



August 8th, 2024

Kyowa Hakko Bio's 2'-Fucosyllactose Receives Novel Food Approval in the EU

KYOWA HAKKO BIO CO., LTD. (Kyowa Hakko Bio), a subsidiary of Kirin Holdings Company, Limited, is pleased to announce that its 2'-Fucosyllactose (2'-FL), a Human Milk Oligosaccharide (HMO), has been approved as a novel food by the European Commission in the European Union¹⁾. This significant approval allows Kyowa Hakko Bio's 2'-FL to be incorporated into a variety of food categories, including infant formula, follow-on formula, foods for special medical purposes and food supplements across 27 EU member states from August 19, 2024. To be approved by the European Commission, the novel food must undergo a safety assessment by the European Food Safety Authority (EFSA) as needed. Kyowa Hakko Bio received a positive opinion on the safety of its 2'-FL from EFSA in November 2023²⁾ and it has now been approved as a novel food.

Commercial production of Kyowa Hakko Bio's HMOs (2'-FL, 3'-Sialyllactose sodium salt (3'-SL) and 6'-Sialyllactose sodium salt (6'-SL)) successfully started in November 2022 in the newly built facility in Thailand. As 3'-Sialyllactose sodium salt (3'-SL)³⁾ and 6'-Sialyllactose sodium salt (6'-SL)⁴⁾ had been previously approved, Now we are ready to supply all 3 HMOs (2'-FL, 3'-SL and 6'-SL) in EU area. We will continue to expand the availability of HMOs in countries and regions where applications for new ingredients have been approved.

We strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

- 1) Commission Implementing Regulation (EU) 2024/ 2036 of 29 July 2024 authorising the placing on the market of 2'-Fucosyllactose produced using a derivative strain of *Escherichia coli* W (ATCC 9637) as a novel food and amending Implementing Regulation (EU) 2017/2470
- 2) 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.
- 3) Commission Implementing Regulation (EU) 2024/1047 of 9 April 2024 authorising the placing on the market of 3'-Sialyllactose sodium salt produced using a derivative strain of *Escherichia coli* W (ATCC 9637) as a novel food and amending Implementing Regulation (EU) 2017/2470
- 4) Commission Implementing Regulation (EU) 2023/2215 of 23 October 2023 authorising the placing on the market of 6'-Sialyllactose sodium salt produced by derivative strain of *Escherichia coli* W (ATCC 9637) as a novel food and amending Implementing Regulation (EU) 2017/2470