U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Amy C. Mozingo
GRAS Associates, LLC
11810 Grand Park Ave, Suite 500
North Bethesda, MD 20852

Re: GRAS Notice No. GRN 001347

Dear Ms. Mozingo:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001347. We received the notice that you submitted on behalf of Hy Co., Ltd. (HyCo) on February 25, 2026, and filed it on July 6, 2026. HyCo submitted an amendment to the notice on September 15, 2026, providing additional information about the analytical methods, batch analyses, manufacturing process, and general recognition of safety.

The subject of the notice is *Lactiplantibacillus plantarum* strain KCTC 13101BP (*L. plantarum* KCTC 13101BP) for use as an ingredient in conventional foods at levels up to 5×10^9 colony forming units (CFU)/serving (excluding use in infant formula, alcoholic beverages, and products under the jurisdiction of the United States Department of Agriculture). The notice informs us of HyCo's view that this use of *L. plantarum* KCTC 13101BP is GRAS through scientific procedures.

HyCo describes *L. plantarum* KCTC 13101BP as a pale-yellow powder. HyCo states that *L. plantarum* KCTC 13101BP is a Gram-positive, acid-tolerant bacterium. HyCo cites a published report describing the isolation of *L. plantarum* KCTC 13101BP from Korean kimchi. HyCo states that the strain is deposited in the Korean Collection for Type Cultures (KCTC) under the number 13101BP. HyCo describes the taxonomic identity of the strain. HyCo also discusses the results of genomic analyses to confirm the strain's identity and states that the strain is not genetically engineered. HyCo describes the results of genomic analyses demonstrating that *L. plantarum* KCTC 13101BP is non-pathogenic and non-toxigenic and lacks genes encoding antimicrobial resistance determinants and biogenic amines.

HyCo describes the manufacture of *L. plantarum* KCTC 13101BP by fermentation of a pure culture under controlled conditions. After fermentation, the culture is cooled and centrifuged to collect the bacterial cells. The bacterial cells are mixed with cryoprotectants, lyophilized, ground, and mixed with maltodextrin to obtain the final ingredient. HyCo states that *L. plantarum* KCTC 13101BP is manufactured in accordance with current good manufacturing practices and that all raw materials and processing aids are food-grade and are used in accordance with applicable U.S. regulations, are GRAS for their intended uses, or are the subject of an effective food

contact notification. HyCo states that the raw materials used in the manufacturing process include ingredients derived from milk, and that appropriate allergen declarations will be provided for the ingredient and products containing the ingredient according to U.S. regulations.

HyCo provides specifications for *L. plantarum* KCTC 13101BP that include *L. plantarum* count (≥ 4×10^{11} CFU/g), moisture (≤ 10%), and limits for heavy metals, including lead (≤ 0.1 mg/kg), and microorganisms, including non-lactic acid bacteria (absent per 10 g), yeast and molds (absent per 25 g), coliforms (absent per 25 g), *Escherichia coli* (absent per 25 g), *Listeria monocytogenes* (absent per 25 g), *Salmonella* serovars (absent per 25 g), and *Staphylococcus aureus* (absent per 25 g). HyCo provides results from the analyses of five batches (including three non-consecutive batches) to demonstrate that *L. plantarum* KCTC 13101BP can be manufactured to meet the specifications. HyCo states that *L. plantarum* KCTC 13101BP is stable for 12 months when stored at 10 ± 0.5°C and 75% relative humidity in polyethylene bags.

HyCo estimates the dietary exposure to *L. plantarum* KCTC 13101BP from the intended uses to be 1×10^{11} CFU/person/d based on the assumption that an individual consumes on average 20 servings of food/d and that all servings of food contain *L. plantarum* KCTC 13101BP at the maximum use level of 5×10^{9} CFU/serving. HyCo states that the intended uses of *L. plantarum* KCTC 13101BP are substitutional for the current uses of other strains of *L. plantarum* and therefore, there will be no increase in the cumulative dietary exposure to *L. plantarum* from the intended uses of *L. plantarum* KCTC 13101BP.

HyCo discusses data and information used to support the safety of *L. plantarum* KCTC 13101BP, including an extensive history of safe consumption of *L. plantarum* strains in fermented foods. HyCo summarizes published animal studies using *L. plantarum* KCTC 13101BP as a test article and describes that no adverse effects were observed in these studies. HyCo also summarizes the results of published animal and human studies using other *L. plantarum* strains supporting the safety of their intended use. HyCo notes that a literature search through January 2026 revealed no safety concerns.

Based on the totality of the information, HyCo concludes that *L. plantarum* KCTC 13101BP is GRAS for its intended use.

Standards of Identity

In the notice, HyCo states its intention to use *L. plantarum* KCTC 13101BP 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 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 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* KCTC 13101BP 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.

Allergen Labeling

The FD&C Act requires that the label of a food that is or contains an ingredient that contains a "major food allergen" declare the allergen's presence (section 403(w)). The FD&C Act defines a "major food allergen" as one of nine foods or food groups (i.e., milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, soybeans, and sesame) or a food ingredient that contains protein derived from one of those foods. *L. plantarum* KCTC 13101BP requires labeling under the FD&C Act because it may contain protein derived from milk.

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 HyCo's notice concluding that *L. plantarum* KCTC 13101BP 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* KCTC 13101BP. Accordingly, our response should not be construed to be a statement that foods containing *L. plantarum* KCTC 13101BP, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that HyCo provided, as well as other information available to FDA, we have no questions at this time regarding HyCo's conclusion that *L. plantarum* KCTC 13101BP is GRAS under its intended conditions of use. This letter is not an affirmation that *L. plantarum* KCTC 13101BP 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

001347 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

SUSAN J. CARLSON -S

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