



2023/2214

24.10.2023

**COMMISSION IMPLEMENTING REGULATION (EU) 2023/2214**

**of 23 October 2023**

**amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use and the specifications of the novel foods *partially defatted chia seed (Salvia hispanica) powders***

(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 <sup>(1)</sup>, and in particular Article 12(1) thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods 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 <sup>(2)</sup> has established a Union list of novel foods.
- (3) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes partially defatted chia seed (*Salvia hispanica*) powders as authorised novel foods.
- (4) Commission Implementing Regulation (EU) 2020/500 <sup>(3)</sup> authorised the placing on the market of partially defatted chia seed (*Salvia hispanica*) powders as novel foods for use in a number of foods intended for the general population.
- (5) On 26 July 2021, the company Functional Products Trading Arica S.A./BENEXIA ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for a change of the conditions of use of the novel foods partially defatted chia seed (*Salvia hispanica*) powders. In particular, the applicant requested to extend the use of partially defatted chia seed (*Salvia hispanica*) powder with a high fibre content to a number of foods intended for the general population, namely: cakes and pastries, processed fruit and vegetables (including vegetable-based dishes), bread and rolls, pasta based products and protein products.
- (6) On 26 July 2021, the applicant also made a request to the Commission for the protection of proprietary data for an acute toxicity study <sup>(4)</sup>, a human study <sup>(5)</sup>, a process contaminants formation assessment study <sup>(6)</sup> and the certificates of analysis <sup>(7)</sup>.
- (7) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 23 March 2022, requesting it to provide a scientific opinion on the change of conditions of use of partially defatted chia seed powders with a high fibre content as a novel food.

<sup>(1)</sup> OJ L 327, 11.12.2015, p. 1.

<sup>(2)</sup> 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).

<sup>(3)</sup> 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 (OJ L 109, 7.4.2020, p. 2).

<sup>(4)</sup> Annex 20.

<sup>(5)</sup> Annex 21.

<sup>(6)</sup> Annex 22.

<sup>(7)</sup> Annexes 23 to 41 and Annex 43.

- (8) On 27 February 2023, the Authority adopted its scientific opinion on the ‘Safety of the extension of use of partially defatted chia seed (*Salvia hispanica* L.) powder with a high fibre content as a novel food pursuant to Regulation (EU) 2015/2283’ <sup>(8)</sup> in accordance with Article 11 of Regulation (EU) 2015/2283.
- (9) In its scientific opinion, the Authority concluded that the proposed change is safe under the proposed conditions of use, and therefore it is appropriate to amend the conditions of use of partially defatted chia seed (*Salvia hispanica*) powder with a high fibre content.
- (10) In its scientific opinion, the Authority noted the incorrect reporting of the specification for *Listeria monocytogenes* (‘Absence/g’) and *Escherichia coli* (‘&lt; 10 MPN/g’) in the novel food as authorised in Implementing Regulation (EU) 2020/500. Therefore, the specification of the novel foods should be amended accordingly by indicating correct maximum levels of *Listeria monocytogenes* as ‘Not detected in 25 g’ and of *Escherichia coli* as ‘Not detected in 10 g’.
- (11) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on the human study, the process contaminants formation assessment study and the certificates of analysis submitted by the applicant without which it could not have assessed the novel food and reached its conclusion.
- (12) The Commission requested the applicant to further clarify the justification provided with regard to its proprietary claim over those data and studies and to clarify their claim to an exclusive right of reference to them in accordance with Article 26(2)(b) of Regulation (EU) 2015/2283.
- (13) The applicant declared that it held proprietary and exclusive rights of reference to the human study, the process contaminants formation assessment study and the certificates of analysis at the time they submitted the application, and that third parties cannot lawfully access, use or refer to those data.
- (14) The Commission assessed all the information provided by the applicant and considered that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the human study, the process contaminants formation assessment study and certificates of analysis should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place partially defatted chia seed powder with a high fibre content for use in cakes and pastries, processed fruit and vegetables (including vegetable-based dishes), bread and rolls, pasta based products and protein products, on the market within the Union during a period of five years from the entry into force of this Regulation.
- (15) However, such a restriction of the authorisation and the reference to the scientific data contained in the applicant’s file for the sole use by them does not prevent subsequent 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 such an authorisation.
- (16) The information provided in the application and the opinion of the Authority give sufficient grounds to establish that the changes to the conditions of use and the specifications of the novel food are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and should be approved.
- (17) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (18) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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<sup>(8)</sup> EFSA Journal 2023;21(4):7904.

HAS ADOPTED THIS REGULATION:

*Article 1*

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

*Article 2*

Only the company Functional Products Trading Arica S.A./BENEXIA <sup>(\*)</sup> is authorised to place on the market within the Union partially defatted chia seed (*Salvia hispanica*) powder with a high fibre content for use in cakes and pastries, processed fruit and vegetables (including vegetable-based dishes), bread and rolls, pasta based products and protein products for a period of 5 years from 13 November 2023, unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of Functional Products Trading Arica S.A./BENEXIA.

*Article 3*

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of 5 years from the date of entry into force of this Regulation without the agreement of Functional Products Trading Arica S.A./BENEXIA.

*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, 23 October 2023.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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<sup>(\*)</sup> Address: Luis Pasteur 5850, Oficina 403, Quinto Piso; Vitacura, Santiago – Chile.

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the entry for ‘Partially defatted chia seed (*Salvia hispanica*) powders’ is replaced by the following:

Authorised novel food		Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
Partially defatted chia seed ( <i>Salvia hispanica</i> L.) powders	Powder with high protein content	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be “Partially defatted chia seed ( <i>Salvia hispanica</i> ) powder”		
		Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non-heat-treated after fermentation	0,7 %			
		Unflavoured fermented milk products, heat-treated after fermentation	0,7 %			
		Flavoured fermented milk products including heat-treated products	0,7 %			
		Confectionery	10 %			
		Fruit juices as defined by Council Directive 2001/112/EC (*) and vegetable juices	2,5 %			
		Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products	2,5 %			
		Flavoured drinks	3 %			
		Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children	7,5 g/day			
	Powder with high fibre content	Confectionery	4 %			Authorised for use in cakes and pastries, processed fruit and vegetables (including vegetable-based dishes), bread and rolls, pasta based products and protein products on 13 November 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
		Fruit juices as defined by Directive 2001/112/EC and vegetable juices	2,5 %			
		Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products	4 %			

	Flavoured drinks	4 %			Applicant: Functional Products Trading Arica S.A./ BENEXIA, Luis Pasteur 5850, Oficina 403, Quinto Piso. Vitacura, Santiago – Chile. During the period of data protection, partially defatted chia seed ( <i>Salvia hispanica</i> L.) powder with a high fibre content for use in cakes and pastries, processed fruit and vegetables (including vegetable-based dishes), bread and rolls, pasta based products and protein products is authorised for placing on the market within the Union only by Functional Products Trading Arica S.A./BENEXIA, unless a subsequent applicant obtains authorisation for the same 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 Functional Products Trading Arica S.A./BENEXIA. End date of the data protection: 13 November 2028.
	Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children	12 g/day			
	Cakes and pastries	5 g/100 g			
	Processed fruit and vegetables (including vegetable-based dishes)	10 g/100 g			
	Bread and rolls	10 g/100 g			
	Pasta based products	8 g/100 g			
	Protein products	10 g/100 g			

(\*) Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption (OJ L 10, 12.1.2002, p. 58).'

(2) in Table 2 (Specifications), the entry for 'Partially defatted chia seed (*Salvia hispanica*) powders' is replaced by the following:

Authorised novel food	Specification	
Partially defatted chia seed ( <i>Salvia hispanica</i> ) powders	<b>Description/Definition:</b>	
	The novel foods are partially defatted chia seed ( <i>Salvia hispanica</i> ) powders obtained by pressing and grinding of the whole seeds of <i>Salvia hispanica</i> L.	
	<b>Physical–sensorial:</b>	
	Foreign matter: 0,1 %	
		Powder with high protein content
		Powder with high fibre content
	Particle size	≤ 130 µm
		≤ 400 µm
	<b>Chemical composition:</b>	
		<i>Salvia hispanica</i> powder with high protein content
		<i>Salvia hispanica</i> powder with high fibre content
	Moisture	≤ 9,0 %
	Protein	≥ 40,0 %
	Fat	≤ 17 %
	Fibre	≤ 30 %
	<b>Microbiological criteria:</b>	
	Total plate count: ≤ 10 000 CFU/g	
	Yeasts: ≤ 500 CFU/g	
	Moulds: ≤ 500 CFU/g	
	<i>Staphylococcus aureus</i> : ≤ 10 CFU/g	
	Coliforms: < 100 MPN/g	
	Enterobacteriaceae: ≤ 100 CFU/g	
	<i>Bacillus cereus</i> : ≤ 50 CFU/g	
	<i>Escherichia coli</i> : Not detected in 10 g	
	<i>Listeria monocytogenes</i> : Not detected in 25 g	
	<i>Salmonella</i> spp.: Absence in 25 g	

**Contaminants:**Arsenic:  $\leq 0,1$  ppmCadmium:  $\leq 0,1$  ppmLead:  $\leq 0,1$  ppmMercury:  $\leq 0,1$  ppmTotal aflatoxins:  $\leq 4$  ppbOchratoxin A:  $\leq 1$  ppb'