Official Journal
of the European Union

EN
L series

2024/1048

10.4.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/1048

of 9 April 2024

authorising the placing on the market of protein concentrate from *Lemna gibba* and *Lemna minor* 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 28 December 2018, the company ABC Kroos BV ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place protein concentrate from *Lemna gibba* and *Lemna minor* on the Union market as a novel food. The applicant requested for the novel food to be used as a food in powdered drink bases, cereal bars, bread and rolls, noodles for the general population and in food supplements, as defined in Directive 2002/46/EC of the European Parliament and of the Council ([3]), for the adult population only.

(4) On 28 December 2018, the applicant also made a request to the Commission for the protection of the following proprietary data: compositional data ([4]), stability data ([5]), an ileal digestion analysis ([6]), a proteomic analysis ([7]), endophytic bacteria screening analyses ([8]), a bacterial reverse mutation test ([9]) and an *in vitro* micronucleus test ([10]).

(5) On 13 May 2021, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of protein concentrate from *Lemna gibba* and *Lemna minor* as a novel food.

(6) On 28 February 2023, the Authority adopted its scientific opinion on the 'Safety of water lentil protein concentrate from a mixture of *Lemna gibba* and *Lemna minor* as a novel food pursuant to Regulation (EU) 2015/2283' ([11]) in accordance with Article 11 of Regulation (EU) 2015/2283.

([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).
([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, ELI: http://data.europa.eu/eli/dir/2002/46/2022-09-30).
([4]) Sections 2.4.3 and 2.9; Section 2.11 (pp. 76–78); Appendix D2, D3, D4, D5, D6, D7.
([5]) Section 2.4.4; Appendix D1, D8, D9, D10, D17.
([6]) Sections 2.8 and 2.9 (p. 65, 68), Appendix B4 and D11.
([7]) Appendix D12.
([8]) Appendix D20, D22, D23, D24.
([9]) Appendix D26.
([10]) Appendix D27.
([11]) *EFSA Journal* 2023;21(4):7903.

(7) In its scientific opinion, the Authority concluded that the novel food, protein concentrate from *Lemna gibba* and *Lemna minor*, is safe under the proposed conditions of use. Therefore, that scientific opinion gives sufficient grounds to establish that protein concentrate from *Lemna gibba* and *Lemna minor*, under the proposed conditions of use, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.

(8) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on the compositional data, stability data, the ileal digestion analysis, the proteomic analysis, the endophytic bacteria screening analyses, the bacterial reverse mutation test and the *in vitro* micronucleus test, without which it could not have assessed the novel food and reached its conclusion.

(9) It is appropriate that the inclusion of protein concentrate from *Lemna gibba* and *Lemna minor* in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283. In this regard, in line with the conditions of use of food supplements containing protein concentrate from *Lemna gibba* and *Lemna minor* as proposed by the applicant and assessed by the Authority, it is necessary to inform consumers through the use of appropriate labelling that food supplements containing protein concentrate from *Lemna gibba* and *Lemna minor* should only be consumed by adults. The Authority in its opinion also noted that intake of the novel food may lead to intake of phylloquinone (vitamin K_1) up to 480 µg/day for adults (160 µg/day from food supplements) and may constitute a risk for patients on anticoagulant medication. Therefore, where the final product contains a quantity of vitamin K that is considered significant in accordance with point 2 of Part A of Annex XIII to Regulation (EU) No 1169/2011 of the European Parliament and of the Council ([12]), the nutrition declaration shall indicate the quantity of vitamin K.

(10) The Commission requested the applicant to further clarify the justification provided with regard to its proprietary claim over those data and studies and to clarify their claim to an exclusive right of reference to them in accordance with Article 26(2)(b) of Regulation (EU) 2015/2283.

(11) The applicant declared that it held proprietary and exclusive rights of reference to the compositional data, stability data, the ileal digestion analysis, the proteomic analysis, the endophytic bacteria screening analyses, the bacterial reverse mutation test and the *in vitro* micronucleus test at the time it submitted the application, and that third parties cannot lawfully access, use or refer to those data.

(12) The Commission assessed all the information provided by the applicant and considered that it has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the compositional data, the stability data, the ileal digestion analysis, the proteomic analysis, the endophytic bacteria screening analyses, the bacterial reverse mutation test and the *in vitro* micronucleus test should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place protein concentrate from *Lemna gibba* and *Lemna minor* on the market within the Union during a period of five years from the entry into force of this Regulation.

(13) However, restricting the authorisation of protein concentrate from *Lemna gibba* and *Lemna minor* and the reference to the data contained in the applicant's file for their sole use does not prevent subsequent applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting such an authorisation.

(14) Protein concentrate from *Lemna gibba* and *Lemna minor* 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.

([12]) Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18, ELI: http://data.europa.eu/eli/reg/2011/1169/2018-01-01).

(15) 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. Protein concentrate from *Lemna gibba* and *Lemna minor* is authorised to be placed on the market within the Union.

Protein concentrate from *Lemna gibba* and *Lemna minor* 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

Only the company ABC Kroos BV ([13]) is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of 5 years from 30 April 2024, unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of ABC Kroos BV.

Article 3

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of 5 years from the date of entry into force of this Regulation without the agreement of ABC Kroos BV.

Article 4

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, 9 April 2024.

For the Commission
The President
Ursula VON DER LEYEN

([13]) Drosteweg 8, 8101 NB Raalte, NETHERLANDS.

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	Data protection
'**Protein concentrate from *Lemna gibba* and *Lemna minor*** **Specified food category**	**Maximum levels**		1. The designation of the novel food on the labelling of the foodstuffs containing it shall be "protein concentrate from the *Lemna gibba* and *Lemna minor* plants" or "protein concentrate from the *Lemna gibba* plant" depending on the presence of *Lemna minor*. 2. Where foods containing the novel food include an amount of vitamin K that is considered significant in accordance with point 2 of Part A of Annex XIII to Regulation (EU) No 1169/2011, the nutrition declaration shall indicate the amount of vitamin K.		Authorised on 30 April 2024. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: ABC Kroos BV, Drosteweg 8, 8101 NB Raalte, NETHERLANDS. During the period of data protection, the novel food protein concentrate from *Lemna gibba* and *Lemna minor* is authorised for placing on the market within the Union only by ABC Kroos BV, unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of ABC Kroos BV. End date of the date protection: 30 April 2029.'
	Cereal bars	10 g/100 g			
	Prepacked bread and rolls	1,7 g/100 g			
	Powdered drink mixes	20 g/100 g			
	Noodles	6 g/100 g			
	Food supplements as defined in Directive 2002/46/EC for the adult population	1 g/day	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be "protein concentrate from the *Lemna gibba* and *Lemna minor* plants" or "protein concentrate from *Lemna gibba* plant" depending on the presence of *Lemna minor*.		

ELI: http://data.europa.eu/eli/reg_impl/2024/1048/oj

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
			2. The labelling of food supplements containing the novel food shall bear a statement that they should only be consumed by adults. 3. Where food supplements containing the novel food include an amount of vitamin K that is considered significant in accordance with point 2 of Part A of Annex XIII to Regulation (EU) No 1169/2011 and Article 8 of Directive 2002/46/EC, the labelling of food supplements containing novel food shall indicate the amount of vitamin K.		

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

Authorised Novel Food	Specification
'**Protein concentrate from *Lemna gibba* and *Lemna minor***	**Description/Definition:** The novel food is a protein concentrate produced from the *Lemna gibba* (70–100 %) and *Lemna minor* (0–30 %) plant species. The manufacturing process of the protein concentrate involves mechanical separation of the protein fraction from insoluble fibres, followed by precipitation under acidic conditions, pasteurisation and spray drying. The cultivation is carried out in basins in greenhouses under controlled conditions. The water used for the cultivation is filtered and UV-treated. The cultivation conditions are monitored to control the growth of algae, yeast and fungi. The pH is maintained between 5,5 and 6,5. **Characteristics/composition:** Appearance: green powder Moisture: 1,5-8 % Protein (Nx6,25): 60-75 % Ash: 4-12 % Fat: 2-11 % Fibre: 6-17 % Ash: 4-12 % Vitamins: β-Carotene: < 755 mg/kg Vitamin K_1 (Phylloquinone): < 16 mg/100 g Minerals: Boron: < 10 mg/kg Copper: < 12 mg/kg Molybdenum: < 40 mg/kg Iron: < 670 mg/kg Zinc: < 50 mg/kg Manganese: < 100 mg/kg **Antinutritional factors:** Oxalic acid: < 1 900 mg/kg

Authorised Novel Food	Specification
	Heavy metals: Lead (mg/kg): ≤ 0,3 Cadmium (mg/kg): ≤ 0,2 Mercury (mg/kg): ≤ 0,1 Arsenic (mg/kg): ≤ 0,2 Cyanotoxins: Microcystins-/Nodularin: < 0,19 mg/kg **Other contaminants:** Lysino-alanine (bound): < 500 mg/kg Lysino-alanine (free): < 10 mg/kg Nitrate: < 3 000 mg/kg **Pesticides:** Pesticide levels in accordance with Code number 0254000 (“Subgroup (d) watercresses” in the group of Leaf vegetables, herbs and edible flowers) set out in Regulation (EC) No 396/2005. **Microbiological criteria:** Total colony count: < 10^4 CFU/g *Bacillus cereus*: < 100 CFU/g *Clostridium perfringens*: < 100 CFU/g Coagulase-positive Staphylococci: < 100 CFU/g *Escherichia coli*: < 10 CFU/g *Enterobacteriaceae*: < 10 CFU/g *Listeria monocytogenes*: Not detected in 25 g *Salmonella* spp.: Not detected in 25 g Yeasts and moulds: < 10 CFU/g

CFU: colony forming units.’.