

Voluntary Report – Voluntary - Public Distribution

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Report Name: NHC Approves GMM Derived Enzymes as Part of New Food Materials and Additives

Country: China - People's Republic of

Post: Beijing

Report Category: Biotechnology - Plants and Animals, FAIRS Subject Report, MISC-Commodity, Sanitary/Phytosanitary/Food Safety, Trade Policy Monitoring

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Report Highlights:

On August 5, 2024, the National Health Commission (NHC) announced the approval of eight new food materials and additives, of which one product is derived from Genetically Modified Microorganisms (GMMs). This report provides a summary of the newly approved food materials and additives listed in the announcement.

Background:

The National Health Commission (NHC) released its [2024 No. 3 Announcement on Eight “Three New Foods” Including Arabinoxylan](#) (*link in Chinese*) on August 5, 2024. This announcement approved eight new food materials and additives for use in China, of which one product is derived from GMMs (see highlighted yellow sections in Table 1). Of note, 2’-fucosyllactose (2’-FL), a purified human milk oligosaccharide (HMO), for use as a food nutrition fortifier, particularly in infant formula was previously approved under NHC [2023 No. 8 Announcement](#) on October 7, 2023. The 2’-FL approved in this announcement is from a different host and donor than the previous approval.

The approved enzymes are considered common enzymes available for use in food processing and in foods with no specific labeling requirements. Please refer to [GAIN Report China Agricultural Biotechnology Annual 2023](#) for detailed information on the regulatory framework, application procedure, labeling, and traceability requirements of GMM derived enzymes.

Additional information on the announcements can be found at the following links:

“Interpretation of the "Announcement on Eight ‘Three New Foods’ including Dendrobium Protocorm” – see link [here \(link in Chinese\)](#).

Table 1. China: NHC Approved Food Materials, Enzymes, and Additives from August 2024 Announcement

		Product	Recommended Usage	Note
New food raw materials	1	Arabinoxylan	≤15/day	Not suitable for consumption by infants, young children, pregnant women and lactating women. Unsuitable groups and consumption limits should be marked on the label and instructions.
	2	Bifidobacterium longum subsp. infantis M-63	N/A	1. Approved to be included in the "List of Bacteria Can be Used in Infant and Young Children's Foods". 2. Food safety indicators should comply with the "National Food Safety Standard: Bacterial Preparations for Food Processing" (GB 31639), and Cronobacter genus shall not be detected (/100 g).
	3	N-	≤500 mg/day	1. Scope of use and maximum

		acetylglucosamine		usage: milk and dairy products (modulated milk and flavored fermented milk 0.5 g/kg, milk powder and its modulated products are converted according to the liquid mass after preparation), beverages (liquid beverages 0.5 g/kg, Solid beverages are prepared according to liquid Mass conversion), jelly (3 g/kg), candy (10 g/kg), pastry (2 g/kg). 2. Not suitable for consumption by infants, young children, pregnant women and lactating women. Unsuitable groups and consumption limits should be marked on the label and instructions.	
New varieties of food additives	No.	Product	Function	Food Name	Maximum Usage (g/kg)
	4	Hydroxytyrosol	Antioxidants	Vegetable oils	0.05
	5	Methylene chloride	extraction solvent	Tea Decaffeination Process	Residue amount ≤ 2 mg/kg
New varieties of food nutrition fortifiers	No.	Product	Function	Food Name	Maximum Usage
	6	2'-fucosyllactose , 2'-FL	Food nutrition fortifiers	Modified milk powder (only milk powder for children), infant formula, older infant and young children formulas, special medical purposes infant formula	0.7-2.4g/L
		Product	Host	Donor	
	2'-fucosyllactose , 2'-FL	大肠杆菌 BL21 star (DE3) Escherichia coli BL21	大肠杆菌 O126 (Escherichia coli O126)a		

			star (DE3)		
			谷氨酸棒状杆菌 ATCC 13032 Corynebacterium glutamicum ATCC 13032	滑动假土地杆菌 (Pseudopedobacter saltans)a	
Expanded use scope of food additives	No.	Product	Function	Food Name	Maximum Usage (g/kg)
	7	Polyglyceryl ricinoleate	emulsifier	Prepare cream	10
New varieties of resins for food contact materials and products	No	Product		Usage Scope	Maximum Usage
	8	Poly (neopentyl glycol-co-terephthalic acid-co-monoethylene glycol-co-isophthalic acid-co-monopropylene glycol-co-Fatty acids, C18-unsaturated, dimers, hydrogenated-co-1,6-hexanediol- co-trimethylol propane)		Paints and coatings	69% (based on coating formula)

Attachments:

No Attachments.