



April 30th, 2024

Kyowa Hakko Bio's 3'-Sialyllactose Sodium Salt 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 3'-Sialyllactose sodium salt (3'-SL), a Human Milk Oligosaccharide (HMO), has been approved as a novel food by the European Commission in the European Union¹⁾, following 6'-Sialyllactose sodium salt (6'-SL) in 2023²⁾. This significant approval allows Kyowa Hakko Bio's 3'-SL 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 April 30, 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 3'-SL from EFSA in June 2023 and it has now been approved as a novel food³⁾.

In addition to 3'-SL and 6'-SL, Kyowa Hakko Bio has submitted applications as novel foods for 2'-Fucosyllactose (2'-FL) and has received EFSA's positive opinion⁴⁾. We plan to launch 2'-FL in EU member countries once it has been approved.

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 built facility in Thailand. 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) 2024/1047 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
- 2) 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
- 3) EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA), et al. "Safety of 3'-sialyllactose (3'-SL) sodium salt produced by a derivative strain (*Escherichia coli* NEO3) of *E. coli* W (ATCC 9637) as a Novel Food pursuant to Regulation (EU) 2015/2283" EFSA Journal 2023;21(9):8224
- 4) 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.