



William J. Rowe
GRAS Associates, LLC
11810 Grand Park Avenue
Suite 500
North Bethesda, MD 20852

Re: GRAS Notice No. GRN 001072

Dear Mr. Rowe:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Lemnature AquaFarms USA, Inc. (Lemnature) to cease our evaluation of GRN 001072, which we filed on September 21, 2022. We received this request on January 20, 2023.

The subject of the notice is Lemnaceae¹ fiber for use as an ingredient, source of dietary fiber, anticaking agent, water binding agent, thickening aid, bulking aid, emulsion stabilizer, formulation aid or binder, or purge reduction aid at levels ranging from 0.5-10% of the food² (baked goods and baking mixes; meal replacement/nutritional bars, cereal bars, and granola bars; protein and nutritional drinks; breakfast cereals, soft candy; imitation cheese and cheese dips; condiments and spreads; confections and frostings; dairy product analogs, salad dressings, fish products; frozen dairy desserts (ice cream); gelatins, puddings, pie fillings; gravies and sauces; hard candy; jams and jellies; pastas; processed meat and poultry products; plant protein products (meat analogs); processed fruit and vegetable juices; snack foods and chips; soups and soup mixes; spices, seasonings, and blends; and sweet sauces, toppings, and syrups). The notice informs us of Lemnature's view that these uses of Lemnaceae¹ fiber are GRAS through scientific procedures.

In a telephone conversation on January 20, 2023, we spoke with representatives of Lemnature. Among the topics discussed with the Lemnature representatives were the unpublished studies; that the 90th percentile estimate of dietary exposure exceeds the Institute of Medicine's (IOM) upper limit for dietary fiber; based on this estimate, the resulting dietary exposure to manganese exceeds the IOM's upper limit for manganese;

¹ Lemnature states that the Lemnaceae fiber may be obtained from any of the following species within the Lemnaceae family: *Lemna minor*, *Lemna gibba*, *Lemna japonica*, *Lemna obscura*, *Lemna turionifera*, *Lemna valdiviana*, *Lemna aequinoctialis*, *Lemna minuta*, *Wolffiella gladiata*, *Wolffia globosa*, *Wolffia arrhiza*, *Wolffia brasiliensis*, *Wolffia columbiana*, or *Spirodela polyrhiza*.

² Lemnature does not intend to use Lemnaceae fiber in foods that are the subject of a standard of identity.

and, that the narrative lacks a discussion about why the 25% protein content in the Lemnaceae fiber does not pose an allergenicity/sensitization issue. As the notifier has the opportunity to request that we cease our evaluation of the notice, we recommended that the notifier take this opportunity to allow adequate time to address these issues, as well as the additional clarification items that we can provide later. Also, we suggested a pre-submission meeting before any future submission for this substance.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001072 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

Digitally signed by Susan
J. Carlson -S
Date: 2023.01.30
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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

cc: Melvin Carter, Ph.D.
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