

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2535**of 21 December 2022****authorising the placing on the market of the freeze-dried powder form of *Antrodia camphorata* mycelia as a novel food and amending Implementing Regulation (EU) 2017/2470****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 12(1) thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ has established a Union list of novel foods.
- (3) On 5 November 2018, the company Golden Biotechnology Corp ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place freeze-dried powder form of *Antrodia camphorata* mycelia on the Union market as a novel food. The applicant requested for freeze-dried powder form of *Antrodia camphorata* mycelia to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ⁽³⁾ at a maximum dose of 990 mg per day, for the general population.
- (4) On 12 May 2020, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of the freeze-dried powder form of *Antrodia camphorata* mycelia as a novel food.
- (5) On 18 May 2022, the Authority adopted its scientific opinion on the 'Safety of freeze-dried mycelia of *Antrodia camphorata* as a novel food pursuant to Regulation (EU) 2015/2283' ⁽⁴⁾ in accordance with Article 11 of Regulation (EU) 2015/2283.
- (6) In its scientific opinion, the Authority concluded that the freeze-dried mycelia of *Antrodia camphorata* were safe for adults and adolescents above 14 years old when added to food supplements at a maximum daily dose of 990 mg/day. However, the Authority has not established the safety of the novel food in food supplements intended for individuals younger than 14 years at the maximum intake level of 990 mg/day as proposed by the applicant, because the intake would exceed the safe level (16,5 mg/kg bw per day) established by the Authority. Therefore, the opinion of the Authority gives sufficient grounds to establish that the freeze-dried mycelia of *Antrodia camphorata*, when used at a maximum daily dose of 990 mg/day in food supplements, intended for individuals aged 14 years and above, fulfil the conditions for their placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

⁽³⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

⁽⁴⁾ EFSA Journal 2022; 20(6):7380.

- (7) In its scientific opinion, the Authority considers that although there is no evidence available of an allergenicity risk, given the protein content of the novel food, some risk cannot be excluded. A literature search performed by the applicant did not identify any published evidence concerning the allergenic potential of *Antrrodia camphorata*, and other information or data normally needed to confirm or exclude the potential risk of allergenicity, is lacking. The Commission however, considers that at present, the potential of *Antrrodia camphorata* mycelia powder to cause allergenicity is unlikely to manifest itself in real life and consequently no specific labelling requirement should be included in the Union list of novel foods in this regard.
- (8) A clear designation of the novel food and a labelling requirement should be laid down for food supplements containing freeze-dried powder form of *Antrrodia camphorata* mycelia, in order to ensure that those food supplements are not consumed by children and adolescents of less than 14 years of age.
- (9) It is therefore appropriate that the inclusion of freeze-dried powder form of *Antrrodia camphorata* mycelia as a novel food in the Union list of novel foods contains the information referred to in Article 9 of Regulation (EU) 2015/2283.
- (10) The freeze-dried powder form of *Antrrodia camphorata* mycelia should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

1. The freeze-dried powder form of *Antrrodia camphorata* mycelia is authorised to be placed on the market within the Union.

The freeze-dried powder form of *Antrrodia camphorata* mycelia shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

2. The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in *the Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 21 December 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
' <i>Antrodia camphorata</i> mycelia powder	<i>Specified food category</i>	<i>Maximum levels</i>	1. The designation of the novel food on the labelling of food supplements containing it shall be ' <i>Antrodia camphorata</i> mycelia powder'. 2. The labelling of the food supplements containing <i>Antrodia camphorata</i> mycelia powder shall bear a statement that this food supplement should not be consumed by infants, children, and adolescents younger than 14 years of age.'	
	Food supplements as defined in Directive 2002/46/EC, excluding infants, children, and adolescents younger than 14 years of age	990 mg/day		

(2) in Table 2 (Specifications), the following entry is inserted:

Authorised novel food	Specification
' <i>Antrodia camphorata</i> mycelia powder	<p>Description/Definition: The novel food is the freeze-dried mycelia of the fungus <i>Antrodia camphorata</i> (strain BCRC 39106), which has been grown by solid-state cultivation. The freeze-dried mycelia are then milled into a powder. <i>Antrodia camphorata</i> is a synonym of <i>Taiwanofungus camphoratus</i> (family: Fomitopsidaceae).</p> <p>Characteristics/Composition: Loss on drying (Moisture): < 10 % Carbohydrates: ≤ 80 g/100 g Protein: ≤ 20 g/100 g Ash: ≤ 6 g/100g Fat: ≤ 6 g/100 g Total triterpenoids: 1,0 – 10,0 g/100 g Antroquinonol: 1,0 – 20,0 mg/g</p> <p>Heavy metals: Arsenic: < 0,5 mg/kg</p> <p>Microbiological criteria: Total aerobic microbial count: ≤ 10³ CFU/g Total yeast and mould count: ≤ 100 CFU/g <i>Escherichia coli</i>: Not detected in 10 g <i>Salmonella</i> spp.: Not detected in 25 g <i>Staphylococcus aureus</i>: Not detected in 10 g *CFU: Colony Forming Units'</p>