Commission Implementing Regulation (EU) 2020/500 of 6 April 2020 authorising the placing on the market of partially defatted chia seed (Salvia hispanica) powders as novel foods 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) 2020/500

of 6 April 2020

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(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 submit a draft implementing act authorising the placing on the Union market of a novel food and on the update of the Union list.

(4) On 18 April 2018, the company Access Business Group International LLC ('the applicant') submitted a request to the Commission to place partially defatted chia seed (*Salvia hispanica*) powder on the Union market as novel food in accordance with Article 10(1) of Regulation (EU) 2015/2283. The applicant requested for the chia seed (*Salvia hispanica*) powder to be used in a number of food categories for the general population as follows: unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non-heat-treated after fermentation; unflavoured fermented milk products, heat-treated after fermentation; flavoured fermented milk products including heat-treated products; confectionery; fruit and vegetable juices; fruit and vegetable nectars and similar products; flavoured drinks;

food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council[3], excluding food supplements for infants and young children; pasta.

(5) On 16 July 2018, the applicant submitted a request to the Commission to place another partially defatted chia (*Salvia hispanica*) seed powder on the Union market as novel food in accordance with Article 10(1) of Regulation (EU) 2015/2283. The applicant requested for the chia seed (*Salvia hispanica*) powder to be used in a number of food categories for the general population as follows: confectionery; fruit and vegetable juices; fruit and vegetable nectars and similar products; flavoured drinks; food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children; pasta.

(6) The two applications to the Commission concern the authorisation of two different partially defatted chia seed (*Salvia hispanica*) powders as a novel food. Both chia seed (*Salvia hispanica*) powders are partially defatted, obtained by pressing and grinding of the whole chia seeds (*Salvia hispanica*). Main differences between the two powders are particle sizes and the content of some macronutrients. The powder with high protein content has a particle size below 130 μm and protein content of at least 40 %, while the powder with high fibre content has a particle size below 400 μm and dietary fibre content of at least 50 %. The proposed uses of both powders are also similar.

(7) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('Authority') on 22 June 2018 and 22 October 2018 respectively, asking it to provide a scientific opinion by carrying out an assessment for chia seed (*Salvia hispanica*) powders as novel foods. Taking into consideration the similarities between the two types of partially defatted chia seed (*Salvia hispanica*) powders, their safety assessment by the Authority was merged.

(8) On 15 May 2019, the Authority adopted the scientific opinion 'Safety of chia seeds (*Salvia hispanica* L.) powders, as novel foods, pursuant to Regulation (EU) 2015/2283'[4]. That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(9) In that opinion, the Authority concluded that partially defatted chia seed (*Salvia hispanica*) powders are safe under the assessed conditions of use. Therefore, the opinion of the Authority gives sufficient grounds to establish that partially defatted chia seed (*Salvia hispanica*) powders, under the assessed uses and use levels, when used in unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non-heat-treated after fermentation; unflavoured fermented milk products, heat-treated after fermentation; flavoured fermented milk products including heat-treated products; confectionery; fruit and vegetable juices; fruit and vegetable nectars and similar products; flavoured drinks; food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children, comply with Article 12(1) of Regulation (EU) 2015/2283.

(10) In its scientific opinion, 'Safety of chia seeds (*Salvia hispanica* L.) as a novel food for extended uses pursuant to Regulation (EU) 2015/2283'[5] the Authority considered one study which pointed to the possible formation of acrylamide when chia seeds (*Salvia hispanica*) are used in foods, requiring heat treatment at or above 120 °C in their

manufacture, processing or preparation. The Authority considered that this study is also applicable to the assessment of the chia seed (*Salvia hispanica*) powders, since they only differ from chia seeds (*Salvia hispanica*) already included in the Union list as regards defatting, a treatment which is neutral with regard to the formation of acrylamide.

(11) The Authority noted that the food 'pasta' may be subject to heat treatment to temperatures above 120 °C and potentially could represent a relevant source of acrylamide, while other proposed food categories do not present safety concerns in relation to possible formation of acrylamide.

(12) In the opinion on safety of chia seed (*Salvia hispanica* L.) powders, the Authority considered that additional information is needed from the applicant and/or from the public domain, to address the potential for acrylamide formation when foods containing chia seed (*Salvia hispanica*) powders undergo heat treatment at or above 120 °C. In accordance with Article 11(4) of Regulation (EU) 2015/2283 the Authority has requested additional information from the applicant relating to potential formation of process contaminants which may be formed during processing and production of a food (at the level of the manufacturer) and/or when a food with added chia seed (*Salvia hispanica*) powders is subjected to cooking (heat treatment at consumer level). The period set for the provision of the additional information was set for the 13 May 2019. Although the applicant provided additional information by the set deadline, the Authority concluded that the information provided is not sufficient to address potential formation of acrylamide in pasta at temperatures above 120 °C which could potentially represent a relevant source of acrylamide at consumer level.

(13) In the absence of information on the potential formation of acrylamide in 'pasta', if subject to such heat treatment, the Authority deferred the evaluation of chia seeds powder in pasta to when the additional information becomes available. It follows, that the Commission, at this stage, does not dispose of the opinion of the Authority necessary pursuant to Article 12(1)(a) and (c) of Regulation (EU) 2015/2283 for the approval of the use of chia seed (*Salvia hispanica*) powders in pasta that may be subject to heat-treatment at or above 120 °C. Therefore, a further decision about such use will be taken after the publication of the relevant opinion of the Authority.

(14) The opinion of the Authority also identified two case reports from the available scientific literature, which linked the consumption of chia seeds (*Salvia hispanica*) to allergic reactions and concluded on this basis that allergic reactions upon consumption of chia seeds may occur. Furthermore, the Authority considers that the allergenic potential of chia seed (*Salvia hispanica*) powders is similar to that of chia seeds (*Salvia hispanica*) because the manufacturing steps employed in the production of the powders are not expected to modify the allergenic potential of the chia seeds (*Salvia hispanica*). Considering that, to date, only those two allergy cases have been reported and, in light of the widespread consumption of chia seeds (*Salvia hispanica*) and their presence on the Union and global market for many years, no specific labelling requirements concerning potential allergic reactions upon consumption of chia seed (*Salvia hispanica*) powders should be included in the Union list of authorised novel foods, until further scientific

evidence on the allergenic potential of chia seeds (*Salvia hispanica*) is obtained and assessed by the Authority.

(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 Partially defatted chia seed (*Salvia hispanica*) powders 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 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.

Article 2

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 3

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, 6 April 2020.

For the Commission

The President

Ursula VON DER LEYEN