COMMISSION IMPLEMENTING REGULATION (EU) 2019/1294

of 1 August 2019

authorising the placing on the market of betaine 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]) was adopted, which establishes a Union list of authorised novel foods.

(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 12 June 2015, the company DuPont Nutrition Biosciences ApS. ('the Applicant') made a request to the competent authority of Finland to place betaine on the Union market as a novel food ingredient within the meaning of point (e) of Article 1(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council ([3]). The application requests for betaine to be used in cereal and protein bars, drink powders, isotonic ready to-drink beverages for persons above the age of 10 engaging in sports activities, and in cereal and protein bars, and foods for special medical purposes and/or total diet replacement as defined in Regulation (EU) No 609/2013 ([4]) of the European Parliament and of the Council, excluding food for infants and young children.

(5) 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.

(6) While the request for placing betaine 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.

(7) On 21 October 2015, the competent authority of Finland issued its initial assessment report. In that report, it came to the conclusion that betaine meets the criteria for novel food ingredient set out in Article 3(1) of Regulation (EC) No 258/97.

([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 foods ingredients (OJ L 43, 14.2.1997, p. 1).
([4]) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

(8) On 23 October 2015, the Commission forwarded the initial assessment report to the other Member States. Reasoned objections were raised by other Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97 with regard to adverse effects being observed at the no-observed-adverse-effect level (NOAEL) proposed by the Applicant for the chronic oral toxicity and carcinogenicity study, the small margin of exposure between the betaine doses at which effects were observed in the toxicological studies, and the proposed daily intake of betaine.

(9) In view of those reasoned objections, the Commission consulted the European Food Safety Authority ('the Authority') on 4 April 2016, asking it to carry out an additional assessment for betaine as novel food ingredient in accordance with Regulation (EC) No 258/97.

(10) On 25 October 2017, the Authority adopted its scientific opinion 'Safety of Betaine as a novel food pursuant to Regulation (EC) No 258/97 ([5])'. That opinion, although elaborated and adopted by the Authority under Regulation (EC) No 258/97 is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(11) In its scientific opinion, the Authority, using the Benchmark Dose Approach (BMD) ([6]), concluded that betaine is safe for the intended population groups when added to foods at a maximum daily dose of 400 mg/day (6 mg/kg body weight per day). In that opinion, the Authority concluded that the safety of betaine, at the proposed uses and use levels as proposed by the Applicant, which would result in intakes of 2 500 mg of betaine per day, has not been established.

(12) On 25 January 2018, the Applicant made a request to the Commission for protection of proprietary data for nine studies submitted in support of the application, namely reports of the acute oral toxicity study ([7]), two sub-acute (14-day ([8]) and 28-day ([9])), and one sub-chronic ([10]) (42-day) oral toxicity studies, three mutagenicity and genotoxicity studies ([11]), a chronic oral toxicity and carcinogenicity study ([12]), and a chronic (six-month) human dietary study ([13]).

(13) On 18 February 2018, the Authority considered ([14]) that, in elaborating its opinion on betaine as a novel food, the data from the chronic oral toxicity and carcinogenicity study served as a basis for the BMD analysis and for deriving safe intake levels of betaine for the target population, the data from the chronic human dietary study served as a basis to derive the safe intake of betaine for the target population, and the data from three genotoxicity studies served as a basis to alleviate concerns with respect to the potential genotoxity of betaine. Therefore, it is considered that the conclusions on the safety of betaine, could not have been reached without the data from the unpublished reports of these studies.

(14) Following the receipt of the Authority's considerations, the Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over the chronic oral toxicity and carcinogenicity study, the chronic human dietary study, and the three mutagenicity and genotoxicity studies, and to clarify their claim to an exclusive right of reference to these studies, as referred to in Article 26(2)(b) of Regulation (EU) 2015/2283.

(15) The Applicant declared that, at the time the application was submitted, it held proprietary exclusive rights to the studies under national law and that therefore third parties could not lawfully access or use these studies.

(16) 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 chronic oral toxicity and carcinogenicity study, the chronic human dietary study, and the three genotoxicity studies contained in the Applicant's file should not be used by the Authority for the benefit of a 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 betaine authorised by this Regulation should be restricted to the Applicant for that period.

([5]) *EFSA Journal* 2017; 15(11):5057.
([6]) *EFSA Journal* 2017; 15(1):4658.
([7]) Life Science Research Limited, 1990, unpublished.
([8]) TNO BIBRA, 2001, unpublished.
([9]) TNO BIBRA, 2001, unpublished.
([10]) Imasde Aglomentaria, 2012 unpublished.
([11]) Asquith 1989 a, b, c. Unpublished.
([12]) Hatano Research Institute. 2002, unpublished studies.
([13]) Unpublished report, undated.
([14]) EFSA Scientific Panel on Dietetic Products, Nutrition and Allergies, Minutes of the 83rd Plenary held on 7-8 February 2018 and agreed on 18 February 2018 (https://www.efsa.europa.eu/sites/default/files/event/180207-1-m.pdf).

(17) However, restricting the authorisation of betaine 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 the authorisation under this Regulation.

(18) On 2 November 2018 the Applicant made a request to the Commission within the meaning of Article 10(1) of Regulation (EU) 2015/2283 for the change in the conditions of use of betaine which were included in the 12 June 2015 request of the Applicant to the competent authority of Finland to place betaine on the Union market as a novel food ingredient. The requested changes concern modifications in the intended uses and use levels of betaine in drink powders, isotonic drinks, protein and cereal bars and meal replacement foods intended for sportsmen, and in the uses of betaine in total diet replacement foods for weight control and in foods for special medical purposes as defined in Regulation (EU) No 609/2013, excluding foods for infants and young children. Those requested changes would ensure that the intake of betaine by the general population will not exceed the 400 mg/day (6 mg/kg body weight per day) deemed by the Authority in its 2017 opinion to be safe.

(19) On 12 December 2018, the Commission consulted the Authority asking it to carry out an additional assessment for the changes in the intended uses and use levels of betaine as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283.

(20) On 14 March 2019, the Authority adopted its scientific opinion 'Safety of Betaine as a novel food pursuant to Regulation (EU) 2015/2283' ([15]). That scientific opinion is in accordance with the requirements of Article 11 of Regulation (EU) 2015/2283.

(21) In that opinion the Authority concluded that betaine is safe under the new proposed conditions of use. Therefore that scientific opinion gives sufficient grounds to establish that betaine, under the proposed uses and use levels, when used as an ingredient in drink powders, isotonic drinks, protein and cereal bars and meal replacement foods intended for sportsmen, and in total diet replacement foods for weight control, and foods for special medical purposes as defined in Regulation (EU) No 609/2013, excluding foods for infants and young children, complies with Article 12(1) of Regulation (EU) 2015/2283.

(22) The safe level of intake of betaine could be exceeded when foods containing betaine are used in conjunction with food supplements containing betaine. It is therefore necessary to inform the consumers with an appropriate label that foods containing betaine should not be used if food supplements containing betaine are also consumed on the same day.

(23) The use of betaine should be authorised without prejudice to Regulation (EU) No 609/2013 laying down requirements on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control.

(24) 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. Betaine 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: DuPont Nutrition Biosciences ApS;

Address: Langebrogade 1 DK-1411 Copenhagen K, Denmark,

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 novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of DuPont Nutrition Biosciences ApS.

([15]) *EFSA Journal* 2019; 17(4):5658.

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.

4. The authorisation provided for in this Article shall be without prejudice to the provisions of Regulation (EU) No 609/2013.

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 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 pf DuPont Nutrition Biosciences ApS.

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, 1 August 2019.

For the Commission
The President
Jean-Claude JUNCKER

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 in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
'**Betaine**	*Specified food category*	*Maximum levels* (*)	The designation of the novel food on the labelling of the foodstuffs containing it shall be "betaine". The labelling of foods containing betaine shall bear a statement that the foods should not be used if food supplements containing betaine are consumed the same day.		Authorised on 22 August 2019. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: DuPont Nutrition Biosciences ApS, Langebrogade 1 Copenhagen K, DK-1411, Denmark. During the period of data protection, the novel food betaine is authorised for placing on the market within the Union only by DuPont Nutrition Biosciences ApS 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 DuPont Nutrition Biosciences ApS, End date of the data protection: 22 August 2024.
	Drink powders, isotonic and energy drinks intended for sportsmen	60 mg/100 g			
	Protein and cereal bars intended for sportsmen	500 mg/100 g			
	Meal replacements intended for sportsmen	20 mg/100 g			
	Total diet replacement for weight control as defined under Regulation (EU) No 609/2013	500 mg/100 g (bar) 136 mg/100 g (soup) 188 mg/100 g (porridge) 60 mg/100 g (beverages)			
	Foods for Special Medical Purposes as defined under Regulation (EU) No 609/2013 for adults	400 mg/day			

(*) Maximum use levels in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.';

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

Authorised Novel Food	Specification
'**Betaine**	**Description/Definition:** Betaine (N,N,N-trimethylglycine or carboxy-N,N,N-trimethylmethanaminium), in anhydrous $(CH_3)_3N^+CH_2COO^-$ (CAS No: 107-43-7) and monohydrate $(CH_3)_3N^+CH_2COO^-.H_2O$ (CAS No: 590-47-6) forms is obtained from processing of sugar beets (i.e. molasses, vinasses or betaine-glycerol). **Characteristics/Composition** Appearance: Free-flowing white crystals Betaine: ≥ 99,0 % (w/w on dry weight basis) Moisture: ≤ 2,0 % (anhydrous); ≤ 15,0 % (monohydrate) Ash: ≤ 0,1 % pH: 5,0-7,0 Residual protein: ≤ 1,0 mg/g **Heavy metals:** Arsenic: < 0,1 mg/kg Mercury: < 0,005 mg/kg Cadmium: < 0,01 mg/kg Lead: < 0,05 mg/kg **Microbiological criteria:** Total viable count: ≤ 100 CFU/g Coliforms: Negative/10 g *Salmonella* sp.: Negative/25 g Yeast: ≤ 10 CFU/g Mould: ≤ 10 CFU/g

CFU: Colony Forming Units.'