor constituents or their structurally-related substances to establish the safety of orange pomace and enzyme-treated orange pomace in the event they are concentrated. The available published toxicological studies on the constituents of orange pomace and enzyme-treated orange pomace show no toxicity in animals at the intended use levels. Human clinical data demonstrate that the minor constituents of orange pomace and enzyme-treated orange pomace are well tolerated. Additionally, PepsiCo notes that FDA did not question the safety of three substances similar to orange pomace and enzyme-treated orange pomace under the conditions of their intended uses.⁵ PepsiCo states that the literature search performed to obtain data and information supporting the safety of orange pomace and enzyme-treated orange pomace covered the period through September 2017.

PepsiCo includes the report of a panel of individuals (PepsiCo's GRAS panel). Based on its review, PepsiCo's GRAS panel concluded that orange pomace and enzyme-treated orange pomace are safe under the conditions of their intended uses.

Based on the totality of the data and information described above, PepsiCo concludes that orange pomace and enzyme-treated orange pomace are GRAS for their intended uses in food.

Standards of Identity

In the notice, PepsiCo states its intention to use orange pomace and enzyme-treated orange pomace 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 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). The notice raises a potential issue under these labeling provisions. In the notice, PepsiCo states that the addition of orange pomace or enzyme-treated orange pomace to new food categories is beneficial.⁶ If products containing orange pomace or enzyme-treated orange pomace bear any

⁵ FDA evaluated three notices and responded with letters stating that the agency had no questions at that time regarding the notifiers' GRAS conclusions for use of dried orange pulp (GRN 000154), dried citrus pulp (GRN 000487), and citrus fiber (GRN 000599) under the intended conditions of use.

⁶ The definition of "dietary fiber" in 21 CFR 101.9(c)(6)(i) was added by FDA's final rule revising the nutrition and supplement facts labels (81 FR 33742, May 27, 2016). This final rule, among other things, defines dietary fiber as non-digestible soluble and insoluble carbohydrates (with three or more monomeric units), and lignin that are intrinsic and intact in plants; isolated or synthetic non-digestible carbohydrates (with three or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health.

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 ONFL in CFSA. OFAS did not evaluate any information in terms of labeling claims. Questions related to food labeling should be directed to ONFL.

Section 301(II) of the FD&C Act

Section 301(II) 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(II)(1)-(4) applies. In our evaluation of PepsiCo's notice concluding that orange pomace and enzyme-treated orange pomace are GRAS under their intended conditions of use, we did not consider whether section 301(II) or any of its exemptions apply to foods containing orange pomace or enzyme-treated orange pomace. Accordingly, our response should not be construed to be a statement that foods containing orange pomace or enzyme-treated orange pomace, if introduced or delivered for introduction into interstate commerce, would not violate section 301(II).

Conclusions

Based on the information that PepsiCo provided, as well as other information available to FDA, we have no questions at this time regarding PepsiCo's conclusion that orange pomace and enzyme-treated orange pomace are GRAS under their intended conditions of use. This letter is not an affirmation that either orange pomace or enzyme-treated orange pomace 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 000719 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Michael A.
Adams -S**

Dennis M. Keefe, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

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