



Tim Lombardo
EAS Consulting Group, LLC
1700 Diagonal Road, Suite 750
Alexandria, VA 22314

Re: GRAS Notice No. GRN 001160

Dear Mr. Lombardo:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Plantible Foods to cease our evaluation of GRN 001160, which we filed on December 11, 2023. We received this request on March 21, 2024.

The subject of the notice is lemna leaf protein (LLP) for use as an ingredient, source of protein, emulsifier, gelation agent/thickener at a maximum level of 20% in baked goods and baking mixes, non-alcoholic beverages, breakfast cereals, frozen dairy desserts, pasta, milk substitutes, milk products (spreads, dips, cream substitutes), plant protein products, processed fruit and fruit juices, snack foods, desserts and mousses, confections, soups and soup mixes, salad dressings, savory extracts, and sauce ingredients¹. The notice informs us of Plantible Foods' view that these uses of LLP are GRAS through scientific procedures.

In an email dated March 9, 2024, we informed you that we identified considerable deficiencies in the notice that were also noted during the pre-submission meeting held on August 7, 2023. We indicated that while you may rely on information in other GRNs, your notice must be specific concerning the data and information to be incorporated as well as present your independent conclusions; that data and information provided in a GRN that are pivotal to the conclusion of safety must be publicly available (i.e., published in a peer-reviewed journal); and that it must be demonstrated that the data on the test articles used in the publicly available, pivotal safety studies that were used to establish your GRAS conclusion can be sufficiently extrapolated to LLP. Given the substantive nature of these issues and the need for significant revisions, FDA recommended that Plantible Foods request that we cease our evaluation of GRN 001160. We also recommended that Plantible Foods request a meeting with us prior to preparing any future submission for use of this ingredient in food.

¹ Plantible Foods states that LLP is not intended for use in infant formula, foods intended for infants and young children, or in products under the jurisdiction of the United States Department of Agriculture.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001160 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.

Carlson -S

Digitally signed by
Susan J. Carlson -S

Date: 2024.05.06
17:58:32 -04'00'

Susan J. Carlson, Ph.D.

Director

Division of Food Ingredients

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition