Benjamin L. Burruss
SafeBridge Regulatory & Life Sciences Group
154 Hansen Road, Suite 201
Charlottesville, VA 22911

Re: GRAS Notice No. GRN 000740

Dear Mr. Burruss:

The Food and Drug Administration (FDA, we) completed our evaluation of the supplement that you submitted on behalf of Lanxess Corporation (Lanxess) to GRN 000740[1]. We received the supplement on October 15, 2020. The supplement addresses additional uses and estimates of dietary exposure for long-chain glycolipids from *Dacryopinax spathularia* (glycolipids preparation). Lanxess submitted clarifying information on February 24, 2021, and March 15, 2021, regarding the intended use and use levels, updated specifications and batch analyses, and technical details of efficacy studies. On March 29, 2022, and March 24, 2023, Lanxess submitted data from additional efficacy studies and expanded the application method for the glycolipids preparation.

We previously responded to GRN 000740 on May 17, 2018. We stated that we had no questions at that time regarding Lanxess's conclusion that glycolipids preparation is GRAS for the intended use as an antimicrobial agent in select non-alcoholic beverages at use levels ranging from 2 to 100 mg/kg.

In the supplement dated October 15, 2020, Lanxess informs us of its view that glycolipids preparation is GRAS, through scientific procedures, for use as an antimicrobial agent on cheese (all types) and dry-cured sausage (including sausage casings prior to filling and dry-curing) at levels resulting in no more than 500 mg/kg and 100 mg/kg, respectively, in the finished food to prevent the growth of yeasts and molds and subsequent spoilage of cheese and dry-cured sausage. Lanxess provides data and information to support the efficacy and application of glycolipids preparation as an antimicrobial agent on cheese and dry-cured sausage.

Our use of the term "glycolipids preparation" in this letter is not our recommendation of that term as an appropriate common or usual name for declaring the substance in accordance with FDA's labeling requirements. Under section 101.4 in Title 21 of the Code of Federal Regulations (21 CFR 101.4), each ingredient must be declared by its common or usual name. In addition, 21 CFR 102.5 outlines general principles to use when establishing common or usual names for non-standardized foods. Issues associated with labeling and the common or usual name of a food ingredient are under

[1] GRN 000740 was submitted by IMD Natural Solutions GmbH, now known as Lanxess Corporation.

the purview of the Office of Nutrition and Food Labeling (ONFL) in the Center for Food Safety and Applied Nutrition. The Office of Food Additive Safety did not consult with ONFL regarding the appropriate common or usual name for "glycolipids preparation."

In the supplement, Lanxess states that the identity and method of manufacture of glycolipids preparation are the same as described in GRN 000740. Lanxess states that the minor updates to the specification parameters of appearance (beige to light brown), turbidity (now analyzed in a 1% solution instead of 0.1% solution), and heavy metals (specification limits are now less than or equal to instead of less than) have no impact on the safety of the glycolipids preparation.

Lanxess estimates cumulative dietary exposure to glycolipids preparation from the existing and intended uses using food consumption data from the 2013-2016 National Health and Nutrition Examination Survey (NHANES). Lanxess estimates the eaters-only cumulative dietary exposure to glycolipids preparation to be 42.04 mg/person(p)/d or 0.70 mg/kg body weight (bw)/d at the mean and 83.93 mg/p/d or 1.44 mg/kg bw/d at the 90$^{th}$ percentile for the total U.S. population.[2]

Lanxess states that an updated search of the published literature through December 2022 was performed and did not result in any relevant new safety data or any new information that would raise safety concerns regarding the proposed new uses of glycolipids preparation.

Based on the totality of the data and information, Lanxess concludes that glycolipids preparation is GRAS for its intended use.

## Standards of Identity

In the supplement to GRN 000740, Lanxess states its intention to use glycolipids preparation in several food categories, including foods for which standards of identity exist, located in Title 21 of the CFR. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity.

## Use in Products under USDA Jurisdiction

As provided under 21 CFR 170.270, during our evaluation of the supplement to GRN 000740, 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

[2] FDA estimated the mean and 90$^{th}$ percentile eaters-only cumulative dietary exposures to glycolipid preparation for the U.S. population aged 2 years and older to be 48 mg/p/d (0.8 mg/kg bw/d) and 95 mg/p/d (1.5 mg/kg bw/d), respectively, using food consumption data from the 2013-2016 NHANES.

not result in products that are adulterated or misleading for consumers.

FSIS completed its review of the information submitted by Lanxess and has no objection to the use of glycolipids preparation as an antimicrobial agent in dry-cured sausages applied as a 1000 ppm (1000 mg/kg) dip solution (not to exceed 60 seconds) prior to drying.[3] Regarding labeling, FSIS requires that dry-cured sausage products treated with glycolipids preparation be labeled in the ingredients statement with "glycolipids" or "mushroom glycolipids" as the common and usual name.

FSIS requested that we advise Lanxess to seek regulatory guidance from its Risk Management and Innovations Staff, Office of Policy and Program Development, about the use of glycolipids preparation in dry-cured sausage. Lanxess should send any questions directly to Jennifer Green, Ph.D. by email at Jennifer.Green@usda.gov.

**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 Lanxess's supplement concluding that glycolipids preparation 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 glycolipids preparation. Accordingly, our response should not be construed to be a statement that foods containing glycolipids preparation, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

**Conclusions**

Based on the information that Lanxess provided, as well as other information available to FDA, we have no questions at this time regarding Lanxess's conclusion that glycolipids preparation is GRAS under its intended conditions of use. This letter is not an affirmation that glycolipids preparation 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 the supplement to GRN 000740 is accessible to the public at

[3] Lanxess states that this application process using a dip solution of 1000 ppm glycolipids preparation results in no more than 100 mg/kg glycolipids preparation in the finished sausage.

www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2023.08.25 17:22:58 -04'00'

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