

**Regulation for The Use Restriction and Labeling
Requirement of the *Ganoderma microsporum* Globulin-like
Protein Concentrate Produced by Genetically Modified
Pichia pastoris Ey72 as a Food Ingredient**

MOHW Food No.1111300075, 16 February 2022

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 *Ganoderma microsporum* globulin-like protein concentrate referred to herein is produced by fermentation process using genetically modified *Pichia pastoris* Ey72. The fermentation broth is concentrated via sequential steps including membrane filtration, concentration, membrane separation, mixing with water, sodium chloride and legal food additives, sterile filtration etc. The final *Ganoderma microsporum* globulin-like protein concentrate shall not contain any genetically modified microorganism and its transgenes.

Article 3

For use as a food ingredient, the *Ganoderma microsporum* globulin-like protein concentrate produced by *Pichia pastoris* Ey72 shall comply with the following requirements:

1. The detection result of genetically modified microorganism and its transgenes by real-time quantitative polymerase chain reaction (qPCR) shall be negative.
2. The content of the *Ganoderma microsporum* globulin-like protein shall be 5.5 ± 1.5 mg/mL.
3. The daily intake of the *Ganoderma microsporum* globulin-like protein

shall not exceed 6 mg.

4. The container or external packaging of the *Ganoderma microsporum* globulin-like protein concentrate produced by *Pichia pastoris* Ey72 shall be displayed one of the following information: “The *Ganoderma microsporum* globulin-like protein concentrate is produced by genetically modified microorganism” or “The *Ganoderma microsporum* globulin-like protein concentrate is produced by genetically modified microorganism, but ultimately does not contain any genetically modified microorganism and its transgenes”. Final products containing the protein concentrate as one of its ingredients are exempted from this labeling requirement.

Article 4

The labelling of food products containing the *Ganoderma microsporum* globulin-like protein concentrate produced by *Pichia pastoris* Ey72 shall bear the following warning statement: Children under twelve years old, pregnant women, lactating women and people with allergies shall avoid consuming.