

# **Draft for The Use Restrictions and Labeling Requirements of 2'-fucosyllactose Produced by Genetically Modified *Escherichia coli* strain K-12 MG1655 INB000846 as a Food Ingredient**

MOHW Food No.1111303853, 9 February 2023

## *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 MG1655 INB000846. The 2'-FL powder can be purified from the fermentation broth via a sequence of purification steps including filtration, removing the antifoaming agents, electrodialysis, ion exchange chromatography, activated charcoal treatment, evaporation, crystallization, and spray 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 MG1655 INB000846 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 MG1655 INB000846 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”. Final products containing 2'-FL as one of its ingredients are exempted from this labeling requirement.

# Appendix

Specifications of the 2'-fucosyllactose produced by genetically modified *Escherichia coli* strain K-12 MG1655 INB000846

Chemical name:	$\alpha$ -L-fucopyranosyl-(1→2)- $\beta$ -D-galactopyranosyl-(1→4)-D-glucopyranose
Chemical formula:	C <sub>18</sub> H <sub>32</sub> O <sub>15</sub>
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:	≥ 94%
D-Lactose:	≤ 3.0%
L-Fucose:	≤ 2.0%
Difucosyllactose:	≤ 2.0%
2'-Fucosyl-D-lactulose:	≤ 1.5%
Sum of 2'-fucosyllactose, D-lactose, L-fucose and Difucosyllactose:	≥ 96%

Genetically modified microorganisms detection:	Negative (Detected by real-time quantitative polymerase chain reaction, qPCR)
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Water:	≤ 9.0%
Total ash:	≤ 0.5%
Residual proteins:	≤ 0.01%

## Heavy Metals

Lead:	≤ 0.05 mg/kg
Arsenic:	≤ 0.2 mg/kg