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⁽¹⁾ Text with EEA relevance.

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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2191

of 10 December 2021

authorising the placing on the market of fresh plants of *Wolffia arrhiza* and/or *Wolffia globosa* as a traditional food from a third country 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 and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 15(4) 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. Traditional food from a third country is a novel food defined in Article 3(2)(c) of Regulation (EU) 2015/2283.
- (2) Commission Implementing Regulation (EU) 2017/2468 ⁽²⁾ lays down administrative and scientific requirements concerning traditional foods from third countries.
- (3) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽³⁾ establishing a Union list of authorised novel foods was adopted.
- (4) On 7 September 2020, the company GreenOnyx Ltd ('the applicant') submitted a notification to the Commission of their intention to place fresh plants of *Wolffia arrhiza* and *Wolffia globosa* on the Union market as a traditional food from a third country in accordance with Article 14 of Regulation (EU) 2015/2283. The applicant requested that the fresh plants of *Wolffia arrhiza* and *Wolffia globosa* be used as such by the general population.
- (5) Pursuant to Article 7(2) of Implementing Regulation (EU) 2017/2468, the Commission requested additional information from the applicant as regards the requirements for validity of the notification. The requested information was submitted on 16 October 2020.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017 laying down administrative and scientific requirements concerning traditional foods from third countries 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. 55).

⁽³⁾ 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).

- (6) The data presented by the applicant demonstrate that fresh plants of *Wolffia arrhiza* and/or of *Wolffia globosa* as such have a history of safe food use in Southeast Asia, in particular in Laos, Myanmar and Thailand.
- (7) Pursuant to Article 15(1) of Regulation (EU) 2015/2283, on 20 January 2021, the Commission forwarded the valid notification to the Member States and to the European Food Safety Authority ('the Authority').
- (8) No duly reasoned safety objections to the placing on the market within the Union of fresh plants of *Wolffia arrhiza* and *Wolffia globosa* were submitted to the Commission by the Member States or the Authority within the 4-month period laid down in Article 15(2) of Regulation (EU) 2015/2283.
- (9) On 30 June 2021, the Authority published its 'Technical Report on the notification of fresh plants of *Wolffia arrhiza* and *Wolffia globosa* as a traditional food from a third country pursuant to Article 14 of Regulation (EU) 2015/2283' ⁽⁴⁾. The Authority concluded that the available data on the composition and the history of use of the fresh plants of *Wolffia arrhiza* and *Wolffia globosa* and the data provided on the traditional food cultivated under the conditions of vertical farming as described in the notification do not raise safety concerns.
- (10) In that report, the Authority noted that the safety of the fresh plants of *Wolffia arrhiza* and *Wolffia globosa* is strongly influenced by the environmental conditions of the waters where these plants are grown. Therefore, the presence of heavy metals and microcystins in these fresh plants cannot be excluded. Moreover, certain levels of some trace elements contained therein, such as copper, molybdenum, zinc, boron and manganese, which may be due to the use of fertilisers in the cultivation of fresh plants of *Wolffia arrhiza* and *Wolffia globosa* may pose a safety concern for human health. It is therefore appropriate to establish maximum levels of heavy metals, microcystins, copper, molybdenum, zinc, boron and manganese in the specifications of this traditional food in the Union list of authorised novel foods.
- (11) The Commission should therefore authorise the placing on the market within the Union of fresh plants of *Wolffia arrhiza* and/or of *Wolffia globosa* as such and update the Union list of authorised novel foods accordingly.
- (12) Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

1. The fresh plants of *Wolffia arrhiza* and/or of *Wolffia globosa*, as specified in the Annex to this Regulation, shall be included as a traditional food from a third country in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.
2. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and specifications laid down in the Annex to this Regulation.

Article 2

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

Article 3

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

⁽⁴⁾ EFSA Supporting Publications, <https://doi.org/10.2903/sp.efsa.2021.EN-6658>

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

Done at Brussels, 10 December 2021.

For the Commission
The President
Ursula VON DER LEYEN

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

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

'Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	Specified food category	Maximum levels		
<i>Wolffia arrhiza</i> and/or <i>Wolffia globosa</i> fresh plants (Traditional food from a third country)	<i>Wolffia arrhiza</i> and/or <i>Wolffia globosa</i> fresh plants as such		The designation of the novel food on the labelling of the foodstuffs containing it shall be “ <i>Wolffia arrhiza</i> and <i>Wolffia globosa</i> ” or “ <i>Wolffia arrhiza</i> ” or “ <i>Wolffia globosa</i> ” depending on the plant used.’	

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

'Authorised Novel Food	Specifications
<i>Wolffia arrhiza</i> and/or <i>Wolffia globosa</i> fresh plants (Traditional food from a third country)	Description/Definition: The traditional food consists of fresh plants of <i>Wolffia arrhiza</i> (L.) Horkel ex Wimm. and/or of <i>Wolffia globosa</i> (Roxb.) Hartog & Plas (family: Araceae). Microbiological criteria: Total plate count: < 10³ CFU/g Total yeast and mould count: < 100 CFU/g Total Enterobacteriaceae: < 100 CFU/g <i>Escherichia coli</i>: < 100 CFU/g <i>Salmonella</i>: Absence in 25 g <i>Listeria monocytogenes</i>: Absence in 25 g <i>Staphylococcus aureus</i>: Absence/10 g Heavy metals: Lead: < 0,3 mg/kg Arsenic (inorganic): < 0,10 mg/kg Cadmium: < 0,2 mg/kg Chromium: < 1 mg/kg Mercury: < 0,10 mg/kg Trace elements: Copper: < 0,8 mg/kg Molybdenum: < 0,3 mg/kg

Zinc: < 5 mg/kg
Boron: < 5 mg/kg
Manganese: < 6 mg/kg

Cyanotoxins:

Microcystins: 0,006 µg/g

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 ⁽¹⁾.

⁽¹⁾ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

^(*) CFU: Colony Forming Units.'

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