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Manufacturing strain of Kyowa Hakko Bio's 2'-fucosyllactose, a human milk oligosaccharide (HMO), passed safety evaluation in China.

KYOWA HAKKO BIO CO., LTD. (Kyowa Hakko Bio) is pleased to announce that its manufacturing strain used for producing 2'-fucosyllactose (2'-FL), the most abundant HMO in human milk, has passed the safety evaluation by the Chinese Ministry of Agriculture and Rural Affairs (MARA), while other manufacturing strains used for producing 3'-sialyllactose (3'-SL) and 6'-sialyllactose (6'-SL) are currently under review.

In China, the safety approval of the manufacturing strains is the first step in the process of registering new raw materials produced with the help of bioengineering technology. Kyowa Hakko Bio is now moving forward to the next step of the approval process which is the 2'-FL authorization of use as food additive in infant formulas. Similar registration procedures of Kyowa Hakko Bio's 3'-SL and 6'-SL will begin once their manufacturing strains have passed the safety evaluation by MARA.

In addition to the above, Kyowa Hakko Bio has already submitted GRAS (Generally Recognized as Safe) notices to the U.S. Food and Drug Administration and Novel Food registration applications to the European Commission. Kyowa Hakko Bio has also started filing for approval of its new ingredients in various Asian countries.

The production of Kyowa Hakko Bio's three HMOs is scheduled to begin in September 2022 at Kyowa Hakko Bio's manufacturing facility in Thailand and will be launched successively from the end of 2022 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.