



Arie Carpenter
Chr. Hansen, Inc.
9015 West Maple Street
Milwaukee, WI 53214 – 4298

Re: GRAS Notice No. GRN 000936

Dear Ms. Carpenter:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000936. We received Chr. Hansen, Inc.'s (Chr. Hansen) notice on April 28, 2020 and filed it on August 17, 2020. Chr. Hansen submitted amendments to the notice on January 26, 2021 and February 22, 2021 that provided clarifications on the specifications and the estimated dietary exposure.

The subject of the notice is *Leuconostoc carnosum* DSM 32756 for use as an ingredient at levels up to 10^9 colony forming units (CFU)/g to inhibit the spoilage of raw cured meat products throughout their shelf-life. The notice informs us of Chr. Hansen's view that this use of *L. carnosum* DSM 32756 is GRAS through scientific procedures.

Chr. Hansen describes *L. carnosum* DSM 32756 as a light-opal colored powder. Chr. Hansen states that *Leuconostocs* are mesophilic, Gram-positive, catalase-negative cocci. *L. carnosum* DSM 32756 was isolated from the surface of sliced vacuum-packed pork products; it is deposited in the strain collection of the Deutsche Sammlung von Mikroorganismen und Zellkulturen (DSMZ) in Braunschweig, Germany with the accession number 32756. Chr. Hansen discusses phenotypic and genotypic characteristics to confirm identity. Chr. Hansen states that *L. carnosum* DSM 32756 is a non-pathogenic and non-toxigenic organism that does not contain any virulence genes or produce biogenic amines.

Chr. Hansen describes the manufacture of *L. carnosum* DSM 32756 by fermentation of a pure culture under controlled conditions. Upon completion, the culture containing the microorganism is cooled, harvested, concentrated by centrifugation, and then frozen into pellets. The pellets are immersed in liquid nitrogen, lyophilized, ground to a powder, and mixed with food-grade excipients. Chr. Hansen states that no components of the fermentation medium are allergens or are derived from allergenic sources, and that *L. carnosum* DSM 32756 is manufactured under current good manufacturing practices using food-grade raw materials.

Chr. Hansen provides specifications for *L. carnosum* DSM 32756 that include limits for

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lead (<0.02 mg/kg)¹ and microorganisms, including *Salmonella* serovars (absent in 25 g), *Listeria monocytogenes* (absent in 25 g), and *Bacillus cereus* (<100 CFU/1 g). Chr. Hansen provides results from the analyses of four non-consecutive lots to demonstrate that *L. carnosum* DSM 32756 is manufactured to conform with the provided specifications.²

Chr. Hansen uses food consumption data from the 2015-2016 National Health and Nutrition Examination Survey to estimate the dietary exposure to *L. carnosum* DSM 32756 from its intended use. Chr. Hansen determines that the average amount of cured meat products consumed by individuals in the U.S. 2 years and older is 27.2 g/p/d. Chr. Hansen estimates the average dietary exposure to *L. carnosum* DSM 32756 to be 2.7 x 10¹⁰ CFU/g based on the conservative assumption that all raw cured meat products are consumed as is and contain *L. carnosum* DSM 32756 at a level of 10⁹ CFU/g. However, Chr. Hansen states that *L. carnosum* DSM 32756 is heat sensitive and would be killed during cooking, and therefore, the dietary exposure to *L. carnosum* DSM 32756 is negligible, if cured meat products are cooked prior to consumption.

Chr. Hansen states that there is a history of safe use of *Leuconostoc* genus in the manufacture of fermented foods, including fermented sausages, fermented vegetables, cereal products, and dairy products. Chr. Hansen relies on published literature to support safety of the oral consumption of *Leuconostoc*. Chr. Hansen notes that some species of the *Leuconostoc* genus are considered opportunistic pathogens based on the clinical cases in immunocompromised patients with underlying disease. However, Chr. Hansen states that there have been no human infections related to ingesting food products containing *Leuconostoc*.

Based on the totality of evidence, Chr. Hansen concludes that *L. carnosum* DSM 32756 is GRAS for its intended use

Use in Products under USDA Jurisdiction

As provided under 21 CFR 170.270, during our evaluation of GRN 000936, we coordinated with the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture. Under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, FSIS determines the efficacy and suitability of ingredients used in meat, poultry, and egg products, and prescribes safe conditions of use. Suitability relates to the ingredient's effectiveness in performing its intended technical effect and the assurance that the ingredient's use will not result in products that are adulterated or misleading for consumers.

¹ Chr. Hansen states that heavy metals are unlikely to be present in food cultures and notes that they monitor for heavy metals by selecting products that are representative of the raw materials used in the manufacturing facilities and that heavy metal testing is performed annually.

² Chr. Hansen provides the analyses of three batches of food cultures containing the raw materials used in the production of *L. carnosum* DSM 32756 and two batches of a product that is a blend of *L. carnosum* DSM 32756 and *S. carnosus* DSM 25010 to demonstrate that *L. carnosum* DSM 32756 meets the specification for lead.

FSIS has completed its review and has no objection to the use of *L. carnosum* DSM 32756 as an ingredient at up to 10⁹ CFU/g to inhibit the spoilage of raw cured meat products. Chr. Hansen is required to label the ingredient as “culture,” “bacterial culture,” “*Leuconostoc carnosum* culture,” or “*L. carnosum* culture,” in the ingredients statement of the products in which it is used.

FSIS requested that we advise Chr. Hansen to seek labeling guidance from Ms. Rosalyn Murphy-Jenkins at (301) 504-0879 or *via* email at Rosalyn.Murphy-Jenkins@usda.gov for questions regarding labeling of *L. carnosum* DSM 32756 used to inhibit the spoilage of raw cured meat products.

Section 301(ll) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)


Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In our evaluation of Chr. Hansen’s notice concluding that *L. carnosum* DSM 32756 is GRAS under its intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing *L. carnosum* DSM 32756. Accordingly, our response should not be construed to be a statement that foods containing *L. carnosum* DSM 32756, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Chr. Hansen provided, as well as other information available to FDA, we have no questions at this time regarding Chr. Hansen’s conclusion that *L. carnosum* DSM 32756 is GRAS under its intended conditions of use. This letter is not an affirmation that *L. carnosum* DSM 32756 is GRAS under 21 CFR 170.35. Unless noted above, our review did not address other provisions of the FD&C Act. Food ingredient manufacturers and food producers are responsible for ensuring that marketed products are safe and compliant with all applicable legal and regulatory requirements.

In accordance with 21 CFR 170.275(b)(2), the text of this letter responding to GRN 000936 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,
**Susan J.
Carlson -S**

 Digitally signed by Susan J.
Carlson -S
Date: 2021.04.19 17:14:32
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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
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cc: Melvin Carter, Ph.D.
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