

**Draft Regulation for The Use Restriction and Labeling
Requirement of 2'-fucosyllactose Produced by Genetically
Modified *Escherichia coli* strain K-12 DH1 MDO
MAP1001d as a Food Ingredient**

MOHW Food No.1091303456, 16 December 2020

Article 1

The regulation is prescribed in accordance with the provisions of Paragraph 2 of Article 15-1 and Subparagraph 10 of Paragraph 1 of Article 22 of the Act Governing Food Safety and Sanitation.

Article 2

The 2'-fucosyllactose (2'-FL) referred to herein is produced by fermentation process using genetically modified *Escherichia coli* strain K-12 DH1 MDO MAP1001d (hereinafter referred to as “*E. coli* K-12 MAP1001d”). The 2'-FL powder can be purified from the fermentation broth via a sequence of purification steps including ion-exchange resin, activated charcoal treatment, filtration, concentration, crystallization with acetic acid, solid-liquid separation, washing and drying etc. The final 2'-FL powder shall not contain any genetically modified microorganism and its transgenes.

Article 3

For use as a food ingredient, the 2'-FL produced by *E. coli* K-12 MAP1001d shall comply with the following requirements:

1. Specifications listed in the Appendix.
2. Can only be used for infant formula, follow-up infant formula and milk powder or similar products for children under 7 years old.
3. The maximum level of 2'-FL is 1.2 g/L in the final product ready for use marketed as such or reconstituted as instructed by the manufacturer.

4. The container or external packaging of 2'-FL produced by *E. coli* K-12 MAP1001d shall be displayed one of the following information: “The 2'-fucosyllactose is produced by genetically modified microorganism” or “The 2'-fucosyllactose is produced by genetically modified microorganism, but ultimately does not contain any genetically modified microorganism and its transgenes”.

Appendix

Specifications of the 2'-fucosyllactose produced by genetically modified *Escherichia coli* strain K-12 DH1 MDO MAP1001d

Chemical name:	α -L-fucopyranosyl-(1 \rightarrow 2)- β -D-galactopyranosyl-(1 \rightarrow 4)-D-glucopyranose
Chemical formula:	C ₁₈ H ₃₂ O ₁₅
Molecular weight:	488.44 g/mol
CAS No:	41263-94-9
Physical parameter:	2'-fucosyllactose is a white to off white powder

Purity

2'-fucosyllactose:	\geq 94%
D-Lactose:	\leq 3.0%
L-Fucose:	\leq 1.0%
Difucosyllactose:	\leq 1.0%
2'-Fucosyl-D-lactulose:	\leq 1.0%
Sum of 2'-fucosyllactose, D-lactose, L-fucose and Difucosyllactose:	\geq 96%

Genetically modified microorganisms detection:	Negative (Detected by real-time quantitative polymerase chain reaction, qPCR)
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pH (20°C, 5% solution):	3.2-5.0
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Water:	\leq 5.0%
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Acetic acid:	\leq 1.0%
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Sulphated ash:	\leq 1.5%
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Residual proteins:	\leq 0.01%
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Heavy Metals

Lead:	\leq 0.1 mg/kg
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