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COMMISSION IMPLEMENTING REGULATION (EU) 2024/2061

of 30 July 2024

authorising the placing on the market of the juice of the stems of the *Angelica keiskei* plant (Ashitaba stem juice) 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 8 August 2019, the company Japan Bio Science Laboratory (JBSL)-USA, Inc. ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place the juice of the stems of the *Angelica keiskei* plant ('Ashitaba stem juice'), on the Union market as a novel food. The applicant requested for Ashitaba stem juice 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 levels of 780 mg/day intended for the adult population excluding pregnant and lactating women. The novel food is made available to consumers as a preparation containing approximately 30 % Ashitaba stem juice and 70 % cyclodextrins.

(4) On 8 August 2019, the applicant also made a request to the Commission for the protection of proprietary scientific studies and data, namely, data on the characterisation of the Ashitaba stem juice ([4]); certificates of raw materials ([5]); methods of analysis ([6]); certificates of analysis ([7]); two bacterial reverse mutation tests ([8]), ([9]); an *in vitro* mammalian cell micronucleus test ([10]); an *in vitro* mammalian chromosomal aberration test ([11]); an acute oral toxicity study in rats ([12]); two 90-day oral toxicity studies in rats (one without ([13]) and one with a 90-day recovery period ([14])); a histopathology consultation report on selected histopathological findings observed in one of the 90-day oral

([1]) OJ L 327, 11.12.2015, p. 1, ELI: http://data.europa.eu/eli/reg/2015/2283/oj.
([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, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).
([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, ELI: http://data.europa.eu/eli/dir/2002/46/oj).
([4]) Japan Bio Science Laboratory (JBSL)-USA, Inc. 2016 (unpublished).
([5]) Japan Bio Science Laboratory (JBSL)-USA, Inc. 2006, 2007, 2014, 2015, 2016 (unpublished).
([6]) Japan Bio Science Laboratory (JBSL)-USA, Inc. 2023 (unpublished).
([7]) Japan Bio Science Laboratory (JBSL)-USA, Inc. 2006, 2009, 2010, 2012, 2014, 2015, 2016, 2017, 2018, 2020, 2022 (unpublished).
([8]) Krul et al. 2002 (unpublished).
([9]) Joshi 2023a (unpublished).
([10]) Joshi 2023b (unpublished).
([11]) De Vogel 2003 (unpublished).
([12]) Prinsen 2002 (unpublished).
([13]) Oda 2006 (unpublished).
([14]) Kukulinski 2013 (unpublished).

toxicity studies in rats ([15]); and a randomised, placebo-controlled, double-blinded and parallel-group study with humans ([16]), submitted in support of the application.

(5) On 19 December 2019, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of the Ashitaba stem juice, as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283.

(6) On 1 February 2024, the Authority adopted its scientific opinion on the 'Safety of ashitaba sap as a Novel food pursuant to Regulation (EU) 2015/2283' ([17]) in accordance with Article 11 of Regulation (EU) 2015/2283.

(7) In its scientific opinion, the Authority concluded that the Ashitaba stem juice is safe under the proposed conditions of use, for the proposed target populations, at levels not exceeding 137 mg/day which would correspond to 35 mg/day of the product as it is intended to be presented to the consumer. The Authority further stated that such intake, although lower than the 780 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 study. Therefore, that scientific opinion gives sufficient grounds to establish that Ashitaba stem juice when used at levels not exceeding 137 mg/day in food supplements intended for the adult population, excluding pregnant and lactating women, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.

(8) In its scientific opinion, the Authority considered that it could not have assessed the novel food and reached its conclusions on the safety of Ashitaba stem juice without the scientific studies and data submitted in support of the application, namely, data on the characterisation of the Ashitaba stem juice; certificates of raw materials; methods of analysis; certificates of analysis; two bacterial reverse mutation tests; an *in vitro* mammalian cell micronucleus test; an *in vitro* mammalian chromosomal aberration test; an acute oral toxicity study in rats; two 90-day oral toxicity studies in rats (one without and one with a 90-day recovery period); a histopathology consultation report on selected histopathological findings observed in one of the 90-day oral toxicity studies in rats; and a randomised, placebo-controlled, double-blinded and parallel-group study with humans.

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

(10) The applicant declared that it held proprietary and exclusive rights of reference to the scientific studies and data on the characterisation of the Ashitaba stem juice; certificates of raw materials; methods of analysis; certificates of analysis; two bacterial reverse mutation tests; an *in vitro* mammalian cell micronucleus test; an *in vitro* mammalian chromosomal aberration test; an acute oral toxicity study in rats; two 90-day oral toxicity studies in rats (one without and one with a 90-day recovery period); a histopathology consultation report on selected histopathological findings observed in one of the 90-day oral toxicity studies in rats; and a randomised, placebo-controlled, double-blinded and parallel-group study with humans, under national law, at the time it submitted the application, and that third parties cannot lawfully access, use or refer to those data and studies.

(11) 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 scientific studies and data on the characterisation of the Ashitaba stem juice; certificates of raw materials; methods of analysis; certificates of analysis; two bacterial reverse mutation tests; an *in vitro* mammalian cell micronucleus test; an *in vitro* mammalian chromosomal aberration test; an acute oral toxicity study in rats; two 90-day oral toxicity studies in rats (one without and one with a 90-day recovery period); a histopathology consultation report on selected histopathological findings observed in one of the 90-day oral

([15]) Seely 2011 (unpublished).
([16]) Tomita 2017 (unpublished).
([17]) DOI: 10.2903/j.efsa.2024, 8645; https://doi.org/10.2903/j.efsa.2024, 8645.

toxicity studies in rats; and a randomised, placebo-controlled, double-blinded and parallel-group study with humans, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place the Ashitaba stem juice 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 the Ashitaba stem juice and the reference to the scientific studies and data contained in the applicant's file for its sole use 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 the Ashitaba stem juice in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283. In line with the conditions of use of food supplements containing the Ashitaba stem juice as assessed by the Authority, it is necessary to inform consumers with an appropriate label that food supplements containing that novel food should only be consumed by the adult population, excluding pregnant and lactating women.

(14) Feedback from some Member States and from published reports in the public domain seem to indicate that preparations produced from the *Angelica keiskei* plant may be placed in the market as medicinal products. Directive 2001/83/EC of the European Parliament and of the Council ([18]) applies where a product, taking into account all its characteristics, may fall both within the definition of 'medicinal product' as laid down in Article 1(2) of that Directive and within the definition of a product covered by Regulation (EU) 2015/2283. In that respect, where a Member State establishes in accordance with Directive 2001/83/EC that a product is a medicinal product, it may restrict the placing on the market of that product in accordance with Union law.

(15) The Ashitaba stem juice 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.

(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. Juice of the stems of the *Angelica keiskei* plant ('Ashitaba stem juice') is authorised to be placed on the market within the Union.

Juice of the stems of the *Angelica keiskei* plant ('Ashitaba stem juice') 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 Japan Bio Science Laboratory (JBSL)-USA, Inc. ([19]) 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 20 August 2024, 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 Japan Bio Science Laboratory (JBSL)-USA, Inc..

([18]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67, ELI: http://data.europa.eu/eli/dir/2001/83/oj).

([19]) Address: 1547 Palos Verdes Mall No 131, Walnut Creek, California 94597, United States of America.

Article 3

The scientific studies and 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 the date of entry into force of this Regulation without the agreement of Japan Bio Science Laboratory (JBSL)-USA, Inc..

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, 30 July 2024.

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 (expressed on the juice)*	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Ashitaba (*Angelica keiskei*) stem juice". The labelling of food supplements containing the juice of the stems of the *Angelica keiskei* plant (Ashitaba stem juice) shall bear a statement that they should be consumed by adults only, excluding pregnant and lactating women.		Authorised on 20 August 2024. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: "Japan Bio Science Laboratory (JBSL)-USA, Inc.", 1547 Palos Verdes Mall No 131, Walnut Creek, California 94597, United States of America. During the period of data protection, the novel food juice of the stems of the *Angelica keiskei* plant ("Ashitaba stem juice") is authorised for placing on the market within the Union only by "Japan Bio Science Laboratory (JBSL)-USA, 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 "Japan Bio Science Laboratory (JBSL)-USA, Inc.". End date of the data protection: 20 August 2029'
'**Juice of the stems of the *Angelica keiskei* plant ("Ashitaba stem juice")**	Food Supplements as defined in Directive 2002/46/EC for the adult population, excluding pregnant and lactating women	137 mg/day			

(2) **in** Table 2 (Specifications), the following entry is inserted in alphabetical order: [*OP, please insert in the EN version in alphabetical order.*]**'**

Authorised Novel Food	Specification
'Juice of the stems of the *Angelica keiskei* plant ('Ashitaba stem juice')	**Description:** The novel food is a viscous yellow liquid obtained via physical means of the stems of mature *Angelica keiskei* ('Ashitaba') plants. *Angelica keiskei* is native to Japan and is called Ashitaba in Japanese, hence the reference to Ashitaba stem juice. The juice is then pasteurised, mixed with cyclodextrins at an approximate ratio of 30 % of Ashitaba stem juice to 70 % cyclodextrins, and the mixture is then sterilised, freeze-dried, and sieved. **Source:** *Angelica keiskei (*family *Apiaceae)* **Characteristics/Composition of the juice:** Chalcones (xanthoangelol +4-hydroxyderricin) (% w/v): 1,0–2,25 Carbohydrates (%): 5,0–7,5 Water (%): 90,0–95,0 Fat (% w/v): 0,1–0,3 Protein (% w/v): 0,15-0,45 Sum of angular-type dihydropyranocoumarins: ≤ 10 mg/kg Sum of furanocoumarins: ≤ 100 mg/kg **Heavy metals:** Lead: ≤ 0,1 mg/kg Arsenic: ≤ 0,3 mg/kg Mercury: ≤ 0,1 mg/kg Cadmium: ≤ 1,0 mg/kg **Microbiological criteria:** Total viable aerobic count: ≤ 1 000 CFU/g Total yeast/moulds count: ≤ 100 CFU/g *Escherichia coli*: Absence in 10 g Coliforms: ≤ 30 CFU/g *Salmonella* spp.: Absence in 25 g CFU: Colony Forming Units'