

Cataya Receives Regulatory Approval in China for Its 2'-Fucosyllactose Ingredient

Milestone achievement enables commercialization of Cataya's flagship HMO in the world's largest infant formula market

Shanghai, China Dec 15, 2025 ([Issuewire.com](https://www.issuewire.com)) - Cataya Bio (Shanghai) Co., Ltd. ("Cataya"), a leading innovator in sustainable, biotechnology-enabled, nutritional ingredients, today announced that its 2'-Fucosyllactose (2'-FL) has recently received regulatory approval from the National Health Commission (NHC) of the People's Republic of China. This approval authorizes the use of Cataya's 2'-FL in infant formula, follow-up formula, young-child formula, and formula for special medical purposes, as well as in cereal-based complementary foods and other baby foods for infants and young children.

This achievement marks a major regulatory milestone for Cataya and positions the company to serve manufacturers across China—the world's largest infant formula market, representing nearly half of global retail value. The decision follows Cataya's successful regulatory progress globally, including receiving a "No Questions" GRAS letter from the U.S. Food and Drug Administration (FDA) earlier in 2025, which affirmed the safety and suitability of Cataya's 2'-FL for use in non-exempt infant formula and a broad range of conventional foods.

2'-Fucosyllactose is the most abundant human milk oligosaccharide (HMO) found in breast milk and is recognized for supporting immune development, digestive health, and cognitive function in infants. "Receiving approval in China is a transformative milestone for Cataya and a strong validation of our technology and commitment to quality," said Dr. Lishan Zhao, CEO of Cataya. "Following the FDA's GRAS acceptance earlier this year, this approval opens the door for our partners in China to formulate next-generation early-life nutrition products that closely mimic the beneficial properties of human milk."

Cataya's 2'-FL is produced using advanced synthetic biology and precision biomanufacturing platforms that deliver high purity, consistent quality, and cost-efficient scalability. The company continues to expand its HMO portfolio, with additional HMO ingredients under regulatory review in multiple regions.

About Cataya

Founded in 2021, Cataya Bio (Shanghai) Co., Ltd. develops and manufactures high-value nutritional and personal-care ingredients using cutting-edge synthetic biology and sustainable large-scale bioproduction. Cataya's mission is to enable efficient, cost-efficient, and environmentally responsible ingredient manufacturing for partners in food & nutrition, personal care, and pharmaceuticals. For more information, visit www.cataya.com.

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