COMMISSION IMPLEMENTING REGULATION (EU) 2023/972

of 10 May 2023

authorising the placing on the market of aqueous ethanolic extract of *Labisia pumila* 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 7 October 2019, the company Medika Natura Sdn. Bhd. ('the applicant', initially Orchid Life Sdn Bhd) submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place aqueous ethanolic extract of *Labisia pumila* on the Union market as a novel food. The applicant requested for aqueous ethanolic extract of *Labisia pumila* to be used 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, at the maximum use level of 750 mg per day.

([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) On 7 October 2019, the applicant also made a request to the Commission for the protection of proprietary data, namely, pharmacokinetic study in rats ([4]), bacterial reverse mutation test ([5]), *in vitro* mammalian chromosome aberration test ([6]), mammalian erythrocyte micronucleus test in mice ([7]), repeated dose (90 days) oral toxicity study in rats ([8]), solubility test ([9]), *in vitro* micronucleus test ([10]) and one year chronic toxicity test ([11]).

(5) On 14 April 2020, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of aqueous ethanolic extract of *Labisia pumila* as a novel food.

(6) On 28 September 2022, the Authority adopted its scientific opinion on the 'Safety of an aqueous ethanolic extract of *Labisia pumila* as a novel food pursuant to Regulation (EU) 2015/2283' ([12]) in accordance with Article 11 of Regulation (EU) 2015/2283.

(7) In its scientific opinion, the Authority concluded that aqueous ethanolic extract (1:1) of the whole plant of *Labisia pumila* mixed with maltodextrin (2:1) which serves as a drying aid, is safe for the target population at levels of up to 350 mg per day. Therefore, that scientific opinion gives sufficient grounds to establish that aqueous ethanolic extract of *Labisia pumila*, when used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council intended for the adult population, excluding pregnant and lactating women, at the maximum use level of 350 mg per day, 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 also noted that its conclusion on the safety of the novel food was based on the solubility test and toxicological information (studies on pharmacokinetics, genotoxicity, subchronic and chronic oral toxicity) 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 its proprietary claim over those data and studies 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 it held proprietary and exclusive rights of reference to the pharmacokinetic study in rats, bacterial reverse mutation test, *in vitro* mammalian chromosome aberration test, mammalian erythrocyte micronucleus test in mice, repeated dose (90 days) oral toxicity study in rats, solubility test, *in vitro* micronucleus test and one year chronic toxicity test at the time it 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 it has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, pharmacokinetic study in rats, bacterial reverse mutation test, *in vitro* mammalian chromosome aberration test, mammalian erythrocyte micronucleus test in mice, repeated dose (90 days) oral toxicity study in rats, solubility test, *in vitro* micronucleus test and one year chronic toxicity test should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place aqueous ethanolic extract of *Labisia pumila* on the market within the Union during a period of five years from the entry into force of this Regulation.

([4]) Annex 48.
([5]) Annex 52.
([6]) Annex 53.
([7]) Annex 54.
([8]) Annex 55.
([9]) Annex 91.
([10]) Annex 92.
([11]) Annexes 93, 94, 97 and 98.
([12]) *EFSA Journal* 2022;20(11):7611.

(12) However, restricting the authorisation of aqueous ethanolic extract of *Labisia pumila* and the reference to the 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 aqueous ethanolic extract of *Labisia pumila* 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. In this regard, in line with the conditions of use of food supplements containing aqueous ethanolic extract of *Labisia pumila* as proposed by the applicant and assessed by the Authority, it is necessary to inform consumers by appropriate labelling that food supplements containing aqueous ethanolic extract of *Labisia pumila* should only be consumed by adults excluding pregnant and lactating women.

(14) Aqueous ethanolic extract of *Labisia pumila* 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. Aqueous ethanolic extract of *Labisia pumila* is authorised to be placed on the market within the Union.

Aqueous ethanolic extract of *Labisia pumila* 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 Medika Natura Sdn. Bhd. ([13]) 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 6 June 2023, 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 Medika Natura Sdn. Bhd.

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 the date of entry into force of this Regulation without the agreement of Medika Natura Sdn. Bhd.

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]) No. 44B Jalan Bola Tampar 13/14 Section 13, 40100 Shah Alam Selangor, Malaysia.

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

Done at Brussels, 10 May 2023.

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
'**Aqueous ethanolic extract of *Labisia pumila***'	Specified food category	Maximum levels	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'aqueous ethanolic extract of *Labisia pumila*'. 2. The labelling of food supplements containing the novel food shall bear a statement that they should only be consumed by persons above 18 years of age excluding pregnant and lactating women.		Authorised on 6 June 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Medika Natura Sdn. Bhd., No. 44B Jalan Bola Tampar 13/14 Section 13, 40100 Shah Alam Selangor, Malaysia. During the period of data protection, the novel food aqueous ethanolic extract of *Labisia pumila* is authorised for placing on the market within the Union only by Medika Natura Sdn. Bhd., 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 Medika Natura Sdn. Bhd. End date of the date protection: 6 June 2028.'
	Food supplements as defined in Directive 2002/46/EC for the adult population, excluding pregnant and lactating women	350 mg/day			

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

Authorised Novel Food	Specification
‘**Aqueous ethanolic extract of *Labisia pumila***	**Description/Definition:** The novel food is a hydroalcoholic extract obtained from a dried whole plant of *Labisia pumila* (Blume) Fern.-Vill. The production process of the novel food starts with washing, drying and grinding of the plant *Labisia pumila*. The ground plant material is then extracted twice with a mixture of water and ethanol (50/50 v/v). The liquid extract is then concentrated, mixed with maltodextrin (which is used as a drying aid) in a ratio of 2:1 and spray-dried. **Characteristics/composition (including maltodextrin):** Particle size: > 90 % through 120 mesh (125 μm) Ash: < 10 % Acid-insoluble ash: < 1 % Moisture: < 8 % Ethanol: < 1 % (w/w) Gallic acid: 2-10 % (w/w) Carbohydrate: 70-90 g/100 g Protein: < 9 % (w/w) Total fat: < 3 % (w/w) Saponin (as ardisiacripsin A): < 1,5 % (w/w) **Microbiological criteria:** Aerobic plate count: < 1×10^4 CFU/g Yeast and mould: < 5×10^2 CFU/g *E. coli*: not detected in 10 g *S.aureus*: not detected in 10 g Salmonella: not detected in 25 g *P. aeruginosa*: not detected in 10 g cfu: colony forming units w/w: weight per weight’