COMMISSION IMPLEMENTING REGULATION (EU) 2020/1821

of 2 December 2020

authorising the placing on the market of an extract from *Panax notoginseng* and *Astragalus membranaceus* 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) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to submit a draft implementing act authorising the placing on the Union market of a novel food and on the update of the Union list.

(4) On 7 June 2018, the company NuLiv Science ('the applicant') introduced an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place an extract from *Panax notoginseng* and *Astragalus membranaceus* on the Union market as a novel food. The applicant requested for an extract from *Panax notoginseng* and *Astragalus membranaceus* to be used as a novel food in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([3]) for the general adult population, excluding food supplements for pregnant women. The applicant also made a request to the Commission for the protection of proprietary data submitted in the application.

(5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('Authority') on 22 October 2018, asking it to provide a scientific opinion by carrying out an assessment for an extract from *Panax notoginseng* and *Astragalus membranaceus* as a novel food.

(6) On 24 March 2020, the Authority adopted the scientific opinion on the 'Safety of a botanical extract derived from *Panax notoginseng* and *Astragalus membranaceus* (AstraGin™) as a novel food pursuant to Regulation (EU) 2015/2283' ([4]). That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(7) In its opinion, the Authority concluded that an extract from *Panax notoginseng* and *Astragalus membranaceus* is safe at an intake level of 0,5 mg/kg bw per day which corresponds to a maximum intake of 35 mg/day for the target population, i.e. adults excluding pregnant women.

(8) The opinion of the Authority gives sufficient grounds to establish that extract from *Panax notoginseng* and *Astragalus membranaceus* under the assessed conditions of use complies with Article 12(1) 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]) EFSA Journal 2020;18(5):6099.

(9) In its opinion the Authority considered that the toxicological data from the repeated dose 28-day oral gavage toxicity study with AstraGin™ in rats ([5]), the bacterial reverse mutation test (Ames test) for AstraGin™ ([6]), the 90-days repeated dose oral toxicity study of Astragin® in Wistar rats ([7]), the Panax notoginseng proprietary extract: *in vitro* micronucleus test in CHO-K1 cells ([8]), and the Astragalus membranaceus extract: *in vitro* micronucleus test in CHO-K1 cells ([9]) served as a basis to establish the safety of the novel food. Therefore, it is considered that the conclusions on the safety of extract from *Panax notoginseng* and *Astragalus membranaceus* could not have been reached without the data from the unpublished reports of those studies.

(10) Following the Authority's opinion, the Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over the repeated dose 28-day oral gavage toxicity study with AstraGin™ in rats, the bacterial reverse mutation test (Ames test) for AstraGin™, the 90-days repeated dose oral toxicity study of Astragin® in Wistar rats, the Panax notoginseng proprietary extract: *in vitro* micronucleus test in CHO-K1 cells, and the Astragalus membranaceus extract: *in vitro* micronucleus test in CHO-K1 cells, and to clarify their claim to an exclusive right of reference to that data, as referred to in Article 26(2)(b) of Regulation (EU) 2015/2283.

(11) The applicant declared that, at the time of the submission of the application, they held proprietary and exclusive right of reference to those studies, and that therefore third parties cannot lawfully access or use those studies or refer to that 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 toxicological data from the studies 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 extract from *Panax notoginseng* and *Astragalus membranaceus*, 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 five years from the date of entry into force of this Regulation. Accordingly, the placing on the market within the Union of an extract from *Panax notoginseng* and *Astragalus membranaceus* should be restricted to the applicant for that period.

(13) However, restricting the authorisation of extract from *Panax notoginseng* and *Astragalus membranaceus* and of 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 authorisation under Regulation (EU) 2015/2283.

(14) 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. Extract from *Panax notoginseng* and *Astragalus membranaceus* 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.

([5]) Pasics Szakonyiné I, 2011 (unpublished study report). Repeated dose 28-day oral gavage toxicity study with AstraGinTM in rats. Study No: 413.407.3084. Toxi-Coop Zrt., Hungary.

([6]) Zin HM, 2016 (unpublished study report). Bacterial reverse mutation test (Ames test) for AstraGinTM. Study code: GLP/J165/2016/48). Environmental Technology Research Centre (ETRC). Shah Alam, Selangor, Malaysia.

([7]) Upadhyaya S and Wang R, 2017 (unpublished study report). 90-days repeated dose oral toxicity study of Astragin® in Wistar rats. 161101/NVS/PC. July 2017. 319pp. Vedic Life Sciences Pvt, Ltd. Mumbai, India.

([8]) Vedic Lifesciences, 2019a (unpublished study report). Panax notoginseng proprietary extract: in vitro micronucleus test in CHO-K1 cells. Study Nr. 190503/NL/PC. Mumbai, India.

([9]) Vedic Lifesciences, 2019b (unpublished study report). Astragalus membranaceus extract: in vitro micronucleus test in CHO-K1 cells. Study Nr. 190502/NL/PC. Mumbai, India.

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

— Company: NuLiv Science,

— Address: 1050 W. Central Ave., Building C, Brea, CA 92821, 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 of this Regulation or with the agreement of NuLiv Science.

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 data contained in the application file on the basis of which the novel food referred to in Article 1 has 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 five years from the date of entry into force of this Regulation without the agreement of NuLiv Science.

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, 2 December 2020.

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
	Specified food category	*Maximum levels*			
'Extract from *Panax notoginseng* and *Astragalus membranaceus*	Food supplements as defined in Directive 2002/46/EC for the general adult population, excluding food supplements for pregnant women	35 mg/day	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Extract from *Panax notoginseng* and *Astragalus membranaceus*' The labelling of food supplements containing extract from *Panax notoginseng* and *Astragalus membranaceus* shall bear a statement that those food supplements should not be consumed by the population under 18 years of age and by pregnant women.		Authorised on 23 December 2020. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: NuLiv Science, 1050 W. Central Ave., Building C, Brea, CA 92821, USA. During the period of data protection, the novel food is authorised for placing on the market within the Union only by NuLiv Science, 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 NuLiv Science. End date of the data protection: 23 December 2025.'

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

Authorised Novel Food	Specification
'Extract from *Panax notoginseng* and *Astragalus membranaceus*	**Description/Definition:** The novel food contains two extracts. One is an ethanol extract of the roots of *Astragalus membranaceus* (Fisch.) Bunge. The other is a hot water extract of the roots of *Panax notoginseng* (Burkill) F.H. Chen that is further concentrated using absorption on a resin and subsequent elution with 60 % ethanol. At the end of the manufacturing process both extracts are mixed (45–47,5 % of each extract) with maltodextrin (5–10 %). **Characteristics/Composition:** Total saponins: 1,5-5 % Ginsenoside Rb1: 0,1-0,5 % Astragaloside I: 0,01-0,1 % Carbohydrates: ≥ 90 % Protein: ≤ 4,5 % Ash: ≤ 1 % Moisture: ≤ 5 % Fat: ≤ 1,5 %

	Heavy metals: Arsenic: ≤ 0,3 mg/kg **Microbiological criteria:** Total plate count: ≤ 5 000 CFU/g Total yeast and mould count: ≤ 500 CFU/g Enterobacteriaceae: < 10 CFU/g *Escherichia coli*: Absence in 25 g *Salmonella*: Absence in 375 g *Staphylococcus aureus*: Absence in 25 g CFU: colony forming units'