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Kyowa Hakko Bio's 2'-fucosyllactose received positive EFSA Opinion

KYOWA HAKKO BIO CO., LTD. (Kyowa Hakko Bio) a leading subsidiary of Kirin Holdings Company, Limited has received a positive opinion from the European Food Safety Authority (EFSA) on 2'-fucosyllactose (2'-FL) as a novel food. This opinion was published in the November 2023 issue of the EFSA Journal¹⁾.

EFSA opinion confirms that Kyowa's 2'-FL is considered safe under the proposed conditions of use. Kyowa has applied 2'-FL as a novel food ingredient for the same uses and use levels already assessed for the 2'-FL produced by fermentation of different manufacturing strains. Following a final approval by European Commission, Kyowa's 2'-FL sodium salt will be able to be used as a novel food in a variety of food categories including infant formula, follow-on formula, food for special medical purposes and food supplements.

The commercial production of Kyowa Hakko Bio's HMOs (2'-fucosyllactose, 3'-sialyllactose sodium salt, 6'-sialyllactose sodium salt) successfully started in November 2022 in the newly -constructed facility in Thailand. We will continue to expand the availability of HMOs in countries and regions where applications for new ingredients have been approved.

Kyowa Hakko Bio is committed to pursuing advances in life science and technology and contributing to the health and prosperity of people around the world through the creation of new value.

- 1) EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA), et al. "Safety of 2'-fucosyllactose (2'-FL) produced by a derivative strain (Escherichia coli SGR5) of *E. coli* W (ATCC 9637) as a Novel Food pursuant to Regulation (EU) 2015/2283." EFSA Journal 21.11 (2023): e08333.