



Shawna Lemke, Ph.D.
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1700 Diagonal Road
Suite 750
Alexandria, VA 22314

Re: GRAS Notice No. GRN 001256

Dear Dr. Lemke:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001256. We received the notice that you submitted on behalf of Plantible Foods (Plantible) on March 19, 2025 and filed it on June 30, 2025. Plantible submitted amendments to the notice on September 26, 2025 and January 29, 2026, clarifying the manufacturing process, analytical results, specifications, intended uses, dietary exposure, and literature search.

The subject of the notice is lemna leaf protein (LLP) for use as an ingredient, emulsifier, gelation agent/thickener, and a source of protein in the foods at the maximum levels as specified in Table 1, excluding uses in infant formula, food for infants and toddlers, and products under the jurisdiction of the United States Department of Agriculture. The notice informs us of Plantible's view that these uses of LLP are GRAS through scientific procedures.

Table 1. Proposed uses for LLP

Food category	Food uses	Maximum use level (%)
Baked goods	Cakes (flour based, excluding cheesecake, pies, cobblers, strudel, ice cream cake, tiramisu, fruit cake)	5
	Cookies (excluding brownies, graham crackers)	5
	Croutons	2.5
	Bread (yeast breads, excluding specialty breads, rolls)	2.5

Food category	Food uses	Maximum use level (%)
	Fine bakery (croissants, scones, excluding doughnuts, sweet rolls, bagels, breakfast tarts)	5
	Muffins (excluding English muffins, cornbread, quick breads or biscuits)	5
Beverages and beverage bases	Enhanced water	4.1
	Beverage concentrates, powdered nutritional beverages	4.1
Breakfast cereals	Ready-to-eat, instant, and regular hot cereals (excluding oatmeal)	2
Fats and oils	Salad dressings	3
Frozen dairy desserts and mixes	Ice cream, ice milks, sherbets, and other frozen dairy desserts and specialties	3
Grain products	Pasta, macaroni and noodles	2.5
	Protein based nutritional bars	5
	Grain-based bars with or without filling or coating (breakfast bars, granola bars, rice cereal bars)	2.5
Milk products	Flavored milk and milk drinks	2
Plant protein products	Meat, seafood, poultry, egg, milk, sour cream, and cheese substitutes	5
	Reconstituted vegetable protein	5
Processed fruits	Fruit smoothies	3
Snack foods	Crackers	2.5
	Corn and potato chips	2.5
Soft candy	Chocolate candy with filling	2.5
Soup and soup mixes	Ramen and Asian-based broth soups	2.5

Our use of the term, “LLP,” 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 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 “LLP.”

Plantible provides information on the identity and composition of LLP. Plantible states that LLP is derived from *Lemna minor*, a duckweed from the plant family Araceae. Plantible states that LLP is a white, odorless powder composed of > 80% protein, moisture (< 10%), dietary fiber (< 15%) and a small amount of fat (< 0.5%). Plantible presents identification information on the 14 most abundant proteins in LLP and notes that the major protein is rubisco (ribulose-1,5-bisphosphate carboxylase/oxygenase), accounting for 74% of the total protein mass. Plantible also presents the amino acid profile of LLP and compares it to the profiles of other duckweeds and other food-derived proteins.

Plantible states that LLP is produced under controlled conditions in large self-contained tanks in enclosed greenhouses. The plants grow vegetatively and are harvested every 2 to 3 days. The *L. minor* leaves are macerated to yield a green juice, followed by removal of the cellulosic material, cell membranes, fiber, and insoluble compounds by decanter centrifugation. The remaining chlorophyll is coagulated with calcium chloride and removed by filtration. The polyphenols are then absorbed using activated carbon. The resulting filtrate is sterilized using microfiltration and an ultrafiltration step to remove salts and excess water. The final concentrate is dried using a freeze or spray dryer. Plantible states that LLP 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.

Plantible provides specifications for LLP that include protein content ($\geq 80\%$), and limits for moisture ($\leq 10\%$), ash ($\leq 4.5\%$), dietary fiber ($\leq 15\%$), total fat content ($\leq 0.5\%$), oxalic acid ($\leq 0.1\%$), arsenic (≤ 0.3 mg/kg), cadmium (≤ 0.05 mg/kg), mercury (≤ 0.05 mg/kg), lead (≤ 0.075 mg/kg) and microorganisms. Plantible provides the results from the analyses of five non-consecutive batches to demonstrate that LLP can be manufactured to meet the specifications. Plantible states that LLP has a shelf-life of 28 months at ambient conditions (20-25 °C) based on results from an accelerated stability study.

Using food consumption data from the 2021-2023 National Health and Nutrition Examination Survey (NHANES), Plantible estimates the eaters-only dietary exposure to LLP from the proposed uses to be 6.6 g/person (p)/d at the mean and 14.1 g/p/d at the 90th percentile for the U.S. population aged 2 years and older. Plantible states that LLP is intended to substitute for other proteins in the diet, and thus, the intended uses will not increase the overall consumption of protein.

Plantible states that duckweeds have been historically consumed safely by humans in several countries. They discussed the high degree of sequence conservation of the genomes across duckweed species in the Lemnaceae family as well as the similarity of compositional characteristics and amino acid profiles. Due to these similarities in composition, Plantible asserts that studies conducted in other duckweed species, such as *Wolffia globosa*, are relevant to provide a basis for safety assessments of LLP derived from *L. minor*.

Plantible conducted a review of the published literature and discuss publicly available safety data of a dried *W. globosa* preparation, compositionally similar to LLP, in a subchronic rodent toxicity study. In this study, rats were fed up to 20% of dry *W. globosa*, corresponding to 13.16 and 15.03 g/kg/d for male and female rats, respectively, for 90 days. The authors noted effects related to electrolyte imbalance and possible prolonged clotting time in the high dose group but concluded these are not indicative of overt toxicity. Plantible states that selecting the 10% level, corresponding to 6.49 and 7.42 g/kg bw/d in male and female rats respectively, that showed no test-article related effects, provides a sufficient margin of exposure based on the 90th percentile dietary exposure from the proposed uses to support their safety conclusions. Plantible states that LLP is highly digestible as a protein, has a well characterized metabolic fate, and the dietary exposure from the intended uses does not exceed the Recommended Daily Value for protein of 50 g/day.

Plantible discusses minor components, such as manganese, copper, heavy metals, nucleic acids and other anti-nutrients that may be present in duckweeds including oxalic acid, carotenoids, tannins and lysinoalanine as being controlled in their production methods to levels that do not present a safety concern. Plantible states that while there are rare and isolated published reports of allergic reactions to the main protein component of LLP, Plantible states that the risk of allergic reaction is likely comparable to other protein-based ingredients. Furthermore, Plantible concluded that their assessment identified no significant population risk of sensitization or cross-reactivity of other allergens to LLP.

Based on the totality of the data and information, Plantible concludes that LLP is GRAS for its intended use.

Standards of Identity

In the notice, Plantible states its intention to use LLP 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 LLP 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 Nutrition Center of Excellence. 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.

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 Plantible’s notice concluding that LLP 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 LLP. Accordingly, our response should not be construed to be a statement that foods containing LLP, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Plantible provided, as well as other information available to FDA, we have no questions at this time regarding Plantible’s conclusion that LLP is GRAS under its intended conditions of use. This letter is not an affirmation that LLP 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 001256 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Susan J.
Carlson -S**

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Director
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