

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

authorising the placing on the market of freeze-dried mycelia of *Antrodia camphorata* as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission 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 1852/2001¹, and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470² 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 mycelia of *Antrodia camphorata* on the Union market as a novel food. The application requested for freeze-dried mycelia of *Antrodia camphorata* to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council³ 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 for freeze-dried mycelia of *Antrodia camphorata* as a novel food.

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).

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- (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 did not establish the safety of freeze-dried mycelia of *Antrodia camphorata* used 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 level which is considered safe (16.5 mg/kg bw per day). However, the Authority concluded that freeze-dried mycelia of *Antrodia camphorata* is safe for adults and adolescents above 14 years old when added to food supplements at a maximum daily dose of 990 mg/day. Therefore, the opinion of the Authority gives sufficient grounds to establish that freeze-dried mycelia of *Antrodia camphorata*, when used at a maximum daily dose of 990 mg/day in food supplements as defined in Directive 2002/46/EC intended for individuals aged 14 years and above, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (7) The Authority in its opinion, using a weight of evidence approach on the basis of the protein content in the novel food, and the results of a literature search performed by the applicant where no publications concerning the allergenic potential of *Antrodia camphorata* were identified, considers that there is no sufficient basis to conclude on the risk of allergenicity although some risk cannot be excluded, given the protein content. However, additional *in vivo* experimental or epidemiological evidence normally needed to confirm or exclude the likelihood that the identified potential risk of allergenicity may manifest itself in real life, is lacking. In view of the lack of such evidence, the Commission considers that at present the potential of *Antrodia camphorata* 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 authorised 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 mycelia of *Antrodia camphorata*, in order to ensure that those food supplements are not consumed by children and adolescents aged less than 14 years of age.
- (9) It is appropriate that the inclusion of freeze-dried mycelia of *Antrodia camphorata* as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283.
- (10) Freeze-dried mycelia of *Antrodia camphorata* 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,

⁴ EFSA Journal 2022; 20(6):7380.

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HAS ADOPTED THIS REGULATION:

Article 1

1. Freeze-dried mycelia of *Antrodia camphorata* is authorised to be placed on the market within the Union.
Freeze-dried mycelia of *Antrodia camphorata* 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,

For the Commission
The President
Ursula VON DER LEYEN