

COMMISSION IMPLEMENTING REGULATION (EU) 2022/673**of 22 April 2022****authorising the placing on the market of mung bean (*Vigna radiata*) protein 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 1852/2001 ⁽¹⁾, 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) 2017/2470 ⁽²⁾ establishing a Union list of authorised novel foods, was adopted.
- (3) On 10 March 2020, the company Eat Just, Inc. ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place mung bean protein on the Union market as a novel food. The applicant requested for mung bean protein, extracted from seeds of the plant *Vigna radiata*, to be used in protein products, excluding dairy analogues and beverage whiteners, intended for the general population. The category protein products refer to protein analogues or substitutes for standard products, such as meat, fish, or egg.
- (4) On 10 March 2020, the applicant also made a request to the Commission for the protection of proprietary data for a number of data submitted in support of their application, namely analytical data on phytic acid, lectins, trypsin inhibitors, cyanogenic glycosides and tannins ⁽³⁾.
- (5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 5 August 2020, with a request to provide a scientific opinion by carrying out an assessment for the suitability of mung bean protein as a novel food.
- (6) On 14 September 2021, the Authority adopted its scientific opinion 'Safety of mung bean protein as a novel food pursuant to Regulation (EU) 2015/2283' ⁽⁴⁾, in accordance with Article 11 of Regulation (EU) 2015/2283.

⁽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⁾ Analytical results Cyanogenic Glycosides (unpublished)
Sayre_2021 cyanogenic glycoside exec sum (unpublished)
Analytical results lectins (unpublished)
CoAs Phytic acid MB flour 5 batches (unpublished)
CoAs Phytic acid MBP 5 batches (unpublished)
Analytical results tannins (unpublished)
CoAs Trypsin Inhibitors MB flour 5 batches (unpublished)
CoAs Trypsin Inhibitors MBP 5 batches (unpublished).

⁽⁴⁾ EFSA Journal 2021;19(10):6846.

- (7) In its opinion, the Authority concluded that mung bean protein, is safe under the proposed in the application conditions of use. Therefore, the Authority's opinion gives sufficient grounds to establish that mung bean protein, when used as a food ingredient added to protein products, excluding dairy analogues and beverage whiteners, within the general population, complies with requirements set in Article 12(1) of Regulation (EU) 2015/2283.
- (8) In its opinion the Authority concluded on the basis of limited published evidence on food allergy related to the consumption of mung bean proteins and on the basis of evidence demonstrating that mung bean proteins contain a number of potentially allergenic proteins that consumption of this novel food may trigger sensitisation. Considering that to date, evidence directly linking the consumption of mung bean protein to cases of primary sensitisation is equivocal, the Commission considers that no specific labelling requirements concerning the potential of mung bean proteins to cause primary sensitisation should be included in the Union list of authorised novel foods.
- (9) By using a weight of evidence approach on the basis of limited studies and one protein sequence homology analysis performed by the applicant between mung bean protein and those of soybean, peanut and lupin, the Authority in its opinion considered that the consumption of mung bean protein has the potential capacity to induce allergic reactions in persons that are allergic to soybean, peanut, lupin and birch pollen. However, additional *in vivo* experimental or epidemiological evidence normally needed to confirm or exclude the likelihood that the identified potential cross-reactivity may manifest itself in the population, is lacking. Taking the lack of such evidence, the Commission considers that at present the potential of mung bean proteins to cause cross-reactivity to soybean, peanut, lupin and birch pollen is unlikely to manifest itself in the population and consequently no specific labelling requirement should be included in the Union list of authorised novel foods in this regard.
- (10) In their opinion, the Authority considered that it could not have reached their conclusions on the safety of the mung bean protein without the proprietary analytical data on phytic acid, lectins, trypsin inhibitors, cyanogenic glycosides and tannins submitted by the applicant.
- (11) The applicant declared that, at the time of the submission of the application, they held proprietary and exclusive rights of reference to the scientific evidence provided at the time they submitted the application. Therefore, third parties cannot lawfully access or use those data or refer to those data.
- (12) The Commission assessed all the information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the data contained in the applicant's file which served as a basis for the Authority to establish the safety of the novel food and to reach its conclusions on the safety of mung bean protein, and without which the novel food could not have been assessed by the Authority, should not be used by the Authority for the benefit of any subsequent applicant for a period of 5 years from the date of entry into force of this Regulation. Accordingly, the placing on the market within the Union of mung bean protein should be restricted to the applicant for that period.
- (13) However, restricting the authorisation of mung bean protein and of the reference to the data contained in the applicant's file to the sole use by the applicant, does not prevent other 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 authorisation under Regulation (EU) 2015/2283.
- (14) The Annex to Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (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. Mung bean protein as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

2. For a period of 5 years from the date of entry into force of this Regulation only the initial applicant:

Company: Eat Just, Inc.;

Address: 2000 Folsom Street San Francisco, CA 94110 USA,

is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for that novel food without reference to the data protected pursuant to Article 2 or with the agreement of the applicant.

3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex.

Article 2

The data contained in the application file on the basis of which mung bean protein has been assessed by the Authority, claimed by the applicant as proprietary and without which the novel food could not have been authorised, therefore fulfil the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283, and shall not be used for the benefit of any subsequent applicant for a period of 5 years from the date of entry into force of this Regulation without the agreement of the applicant.

Article 3

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

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, 22 April 2022.

For the Commission
The President
Ursula VON DER LEYEN

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
Mung bean (<i>Vigna radiata</i>) protein	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be “mung bean protein from <i>Vigna radiata</i> ”.		Authorised on 15 May 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Eat Just, Inc., 2000 Folsom Street San Francisco, CA 94110 USA. During the period of data protection, the novel mung bean protein is authorised for placing on the market within the Union only by Eat Just, Inc., 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 Eat Just, Inc. End date of the date protection: 15 May 2027.’
	Protein products	20 g/100 g			

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

Authorised Novel Food	Specification
Mung bean (<i>Vigna radiata</i>) protein	<p>Description/Definition: The novel food is mung bean protein powder extracted from seeds of the plant <i>Vigna radiata</i> by several processing steps followed by pasteurization and spray drying.</p> <p>Characteristics/composition: Moisture: ≤ 6 % Protein (w/w)^(a): ≥ 84 % Ash (w/w): ≤ 6,0 % Fat (w/w): ≤ 5,5 % Carbohydrate (w/w): ≤ 5,0 by calculation</p> <p>Microbiological criteria: Aerobic plate count: < 5 000 CFU/g ^(b) Yeasts and moulds: < 100 CFU/g Coliforms: < 100 CFU/g <i>Escherichia coli</i>: < 10 CFU/g <i>Listeria monocytogenes</i>: Not detected in 25 g <i>Salmonella</i> spp.: Not detected in 25 g</p> <p>^(a) w/w: weight per weight. ^(b) CFU: colony forming units.’</p>