U.S. FOOD & DRUG ADMINISTRATION
Human Foods Program

Hannes Malfroy
Atova Regulatory Consulting
Passeig de Gracia 50, 5
Barcelona, 08019
SPAIN

Re: GRAS Notice No. GRN 001228

Dear Mr. Malfroy:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Fermify GmbH (Fermify) that we cease our evaluation of GRN 001228. We received this request on June 3, 2025. We received Fermify's notice on October 14, 2024 and filed it on February 4, 2025.

The subject of the notice is ß-casein produced by *E. coli* DSM 35048 (ß-casein) for use as an ingredient in cheese and cheese analogs, non-alcoholic beverages, dairy product analogs, frozen dairy desserts, milk products, and plant protein products at a levels up to 15%. The notice informs us of Fermify's view that these uses of ß-casein are GRAS through scientific procedures.

In a meeting on May 14, 2025, we communicated with you and Eva Sommer as Fermify's representatives regarding additional information needed to support a GRAS conclusion. We noted that the sodium level in the ingredient is high and the levels of sodium and heavy metals will be substantially increased if the ß-casein is to be further concentrated. We suggested that Fermify provide information on the concentrating process, and safety implications with regard to the cumulative dietary exposure to sodium. Furthermore, FDA stated that Fermify should consider if additional manufacturing/processing steps to lower sodium content may be necessary. We also suggested that Fermify discuss the safety of other impurities remaining in the ß-casein.

We have ceased our evaluation of the notice at Fermify's request. We remind Fermify 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 Fermify 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).

Fermify's request does not preclude Fermify from submitting a future GRAS notice with respect to the subject of this notice (21 CFR 170.260(b)). We recommend that Fermify address the data deficiencies to adequately support a GRAS conclusion. We also recommend a pre-submission meeting prior to resubmission. Finally, we remind Fermify of the signed statements and certification (part 1 of a GRAS notice, 21 CFR 170.225) by which Fermify 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 001228 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2025.06.13 14:38:43 -04'00'

Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
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