

## II

(Non-legislative acts)

## REGULATIONS

## COMMISSION IMPLEMENTING REGULATION (EU) 2021/120

of 2 February 2021

**authorising the placing on the market of partially defatted rapeseed powder from *Brassica rapa* L. and *Brassica napus* L. 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 <sup>(1)</sup>, 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 <sup>(2)</sup> establishing a Union list of authorised novel foods was adopted.
- (3) On 31 December 2018, the company Avena Nordic Grain Oy ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place partially defatted rapeseed powder from *Brassica rapa* L. and *Brassica napus* L. low cultivars (00), on the Union market as a novel food. The applicant requested for the partially defatted rapeseed powder from *Brassica rapa* L. and *Brassica napus* L. to be used in cereal bars, muesli and similar mixed breakfast cereals, extruded breakfast cereal products, snacks other than chips and similar, brown gluten-free breads, bread and rolls with special ingredients added, multigrain bread and rolls, meat substitutes, and meat balls.
- (4) The applicant also proposed that, because the protein fraction of the partially defatted rapeseed powder from *Brassica rapa* L. and *Brassica napus* L. is similar to that of the rapeseed protein authorised as a novel food by Commission Implementing Decision 2014/424/EU <sup>(3)</sup> for which the European Food Safety Authority ('the Authority') had concluded <sup>(4)</sup> that a risk of sensitisation cannot be excluded and that it is likely that it can trigger allergic reactions

<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 Decision 2014/424/EU of 1 July 2014 authorising the placing on the market of rapeseed protein as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 196, 3.7.2014, p. 27.)

<sup>(4)</sup> EFSA Journal 2013; 11(10):3420.

in people allergic to mustard, the labelling of food products containing partially defatted rapeseed powder from *Brassica rapa* L. and *Brassica napus* L. is such to allow people who are allergic to mustard to avoid consumption of those foods.

- (5) On 31 December 2018, the applicant also made a request to the Commission for the protection of proprietary data for a randomised double-blind, controlled, parallel group, 4-week intervention human clinical trial study, to assess the safety and tolerability of the novel food among healthy consumers <sup>(5)</sup>.
- (6) On 19 June 2019, the Commission requested the Authority to carry out an assessment of the partially defatted rapeseed powder from *Brassica rapa* L. and *Brassica napus* L. as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283.
- (7) On 30 June 2020, the Authority adopted its scientific opinion 'Safety of rapeseed powder from *Brassica rapa* L. and *Brassica napus* L. as a novel food pursuant to Regulation (EC) 2015/2283' <sup>(6)</sup> in accordance with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (8) In its scientific opinion, the Authority concluded that partially defatted rapeseed powder from *Brassica rapa* L. and *Brassica napus* L. is safe under the proposed conditions of use. However, it also concluded that the partially defatted rapeseed powder from *Brassica rapa* L. and *Brassica napus* L. rapeseed may trigger allergic reactions in people allergic to mustard. Therefore, that scientific opinion gives sufficient grounds to establish that partially defatted rapeseed powder from *Brassica rapa* L. and *Brassica napus* L., when used in cereal bars, muesli and similar mixed breakfast cereals, extruded breakfast cereal products, snacks other than chips and similar, brown gluten-free breads, bread and rolls with special ingredients added, multigrain bread and rolls, meat substitutes, and meat balls, and provided that the labelling of the foods containing partially defatted rapeseed powder from *Brassica rapa* L. and *Brassica napus* L. is such to allow people who are allergic to mustard to avoid consumption of those foods, complies with the authorisation requirements of Article 12(1) of Regulation (EU) 2015/2283.
- (9) The opinion of the Authority and the composition and specification data submitted by the applicant also give sufficient grounds to include total carbohydrates in the novel food specification as this is an important nutritional component whose inclusion will complete the proximate profile of this novel food.
- (10) In its scientific opinion, the Authority considered that it could have reached its conclusions on the safety of the partially defatted rapeseed powder from *Brassica rapa* L. and *Brassica napus* L. under the proposed conditions of use without the data claimed as proprietary by the applicant (a randomised double-blind, controlled, parallel-group, 4-week intervention, human clinical trial study, to assess the safety and tolerability of the novel food among healthy consumers).
- (11) Therefore, the Commission considers that the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283 have not been fulfilled, and the requested protection of the proprietary data included in the application cannot be granted. It is therefore appropriate that the authorisation of the partially defatted rapeseed powder from *Brassica rapa* L. and *Brassica napus* L. as a novel food and its inclusion in the Union list of authorised novel foods should contain only the information referred to in Article 9(3) of Regulation (EU) 2015/2283.
- (12) The Annex to Implementing Regulation (EU) 2017/2470 should be therefore be amended accordingly.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(5)</sup> Medfiles Ltd, 2018 (Unpublished).

<sup>(6)</sup> EFSA Journal 2020;18(7):6197.

HAS ADOPTED THIS REGULATION:

*Article 1*

1. Partially defatted rapeseed powder from *Brassica rapa* L. and *Brassica napus* L. 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, 2 February 2021.

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

---

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

(1) in Table 1 (Authorised novel foods), the following entry is inserted in alphabetical order:

| Authorised novel food   | Conditions under which the novel food may be used   |                       | Additional specific labelling requirements   | Other requirements |
|---|---|-----------------------|--|--------------------|
|   | <i>Specified food category</i>  | <i>Maximum levels</i> |  |                    |
| <b>Partially defatted rapeseed powder from <i>Brassica rapa</i> L. and <i>Brassica napus</i> L.</b> | Cereal bars mixed   | 20 g/100 g            | The designation of the novel food on the labelling of the foodstuffs containing it shall be "Partially defatted Rapeseed powder". Any foodstuff containing "Partially defatted Rapeseed powder" from <i>Brassica rapa</i> L. and <i>Brassica napus</i> L.' shall bear a statement that this ingredient may cause allergic reaction to consumers who are allergic to mustard and products thereof. That statement shall appear in close proximity to the list of ingredients. ' |                    |
|   | Muesli and similar breakfast cereals  | 20 g/100 g            |  |                    |
|   | Extruded breakfast cereal products  | 20 g/100 g            |  |                    |
|   | Snacks (excluding potato crisps)  | 15 g/100 g            |  |                    |
|   | Breads and rolls with added special ingredients (such as seeds, raisins, herbs)   | 7 g/100 g             |  |                    |
|   | Brown breads bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014 | 7 g/100 g             |  |                    |
|   | Multigrain bread and rolls  | 7 g/100 g             |  |                    |
|   | Meat substitutes  | 10 g/100 g            |  |                    |
|   | Meat balls  | 10 g/100 g            |  |                    |

(2) in Table 2 (Specifications), the following entry is inserted in alphabetical order:

| Authorised Novel Food  | Specifications   |
|--|--|
| <p><b>Partially defatted rapeseed powder from <i>Brassica rapa</i> L. and <i>Brassica napus</i> L.</b></p> | <p><b>Definition:</b> The powder is produced from the partially defatted seeds of non-genetically modified <i>Brassica rapa</i> L. and <i>Brassica napus</i> L. double low (00) cultivars through a series of processing steps to reduce glucosinolates and phytates.</p> <p><b>Source:</b> <i>Brassica rapa</i> L. and <i>Brassica napus</i> L. seeds</p> <p><b>Characteristics/Composition:</b><br/>           Protein (N × 6,25): 33,0-43,0 %<br/>           Lipids: 14,0 – 22,0 %<br/>           Total Carbohydrates(*): 33,0 – 40,0 %<br/>           Total Fibre(**): 33,0 – 43,0 %<br/>           Moisture: &lt; 7,0 %<br/>           Ash: 2,0–5,0 %<br/>           Total Glucosinolates: &lt; 0,3 mmol/kg (≤ 120 mg/kg)<br/>           Phytate: &lt; 1,5 %<br/>           Peroxide value (in novel food weight): ≤ 3,0 mEq O<sub>2</sub>/kg</p> <p><b>Heavy Metals:</b><br/>           Lead: &lt; 0,2 mg/kg<br/>           Arsenic (inorganic): &lt; 0,2 mg/kg<br/>           Cadmium: &lt; 0,2 mg/kg<br/>           Mercury: &lt; 0,1 mg/kg<br/>           Aluminium: &lt; 35,0 mg/kg</p> <p><b>Microbiological criteria:</b><br/>           Total plate count (30 °C): &lt; 5 000 CFU/g<br/>           Enterobacteriaceae: &lt; 10 CFU/g<br/>           Salmonella sp.: Negative/25 g<br/>           Yeast and mould: &lt; 100 CFU/g<br/>           Bacillus cereus: &lt; 100 CFU/g</p> <p>(*) By difference: 100 % – [protein % + moisture % + fat % + ash %]<br/>           (**) AOAC 2011.25 (Enzymatic gravimetry)<br/>           CFU: Colony Forming Units, AOAC: Association of Official Agricultural Chemists'</p> |