

**Regulation for The Use Restrictions and Labeling
Requirements of Astaxanthin Produced by Genetically
Modified *Escherichia coli* strain Ast12 as a Food Ingredient**

MOHW Food No.1101300104, 11 March 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 astaxanthin referred to herein is produced by genetically modified *Escherichia coli* strain Ast12 (hereinafter referred to as “The astaxanthin produced by *E. coli* Ast12”). The manufacturing process includes the following steps: fermentation to obtain astaxanthin-rich microbial biomass, sterilization of the fermentation broth, centrifugation, drying, extraction of astaxanthin from microbial biomass by ethyl acetate, filtration to separate and remove microbial biomass, crystallization of astaxanthin by ethanol. The final pure crystallized astaxanthin shall not contain any genetically modified microorganism (*E. coli* Ast12) and its transgenes.

Article 3

For use as a food ingredient, the astaxanthin produced by *E. coli* Ast12 shall comply with the following requirements:

1. Specifications listed in the Appendix.
2. The daily intake of the astaxanthin shall not exceed 2 mg.
3. The container or external packaging of the astaxanthin produced by *E. coli* Ast12 shall be displayed one of the following information: “The astaxanthin is produced by genetically modified microorganism” or

“The astaxanthin is produced by genetically modified microorganism, but ultimately does not contain any genetically modified microorganism and its transgenes”.

Article 4

The labelling of food products containing the astaxanthin produced by *E. coli* Ast12 shall bear the following warning statement: Children under twelve years old, pregnant women, lactating women and people taking drugs for hepatic or metabolic diseases shall avoid consuming.

Appendix

Specifications of the astaxanthin produced by genetically modified *Escherichia coli* strain Ast12

Chemical name	: 3,3'-dihydroxy- β,β -carotene-4,4'-dione
Chemical formula	: C ₄₀ H ₅₂ O ₄
Molecular weight	: 596.84 g/mol
CAS No.	: 472-61-7
Appearance	: Violet brown powder
Total carotenoids	: \geq 95%
Astaxanthin	: \geq 80%
Genetically Modified Microorganisms detection	: Negative (detected by Real-Time Quantitative Polymerase Chain Reaction, qPCR)
Loss on drying	: \leq 0.1%
Lead	: \leq 2 mg/kg
Arsenic	: \leq 3 mg/kg
Heavy metal (as Pb)	: \leq 10 mg/kg