U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Joshua Garey
Kaneka Americas Holding, Inc.
6250 Underwood Rd. Gate 2W
Pasadena, TX 77507

Re: GRAS Notice No. GRN 001205

Dear Mr. Garey:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001205. We received Kaneka Americas Holding, Inc. (Kaneka)'s notice on July 3, 2024, and filed it on September 20, 2025. Kaneka submitted amendments to the notice on December 5, 2024, March 17, 2025, and March 18, 2025, that clarified the manufacturing process, specifications, intended uses, and dietary exposure.

The subject of the notice is *Lactiplantibacillus plantarum* DR7 (*L. plantarum* DR7) for use as an ingredient in conventional foods at a maximum level of 1 x 10^{10} colony forming units (CFU)/serving.[1] The notice informs us of Kaneka's view that these uses of *L. plantarum* DR7 are GRAS through scientific procedures.

Kaneka states that *L. plantarum* DR7 is a non-pathogenic, non-toxigenic, Gram-positive, rod-shaped, non-motile bacterium. Kaneka notes that the strain was isolated from fresh cow's milk in Penang, Malaysia. The strain was deposited in the Korean Collection for Type Cultures (KCTC) under accession number KCTC 13909BP and the Spanish Type Culture Collection (CECT) under accession number CECT 7481. Kaneka defines the carbohydrate metabolism profile of *L. plantarum* DR7. Kaneka describes the taxonomic analysis for the identity of the strain, which was obtained from 16s ribosomal RNA sequencing. Kaneka also discusses the results of *de novo* genomic sequence analyses and states that the strain is not genetically engineered. Kaneka discusses the results of phenotypic and genotypic characterization performed on *L. plantarum* D7 and concludes that the strain neither carries antimicrobial resistance genes in its genome nor produces any virulence factors or biogenic amines.

Kaneka describes the manufacturing process of *L. plantarum* D7 by fermentation of a pure culture under controlled conditions. After fermentation, the cells are separated and concentrated by centrifugation. The resulting concentrated broth is lyophilized in the presence of cryoprotectants (trehalose, D-mannitol, maltodextrin, dextrose, sodium ascorbate, sodium citrate)to remove water. The lyophilized powder is milled, passed through a sieve, and blended with maltodextrin, microcrystalline cellulose, or corn starch to achieve a desired concentration. Kaneka states that *L. plantarum* D7 is

[1] *L. plantarum* DR7 is not intended for use in infant formula, other foods intended for consumption by infants, alcoholic beverages, products under the jurisdiction of the United States Department of Agriculture, and in foods where standards of identity preclude its use.

manufactured in accordance with current good manufacturing practices and that all raw materials and processing aids used in the manufacturing process are food-grade and are used in accordance with applicable U.S. regulations, are GRAS for their intended use, or are the subject of an effective food contact notification. Kaneka states that all raw materials and processing aids are non-allergenic.

Kaneka provides specification for *L. plantarum* D7 that include bacterial count (>1.0x10^{11} CFU/g), yeast and molds (<10 CFU/g), *Enterobacteria* (<10 CFU/g), *Escherichia coli* (not detected in 1 g), *Staphylococci* (coag +) (not detected in 1 g), *Bacillus cereus* (<100 CFU/g), *Listeria monocytogenes* (not detected in 25 g), *Salmonella* spp. (not detected in 25 g), and heavy metals, including lead (<0.1 mg/kg). Kaneka provides the results from the analyses of three non-consecutive batches to demonstrate that *L. plantarum* D7 can be manufactured to meet these specifications.

Kaneka estimates the dietary exposure to *L. plantarum* D7 from its intended uses to be 2 x 10^{11} CFU/person (p)/d based on the assumption that an individual consumes on average 20 servings of food/d in the U.S. containing *L. plantarum* D7 at the maximum use level of 1 x 10^{10} CFU/serving. Kaneko states that the intended uses of *L. plantarum* D7 are substitutional to the uses of other *L. plantarum* strains and therefore, there is not expected to be an increase in the dietary exposure to *L. plantarum*.

Kaneka discusses data and information used to support the safety of *L. plantarum* D7, including a history of safe use of the *L. plantarum* species in fermented foods. Kaneka incorporates into their notice and provides summaries of the information pertaining to the safety of the *L. plantarum* strains discussed in GRNs 000685, 000722, and 000847.[2] Kaneka notes the ability of *L. plantarum* D7 to produce both L-lactate and D-lactate. Kaneka summarizes published animal and human studies on *L. plantarum* consumption and concludes that there are no indications of safety concerns.

Based on the totality of evidence, Kaneka concludes that *L. plantarum* DR7 is GRAS for its intended use.

Standards of Identity

In the notice, Kaneka states its intention to use *L. plantarum* D7 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.

Potential Labeling Issues

Under section 403(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a food is misbranded if its labeling is false or misleading in any way. Section 403(r) of the FD&C Act lays out the statutory framework for labeling claims characterizing a nutrient level in

[2] *L. plantarum* strains 299v, Lp-115, and ECGC 13110402 were the subjects of GRNs 000685, 000722, and 000847, respectively. We evaluated these notices and responded in letters dated October 31, 2017, February 16, 2018, and September 30, 2019, respectively, stating that we had no questions at the time regarding the notifiers' GRAS conclusions.

a food or the relationship of a nutrient to a disease or health-related condition (also referred to as nutrient content claims and health claims). If products containing *L. plantarum* DR7 bear any nutrient content or health claims on the label or in labeling, such claims are subject to the applicable requirements and are under the purview of the Office of Nutrition and Food Labeling (ONFL) in the Nutrition Center of Excellence. The Office of Pre-Market Additive Safety did not consult with ONFL on this issue or evaluate any information in terms of labeling claims. Questions related to food labeling should be directed to ONFL.

Section 301(ll) of the 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 Kaneka's notice concluding that *L. plantarum* DR7 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. plantarum* DR7. Accordingly, our response should not be construed to be a statement that foods containing *L. plantarum* DR7, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Kaneka provided, as well as other information available to FDA, we have no questions at this time regarding Kaneka's conclusion that *L. plantarum* DR7 is GRAS under its intended conditions of use. This letter is not an affirmation that *L. plantarum* DR7 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 001205 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2025.03.24 12:50:42 -04'00'

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