

Use Restrictions and Labeling Requirements of *trans*-Resveratrol Produced by Genetically Modified *Saccharomyces cerevisiae* Strain EFSC4687 as a Food Ingredient

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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 *trans*-resveratrol referred to herein is produced by fermentation process using genetically modified *Saccharomyces cerevisiae* strain EFSC4687. The *trans*-resveratrol powder can be purified from the fermentation via a sequence of purification steps including ultrafiltration, washing with water, pH adjustment with sodium hydroxide, diafiltration, precipitation with sulfuric acid, concentration, filtration, dissolution with ethanol, anion-exchange resin, carbon treatment, crystallization with water, filtration and drying etc. The final *trans*-resveratrol powder shall not contain any genetically modified microorganism and its transgenes.

Article 3

For use as a food ingredient, the *trans*-resveratrol produced by *S. cerevisiae* strain EFSC4687 shall comply with the following requirements:

1. Specifications listed in the Appendix.
2. Can only be used for food supplements intended for adult population, and the daily intake shall not exceed 150 mg.
3. The container or external packaging of *trans*-resveratrol produced by *S. cerevisiae* strain EFSC4687 shall be displayed one of the following

information: “The *trans*-resveratrol is produced by genetically modified microorganism” or “The *trans*-resveratrol is produced by genetically modified microorganism, but ultimately does not contain any genetically modified microorganism and its transgenes”. Final products containing *trans*-resveratrol as one of its ingredients are exempted from this labeling requirement.

Article 4

The labelling of food products containing the *trans*-resveratrol shall bear the following warning statements: This product can only be used for adult population, pregnant women and lactating women shall avoid consuming. People using medicines shall only consume the product under medical supervision.

Appendix

Specifications of the *trans*-resveratrol produced by genetically modified *Saccharomyces cerevisiae* strain EFSC4687

Chemical name: 5-[(E)-2-(4-hydroxyphenyl)ethenyl]benzene-1,3-diol

Chemical formula: C₁₄H₁₂O₃

Molecular weight: 228.25 Da

CAS No: 501-36-0

Appearance: Off-white to slight yellow powder

Purity

trans-resveratrol: $\geq 98\%$ (dry weight basis)

Genetically modified microorganisms and their transgenes detection: Negative (Detected by polymerase chain reaction, PCR)

Ash: $\leq 0.5\%$

Water: $\leq 3.0\%$

Heavy Metals

Lead: < 1 ppm

Arsenic: < 1.5 ppm

Cadmium: < 1 ppm

Mercury: < 0.1 ppm