



January 18th, 2023

Manufacturing strains of Kyowa Hakko Bio's 3'-sialyllactose and 6'-sialyllactose, human milk oligosaccharides (HMOs), passed safety evaluation in China.

KYOWA HAKKO BIO CO., LTD. (Kyowa Hakko Bio) is pleased to announce that its manufacturing strains used for producing 3'-sialyllactose (3'-SL) and 6'-sialyllactose (6'-SL) have passed the Chinese Ministry of Agriculture and Rural affairs' (MARA) safety evaluation. As we reported last June, the manufacturing strain of 2'-fucosyllactose (2'-FL) has already passed the same evaluation. This means that the first step of the approval process (safety evaluation) is therefore completed for the three HMOs to be launched in China.

Kyowa Hakko Bio is now moving to the next step of the approval process, namely the authorization of 3'-SL and 6'-SL as food additives in infant formulas, while the application of 2'-FL for the same process has already been completed and is currently under review.

In addition, Kyowa Hakko Bio has already submitted GRAS (Generally Recognized as Safe) notices to the U.S. Food and Drug Administration and submitted Novel Food applications to the European Commission for approval of the above three HMOs as food ingredients. Kyowa Hakko Bio has also started filing applications for approval of the three HMOs in various Asian and Oceanian countries such as Malaysia, Thailand, Singapore, Indonesia, Philippines, India, Australia, and New Zealand.

The commercial production of Kyowa Hakko Bio's HMOs (2'-FL, 3'-SL, 6'-SL) successfully started in November 2022 in the newly -constructed facility in Thailand. The three HMOs will be launched successively from February 2023 for countries and regions where applications for the 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.