

Yvonne Dommels
The Protein Brewery B.V.
Goeseelsstraat 10
4817 MV Breda
NETHERLANDS

Re: GRAS Notice No. GRN 001268

Dear Dr. Dommels:

The Food and Drug Administration (FDA, we) is granting the request that we cease our evaluation of GRN 001268. We received this request on February 13, 2026. We received The Protein Brewery B.V. (The Protein Brewery)'s notice on March 14, 2025 and filed it on August 19, 2025.

The subject of the notice is mycelial biomass from *Rhizomucor pusillus* (fungal protein) for use as a source of protein and fiber at levels up to 100% in cakes, breads, rolls, muffins, tortillas, waffles, bagels, brownies, crackers, breadsticks, non-milk based protein and nutrition powders, hot breakfast cereals, non-dairy yogurts and non-dairy cheese, cereal bars, protein bars, nutritional bars, pasta, noodles, nut spreads, chips, cereal and root-based snacks, chocolate confectionary, and chocolate and other sweet spreads (excluding use in infant formula, foods intended for infants, and products under the jurisdiction of the United States Department of Agriculture). The notice informs us of The Protein Brewery's view that these uses of fungal protein are GRAS through scientific procedures.

In an email dated February 11, 2026, we communicated regarding additional information needed to support a GRAS conclusion. We noted that The Protein Brewery needed to address deficiencies in the notice, including: significant design flaws in animal studies that compromise data interpretation; insufficient data to support safety at the proposed dietary exposure levels; inadequate safety assessment of key compositional elements with known antinutrient properties; inadequate bioinformatics and *in silico* approaches; and absence of organism-specific secondary metabolite characterization. Given the extent of the information needed to continue our evaluation, we recommended that The Protein Brewery request that we cease our evaluation of the notice.

We have ceased our evaluation of the notice at your request. We remind The Protein Brewery of a manufacturer's responsibility to ensure the safety and regulatory status of the substances that it markets for use in food or that it uses in food. We also remind The Protein Brewery that the use of a substance in food that is not GRAS (and is not

otherwise excluded from the definition of a food additive), must have pre-market approval by FDA for its use in food (21 CFR 170.30(g)). More information about the criteria for GRAS is available in our regulations (21 CFR part 170).

Your request does not preclude The Protein Brewery from submitting a future GRAS notice with respect to the subject of this notice (21 CFR 170.260(b)). We recommend that The Protein Brewery address these issues to adequately support a GRAS conclusion. Finally, we remind The Protein Brewery of the signed statements and certification (part 1 of a GRAS notice, 21 CFR 170.225) by which The Protein Brewery agrees to make all data and information regarding its GRAS conclusion available to FDA upon request.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001268 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Susan J.
Carlson -S**

Digitally signed by Susan J.
Carlson -S
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Susan J. Carlson, Ph.D.
Director
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