

19 September 2022

Citizen Petition Regarding the Listing of (1-3)(1-6) β -glucan as a Dietary Fiber

Division of Dockets Management Food and Drug Administration
Department of Health and Human Services
5630 Fisher Lane
Room 1061
Rockville, MD 20852

Dear Commissioner,

The Protein Brewery submits this Citizen Petition in accordance with 21 CFR 10.30 and 21 CFR 10.20 to request that (1-3)(1-6) β -glucan be considered to meet the FDA definition of dietary fiber for the purposes of food labeling under 21 CFR 101.9(C)(6)(i). The basis for this request is set forth below.

A. Action Requested

The Protein Brewery (TPB) is located in Breda, The Netherlands. TPB's mission is to develop novel ways to develop food proteins through fermentation technologies. A major novel protein source that is produced at TBP is a fungus that, when fermented, produces a biomass which is rich in protein, but also rich in non-digestible carbohydrates. The name of the particular fungus is called *Rhizomucor pusillus*. Like plants, fungi have a cell wall that provides structural support. However, the nondigestible carbohydrates present in fungal cell walls (including mushrooms) are not the same as in plant cell walls and include non-digestible carbohydrates such as chitin, chitosan and (1-3)(1-6) β -glucan.

As a food ingredient, fungal-based ingredients can be a source of nutrients, including dietary fiber that is beneficial to human health. For this reason, a thorough science review has been completed and it is being requested that FDA review this petition and the evidence that discusses the mechanism of action by which and the evidence for (1-3)(1-6) β -glucan consumption and its beneficial effect on immunomodulation.

B. Statement of Grounds

The detailed rationale for recognition of (1-3)(1-6) β -glucan as a dietary fiber is provided in Attachment A, "Evidence to Support (1-3)(1-6) β -glucan as a Dietary Fiber: Summary of its Beneficial Effects on Immunomodulation." This document includes a thorough review of the scientific evidence related to the physiological benefits effects of (1-3)(1-6) β -glucan.

The conclusion of the scientific review (Attachment A) is that the information presented demonstrates that (1-3)(1-6) β -glucan provides beneficial physiological effects to human health by improving immune innate response, as measured by the incidence of upper respiratory tract infections. In light of the evidence presented in Attachment A, we believe that (1-3)(1-6) β -glucan should be listed as a dietary fiber under 21 CFR 101.9(c)(6)(i).

C. Environmental Impact

The actions requested in this Petition are not within any of the categories for which an environmental assessment is required pursuant to 21 CFR Section 25.22. Additionally, the actions requested in this Petition are exempt from the requirement of an environmental assessment pursuant to 21 CFR Section 25.30(k). Furthermore, the undersigned does not believe that the actions requested in this Petition would have any environmental impact.

D. Economic Impact

An economic impact report is required only when requested by the Administration and such report has not been requested (21 CFR 10.30(b)).

E. Certification

The undersigned certifies, that to the best knowledge, this petition includes all the representative data and information known to the petitioner which are favorable and unfavorable to the petition.

Sincerely,

Elisa Leune

The Protein Brewery B.V.

Goeseelsstraat 10, 4817 MV Breda, The Netherlands

elisaleune@theproteinbrewery.nl

+31 612330627



Dr Maha Tahiri

CEO Nutrition Sustainability Strategies

Adjunct Professor Tufts University, Friedman School of Nutrition Science and policy

7985 4th Ave St, St Petersburg, 33707, FL

maha@nutritionsustainability.com

612 940 184



List of Attachments

Attachment A

Evidence to Support (1-3) (1-6) β -Glucan as a Dietary Fiber: Summary of its Beneficial Effects on Immunomodulation