

Kyowa Hakko Bio's 2'-Fucosyllactose Receive Approval as a Food Additive in China

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 food additive by National Health Commission of the People's Republic of China on 10th, February 2025. This milestone marks the entry of Kyowa Hakko Bio's HMO into the Chinese market, the global leader in the production and consumption of infant formulas. This significant approval allows Kyowa Hakko Bio's 2'-FL to be incorporated into four food categories, including infant formula, formula for older infants and young children, and infant formula for special medical purposes. 2'-FL, the most abundant HMO in human breast milk, is widely recognized for its potential prebiotic benefits and is globally utilized not only in infant formula but also in supplements for all age groups.

"We're thrilled that our 2'-FL has received approval as a food additive for infant nutrition in China," said Masayuki Ochiai, Product Manager of HMOs at Kyowa Hakko Bio. "This milestone underscores the quality and safety of our product. We are confident that the introduction of our first HMO, 2'-FL, into the Chinese market will play a significant role in supporting the healthy growth and development of infants in the region."

Kyowa Hakko Bio has been at the forefront of HMOs production, with successful commercial production of 3 HMOs (2'-FL, 3'-SL (3'-Sialyllactose sodium salt), and 6'-SL (6'-Sialyllactose sodium salt)) in our state-of-the-art facility backed by a trusted quality assurance system in Thailand since November 2022. Kyowa Hakko Bio's HMOs have been available in global market including the US, EU, and South East Asia. With our groundbreaking entry into China's rapidly growing markets, we are reaching a historic milestone in our journey. As we move forward, Kyowa Hakko Bio remains committed to expanding the availability of our innovative products worldwide, fostering global health and well-being.



<Figure 1: Thai Kyowa Production Facility>



<Figure 2: Fermentation Tank Where HMOs Are Produced by Microbiome Cultivation>



<Figure 3: Quality Control Laboratory>

**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.**