

# 2024/2047

## COMMISSION IMPLEMENTING REGULATION (EU) 2024/2047

## of 29 July 2024

authorising the placing on the market of seeds and seed flour of *Vigna subterranea* (L.) Verdc. as a traditional food from a third country 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 (<sup>1</sup>), and in particular Article 15(4) thereof,

Whereas:

- 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. On the basis of the definition set out in Article 3(2)(c) of Regulation (EU) 2015/2283, traditional food from a third country is considered a novel food.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 (<sup>2</sup>) has established a Union list of novel foods.
- (3) On 10 October 2019, the company WhatIF F&I Pte Ltd ('the applicant') submitted a notification to the Commission in accordance with Article 14 of Regulation (EU) 2015/2283 of their intention to place seeds and seed flour of *Vigna subterranea* (L.) Verdc. on the Union market as a traditional food from a third country. The applicant requested that the food concerned be used as such (cooked seeds) or as flour and it is intended for the general population.
- (4) The notification complies with the requirements laid down in Article 14 of Regulation (EU) 2015/2283. In particular, the data presented by the applicant demonstrate that the seeds and seed flour of *Vigna subterranea* (L.) Verdc. have a history of safe food use in Africa.
- (5) Pursuant to Article 15(1) of Regulation (EU) 2015/2283, on 14 September 2023, the Commission forwarded the valid notification to the Member States and to the European Food Safety Authority ('the Authority').
- (6) No duly reasoned safety objections to the placing on the market within the Union of the food concerned were submitted to the Commission by the Member States or the Authority within the period set in Article 15(2) of Regulation (EU) 2015/2283.
- (7) On 29 January 2024 the Authority published its 'Technical Report on the notification of dried seeds and flour thereof of Vigna subterranea (L.) Verdc. as a traditional food from a third country pursuant to Article 14 of Regulation (EU) 2015/2283 (<sup>3</sup>)'. In that report, the Authority concluded that the available data on the composition and the history of the requested use of seeds and seed flour of Vigna subterranea (L.) Verdc. do not raise safety concerns.

<sup>(1)</sup> OJ L 327, 11.12.2015, p. 1.

 <sup>(&</sup>lt;sup>2</sup>) 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).
 (<sup>3</sup>) EFSA Supporting publication 2024:EN-8571.

<sup>()</sup> Elorioupporting publication 202 her( 0)/ 1.

- (8) The Commission should therefore authorise the placing on the market within the Union of seeds and seed flour of *Vigna subterranea* (L.) Verdc. as a traditional food from a third country and update the Union list of novel foods accordingly.
- (9) In its report, the Authority noted that allergic reactions may be expected after the consumption of the traditional food especially in individuals sensitised to peanuts and soybeans. The Authority in its report also noted that the dried seeds should be subjected to soaking and boiling before consumption like other dried legumes. Therefore, it is appropriate that seeds and seed flour of *Vigna subterranea* (L.) Verdc. made available to the consumers are appropriately labelled following the requirements of Article 9 of Regulation (EU) 2015/2283.
- (10) Seeds and seed flour of Vigna subterranea (L.) Verdc. should be included as a traditional food from a third country 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,

HAS ADOPTED THIS REGULATION:

Article 1

1. Seeds and seed flour of Vigna subterranea (L.) Verdc. is authorised to be placed on the market within the Union.

Seeds and seed flour of *Vigna subterranea* (L.) Verdc. shall be included as a traditional food from a third country 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, 29 July 2024.

For the Commission The President Ursula VON DER LEYEN

OJ L, 30.7.2024

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
"Seeds and seed flour of	Specified food category	Maximum levels		The designation of the novel food on the labelling of the foodstuffs	
Vigna subterranea (L.) Verdc. (traditional food from a third country)	Not specified		2.	<ul> <li>containing it shall be</li> <li>'Bambara (<i>Vigna subterranea</i>) seeds/nut/bean/groundnut'</li> <li>or</li> <li>'Bambara (<i>Vigna subterranean</i>) seed/nut/bean/groundnut flour' depending on the form used.</li> <li>The labelling of the foodstuffs containing the traditional food shall bear a statement that the seeds and the seed flour of <i>Vigna subterranea</i> may cause allergic reactions to consumers with known allergies to peanuts and soybeans. This statement shall appear in close proximity to the list of ingredients or, in the absence of a list of ingredients, in close proximity to the name of the food.</li> <li>When the seeds are sold uncooked, the labelling shall bear a statement that they should be soaked and boiled before consumption."</li> </ul>	

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

Authorised Novel Food	Specification		
"Seeds and seed flour of Vigna sub- terranea (L.) Verdc. (traditional food from a third country)	<b>Description/Definition:</b> The traditional food consists of de-shelled whole dried seeds of <i>Vigna subterranea</i> (L.) Verdc. [Family: Fabaceae (alt. Leguminosae)] or the flour obtained by several steps, including heat treatment and milling of the seeds. Synonyms: <i>Cryptolobus subterraneus</i> (L.) Spreng., <i>Glycine subterranea</i> L., <i>Tetrodea subterranea</i> (L.) Raf., <i>Voandzeia subterranea</i> (L.) Thouars. Common names: Bambara groundnut, Bambara nut, Bambara bean, Bambara pea, Nyimo bean.		

#### Dried seeds Typical composition range:

Moisture: 7-11 % Protein : > 15 % Carbohydrates: 32-65 % Sugar: < 6,0 % Fat: 4-7 % Fiber: 7-31 %

#### Heavy metals:

Arsenic: < 0,05 mg/kg Cadmium: < 0,02 mg/kg Lead: < 0,05 mg/kg Mercury: < 0,01 mg/kg

#### **Mycotoxins:**

Sum of Aflatoxins (B1+B2+G1+G2): < 4 μg/kg Aflatoxin B1: < 2 μg/kg Sum of Fumonisin (B1+B2+B3): < 60 μg/kg Deoxynivalenol: < 0,1 mg/kg Ochratoxin A: < 0,5 μg/kg Zearalenone: < 0,1 mg/kg

#### Other contaminants or anti-nutrient factors:

Hydrocyanic acid (including hydrocyanic acid bound in cyanogenic glycosides): < 15 mg/kg

#### Microbiological criteria:

Aerobic mesophilic spores: < 1 Spore/g Alicyclobacillus: Not detected in 10 g Presumptive Bacillus cereus: < 10 cfu/g Coliforms: < 10 cfu/g E. coli: < 10 cfu/g Salmonella: Not detected in 25 g Staphylococcus aureus: < 10 cfu/g Total Plate Count: < 5 000 cfu/g Yeast & Moulds: < 100 cfu/g

### Dried seed flour

**Typical composition range:** Moisture: 4-7 % Protein : > 15 % Carbohydrates: 55-75 % Sugar: < 20 % Fat: 4-9 % Fiber: 10-30 %

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Heavy metals: Arsenic: < 0,05 mg/kg Cadmium: < 0,02 mg/kg Lead: < 0,05 mg/kg Mercury: < 0,01 mg/kg
<b>Mycotoxins:</b> Sum of Aflatoxins (B1+B2+G1+G2): $< 4 \mu g/kg$ Aflatoxin B1: $< 2 \mu g/kg$ Sum of Fumonisin (B1+B2+B3): $< 60 \mu g/kg$ Deoxynivalenol: $< 0,1 mg/kg$ Ochratoxin A: $< 0,5 \mu g/kg$ Zearalenone: $< 0,1 mg/kg$
<b>Other contaminants or anti-nutrient factors:</b> Hydrocyanic acid (including hydrocyanic acid bound in cyanogenic glycosides): < 10 mg/kg Phytic acid: < 0,01 g/100 g
Microbiological criteria: Aerobic mesophilic spores: < 1 Spore/g Alicyclobacillus: Not detected in 10 g Presumptive Bacillus cereus: < 10 cfu/g Coliforms: < 10 cfu/g E. coli: < 10 cfu/g Salmonella: Not detected in 25 g Staphylococcus aureus: < 10 cfu/g Total Plate Count: < 1 000 cfu/g Yeast & Moulds: < 100 cfu/g
cfu: colony forming units"