Commission Implementing Regulation (EU) 2018/1631 of 30 October 2018 authorising the placing on the market of cranberry extract powder 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)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1631

of 30 October 2018

authorising the placing on the market of cranberry extract powder 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 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 updating the Union list.

(4) On 20 September 2011, the company Ocean Spray Cranberries Inc. (‘the Applicant’) made a request to the competent authority of France to place cranberry extract powder on the Union market as a novel food within the meaning of point (c) of Article 1(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council[(3)]. The application requested for cranberry extract powder to be used in fruit-flavoured beverages, isotonic beverages, tea beverages, vitamin enhanced waters, yogurts and yogurt drinks.

(5) On 11 December 2014, the competent authority of France issued its initial assessment report. In that report it came to the conclusion that cranberry extract powder meets the criteria for novel food ingredients set out in Article 3(1) of Regulation (EC) No 258/97. In the same report, the competent authority of France also expressed concerns

regarding possible nutritional risks associated with the overconsumption of polyphenols for children between one and three years of age resulting from the intake of polyphenols from the novel food, and from other sources of polyphenols in children's diet.

(6) On 16 January 2015, 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 with regard to insufficient data excluding the risk for young children aged between one and three years, incomplete specification of the novel food, and lack of information on the protein content needed to exclude allergy risk.

(7) In view of the initial assessment report issued by the competent authority of France and the objections raised by some Member States, the Commission consulted the European Food Safety Authority ('the Authority') on 20 April 2016, asking it to carry out an additional assessment for cranberry extract powder as a novel food in accordance with Regulation (EC) No 258/97.

(8) In contacts with the Authority the Applicant has declared that the novel food is not intended to be marketed to infants, toddlers and children of below 19 years of age.

(9) On 4 April 2017, the Authority adopted a 'Scientific Opinion on the safety of cranberry extract powder as a novel food ingredient pursuant to Regulation (EC) No 258/97' in which it concluded that cranberry extract is safe for the uses communicated by the Applicant[(4)]. 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.

(10) On 7 June 2017 the Commission informed the applicant of its and certain Member States' positions that, in view of the risk that infants, toddlers and children of below 19 years of age could consume the intended products, an authorisation would require an additional safety evaluation for these age groups. Alternatively, the Commission suggested that the risk of consumption by the age groups for which the Authority had not concluded on safety could be sufficiently contained, if cranberry extract would be authorised as a novel food supplement for the adult population.[(5)]

(11) On 22 December 2017, the Applicant informed the Commission of its decision to, at this stage, pursue the authorisation of cranberry extract for use in food supplements for the general adult population, without prejudice to a subsequent further application for an extension of the conditions of use based on a further safety assessment by the Authority.

(12) 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.The application also meets the requirements laid down in Regulation (EU) 2015/2283.

(13) The opinion of the Authority gives sufficient grounds to establish that cranberry extract powder, when used in food supplements for general adult population, complies with Article 12(1) of Regulation (EU) 2015/2283.

(14) On 2 May 2018, the applicant made a request to the Commission for protection of proprietary data for three studies submitted in support of the application namely, a ten-week clinical study in healthy adults[6], a twelve-week clinical study in adults with low to moderate cardiovascular disease risk[7] and a report on the influence on systemic immune functions, urinary and systemic biomarkers of health and faecal characteristics of human subjects during a 10 weeks administration[8]. The applicant also made a request to the Commission for protection of proprietary data for consumption information of their cranberry juice cocktail product in Europe, as well as consumption information relating to children[9]. A request to the Commission for protection of proprietary data was also made for the compositional data[10] and the intake estimate on cranberry beverage consumption[11].

(15) On 27 June 2018, the Authority considered[12] that in elaborating its opinion on cranberry extract powder as a novel food, the compositional information (Table IX.b-1, original application, dated June 2011, page 24) and the intake estimate on cranberry beverage consumption (File: 'Ocean Spray's response to Member States' objections', dated November 2015) were needed for the characterisation and setting of specifications of the novel food, as well as for hazard identification, and for the assessment whether the potential intake of proanthocyanidins (PAC) from the novel food is comparable to the PAC intake from the consumption of cranberry juice products. Therefore, it is considered that the conclusions on the safety of cranberry extract powder could not have been reached without the aforementioned data.

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

(17) The applicant declared that, at the time the application was submitted, it held proprietary and exclusive rights of reference to the evidence and data under national law and that therefore third parties could not lawfully access or use that scientific evidence or scientific data. 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.

(18) Accordingly, as provided for under Article 26(2) of Regulation (EU) 2015/2283, the compositional data and the intake estimate contained in the applicant's file and without which the novel food could not have been assessed by the Authority should not be used by 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 the novel food authorised by this Regulation should be restricted to the applicant for a period of five years.

(19) However, restricting the authorisation of this novel food and of the reference to the scientific evidence or scientific data 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.

(20) Directive 2002/46/EC lays down requirements on food supplements. The use of cranberry extract powder should be authorised without prejudice to the requirements of that Directive.

(21) 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 Cranberry extract powder 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 Applicant:

— Company: Ocean Spray Cranberries Inc.

— Address: One Ocean Spray Drive Lakeville-Middleboro, MA, 02349, 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 Ocean Spray Cranberries Inc.

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 Directive 2002/46/EC.

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 fulfilling the requirements laid down in Article 26(2) of Regulation (EC) No 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 Ocean Spray Cranberries 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, 30 October 2018.

For the Commission

The President

Jean-Claude JUNCKER