

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 *Lemna minor* and *Lemna gibba* whole plant material 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 1852/2001¹, 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) 2017/2470² has established a Union list of novel foods.
- (3) On 20 Mayⁱ 2020, the company Wageningen Plant Research ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place *Lemna minor* and *Lemna gibba* whole plant material on the Union market as a novel food. The applicant requested for the novel food to be used as such, cooked or added to ready-to-eat products for the general population.
- (4) On 20 Mai 2020, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of *Lemna minor* and *Lemna gibba* whole plant material as a novel food.
- (5) On 28 September 2022, the Authority adopted its scientific opinion on the 'Safety of *Lemna minor* and *Lemna gibba* whole plant material as a novel food pursuant to

¹ OJ L 327, 11.12.2015, p. 1, ELI: <http://data.europa.eu/eli/reg/2015/2283/oj>.

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, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).

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Regulation (EU) 2015/2283³ in accordance with Article 11 of Regulation (EU) 2015/2283.

- (6) In its scientific opinion, the Authority concluded that the novel food, contains higher amounts of manganese as compared to the normally present concentration of manganese in other leafy vegetables, which may be of safety concern. Therefore, the safety of the novel food could not be established.
- (7) Following the adoption of the scientific opinion, the applicant has requested to the Commission the possibility to address the safety concerns emphasised by the Authority in its conclusion by providing additional information showing that by reducing the manganese concentrations in the cultivation medium, the manganese content in *Lemna gibba* does not exceed the manganese content in leafy vegetables. ~~The report also indicates that as both species of *Lemna* display similar manganese contents, it is considered reasonable to assume that under the newly applied cultivation conditions, an equivalent reduction in manganese content as obtained in *Lemna gibba* can be achieved in *Lemna minor*.~~
- (8) On 30 April 2024, the Commission requested the Authority for scientific and technical assistance with respect to the EFSA scientific opinion on “Safety of *Lemna minor* and *Lemna gibba* whole plant material as a novel food pursuant to Regulation (EU) 2015/2283”, in order to further evaluate whether the additional information provided by the applicant addresses the concerns related to the manganese intake.
- (9) On 10 July 2024, the Authority adopted the “Scientific and technical assistance report on the evaluation of the safety of *Lemna gibba* and *Lemna minor* whole plant material as a novel food”⁴. In its report, the Authority noted that the content of manganese in *Lemna gibba* was reduced to a level of 6 mg/kg fresh weight (FW), which is comparable to spinaches which were found to have the highest content of manganese among leafy vegetables, with levels up to 9 mg/kg in FW. Thus, the Authority concluded that the contents of manganese in the novel food have been reduced to levels not exceeding those in other leafy vegetables. The report also indicates that as both species of *Lemna* display similar manganese contents, it is considered reasonable to assume that under the newly applied cultivation conditions, an equivalent reduction in manganese content as obtained in *Lemna gibba* can be achieved in *Lemna minor*.
- (10) On that basis, the Commission considers that the scientific opinion and the technical report give sufficient grounds to establish that *Lemna gibba* and *Lemna minor* whole plant material fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (11) It is appropriate that the inclusion of *Lemna minor* and *Lemna gibba* whole plant material 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.

³ EFSA Journal 2022;20(11):7598.

⁴ <https://doi.org/10.2903/sp.efsa.2024.EN-8963>

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- (12) *Lemna minor* and *Lemna gibba* whole plant material 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.
- (13) 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. *Lemna minor* and *Lemna gibba* whole plant material is authorised to be placed on the market within the Union.

Lemna minor and *Lemna gibba* whole plant material 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 Luxembourg,

For the Commission
The President
Ursula VON DER LEYEN