COMMISSION IMPLEMENTING REGULATION (EU) 2021/668

of 23 April 2021

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

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

(5) On 18 September 2015, the competent authority of Ireland issued an official letter ([6]) in accordance with Regulation (EC) No 258/97, authorising an extension of use of the novel food chia seeds in additional food categories, namely fruit juice and fruit/vegetable blend beverages.

(6) On 17 October 2017, the competent authority of Austria issued an official letter ([7]) in accordance with Regulation (EC) No 258/97, authorising an extension of use of the novel food chia seeds in an additional food category, namely fruit spreads.

([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]) Commission Decision 2009/827/EC of 13 October 2009 authorising the placing on the market of Chia seed (*Salvia hispanica*) as novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 294, 11.11.2009, p. 14).

([4]) 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).

([5]) Commission Implementing Decision 2013/50/EU of 22 January 2013 authorising an extension of use of Chia (*Salvia hispanica*) seed as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 21, 24.1.2013, p. 34).

([6]) Letter of 18 September 2015 (https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_authorisation_2015_auth-letter_chia-seeds-2_en.pdf).

([7]) Letter of 17 October 2017 (https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_authorisation_2017_auth-letter_chia-seeds_en.pdf).

(7) On 2 November 2017, the competent authority of Spain issued an official letter ([8]) in accordance with Regulation (EC) No 258/97, authorising an extension of use of the novel food chia seeds in additional food categories, namely sterilised ready meals based on cereal grains, pseudocereal grains and/or pulses.

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

(9) Commission Implementing Regulation (EU) 2020/24 ([10]) authorised an extension of use of the novel food chia seeds to be used in a number of additional food categories, certain changes of the conditions of use and the specific labelling requirements of chia seeds in accordance with Regulation (EU) 2015/2283.

(10) In line with previous authorisations, chia seeds are authorised for placing on the market within the Union under the specified conditions of use, including 'pre-packaged chia seed as such'. In January 2020, the Commission received a query from the association 'Réseau Vrac' on whether non pre-packaged (loose, bulk) chia seeds as such may also be placed on the Union market.

(11) Following this query, the Commission has further evaluated whether the removal of the term 'pre-packaged' from the category 'pre-packaged chia seed as such' is also safe. That amendment would allow food business operators to place chia seeds as such on the Union market in both pre-packaged and non-pre-packaged (loose, bulk) forms. Therefore, the Commission is of the view that the Union list should be amended accordingly.

(12) In accordance with Article 10(1) of Regulation (EU) 2015/2283, the Commission started the procedure for updating the Union list of novel foods on its own initiative.

(13) In its opinion of 14 March 2019 concerning the 'Safety of chia seeds (*Salvia hispanica* L.) as a novel food for extended uses pursuant to Regulation (EU) 2015/2283' ([11]), the European Food Safety Authority ('the Authority') concluded that the use of chia seeds in foods which do not require heat treatment at or above 120 °C in their manufacture, processing or preparation is safe without any specific restrictions and precautions regarding their use levels.

(14) The Commission considers that a safety evaluation by the Authority of the proposed change to the conditions of use in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary, as the change of the conditions of use of the novel food chia seeds (*Salvia hispanica*), by removing forms in which chia seeds as such may be placed on the market is not liable to have an effect on human health.

(15) It is therefore appropriate to authorise the placing on the market of chia seeds also without pre-packaging.

(16) Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([8]) Letter of 2 November 2017 (https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_authorisation_2017_auth-letter_chia-seeds-ext-steri_en.pdf).

([9]) Commission Implementing Decision (EU) 2017/2354 of 14 December 2017 authorising an extension of use of Chia seeds (*Salvia hispanica*) as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 336, 16.12.2017, p. 49).

([10]) 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 (OJ L 8, 14.1.2020, p. 12).

([11]) *EFSA Journal* 2019;17(4):5657.

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 the Annex to Implementing Regulation (EU) 2017/2470, referring to the novel food chia seeds (*Salvia hispanica*), shall be 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.

Article 2

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, 23 April 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

The entry for 'Chia seeds (*Salvia hispanica*)' in Table 1 of the Annex to Implementing Regulation (EU) 2017/2470 is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
'Chia seeds (*Salvia hispanica*)	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Chia seeds (*Salvia hispanica*)'"	
	Bread products	5 % (whole or ground chia seeds)		
	Baked products	10 % whole chia seeds		
	Breakfast cereals	10 % whole chia seeds		
	Sterilised ready to eat meals based on cereal grains, pseudocereal grains and/or pulses	5 % whole chia seeds		
	Fruit, nut and seed mixes			
	Chia seeds as such			
	Confectionery (including chocolate and chocolate products), excluding chewing gums			
	Dairy products (including yoghurt) and analogues			
	Edible ices			
	Fruit and vegetables products (including fruit spreads, compotes with/without cereals, fruit-preparations to underlay or to be mixed with dairy products, fruit desserts, mixed fruits with coconut milk for a twin pot)			
	Non-alcoholic beverages (including fruit juice and fruit/vegetable blend beverages)			
	Puddings that do not require heat treatment at or above 120 °C in their manufacture, processing or preparation			