

**Draft 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.1101301978, 15 September 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 *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”.

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.