COMMISSION IMPLEMENTING REGULATION (EU) 2022/965

of 21 June 2022

authorising the placing on the market of kernels from the edible variety of *Jatropha curcas* L. 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 29 August 2016, the company 'JatroSolutions GmbH' ('the applicant') submitted an application to the competent authority of Germany to place kernels from the edible variety of *Jatropha curcas* L., on the Union market as a novel food ingredient within the meaning of point (c) of Article 1(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council ([3]). The applicant requested for hydrothermally treated whole and broken kernels from the edible variety of *Jatropha curcas* L. to be used as such (or candied or sugar preserved) or as processed nuts as snack, and as a food ingredient in cereal bars, in breakfast cereals, and in dried fruits.

(4) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, and for which the final decision has not been taken before 1 January 2018 are to be treated as an application submitted under Regulation (EU) 2015/2283.

(5) While the request for placing kernels from the edible variety of *Jatropha curcas* L. on the market as a novel food within the Union was submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97, the application also meets the requirements laid down in Regulation (EU) 2015/2283.

(6) On 1 March 2018, the applicant also made a request to the Commission for the protection of proprietary data on the management of the cultivation of the *Jatropha curcas* L. plant and the use of molecular markers ([4]), the compositional data including the nutritional information ([5]) and data on allergens ([6]), the information on biological and process contaminants ([7]), the analytical methods, including their validation, for the detection of phorbol esters in the *Jatropha curcas* L. kernels ([8]), the procedures for the verification of the phorbol ester content of the *Jatropha*

([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]) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).
([4]) JatroSolutions GmbH (2018 and 2019, unpublished)
([5]) JatroSolutions GmbH (2021, unpublished)
([6]) JatroSolutions GmbH (2020 and 2021, unpublished)
([7]) JatroSolutions GmbH (2021, unpublished)
([8]) JatroSolutions GmbH (2021, unpublished)

curcas L. kernels ([9]), bacterial reverse mutation assays with the edible and non-edible *Jatropha curcas* L. defatted kernel meal and oil ([10]), and an *in vitro* mammalian cell micronucleus tests with the edible and non-edible *Jatropha curcas* L. defatted kernel meal and oil ([11]), submitted in support of the application.

(7) On 19 October 2018, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of kernels from the edible variety of *Jatropha curcas* L. as a novel food.

(8) On 24 November 2021, the Authority adopted its scientific opinion 'Safety of hydrothermally treated kernels from edible Jatropha curcas L. ('Chuta') as a novel food pursuant to Regulation (EU) 2015/2283 ([12]) in accordance with Article 11 of Regulation (EU) 2015/2283.

(9) In its scientific opinion, the Authority concluded that kernels from the edible variety of *Jatropha curcas* L. are safe under the proposed conditions of use. Therefore, that scientific opinion gives sufficient grounds to establish that novel food kernels from the edible variety of *Jatropha curcas* L., when used as such (or candied or sugar preserved) or as processed nuts as snack and as a food ingredient in cereal bars, in breakfast cereals, and in dried fruits, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.

(10) In its scientific opinion, the Authority also concluded that consumption of this novel food may either induce primary sensitisation to kernels from the edible variety of *Jatropha curcas* L. that could lead to allergic reactions or could elicit allergic reactions to persons that are allergic to nuts. It came to such conclusion on the basis of the weight of the available evidence and considering the elevated (32 %) protein content of the kernels from the edible variety of *Jatropha curcas* L., and published information demonstrating the presence of a number of allergenic proteins in the kernels from the non-edible variety of *Jatropha curcas* L.. However, considering that at present there is no epidemiological evidence on allergic reactions to kernels from the edible variety of *Jatropha curcas* L. in the areas of Mexico where they are commonly consumed, and considering the negative cross reactivity results of proteins from the kernels from the edible variety of *Jatropha curcas* L. to proteins from some common nuts in *in vitro* enzyme-linked immunosorbent assays ('ELISA'), and the negative polymerase chain reaction ('PCR') tests conducted with the kernels from the edible variety of *Jatropha curcas* L. for allergens of other nuts, the Commission considers that no specific labelling requirement as to its allergenicity should be included in the Union list of authorised novel foods.

(11) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on the scientific data on the management of the cultivation of the *Jatropha curcas* L. plant and the use of molecular markers, the compositional data including the nutritional information and data on allergens, the information on biological and process contaminants, the analytical methods, including their validation, for the detection of phorbol esters in the *Jatropha curcas* L. kernels, the procedures for the verification of the phorbol ester content of the *Jatropha curcas* L. kernels, the bacterial reverse mutation assays with the edible and non-edible *Jatropha curcas* L. defatted kernel meal and oil, and the *in vitro* mammalian cell micronucleus tests with the edible and non-edible *Jatropha curcas* L. defatted kernel meal and oil, without which it could not have assessed the novel food and reached its conclusion.

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

(13) The applicant declared that they held proprietary and exclusive rights of reference to the scientific data from the management of the cultivation of the *Jatropha curcas* L. plant and the use of molecular markers, the compositional data including the nutritional information and data on allergens, the information on biological and process contaminants, the analytical methods, including their validation, for the detection of phorbol esters in the *Jatropha curcas* L. kernels, the sampling procedures for the verification of the phorbol ester content of the *Jatropha curcas* L. kernels, the bacterial reverse mutation assays with the edible and non-edible *Jatropha curcas* L. defatted kernel meal

([9]) JatroSolutions GmbH (2021, unpublished)
([10]) JatroSolutions GmbH (2021, unpublished)
([11]) JatroSolutions GmbH (2021, unpublished)
([12]) EFSA Journal 2022; 20(1):6998.

and oil, and the *in vitro* mammalian cell micronucleus tests with the edible and non-edible *Jatropha curcas* L. defatted kernel meal and oil, at the time they submitted the application and therefore third parties could not lawfully access, use or refer to those data.

(14) The Commission assessed all the information provided by the applicant and considered that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the scientific data on the management of the cultivation of the *Jatropha curcas* L. plant and the use of molecular markers, the compositional data including the nutritional information and data on allergens, the information on biological and process contaminants, the analytical methods, including their validation, for the detection of phorbol esters in the *Jatropha curcas* L. kernels, the procedures for the verification of the phorbol ester content of the *Jatropha curcas* L. kernels, the bacterial reverse mutation assays with the edible and non-edible *Jatropha curcas* L. defatted kernel meal and oil, and the *in vitro* mammalian cell micronucleus tests with the edible and non-edible *Jatropha curcas* L. defatted kernel meal and oil, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place kernels from *Jatropha curcas* L. on the market within the Union during a period of 5 years from the entry into force of this Regulation.

(15) However, restricting the authorisation of kernels from the edible variety of *Jatropha curcas* L. and the reference to the scientific data contained in the applicant's file for the sole use by them 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.

(16) 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. Kernels from the edible variety of *Jatropha curcas* L. are authorised to be placed on the market within the Union.

Kernels from the edible variety of *Jatropha curcas* L. 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 'JatroSolutions GmbH' ([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 12 July 2022, 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 'JatroSolutions GmbH'.

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 12 July 2022 without the agreement of 'JatroSolutions GmbH'.

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*.

([13]) Address: Echterdinger Strasse 30, 70599 Stuttgart, Germany.

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

Done at Brussels, 21 June 2022.

For the Commission
The President
Ursula VON DER LEYEN

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
'*Jatropha curcas* L. (edible variety) kernels	*Specified food category*	*Maximum levels (g/100g)*	The designation of the novel food on the labelling of the foodstuffs containing it shall be "kernels from edible *Jatropha curcas* L."		Authorised on 12 July 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: "JatroSolutions GmbH", Echterdinger Strasse 30, 70599 Stuttgart, Germany. During the period of data protection, the novel food kernels from the edible variety of *Jatropha curcas* L. is authorised for placing on the market within the Union only by "JatroSolutions GmbH", 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 "JatroSolutions GmbH". End date of the data protection: 12 July 2027.'
	Kernels as such, candied or sugar preserved and as processed nuts				
	Cereal bars	5			
	Breakfast cereals	5			
	Dried fruits	5			

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

Authorised Novel Food	Specification
'*Jatropha curcas* L. (edible variety) kernels	**Description:** The kernels are obtained from the seeds of the ripe fruits of the edible variety of the *Jatropha curcas* L. plants that produce kernels with non-detectable levels of phorbol esters, following a series of steps involving the cleaning and de-husking of the fruits to obtain the seeds, the drying of the seeds, the cleaning of the seeds to remove debris and other residues, mechanical deshelling of the seeds to obtain the kernels, and the hydrothermal treatment (> 120 °C for 40 minutes) of the kernels to reduce anti-nutrients and the microbiological load. As the edible variety of the *Jatropha curcas* L. plants, producing kernels that contain non-detectable levels of phorbol esters, are phenotypically undistinguishable from the non-edible variety, only the appropriate edible variety of *Jatropha curcas* L. plants should be used in the production of the novel food. The entire production process must ensure that the mixing of edible and non-edible kernels does not occur.

The absence of mixing of edible with non-edible kernels shall be confirmed by analytical controls for phorbol esters carried on each batch of the seeds after the seed-drying step and before the deshelling step according to the sampling procedure of Table A. Five laboratory samples extracted from each aggregate sample are de-shelled, ground, and analysed for phorbol esters using a validated UHPLC-UV-MS[(b)] method. Only the batches in which phorbol esters are undetectable in all five samples are further processed to the seed deshelling and kernel hydrothermal treatment steps.

Table A

Batch weight (tons)	Weight or number of sublots	Number of incremental samples
≥ 500	100 tons	100
> 100 and < 500	5 sub-lots	100
> 10 and ≤ 100	5 sub-lots	100
> 5,0 and ≤ 10	-	80
> 1 and ≤ 5,0	-	60
> 0,1 and ≤ 1,0	-	30
≤ 0,1	-	10

Each sub-lot shall be sampled separately. Aggregate samples are composed by a minimum of 10 incremental samples. The minimum amount of an aggregate sample shall be 3,5 kg. This amount may increase proportionally according to the number of incremental samples taken.

Characteristics/Composition:

Moisture: ≤ 3,0 %

Total fat: 54,0 – 61,0 %

Total protein: 21,0 – 32,0 %

Total fibre: 6,0 – 10,0 %

Ash: 3,0 – 5,0 %

Contaminants:

Phorbol esters (µg TPA eq[(a)]/g kernel)[(b)]: ≤ 0,75 (LOD)[(c)]

Lead: ≤ 0,20 mg/kg

Cadmium: ≤ 0,20 mg/kg

Sum of aflatoxins B1, B2, G1, G2: ≤ 4,0 µg/kg

Microbiological criteria:

Total aerobic microbial count: ≤ 1 000 CFU/g

Total yeast/moulds count: ≤ 100 CFU/g

	Enterobacteriaceae: ≤ 10 CFU/g *Salmonella* sp.: Absent in 25 g *Listeria monocytogenes*: ≤ 100 CFU/g [a] TPAeq: 12-O-tetradecanoylphorbol-13-acetate equivalent; [b]Validated Ultra-High-Performance Liquid Chromatography coupled to Ultraviolet Spectrophotometry and Mass Spectrometry (UHPLC-UV-MS) method for detection of phorbol ester peaks; [c] Limit of Detection (Only batches with concentrations of PEs below the LOD can be fully processed.); CFU: Colony Forming Units'