

dsm-firmenich achieves regulatory clearance in China for HMO ingredients

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dsm-firmenich, the leading innovator in health, nutrition and beauty, announced that two of its human milk oligosaccharide (HMO) ingredients have been approved as fortifiers for infant nutrition in China. This approval is a significant milestone as it will create new opportunities for innovation in the field of early-life nutrition and make the unique benefits of HMOs accessible to infants and young children in China.

The two HMOs that received approval in China include GlyCare 2'-fucosyllactose (2'-FL), the most prevalent HMO in human breast milk, and GlyCare lacto-N-neotetraose (LNnT), a complex sugar in human milk that is biologically relevant in the early development of the infant gut flora. The 2'-FL HMO has been approved for use in four food categories, including infant formula, formula for elder infants and young children, infant formula for special medical purposes, and formulated milk powder at a usage level between 0.7-2.4 g/L. LNnT is available for the same applications at 0.2-0.6 g/L.

Data on concentrations of HMOs found in human breast milk globally were taken into consideration by the China National Center for Food Safety Risk Assessment (CFSA) to set the approved maximum usage level. Currently, 2'-FL and LNnT are the only HMO ingredients approved in the Chinese market.

"We are extremely pleased to be able to announce this huge milestone for the China infant formula market and dsm-firmenich," says James Young, Vice-President of Early Life Nutrition at dsm-firmenich. "As the only company with these two HMOs approved for use in China, this approval reaffirms dsm-firmenich's lead position in the global HMO market. HMOs are the next important ingredient for bringing the composition of infant formula closer to breast milk, the gold standard of infant nutrition, and this approval ensures that all infants in China now have access to this important nutrient."

Christoph R hrig, Head of HNC Glycans & HMO Regulatory Affairs at dsm-firmenich added, "We followed a rigorous regulatory process to ensure all safety and health requirements were met. In the first phase of this process, we achieved safety clearance from the Chinese Ministry of Agriculture and Rural Affairs (MARA) for several of our HMO production strains, including 2'-FL and LNnT. This was followed by the food additive approval process, which comprised a rigorous multiple-phase technical assessment by the China National Centre for Food Safety Risk Assessment (CFSA), including the opportunity

for public comments that required the questions of diverse stakeholders to be addressed. With this breakthrough approval of two of our leading HMO ingredients in China, we are now able to offer two very important HMOs to the domestic infant nutrition market.â•