

**Draft Regulation for The Use Restrictions and Labeling
Requirement of 2'-fucosyllactose Produced by Genetically
Modified *Escherichia coli* strain BL21 (DE3) #1540 as a
Food Ingredient**

MOHW Food No.1091301423, 22 July 2020

Article 1

The regulations are 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 BL21 (DE3) #1540 (hereinafter referred to as “*E. coli* BL21 (DE3) #1540”). The 2'-FL liquid concentrate can be purified from the fermentation medium via a sequence of purification steps including cation and anion exchange chromatography, concentration, activated carbon treatment, filtration, electrodialysis etc. The 2'-FL powder is derived from the 2'-FL liquid concentrate by spray drying. The final 2'-FL liquid concentrate and 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* BL21 (DE3) #1540 shall comply with the following requirements:

1. Specifications listed in the Appendix.
2. Can only be used for infant formula and follow-up infant formula.
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*

BL21 (DE3) #1540 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 BL21 (DE3) #1540

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 and the liquid concentrate aqueous solution is a colourless to slight yellow clear aqueous solution

Purity

2'-fucosyllactose:	\geq 90%
Lactose:	\leq 5.0%
3-fucosyllactose:	\leq 5.0%
Difucosyllactose:	\leq 5.0%
Fucosylgalactose:	\leq 3.0%
Glucose:	\leq 3.0%
Galactose:	\leq 3.0%
Fucose:	\leq 3.0%
Genetically modified microorganisms detection:	Negative (Detected by real-time quantitative polymerase chain reaction, qPCR)
Water:	\leq 9.0% (powder)
Solids content:	45% w/v (\pm 5% w/v) (liquid)
Sulphated ash:	\leq 0.5%
Residual proteins:	\leq 0.01%

Heavy Metals

Lead:	\leq 0.02 mg/kg
Arsenic:	\leq 0.2 mg/kg
Cadmium:	\leq 0.1 mg/kg
Mercury:	\leq 0.5 mg/kg

* Specifications listed in this appendix apply to concentrated liquid and powder except for those specifically indicated applicable type.