COMMISSION IMPLEMENTING REGULATION (EU) 2021/1974

of 12 November 2021

authorising the placing on the market of dried fruits of *Synsepalum dulcificum* 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 14 November 2018, the company Medicinal Gardens S.L. ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place dried fruits of *Synsepalum dulcificum* on the Union market as a novel food. The application requested for dried fruits of *Synsepalum dulcificum* to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([3]) at the maximum intake level of 0,9 g/day, the target population being the general adult population with the exception of pregnant and lactating women.

(4) The applicant also made a request to the Commission for the protection of proprietary scientific data for a number of studies submitted in support of the application, namely compositional studies ([4]), acute oral toxicity study in rats ([5]), bacterial reverse mutation tests ([6]), *in vivo* mammalian erythrocyte micronucleus test ([7]), *in vitro* mammalian cell micronucleus test ([8]), 90-day repeated dose oral toxicity study with a 14-day recovery period ([9]), and a sensory study ([10]).

(5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 25 March 2019, asking it to provide a scientific opinion by carrying out a safety assessment for dried fruits of *Synsepalum dulcificum* as a novel food.

([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]) 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).
([4]) Medicinal Gardens S.L., 2017-20 (unpublished)
([5]) Medicinal Gardens S.L. Study No. IF-81517 (unpublished, 2018c)
([6]) Medicinal Gardens S.L. Study No. IF-74616 (unpublished, 2018a) and Study No 20229053 (unpublished, 2020a)
([7]) Medicinal Gardens S.L. Study No. IF-74516 (unpublished, 2018b)
([8]) Medicinal Gardens S.L. Study code: 20/020-013C (unpublished, 2020b)
([9]) Medicinal Gardens S.L. Study No 73416 (unpublished, 2018d)
([10]) Medicinal Gardens S.L. Sensory study with healthy young adults (unpublished, 2018)

(6) On 27 April 2021, the Authority adopted a scientific opinion on the safety of dried fruits of *Synsepalum dulcificum* as a novel food ([11]), in accordance with Article 11 of Regulation (EU) 2015/2283.

(7) In its opinion, the Authority did not establish the safety of dried fruits of *Synsepalum dulcificum* used in food supplements intended for adults at the maximum intake level of 0,9 g/day as proposed by the applicant because the intake would exceed the level which is considered safe (10 mg/kg bw per day). However, the Authority concluded that dried fruits of *Synsepalum dulcificum* is safe for adults when added to food supplements at a maximum daily dose of 0,7 g/day which corresponds to the safe level of intake for an adult person with a default body weight of 70 kg. Therefore, the opinion of the Authority gives sufficient grounds to establish that dried fruits of *Synsepalum dulcificum* at a maximum daily dose of 0,7 g/day complies with Article 7, points (a) and (b) and Article 12(1) of Regulation (EU) 2015/2283.

(8) The Authority in its opinion, using a weight of evidence approach on the basis of *in silico* protein sequence homology analyses between miraculin and the peanut proteins, and the results of a preliminary *in vitro* enzyme-linked immunosorbent assay ('ELISA') screening experiment, identified a potential for cross-reactivity between dried fruits of *Synsepalum dulcificum* and peanuts. 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 real life, is lacking. Taking the lack of such evidence together with the available *in vitro* data showing that miraculin will be rapidly and completely broken down after ingestion, the Commission considers that at present the potential of dried fruits of *Synsepalum dulcificum* to cause cross-reactivity to peanuts is unlikely to manifest itself in real life and consequently no specific labelling requirement should be included in the Union list of authorised novel foods in this regard.

(9) In its opinion, the Authority noted that its conclusion on the safety of the novel food was based on the compositional studies, the acute oral toxicity study in rats, the two bacterial reverse mutation tests, the *in vivo* mammalian erythrocyte micronucleus test, the *in vitro* mammalian cell micronucleus test, and the 90-day repeated dose oral toxicity study with a 14-day recovery period. It also noted that it could not have reached that conclusion without the data from the unpublished reports of the studies contained in the applicant's file.

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

(11) The applicant declared that they held proprietary and exclusive right of reference to the compositional studies, the acute oral toxicity study in rats, the two bacterial reverse mutation tests, the *in vivo* mammalian erythrocyte micronucleus test, the *in vitro* mammalian cell micronucleus test, and the 90-day repeated dose oral toxicity study with a 14-day recovery period at the time they submitted the application and that therefore third parties cannot lawfully access, use or refer to those studies.

(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 specific studies on the compositional studies, the acute oral toxicity study in rats, the two bacterial reverse mutation tests, the *in vivo* mammalian erythrocyte micronucleus test, the *in vitro* mammalian cell micronucleus test, and the 90-day repeated dose oral toxicity study with a 14-day recovery period, contained in the applicant's file, on which the Authority based its conclusion on the safety of the novel food and without which it could not have assessed the novel food, should 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. Accordingly, only the applicant should be authorised to place dried fruits of *Synsepalum dulcificum* on the market within the Union during that period.

([11]) Safety of dried fruits of *Synsepalum dulcificum* as a novel food pursuant to Regulation (EU) 2015/2283; EFSA Journal 2021;19(6):6600

(13) However, restricting the authorisation of dried fruits of *Synsepalum dulcificum* and the reference to the studies contained in the applicant's file for the sole use of 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 an authorisation.

(14) The Annex to Implementing 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. Dried fruits of *Synsepalum dulcificum*, 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 5 December 2021, only the initial applicant,

Company: Medicinal Gardens S.L.;

Address: Marqués de Urquijo 47, 1° D, Office 1, Madrid, 28008, Spain,

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 the novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of Medicinal Gardens S.L.

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 to this Regulation.

Article 2

The studies contained in the application file on the basis of which the novel food referred to in Article 1 have been assessed by the Authority, claimed by the applicant as proprietary and without which the novel food could not have been authorised, shall not be used for the benefit of a subsequent applicant for a period of 5 years from 5 December 2021 without the agreement of Medicinal Gardens S.L.

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, 12 November 2021.

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
'**Synsepalum dulcificum dried fruits**	Specified food category	Maximum levels	1. The designation of the novel food on the labelling of food supplements containing it shall be 'dried *Synsepalum dulcificum* fruits'		Authorised on 5 December 2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Medicinal Gardens S.L. Marqués de Urquijo 47, 1° D, Office 1, Madrid, 28008, Spain. During the period of data protection, the novel food is authorised for placing on the market within the Union only by Medicinal Gardens S.L. unless a subsequent applicant obtains authorisation for that 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 Medicinal Gardens S.L. End date of the data protection: 5 December 2026.'
	Food Supplements as defined in Directive 2002/46/EC for adult population excluding pregnant and lactating women	0,7 g/day	2. The labelling of food supplements containing *Synsepalum dulcificum* dried fruits shall bear a statement that this food supplement should be consumed by adults only excluding pregnant and lactating women.		

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

Authorised Novel Food	Specification
'***Synsepalum dulcificum* dried fruits**	**Description/Definition:** The novel food is lyophilised pulp and skin of pitted fruits of *Synsepalum dulcificum* (Schumach. & Thonn.) Daniell that belongs to the Sapotaceae family. The resulting dried cake is milled into a powder. **Characteristics/Composition:** Moisture (g/100 g): < 6 Ash (g/100 g): 3,5-8,5 Total carbohydrates (g/100 g): 70-87

	Sugars (g/100 g): 50-75 Fibre (g/100 g): 1-6,5 Total protein (g/100 g): 3,5-6,0 Miraculin (*) (g/100 g): 1,5-2,5 Total fat (g/100 g): 0,50-3,50 **Microbiological criteria:** Total aerobic colony count: < 10^4 CFU (**)/g *Bacillus cereus* (presumptive): < 100 CFU/g Sulfite-reducing *Clostridia*: ≤ 30 CFU/g Total Enterobacteriaceae: < 100 CFU/g Yeasts and moulds: < 500 CFU/g **Pesticides:** Pesticide levels in accordance with Code number 0820990 ('others' in the group of fruit spices) set out in Regulation (EC) No 396/2005 ([1])

(*) Miraculin is part of the total protein content.

(**) CFU: colony forming units.

([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).'