



Evangelia Pelonis
Keller and Heckman, LLP
1001 G Street, N.W., Suite 500 West
Washington, DC 20001

Re: GRAS Notice No. GRN 001031

Dear Ms. Pelonis:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001031. We received the notice that you submitted on behalf of EverGrain, LLC (EverGrain) on October 26, 2021, and filed it on January 12, 2022. EverGrain submitted amendments to the notice on April 29, 2022, and June 3, 2022, providing additional information regarding the identity, intended use, manufacturing, dietary exposure, and safety narrative.

The subject of the notice is barley and rice protein hydrolysate (BRPH) as a protein source in various foods at the use levels specified in Table 1.¹ The notice informs FDA of EverGrain's view that the use of BRPH is GRAS through scientific procedures.

Table 1. Intended food categories and use levels for BRPH

Food Category	BRPH use level (%)
Baked Goods and Baking Mixes (e.g., bread, quick breads, brownies, cookies, crackers)	0.5 to 5
Beverages and Beverage Bases (e.g., ready-to-drink (RTD) energy drinks, RTD nutritional, meal replacement, and protein beverages (non-milk based))	1 to 90
Breakfast cereals (e.g., hot breakfast cereals, ready-to eat (RTE) breakfast cereals)	1 to 10
Dairy Product Analogs (e.g., non-dairy milk, non-dairy milk shakes and smoothies, non-dairy cream)	1 to 40
Grain Products and Pastas (e.g., protein bars, nutrition bars, dry rice sides)	1 to 30
Gravies and Sauces (e.g., specialty types and tomato-, milk-, and buttery-based sauces)	1 to 10
Nuts and Nut Products (e.g., nut-based spreads and butters)	1 to 20

¹ EverGrain states that BRPH is not intended for use in infant formula or products under the jurisdiction of the United States Department of Agriculture (USDA).

Plant Protein Products (e.g., meat analogs, plant-based spreads)	1 to 20
Snack Foods	1 to 10
Soft Candy	1 to 15
Soup and Soup Mixes	1 to 15
Sweet Sauces, Toppings and Syrups	1 to 10

Our use of the term “barley and rice protein hydrolysate” or “BRPH” 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 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 “barley and rice protein hydrolysate” or “BRPH.”

EverGrain provides information on the identity and composition of BRPH. EverGrain describes BRPH as an off-white powder consisting of 40-99% barley (*Hordeum vulgare*) and 1-60% rice (*Oryza sativa*) obtained from the mash step of beer production. EverGrain notes that BRPH has an amino acid profile similar to native barley and native rice protein.²

EverGrain describes the method of manufacture of BRPH. EverGrain states that brewer’s spent grains are mixed with water, heated, and treated with a food-grade glucoamylase-pullulanase enzyme blend to hydrolyze the starch. The mixture is then treated with a food-grade protease enzyme under controlled pH to hydrolyze the protein. The added enzymes are deactivated by heating and the mixture is centrifuged to separate the solids from the liquid protein. The separated solids are washed with water, decanted, and screw pressed to increase protein recovery and reduce moisture and fiber content. The liquid resulting from the wash steps is combined with the liquid from the enzyme treatment; this is then subjected to microfiltration followed by nanofiltration, evaporation and spray drying. EverGrain states BRPH is manufactured according to current good manufacturing practices. EverGrain notes that all raw materials, processing aids, additives and food contact materials used in the manufacture of BRPH are food-grade, or equivalent, and are used in accordance with applicable U.S. regulations.

EverGrain provides the specifications for BRPH that include protein ($\geq 85\%$, on a dry matter basis), moisture ($< 8\%$), arsenic (< 0.1 mg/kg), cadmium (< 0.1 mg/kg), lead (< 0.2 mg/kg), mercury (< 0.1 mg/kg) and limits for microorganisms. EverGrain also states that BRPH is typically composed of fat ($< 2\%$), total carbohydrates ($< 10\%$), total fiber

² EverGrain provides data from eight non-consecutive batches to demonstrate the consistency of the amino acid composition of BRPH.

(<5%) and ash (<10%). EverGrain provides results from five non-consecutive batches to demonstrate that BRPH is manufactured to meet the specifications.

EverGrain uses USDA's mean protein intake for the U.S. population aged 1 year and older of 79.2 g/person (p)/day (d) as an upper limit for the dietary exposure to BRPH. EverGrain multiplied the mean value by a factor of 2 to obtain an upper bound 90th percentile dietary exposure of 158.4 g/p/d for the U.S. population aged 1 year and older. EverGrain also states that the intended uses of BRPH will not increase dietary exposure to overall protein in the diet.

EverGrain discusses all relevant safety information provided in the notice. EverGrain states that BRPH is minimally processed and is expected to be compositionally and nutritionally similar to native barley and native rice. In support, EverGrain reports similar protein digestibility scores, amino acid content, and impurities between barley, rice, and BRPH. EverGrain summarizes and discusses published literature on the safe consumption of barley and rice. EverGrain also discusses published acute oral toxicology studies in rodents using BRPH's starting material, brewer's spent grains, and reports no adverse effects under the conditions of the studies. EverGrain addresses the allergenicity of barley, rice, and brewer's spent grains through a literature search, discusses that allergic reactions to both barley and rice are rare, and notes that there are no published reports of allergenic reactions to brewer's spent grains. Based on the available data and information, EverGrain concludes that dietary exposure to BRPH from the intended uses is safe.

Based on the totality of information, EverGrain concludes that BRPH is GRAS under the conditions of intended use.

Standards of Identity

In the notice, EverGrain states its intention to use BRPH 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 BRPH 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 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 EverGrain’s notice concluding that BRPH 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 BRPH. Accordingly, our response should not be construed to be a statement that foods containing BRPH, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that EverGrain provided, as well as other information available to FDA, we have no questions at this time regarding EverGrain’s conclusion that BRPH is GRAS under its intended conditions of use. This letter is not an affirmation that BRPH 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 001031 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Susan J.
Carlson -S**

Digitally signed by Susan
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Susan Carlson, Ph.D.
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