

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

EN

ANNEX

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	Data protection
Rapeseed protein concentrate	<i>Specified food category</i>	<i>Maximum levels</i>	<p>The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘rapeseed protein concentrate’.</p> <p>The labelling of food supplements containing rapeseed protein concentrate shall bear a statement</p> <p>a) that they should not be used if other foods containing added rapeseed protein concentrate are</p>		<p>Authorised on [...] <i>[OP, please insert the date dd.mm.yyyy - 20th day following its publication]</i>. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU)</p>
	Bakery products (bread and rolls, fine bakery wares)	20 g/100g			
	Bread bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Implementing Regulation (EU) No 828/2014	20 g/100g			
	Breakfast cereals	20 g/100g			
	Cereal bars	20 g/100g			
	Pasta	10 g/100g			
	Pasta products bearing	10 g/100g			

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

statements on the absence or reduced presence of gluten in accordance with the requirements of Implementing Regulation (EU) No 828/2014		consumed the same day and b) they should not be consumed by infants and children under 10 years of age.	2015/2283.
Non-alcoholic powdered drinks	5 g/100 ml (reconstituted according to the instructions)	Any foodstuff containing 'rapeseed protein concentrate' 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.	Applicant: "NapiFeryn BioTech Sp. z o.o.", Stanisława Dubois 114/116, 93-465 Łódź, Poland. During the period of data protection, the novel food rapeseed protein-fibre concentrate is authorised for placing on the market within the Union only by "NapiFeryn BioTech Sp. z o.o." unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with
Fruit-based liquid foodstuffs (of the 'smoothie' variety)	3 g/100g		
Dairy analogues	5 g/100g		
Meat analogues	15 g/100g		
Soups (dry mixture) and (ready-to-eat)	5 g/100ml (marketed as such or reconstituted according to the instructions)		
Savoury sauces	5 g/100g		
Salad dressing	5 g/100g		
Vegetable puree	7 g/100g		
Nut spreads	7 g/100g		
Chocolate confectionary	7 g/100g		
Chips, crisps, fries and dough-based analogues	15 g/100g		
Snacks other than chips	20 g/100g		

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

	Meat products	15 g/100g			Article 26 of Regulation (EU) 2015/2283 or with the agreement of “NapiFeryn BioTech Sp. z o.o.”.
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013, excluding foods for infants and children under 10 years of age.	In accordance with the particular nutritional requirements of the persons for whom the products are intended but, in any case, not higher than 30 g/day in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			End date of the data protection: [...] <i>[OP please insert the date dd.mm.yyyy – after 5 years]</i> .
	Food supplements as defined in Directive 2002/46/EC, for the general population, excluding infants and children under 10 years of age.	10 g/day for the general population above 10 years of age			

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

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

Authorised novel food	Specification
Rapeseed protein concentrate	<p>Description:</p> <p>The novel food is a white to off-white dried powder remaining after aqueous and organic solvent extraction of hulled and dehulled cold-pressed rapeseed cake originating from non-genetically modified double low (00) cultivars of <i>Brassica napus</i> L. and <i>Brassica rapa</i> L.</p> <p>Characteristics/Composition:</p> <p>Crude protein (% w/w): 28-45</p> <p>Fat (% w/w): ≤ 2</p> <p>Ash (% w/w): ≤ 5</p> <p>Moisture (% w/w): ≤ 7</p> <p>Total fibre (% w/w): 37–70</p> <p>Total glucosinolates (mmol/kg (mg/kg)): ≤ 0.1 (≤ 40)</p> <p>Phytates (% w/w): ≤ 2</p> <p>Heavy and other metals:</p> <p>Lead (mg/kg): ≤ 0.2</p> <p>Arsenic (total) (mg/kg): ≤ 0.1</p>

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

	<p>Cadmium (mg/kg): ≤ 0.1 Mercury (mg/kg): ≤ 0.02 Aluminium (mg/kg): ≤ 35 Residual solvents Residual ethanol (mg/kg): < 200 Residual ethyl acetate (mg/kg): < 200 Microbiological criteria: Total plate count: $\leq 10,000$ CFU^b/g Enterobacteriaceae: ≤ 10 CFU/g <i>E.coli</i>: Absent in 10 g <i>Salmonella</i> spp.: Absence in 25 g Yeast and moulds: ≤ 100 CFU/g Total coliform count: ≤ 10 CFU/g <i>B. cereus</i>: ≤ 100 CFU/g ^aTotal dietary fibre: The EFSA Panel interprets that ‘dietary fibre’ refers to non-digestible polysaccharides classified as dietary fibre by EFSA for the specific purpose of setting Dietary Reference Values (DRV) for carbohydrates and dietary fibre (EFSA NDA Panel, 2010). ^b CFU: Colony Forming Units</p>
--	---

,