



November 16th, 2023

Kyowa Hakko Bio's 6'-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 6'-Sialyllactose sodium salt (6'-SL), a Human Milk Oligosaccharide (HMO), has been approved as a novel food by the European Commission in the European Union.¹⁾ This significant approval allows Kyowa Hakko Bio's 6'-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 November 13, 2023. 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 6'-SL from EFSA in June 2023²⁾³⁾ and it has now been approved as a novel food.

In addition to 6'-SL, Kyowa Hakko Bio has submitted applications as novel foods for 2'-Fucosyllactose (2'-FL) and 3'-Sialyllactose sodium salt (3'-SL) and has received EFSA's positive opinion for each product. We plan to launch these products in EU member countries once they have 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) 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
- 2) EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA), et al. "Safety of 6'-sialyllactose (6'-SL) sodium salt produced by a derivative strain (*Escherichia coli* NEO6) of *E. coli* W (ATCC 9637) as a Novel Food pursuant to Regulation (EU) 2015/2283." EFSA Journal 21.6 (2023): e08025.
- 3) Kyowa Hakko Bio's News Release: Kyowa Hakko Bio's 6'-sialyllactose received positive EFSA Opinion