Commission Implementing Regulation (EU) 2020/24 of 13 January 2020 authorising an extension of use of chia seeds (Salvia hispanica) as a novel food and the change of the conditions of use and the specific labelling requirements of chia seeds (Salvia hispanica) 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) 2020/24

of 13 January 2020

authorising an extension of use of chia seeds (*Salvia hispanica*) as a novel food and the change of the conditions of use and the specific labelling requirements of chia seeds (*Salvia hispanica*) 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)] 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 placing on the Union market of a novel food and on the updating of the Union list.

(4) Commission Decision 2009/827/EC[(3)] authorised, in accordance with Regulation (EC) No 258/97, the placing on the market in the Union of chia seeds (*Salvia hispanica*) as a novel food to be used in bread products.

(5) Commission Implementing Decision 2013/50/EU[(4)] authorised, in accordance with Regulation (EC) No 258/97, an extension of use of chia seeds (*Salvia hispanica*) as a novel food to be used in additional food categories as follows: baked products; breakfast cereals; fruit, nut and seed mixes, and pre-packed chia seeds as such.

(6) On 18 September 2015, an authorisation letter was issued by the competent authority of Ireland[5], in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council[6], for an extension of use of the novel food chia seeds (*Salvia hispanica*) to be used in additional food categories, namely, in fruit juice and fruit/vegetable blend beverages.

(7) On 17 October 2017, an authorisation letter was issued by the competent authority of Austria[7], in accordance with Regulation (EC) No 258/97, for an extension of use of the novel food chia seeds (*Salvia hispanica*) to be used in additional food category, namely, fruit spreads.

(8) On 02 November 2017, an authorisation letter was issued by the competent authority of Spain[8], in accordance with Regulation (EC) No 258/97, for an extension of use of the novel food chia seeds (*Salvia hispanica*) to be used in additional food categories, namely, sterilised ready meals based on cereal grains, pseudocereal grains and/or pulses.

(9) Commission Implementing Decision (EU) 2017/2354[9] authorised, in accordance with Regulation (EC) No 258/97, an extension of use of the novel food chia seeds (*Salvia hispanica*) to be used in additional food category, namely, in yoghurt.

(10) On 13 April 2017, the company Zentis GmbH & Co. KG submitted a request in accordance with Article 4 of Regulation (EC) No 258/97 to the competent authority of Germany to change the conditions of use of the novel food chia seeds (*Salvia hispanica*). The application requested to extend the use of chia seeds (*Salvia hispanica*) in additional food categories, namely, fruit desserts, mixed fruits with coconut milk for a twin pot, fruit-preparations to underlay dairy products and fruit-preparations to be mixed with dairy products, and to increase maximum use level of chia seeds (*Salvia hispanica*) in an already authorised food category, namely fruit spreads.

(11) On 12 September 2017, the company Sanchis Mira S.A. submitted a request in accordance with Article 4 of Regulation (EC) No 258/97 to the competent authority of Spain for an extension of use of the novel food chia seeds (*Salvia hispanica*) in chocolate. On 25 September 2017, the competent authority of Spain issued its initial assessment report. In that report, it came to the conclusion that the extension of use and proposed maximum use level of chia seeds (*Salvia hispanica*) meet the criteria for novel foods set out in Article 3(1) of Regulation (EC) No 258/97.

(12) On 17 October 2017, the Commission forwarded the initial assessment report to the other Member States. One Member State raised objections, questioning the overall safety of the novel food in light of the 2009 European Food Safety Authority ('the Authority') NDA Panel assessment[10] as a result of the increasing dietary intake of chia seeds (*Salvia hispanica*) from the growing number of authorised uses. The objecting Member State underlined that while individual uses, including the proposed use in chocolate at 3 %, may be safe, there is a need to assess the overall dietary intake from all authorised uses since 2009 including the current request for the extension of use and if necessary, revise the 2009 NDA Panel safety assessment.

(13) 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.

(14) While the requests for an extension of use of chia seeds (*Salvia hispanica*) were submitted to the Member States in accordance with Article 4 of Regulation (EC) No 258/97, the applications also meet the requirements laid down in Regulation (EU) 2015/2283.

(15) On 2 February 2018, the company Parry's Pots Limited (PPL) submitted a request to the Commission to change the conditions of use of the novel food chia seeds (*Salvia hispanica*) within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requested to increase maximum use level of chia seeds (*Salvia hispanica*) in an already authorised food category, namely fruit spreads.

(16) On 12 June 2018, the company Naturkost Übelhör GmbH & Co. KG submitted a request to the Commission to change the conditions of use of the novel food chia seeds (*Salvia hispanica*) within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requested to extend the use of chia seeds (*Salvia hispanica*) in additional food categories, namely, chocolate and chocolate products.

(17) On 15 June 2018, the company Majami Sp.zo.o.Sp.k. submitted a request to the Commission to change the conditions of use of the novel food chia seeds (*Salvia hispanica*) within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requested to extend the use of chia seeds (*Salvia hispanica*) in additional food category, namely, confectionery.

(18) On 16 July 2018, the company The Chia Co submitted a request to the Commission to change the conditions of use of the novel food chia seeds (*Salvia hispanica*) within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requested to extend the use of chia seeds (*Salvia hispanica*) in additional food categories as follows: confectionery, excluding chewing gums; dairy products and analogues; edible ices; fruit and vegetable products; cereal and cereal products; bakery wares; herbs, spices, seasonings, soups and broths, sauces, salads and savoury based sandwich spreads and protein products; total diet replacement foods for weight control; foods bearing statements on the absence or reduced presence of gluten; non-alcoholic beverages; ready-to-eat savouries and snacks; and desserts.

(19) On 3 August 2018, the company Materne SAS submitted a request to the Commission to change the conditions of use of the novel food chia seeds (*Salvia hispanica*) within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requested to extend the use of chia seeds (*Salvia hispanica*) in additional food categories, namely, compotes from fruit and/or vegetables and/or with cereals.

(20) On 9 January 2019, the company RFH Produktion AB submitted a request to the Commission to change the conditions of use of the novel food chia seeds (*Salvia hispanica*) within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requested to extend the use of chia seeds (*Salvia hispanica*) in additional food category, namely, puddings.

(21) In accordance with Article 10(3) of Regulation (EU) 2015/2283 and in the light of the growing number of requests for the authorisation of a number of extended uses of chia seeds (*Salvia hispanica*), the new authorised uses in recent years, and the resulting potential increase in the dietary intake of chia seeds (*Salvia hispanica*), the Commission consulted the Authority on 16 July 2018, asking it to carry out an assessment on the overall dietary exposure for all the potential extensions of use of chia seeds (*Salvia hispanica*) as a novel food.

(22) On 14 March 2019, the Authority adopted the scientific opinion 'Safety of chia seeds (*Salvia hispanica* L.) as a novel food for extended uses pursuant to Regulation (EU) 2015/2283'[11]. That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(23) In that opinion the Authority concluded, in reply to the Commission's request for a general assessment of the safety without restrictions or precautions regarding the use levels, that the use of chia seeds (*Salvia hispanica*) in foods which do not require heat treatment at or above 120 °C in their manufacture, processing or preparation, including chocolate, fruit spreads, fruit desserts, mixed fruit with coconut milk in twin pot, fruit-preparations to underlay dairy products, fruit-preparations to be mixed with dairy products, confectionery (excluding chewing gums), dairy products and analogues, edible ices, fruit and vegetables products, non-alcoholic beverages and compotes from fruit and/or vegetables and/or with cereals, are safe without any specific restrictions and precautions regarding their use levels. Therefore, that scientific opinion gives sufficient grounds to establish that the above-mentioned uses of chia seeds (*Salvia hispanica*) comply with the requirements of Article 12(1) of Regulation (EU) 2015/2283. It is therefore appropriate that the conditions of use of chia seeds (*Salvia hispanica*) as listed in the Union list of authorised novel foods are amended by including all of the above food categories and to remove the setting of maximum levels and the corresponding specific labelling requirement relating to the maximum daily intake. In addition, although the use of chia seeds (*Salvia hispanica*) in puddings was not explicitly included in the assessment of the Authority, the opinion gives sufficient grounds to also authorise the extension of use of chia seeds (*Salvia hispanica*) to puddings that do not require heat treatment at or above 120 °C in their manufacture, processing or preparation. Puddings are to be understood as a subcategory of products commonly known as desserts, which are usually flavoured and sweet in taste.

(24) In the same opinion, the Authority considered one study, retrieved by the Authority itself from the publicly available scientific literature, and which was not part of the evidence submitted by applicants in support of the proposed extensions of use of chia seeds (*Salvia hispanica*), which pointed to the possible formation of acrylamide when chia seeds (*Salvia hispanica*) are used in foods which require heat treatment at or above 120 °C in their manufacture, processing or preparation.

(25) In that opinion, the Authority considered that additional information is needed from applicants and/or from the public domain, to address the potential for acrylamide formation when foods containing chia seeds (*Salvia hispanica*) 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 relevant 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 seeds (*Salvia hispanica*) is subjected to cooking (heat treatment at consumer level). The period set established for the provision of the additional information ends in March 2020. In the absence of such information in the submitted applications, the Authority deferred the evaluation of those extensions of use of chia seeds (*Salvia hispanica*) in foods which require heat treatment at or above 120 °C in their manufacture, processing or preparation (bakery wares, cereal and cereal products, herbs, spices, seasonings, soups and broths, sauces, salads and savoury based sandwich spreads and protein products, total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council[(12)], foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014[(13)], ready to eat savouries and snacks and desserts) 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 extension of uses involving the treatment of chia seeds (*Salvia hispanica*) at or above 120 °C. Therefore, a further decision about such uses will be taken after the publication of the relevant opinion of the Authority.

(26) 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 the basis of this evidence that allergic reactions upon consumption of chia seeds (*Salvia hispanica*) may occur. Considering that, to date, only those two allergic cases have been reported, in light of the widespread consumption of chia seeds (*Salvia hispanica*) and their presence on the Union and global market for many years, the Commission considers that no specific labelling requirements concerning potential allergic reactions upon consumption of chia seeds (*Salvia hispanica*) 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.

(27) 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 The entry in the Union list of authorised novel foods as provided for in Article 6 of Regulation (EU) 2015/2283 and included in Implementing Regulation (EU) 2017/2470, referring to the novel food chia seeds (*Salvia hispanica*) is amended as specified in the Annex to this Regulation.

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 to this Regulation.