

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

MOHW Food No.1111302440, 20 September 2022

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 removal, 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 and follow-up 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: C₁₈H₃₂O₁₅

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)

pH (20°C, 5% solution): 3.2-5.0

Water: \leq 5.0%

Acetic acid: \leq 1.0%

Sulphated ash: \leq 1.5%

Residual proteins: \leq 0.01%

Heavy Metals

Lead: \leq 0.1 mg/kg