COMMISSION IMPLEMENTING REGULATION (EU) 2019/506

of 26 March 2019

authorising the placing on the market of D-ribose 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 decide on the authorisation and on the placing on the Union market of a novel food and on the updating of the Union list.

(4) On 17 March 2008, the company Bioenergy Life Science, Inc. ('the Applicant'), submitted a request to the competent authority of the United Kingdom to place D-ribose on the Union market as a novel food ingredient within the meaning of point (d) of Article 1(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council ([3]). The application requests for the novel food to be used in a variety of foods, including foods for special medical purposes and total diet replacement for weight control, and in food supplements, the target population being adults and adolescents above 14 years of age.

(5) The competent authority of the United Kingdom requested additional information to resolve uncertainties arising from a study on reproductive toxicity. In November 2013, the applicant submitted a revised dossier to the competent authority of the United Kingdom.

(6) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 and for which the final decision has not been taken before 1 January 2018 shall be treated as an application submitted under Regulation (EU) 2015/2283.

(7) While the request for placing D-ribose on the market as a novel food within the Union was submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97, the application also meets the requirements laid down in Regulation (EU) 2015/2283.

(8) On 23 February 2016, the competent authority of the United Kingdom issued its initial assessment report. In that report it came to the conclusion that D-ribose meets the criteria for novel food ingredients set out in Article 3(1) of Regulation (EC) No 258/97.

(9) On 17 May 2016, the Commission forwarded the initial assessment report to the other Member States. Reasoned objections were raised by the other Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97, in particular with regard to the lack of data on the amount of free D-ribose to be consumed as part of the normal diet, the lack of long-term studies analysing the effect of high doses of D-ribose and the low margin of exposure for toddlers.

([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]) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

(10) In view of the objections raised by the other Member States, the Commission consulted the European Food Safety Authority ('the Authority') on 19 May 2017, asking it to carry out an additional assessment for D-ribose as a novel food ingredient in accordance with Regulation (EC) No 258/97.

(11) In a subsequent application, submitted on 2 March 2018, the applicant made a request to the Commission for the protection of proprietary data for a number of studies submitted in support of the application, namely, the oral embryotoxicity/teratogenicity study with D-ribose in rats ([4]) and the sub-chronic (13-week) oral toxicity study with D-ribose in rats ([5]).

(12) On 18 April 2018, the Authority adopted its 'Scientific opinion on the safety of D-ribose as a novel food.' ([6]) This opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(13) In its opinion, the Authority did not establish the safety of D-ribose at the intended uses and use levels as proposed by the applicant because the intake would exceed the level of 36 mg/kg bw per day, which is considered safe. The Authority ascertained that the data of the oral embryotoxicity/teratogenicity study with D-ribose in rats and of the sub-chronic (13-week) oral toxicity study with D-ribose in rats served as a basis to assess the safety of D-ribose. Therefore, the Authority considered that without the data from the oral embryotoxicity/teratogenicity study with D-ribose in rats and the sub-chronic (13-week) oral toxicity study with D-ribose in rats it could not have come to the conclusions on the safety of D-ribose.

(14) In view of the Authority's opinion, on 22 August 2018, the applicant modified its request by removing some of the proposed food categories included in the original application and by reducing the maximum use levels of the remaining proposed uses of D-ribose so as to alleviate the safety concerns. Following a request from the European Commission, the Authority was asked on 4 September 2018 to carry out a supplementary safety assessment for D-ribose by considering the new proposed uses and use levels submitted by the applicant. On 24 October 2018, in its reviewed opinion on the safety of D-ribose ([7]), the Authority concluded that D-ribose is safe under the new proposed conditions of use for the general population. This opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(15) That opinion gives sufficient grounds to establish that D-ribose, under the proposed uses and use levels, when used as an ingredient in cereal bars, fine bakery wares, chocolate confectionery, milk-based drinks, drinks intended to meet the expenditure of intense muscular effort especially for sportsmen, isotonic and energy drinks, meal replacement for weight control (as drinks and as bars), bars intended to meet the expenditure of intense muscular effort especially for sportsmen, confectionery, and tea and infusions complies with Article 12(1) of Regulation (EU) 2015/2283.

(16) Based on the Authority's opinion, the Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over the studies and to clarify their claim to an exclusive right of reference to those studies, as referred to in points (a) and (b) of Article 26(2) of Regulation (EU) 2015/2283.

(17) The applicant has also declared that, at the time the application was submitted, they held proprietary and exclusive rights to the studies under national law and that therefore third parties could not lawfully access or use those studies. The Commission has 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.

(18) Accordingly, as provided for under Article 26(2) of Regulation (EU) 2015/2283, the oral embryotoxicity/teratogenicity study with D-ribose in rats and the sub-chronic (13-week) oral toxicity study with D-ribose in rats contained in the applicant's file without which D-ribose could not have been assessed by the Authority, should not be used by it for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation. As a consequence, the placing on the market within the Union of D-ribose under this Regulation should be restricted to the applicant for a period of five years.

(19) However, restricting the authorisation of this novel food and the reference to the oral embryotoxicity/teratogenicity study with D-ribose in rats and the sub-chronic (13-week) oral toxicity study with D-ribose in rats 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 ingredient provided that their application is based on legally obtained information supporting the authorisation under this Regulation.

([4]) TNO report V2657 for Bioenergy Life Science, Inc., December 2005 (unpublished).
([5]) TNO report V99.115 for Bioenergy Life Science, Inc., December 2005 (unpublished).
([6]) EFSA Journal 2018; 16(5):5265.
([7]) EFSA Journal 2018; 16(12):5485.

(20) The acceptable level of intake in food containing D-ribose, if used in conjunction with food supplements containing D-ribose, should not be exceeded. It is therefore necessary to inform the consumers with an appropriate label.

(21) The Annex to Regulation (EU) 2017/2470 should therefore be amended accordingly.

(22) 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. D-ribose 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 five years from the date of entry into force of this Regulation only the initial Applicant:

Company: Bioenergy Life Science, Inc.

Address: 13840 Johnson St. NE, Minneapolis, Minnesota, 55304, 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 the same novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of Bioenergy Life Science, Inc.

3. The entry in the Union list referred to in the first paragraph 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 has been assessed by the Authority, claimed by the applicant as fulfilling the requirements 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 Bioenergy Life Science, Inc.

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, 26 March 2019.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) the following last column is added in Table 1 (Authorised novel foods):

'Data Protection'

(2) the following entry is inserted in Table 1 (Authorised novel foods) in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
'**D-ribose**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'D-ribose'. The labelling of foods containing D-ribose shall bear a statement that the foods should not be used if food supplements containing D-ribose are consumed the same day.		Authorised on 16 April 2019. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Bioenergy Life Science, Inc., 13840 Johnson St. NE, Minneapolis, Minnesota, 55304, USA. During the period of data protection, the novel food D-ribose is authorised for placing on the market within the Union only by Bioenergy Life Science, 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 Bioenergy Life Science, Inc. End date of the data protection: 16 April 2024 (5 years).'
	Cereal bars	0,20 g/100 g			
	Fine bakery wares	0,31 g/100 g			
	Chocolate confectionery (excluding chocolate bars)	0,17 g/100 g			
	Milk-based drinks (excluding malts and shakes)	0,08 g/100 g			
	Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen, isotonic and energy drinks	0,80 g/100 g			
	Bars intended to meet the expenditure of intense muscular effort especially for sportsmen	3,3 g/100 g			
	Meal replacement for weight control (as drinks)'	0,13 g/100 g			
	Meal replacement for weight control (as bars)	3,30 g/100 g			
	Confectionery	0,20 g/100 g			
	Tea and infusions (in powder form to be reconstituted)	0,23 g/100 g			

(3) The following entry is inserted in Table 2 (Specifications) in alphabetical order:

Authorised Novel Food	Specification
'**D-ribose**	**Description** D-ribose is an aldopentose monosaccharide which is produced by fermentation using a transketolase-deficient strain of *Bacillus subtilis*. Chemical formula: $C_5H_{10}O_5$ CAS No: 50-69-1 Molecular mass: 150,13 Da **Characteristics/Composition** Appearance: Dry with powdery texture, white to slightly yellow in colour Specific rotation $[\alpha]_D^{25}$: – 19,0° to – 21,0° D-ribose purity (% dry basis): -HPLC/RI (*) Method 98,0–102,0 % Ash: < 0,2 % Loss on drying (moisture): < 0,5 % Clarity on solution: ≥ 95 % transmittance **Heavy metals** Lead: ≤ 0,1 mg/kg Arsenic: ≤ 0,1 mg/kg Cadmium: ≤ 0,1 mg/kg Mercury: ≤ 0,1 mg/kg **Microbiological criteria** Total plate count: ≤ 100 CFU (**)/g Yeast: ≤ 100 CFU/g Moulds: ≤ 100 CFU/g Coliforms: ≤ 10 CFU/g *Salmonella* sp: Negative/25 g

(*) HPLC/RI: High-performance liquid chromatography coupled with refractive index detection.
(**) CFU: Colony-forming unit'