

Voluntary Report – Voluntary - Public Distribution

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Report Name: NHC Approves New Food Materials and Additives including GMM Derived Enzymes

Country: China - People's Republic of

Post: Beijing

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

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Report Highlights:

On March 13, 2024, the National Health Commission (NHC) announced approval of 23 new food materials and additives, of which three are products derived from Genetically Modified Microorganisms (GMMs). This report provides a summary of the newly approved food materials and additives from the announcement.

The National Health Commission (NHC) released its [2024 No. 2 Announcement on 23 "Three New Foods"¹ Including Dendrobium Protocorm](#) (link in Chinese) on March 13, 2024. This announcement approved 23 new food materials and additives for use in China, of which three are products 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 the 2024 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 23 ‘Three New Foods’ including Dendrobium Protocorm” – see link [here \(link in Chinese\)](#).

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

		Product	Recommended Usage	Note
New food raw materials	1	Dendrobium protocorm	Dry product \leq 3.5g/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	Meso-zeaxanthin	\leq 8 mg/day	The scope of use does not include food for infants and young children.
	3	Pichia kluyveri	N/A	Approved to be included in the "List of strains that can be used in food", the scope of use includes the fermentation processing of fermented wine, fruit and vegetable juices and beverages, tea beverages, protein beverages, and plant beverages, excluding infant food. The scope of use should be indicated on the label and

¹ "Three new foods" refers to new food raw materials, new varieties of food-related products and new varieties of food additives.

				instructions.
	4	Bacillus subtilis DE111	N/A	Approved to be included in the "List of strains that can be used in food", the scope of use does not include infant food.
	5	L-alpha-Glycerolphosphorylcholine	≤600mg/day	It is not suitable for infants, young children, pregnant women and lactating women. Labels and instructions should indicate unsuitable groups and consumption limits.
	6	Leuconostoc pseudomesenteroides	N/A	Approved to be included in the "List of strains that can be used in food", the scope of use includes fermented milk, flavored fermented milk, cheese, fermented milk beverages, lactic acid bacteria beverages (non-solid beverages), cream, cream (butter) and anhydrous cream (anhydrous butter), excluding food for infants and young children.

	No.	Product	Function	Food Name	Maximum Usage (g/kg)
New varieties of food additives	7	Mixed tocotrienol tocopherol concentrate	Antioxidants	Vegetable oils	0.2
	8	Enzymatically produced steviol glycosides	Sweetener	Modified milk,	0.18
				flavored fermented milk,	0.2
				ice cream	0.5
				gum-based candies	3.5
				Beverages [except packaged drinking water, fruit and vegetable juice (pulp), and concentrated fruit and vegetable juice (pulp)]	0.2
	Product	Host	Donor		
	Enzymatically produced steviol glycosides	大肠杆菌BL21 (DE3) Escherichia coli BL21 (DE3)	甲基杆 (Methylocaldum Szegediense), 甜叶菊 (Stevia rebaudiana Bertoni) 和马铃薯		

				(Solanum tuberosum)	
New varieties of enzyme preparations for food industry	No.	Enzyme	Host	Donor	
	9	D-阿洛酮糖-3-差向异构酶 D-psicose 3-epimerase	枯草芽孢杆菌 Bacillus subtilis	闪烁梭菌 ATCC35704 Clostridium scindens ATCC35704	
	10	环糊精葡萄糖苷转移酶 Cyclomaltodextrin glucanotransferase	热解蛋白无氧芽孢杆菌 Anoxybacillus caldiproteolyticus	—	
	11	纤维素酶 Cellulase	草酸青霉 Penicillium oxalicum	—	
New varieties of food nutrition fortifiers	No.	Product	Function	Food Name	Maximum Usage
	12	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(DE3) Escherichia coli BL21(DE3)	幽门螺杆菌 (Helicobacter pylori)	
	No.	Product	Function	Food Name	Maximum Usage
13	d-ribose	Food nutrition fortifiers	Other special dietary foods (sports nutrition foods only)	1-2g/day	
	No.	Product	Function	Food Name	Maximum Usage (g/kg)
	14	Propylene glycol alginate	Thickener	vermicelli	1.5
	15	Polyoxyethylene (20) Sorbitan Monooleate	Emulsifier	Collagen, casings	0.5

Expanded use scope of food additives	16	Ascorbyl Palmitate (enzyme method) Rosemary extract	Antioxidants	Modified milk powder and modified cream powder,	0.2
				Tea drinks	0.2
	17	Sucralose	Antioxidants	Processed nuts and seeds	0.3
	18	Propylene glycol alginate	Sweetener	Cooked nuts and seeds in shell	4.0
Shelled cooked nuts and seeds				2.0	
New varieties of additives for food contact materials and products	No	Product	Usage Scope	Maximum Usage	
	19	Chromium iron oxide	Plastic	2%	
	20	Bicyclo[2.2.1] heptane-2,3-dicarboxylic acid, calcium salt (1:1), (1R,2R,3S,4S)-rel-	Plastic, Polypropylene (PP), polyethylene (PE)	0.25%	
New varieties of resins for food contact materials and products	No	Product	Usage Scope	Maximum Usage	
	21	Polybutylene succinate adipate	Plastic	Appropriate use according to production needs	
	22	1,3-Benzenedicarboxylic acid, polymer with 1,4-benzenedicarboxylic acid and 1,4-cyclohexanedimethanol	Plastic	Appropriate use according to production needs	
Expanded use scope of resin for food contact materials and products	No	Product	Usage Scope	Maximum Usage	
	23	Undecanoic acid, 11-amino-, homopolymer	Plastic	Appropriate use according to production needs	

Attachments:

No Attachments.