

ANNEX

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

- (1) the following last column is added in Table 1 (Authorised novel foods):

Data Protection

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

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
‘Bovine milk basic whey protein isolate	<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 “Milk whey protein isolate”. Food supplements containing bovine milk basic whey protein isolate shall bear the following statement: This food supplement should not be consumed by children/ adolescents under the age of three/ eighteen (*) years		Authorised on 20 November 2018. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Armor Protéines S.A.S., 19 bis, rue de la Libération 35460 Saint-Brice-en-Coglès, France. During the period of data protection the novel food bovine milk basic whey
	Infant formulae as defined in Regulation (EU) No 609/2013	30 mg/100 g (powder) 3,9 mg/100 mL (reconstituted)			
	Follow-on formulae as defined in Regulation (EU) No 609/2013	30 mg/100 g (powder) 4,2 mg/100 mL (reconstituted)			
	Total diet replacement foods for weight control as defined by Regulation (EU) No 609/2013	300 mg/day			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	58 mg/day for young children 380 mg/day for children and adolescents from 3 to 18 years of age 610 mg/day for adults			
(*)	Depending on the age group				

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1632. (See end of Document for details)

Food Supplements as defined in Directive 2002/46/EC	58 mg/day for young children 250 mg/day for children and adolescents from 3 to 18 years of age 610 mg/day for adults	the food supplement is intended for.	protein isolate is authorised for placing on the market within the Union only by Armor Protéines S.A.S. unless a subsequent applicant obtains authorisation for the 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 Armor Protéines S.A.S.. End date of the data protection: 20 November 2023.'
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(3) the following entry is inserted in Table 2 (Specifications) in alphabetical order:

Authorised Novel Food	Specification
‘Bovine milk basic whey protein isolate	Description Bovine milk basic whey protein isolate is a yellowish grey powder obtained

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from bovine skimmed milk via a series of isolation and purification steps.

Characteristics/Composition

Total protein (w/weight of product): \geq 90 %

Lactoferrin (w/weight of product): 25-75 %

Lactoperoxidase (w/weight of product): 10-40 %

Other proteins (w/weight of product): \leq 30 %

TGF- β 2: 12-18 mg/100 g

Moisture: \leq 6,0 %

pH (5 % solution w/v): 5,5 – 7,6

Lactose: \leq 3,0 %

Fat: \leq 4,5 %

Ash: \leq 3,5 %

Iron: \leq 25 mg/100 g

Heavy Metals

Lead: $<$ 0,1 mg/kg

Cadmium: $<$ 0,2 mg/kg

Mercury: $<$ 0,6 mg/kg

Arsenic: $<$ 0,1 mg/kg

Microbiological criteria:

Aerobic mesophilic count: \leq 10 000 CFU/g

Enterobacteriaceae: \leq 10 CFU/g

Escherichia coli: Negative/g

Coagulase positive *Staphylococci*: Negative/g

Salmonella: Negative/25 g

Listeria: Negative/25 g

Cronobacter spp.: Negative/25 g

Moulds: \leq 50 CFU/g

Yeasts: \leq 50 CFU/g

CFU : Colony Forming Units'

Changes to legislation:

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