COMMISSION IMPLEMENTING REGULATION (EU) 2022/961

of 20 June 2022

authorising the placing on the market of tetrahydrocurcuminoids 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 22 January 2020, the company 'Sabinsa Europe GmbH' ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place tetrahydrocurcuminoids on the Union market as a novel food. The tetrahydrocurcuminoids are produced by the hydrogenation of curcuminoids extracted from the rhizomes of the turmeric plant (*Curcuma longa* L.). The applicant requested for tetrahydrocurcuminoids to be used at levels not exceeding 300 mg/day, in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([3]), intended for the adult population, excluding pregnant and lactating women.

(4) On 22 January 2020, the applicant also made a request to the Commission for the protection of proprietary data for the analytical data ([4]), a bacterial reverse mutation test ([5]), an *in vitro* micronucleus assay ([6]), a 90-day oral sub-chronic toxicity study and a reproduction/developmental toxicity screening test in rodents ([7]), submitted in support of the application.

(5) On 29 July 2020, the Commission, requested the European Food Safety Authority ('the Authority') to carry out an assessment of tetrahydrocurcuminoids as a novel food.

(6) On 27 October 2021, the Authority adopted its scientific opinion on the 'Safety of tetrahydrocurcuminoids from turmeric (*Curcuma longa* L.) as a novel food pursuant to Regulation (EU) 2015/2283' ([8]) 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]) 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]) Sabinsa Europe GmbH (2019, unpublished).
([5]) Indian Institute of Toxicology (2004, unpublished).
([6]) Indian Institute of Toxicology (2004, unpublished).
([7]) Majeed M., et al., 2019. Subchronic and reproductive/developmental toxicity studies of tetrahydrocurcumin in rats. Toxicological Research 35:65-74.
([8]) *EFSA Journal* 2021;19(12):6936.

(7) In its scientific opinion, the Authority concluded that tetrahydrocurcuminoids are safe under the proposed conditions of use, for the proposed target populations, at levels not exceeding 140 mg/day. The Authority further stated that such intake, although lower than the 300 mg/day level proposed by the applicant, provides an adequate Margin of Exposure ('MoE') to the identified No Observed Adverse Effect Levels ('NOAELs') from the subchronic toxicity and the reproductive/developmental toxicity studies. Therefore, that scientific opinion gives sufficient grounds to establish that tetrahydrocurcuminoids when used at levels not exceeding 140 mg/day in food supplements intended for the adult population, excluding pregnant and lactating women, fulfil the conditions for their placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.

(8) In its scientific opinion, the Authority noted that its conclusion on the safety of the novel food was based on the analytical data, the bacterial reverse mutation test, the *in vitro* micronucleus assay, the 90-day oral sub-chronic toxicity study and the reproduction/developmental toxicity screening test in rodents, contained in the applicant's file, without which it could not have assessed the novel food and reached its conclusion.

(9) 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 their claim to an exclusive right of reference to them in accordance with Article 26(2)(b) of Regulation (EU) 2015/2283.

(10) The applicant declared that they held proprietary and exclusive rights of reference to the analytical data, the bacterial reverse mutation test, the *in vitro* micronucleus assay, the 90-day oral sub-chronic toxicity study and the reproduction/developmental toxicity screening test in rodents, at the time they submitted the application, and that third parties cannot lawfully access, use or refer to those data.

(11) 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 analytical data, the bacterial reverse mutation test, the *in vitro* micronucleus assay, and the 90-day oral sub-chronic toxicity study and the reproduction/developmental toxicity screening test in rodents, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place tetrahydrocurcuminoids on the market within the Union during a period of five years from the entry into force of this Regulation.

(12) However, restricting the authorisation of tetrahydrocurcuminoids 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.

(13) It is appropriate that the inclusion of tetrahydrocurcuminoids as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283. Non-hydrogenated curcuminoids and/or curcumin have been used in food supplements on the Union market before 15 May 1997. Curcumin and curcuminoids are metabolised in the body via the same metabolic pathways that would metabolise the tetrahydrocurcuminoids. As it cannot be excluded that the intake of curcuminoids from the combined use of both would result in a MoE that is lower than the MoE established by the Authority, it is necessary to inform consumers that food supplements containing tetrahydrocurcuminoids should not be consumed if food supplements containing curcumin and/or curcuminoids are consumed on the same day.

(14) Tetrahydrocurcuminoids should be included 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.

(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. Tetrahydrocurcuminoids is authorised to be placed on the market within the Union.

Tetrahydrocurcuminoids 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 'Sabinsa Europe GmbH' ([9]) is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of five years from 11 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 Sabinsa Europe 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 five years from 11 July 2022 without the agreement of 'Sabinsa Europe 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*.

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

Done at Brussels, 20 June 2022.

For the Commission
The President
Ursula VON DER LEYEN

([9]) Address: Monzastrasse 4, 63225 Langen, Germany.

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
'**Tetrahydrocurcuminoids**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be "tetrahydrocurcuminoids". The labelling of food supplements containing tetrahydrocurcuminoids shall bear a statement that a) they should be consumed by adults only, excluding pregnant and lactating women; b) they should not be consumed if other food supplements containing curcumin and/or curcuminoids are consumed on the same day.		Authorised on 11 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: "Sabinsa Europe GmbH", Monzastrasse 4, 63225 Langen, Germany. During the period of data protection, the novel food tetrahydrocurcuminoids is authorised for placing on the market within the Union only by "Sabinsa Europe 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 "Sabinsa Europe GmbH". End date of the data protection: 11 July 2027.'
	Food Supplements as defined in Directive 2002/46/EC for the adult population, excluding pregnant and lactating women	140 mg/day			

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

Authorised Novel Food	Specification
'**Tetrahydrocurcuminoids**	**Description:** The tetrahydrocurcuminoids are produced via a series of steps involving the extraction of curcuminoids from the dried, pulverised rhizomes of turmeric (*Curcuma longa* L.), hydrogenation (using palladium on carbon (Pd/C) as a catalyst), concentration, crystallisation, drying, and milling into a powder. **Characteristics/Composition:** Total tetrahydrocurcuminoids (dry basis) (% w/w): > 95,0 Moisture (% w/w): ≤ 1,0 Ash (% w/w): ≤ 1,0 Palladium (mg/kg): < 5,0 **Microbiological criteria:** Total aerobic microbial count: ≤ 5 000 CFU/g Total yeast/moulds count: ≤ 100 CFU/g *Escherichia coli*: < 10 CFU/g *Staphylococcus aureus*: ≤ 10 CFU/g Enterobacteriaceae: ≤ 10 CFU/g *Salmonella* spp.: Absence in 25 g Coliforms: ≤ 10 CFU/g CFU: Colony Forming Units'