

**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.1101301211, 16 June 2021

*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 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:  $\alpha$ -L-fucopyranosyl-(1 $\rightarrow$ 2)- $\beta$ -D-galactopyranosyl-(1 $\rightarrow$ 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:  $\geq$  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