



Kevin J. Ruff, Ph.D., MBA
ESM Technologies, LLC
2213 Missouri Ave.
Carthage, MO 64836

Re: GRAS Notice No. GRN 001194

Dear Dr. Ruff:

The Food and Drug Administration (FDA, we) is granting the request that we cease our evaluation of GRN 001194, which we filed on August 19, 2024. We received this request on November 26, 2024.

The subject of the notice is partially hydrolyzed eggshell membrane powder derived from chicken eggs for use as an ingredient in ready-to-eat baked goods, non-alcoholic beverages and beverage bases, processed fruit juices, and soft candy at a level of 500 mg per serving. The notice informs us of ESM Technologies, LLC's view that these uses of partially hydrolyzed eggshell membrane powder derived from chicken eggs are GRAS through scientific procedures.

In a telephone conversation on November 25, 2024, we spoke with you as ESM Technologies, LLC's representative, regarding additional information needed to support a GRAS conclusion. Among the topics discussed with you were the limited characterization and nutritional analyses of partially hydrolyzed eggshell membrane powder derived from chicken eggs, coincidental ingestion of residual amounts of eggshell membrane does not support the safety of the intended use of partially hydrolyzed eggshell membrane powder derived from chicken eggs, deficiencies in the published 90-day repeat oral toxicity study that limit its use as the key safety data to support a GRAS conclusion, a reminder that assurance of safety requires an evaluation of potential effects of long-term use within various segments of the population, a reminder that purported therapeutic effects or benefits do not demonstrate safety and are not relevant to the determination of safety for use in conventional food, information characterizing the identity of proteins that are present in partially hydrolyzed eggshell membrane powder derived from chicken eggs and discussion regarding compliance with appropriate allergenic food labeling for the protein components of partially hydrolyzed eggshell membrane powder derived from chicken eggs. In addition we discussed with you, the need to correctly estimate the dietary exposure to partially hydrolyzed eggshell membrane powder derived from chicken eggs, the need to consider the dietary exposure to the calcium component of partially hydrolyzed eggshell membrane powder derived

from chicken eggs plus the cumulative calcium dietary exposure from all dietary sources, indicating whether the intended uses are for all foods in a broad food category or limited to specific foods within the broader food category, and the specification for arsenic given the results of the batch analyses provided in the notice.

We have ceased our evaluation of the notice at ESM Technologies, LLC's request. We remind ESM Technologies, LLC 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 ESM Technologies, LLC 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).

ESM Technologies, LLC's request does not preclude ESM Technologies, LLC from submitting a future GRAS notice with respect to the subject of this notice (21 CFR 170.260(b)). We recommend that ESM Technologies, LLC address these issues, as well as the additional clarifications that we provided after the November 25th conversation to adequately support a GRAS conclusion. Also, we recommend that ESM Technologies, LLC request a pre-submission meeting with us before any future submission for partially hydrolyzed eggshell membrane powder derived from chicken eggs. Finally, we remind ESM Technologies, LLC of the signed statements and certification (part 1 of a GRAS notice, 21 CFR 170.225) by which ESM Technologies, LLC 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 001194 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.

Carlson -S

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Susan J. Carlson -S
Date: 2025.02.04
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Susan J. Carlson, Ph.D.

Director

Division of Food Ingredients

Office of Pre-Market Additive Safety

Office of Food Chemical Safety, Dietary

Supplements, and Innovation

Human Foods Program