II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2023/65

of 6 January 2023

correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods, Implementing Regulation (EU) 2018/1648 authorising the placing on the market of xylooligosaccharides as a novel food, Implementing Regulation (EU) 2019/1686 authorising the extension of use of bovine milk basic whey protein isolate as a novel food, and Implementing Regulation (EU) 2021/96 authorising the placing on the market of 3'-sialyllactose sodium salt as a novel food

(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 Articles 8 and 12 thereof,

Whereas:

- (1) Pursuant to Article 8 of Regulation (EU) 2015/2283, the Commission was to establish, by 1 January 2018, the Union list of novel foods authorised or notified under Regulation (EC) No 258/97 of the European Parliament and of the Council (2).
- (2) The Union list of novel foods authorised or notified under Regulation (EC) No 258/97 was established by Commission Implementing Regulation (EU) 2017/2470 (3).
- (3) The Commission has identified errors in the Annex to Implementing Regulation (EU) 2017/2470. Corrections are needed in order to provide clarity and legal certainty to food business operators and to the Member States' competent authorities, thus ensuring the proper implementation and use of the Union list of novel foods.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ 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).

^(*) 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).

- (4) The conditions of use of the novel food 'bovine milk basic whey protein isolate', authorised by Commission Implementing Regulation (EU) 2018/1632 (4), were subsequently extended by Commission Implementing Regulation (EU) 2019/1686 (5). In Table 1 of the Annex to Implementing Regulation (EU) 2019/1686, the lines separating the specified food categories and the maximum authorised levels were erroneously omitted, thereby making unclear what food category corresponds to what authorised use. That might create confusion for enforcement authorities and the food business operators. Therefore, a correction of the Annex to Implementing Regulation (EU) 2019/1686 and Table 1 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.
- (5) The novel food '3'-Sialyllactose sodium salt (microbial source)' was authorised by Commission Implementing Regulation (EU) 2021/96 (6). The maximum levels indicated for the food category 'Flavoured fermented milk-based products including heat-treated products' were erroneously added to the food category 'Unflavoured fermented milk-based products', and vice versa. Therefore, a correction of Table 1 of Annex to Implementing Regulation (EU) 2021/96 and Table 1 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.
- (6) The novel food 'Galacto-oligosaccharide' was authorised under certain conditions of use pursuant to Article 5 of Regulation (EC) No 258/97. The microbial source 'Bacillus circulans' of the enzyme 'β-galactosidase' used for the production of the Galacto-oligosaccharide was erroneously added to the specifications. Therefore, this source of β-galactosidase should be removed from the entry 'Galacto-oligosaccharide' in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470.
- (7) The novel food 'Xylo-oligosaccharide' was authorised under certain conditions of use by Commission Implementing Regulation (EU) 2018/1648 (7), based on a favourable opinion on the safety of the novel food by the European Food Safety Authority ('the Authority'). The specifications of the syrup form of 'Xylo-oligosaccharide' erroneously did not contain the parameter 'dry material' in the corresponding column. This error has been corrected in the revised scientific opinion of the Authority (8). Therefore, the specifications concerning 'Xylo-oligosaccharide' in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470 and in the Annex to Implementing Regulation (EU) 2018/1648 should be corrected accordingly.
- (8) Implementing Regulation (EU) 2017/2470, Implementing Regulation (EU) 2018/1648, Implementing Regulation (EU) 2019/1686 and Implementing Regulation (EU) 2021/96 should therefore be corrected accordingly.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

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

- (4) Commission Implementing Regulation (EU) 2018/1632 of 30 October 2018 authorising the placing on the market of bovine milk basic whey protein isolate 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 (OJ L 272, 31.10.2018, p. 23).
- (5) Commission Implementing Regulation (EU) 2019/1686 of 8 October 2019 authorising the extension of use of bovine milk basic whey protein isolate 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 (OJ L 258, 9.10.2019, p. 13).
- (6) Commission Implementing Regulation (EU) 2021/96 of 28 January 2021 authorising the placing on the market of 3'-sialyllactose sodium salt 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 (OJ L 31, 29.1.2021, p. 201).
- (7) Commission Implementing Regulation (EU) 2018/1648 of 29 October 2018 authorising the placing on the market of xylooligosaccharides 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 (OJ L 275, 6.11.2018, p. 1).
- (8) EFSA Journal 2018;16(7):5361.

Article 2

Implementing Regulation (EU) 2018/1648 is corrected in accordance with Annex II to this Regulation.

Article 3

Implementing Regulation (EU) 2019/1686 is corrected in accordance with Annex III to this Regulation.

Article 4

Implementing Regulation (EU) 2021/96 is corrected in accordance with Annex IV to this Regulation.

Article 5

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, 6 January 2023.

For the Commission The President Ursula VON DER LEYEN

Correction of Implementing Regulation (EU) 2017/2470

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

(1) in Table 1 (Authorised novel foods), the entry for 'Bovine milk basic whey protein isolate' 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
Bovine milk basic whey protein isolate	Specified food category Infant formulae as defined in Regulation (EU) No 609/2013 Follow-on formulae as defined in Regulation (EU) No 609/2013 Total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013 Foods for special medical purposes as defined in Regulation (EU) No 609/2013	Maximum levels 30 mg/100 g (powder) 3,9 mg/100 mL (reconstituted)	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 infants/children/ adolescents under the age of one/three/ eighteen (*) years" (*) Depending on the age group the food supplement is intended for.	requirements	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 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.'

	4,2 mg/100 mL (reconstituted formula for infants when appropriate complementary feeding is introduced)
	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
Food supplements as defined	25 mg/day for infants
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

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Authorised novel food	d Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
'3'-Sialyllactose (3'-SL) sodium salt (microbial source)	Specified food category	Maximum levels (expressed as 3'- Sialyllactose)	The designation of the novel food on the labelling of the foodstuffs containing it shall be "3'-Sialyllactose sodium salt". The labelling of food supplements containing 3'-Sialyllactose sodium salt shall bear a statement that they should not be consumed: a) if foods containing added 3'-Sialyllactose sodium salt are consumed on the same day. b) by infants and young children		Authorised on 18 February 2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Glycom A/S, Kogle Allé 4, DK-2970 Hørsholm, Denmark. During the period of data protection, the novel food 3'-sialyllactose sodium salt is authorised for placing on the market within the Union only by Glycom 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 Glycom A/S. End date of the data protection: 18 February 2026.'
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0,25 g/L			
	Unflavoured fermented milk- based products	0,25 g/L (beverages)			
		0,5 g/kg (products other than beverages)			
	Flavoured fermented milk- based products including heat-treated products	0,25 g/L (beverages)			
		2,5 g/kg (products other than beverages)			
	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	0,25 g/L			
	Cereal bars	2,5 g/kg			
	Infant formula as defined in Regulation (EU) No 609/2013	0,2 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Follow-on formula as defined in Regulation (EU) No 609/2013	0,15 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013	0,15 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			

	1,25 g/kg for products other than beverages
Milk-based drinks and similar products intended for young children	0,15 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Total diet replacement foods for weight control as defined	0,5 g/L (beverages)
in Regulation (EU) No 609/2013	5 g/kg (products other than beverages)
Food for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	

(3) in Table 2 (Specifications), the entry for 'Galacto-oligosaccharide' is replaced by the following:

'Galacto-oligosaccharide	Description/Definition: Galacto-oligosaccharide is produced from milk lactose by an enzymatic process using β-galactosidases from Aspergillus oryzae, Bifidobacterium bifidum, Pichia pastoris, Sporobolomyces singularis, Kluyveromyces lactis and Papiliotrema terrestris.
	GOS: min. 46 % Dry Matter (DM)
	Lactose: max. 40 % DM
	Glucose: max. 22 % DM
	Galactose: min. 0,8 % DM
	Ash: max. 4,0 % DM
	Protein: max. 4,5 % DM
	Nitrite: max. 2 mg/kg'

(4) in Table 2 (Specifications), the entry for 'Xylo-oligosaccharide' is replaced by the following:

Authorised novel food	Specification					
'Xylo- oligosaccharides	Description: The novel food is a mixture of xylo-oligosaccharides (XOS) which are obtained from corncobs (<i>Zea mays</i> subsp. <i>mays</i>) via hydrolysis by a xylanase from <i>Trichoderma reesei</i> followed by a purification process. Characteristics/Composition:					
	Parameter	Powder form 1	Powder form 2	Syrup form		
	Moisture (%)	≤ 5,0	≤ 5,0	-		
	Dry material (%)	-	-	70-75		
	Protein (g/100 g)	< 0,2				
	Ash (%)		≤ 0,3			
	pH 3,5-5,0					
	Total carbohydrate content (g/100 g)	≥ 97	≥ 95	≥ 70		
	XOS content (dry basis) (g/100 g)	≥ 95	≥ 70	≥ 70		
	Other carbohydrates (g/100 g) ^a	2,5-7,5	2-16	1,5-31,5		
	Monosaccharides total (g/100 g)	0-4,5	0-13	0-29		
	Glucose (g/100 g)	0-2	0-5	0-4		
	Arabinose (g/100 g)	0-1,5	0-3	0-10		
	Xylose (g/100 g)	0-1,0	0-5	0-15		
	Disaccharides total (g/100 g)	27,5-48	25-43	26,5-42,5		
	Xylobiose (XOS DP2) (g/100 g)	25-45	23-40	25-40		
	Cellobiose (g/100 g)	2,5-3	2-3	1,5-2,5		
	Oligosaccharides total (g/100 g)	41-77	36-72	32-71		
	xylotriose (XOS DP3) (g/100 g)	27-35	18-30	18-30		
	xylotetraose (XOS DP4) (g/100 g)	10-20	10-20	8-20		
	xylopentaose (XOS DP5) (g/100 g)	3-10	5-10	3-10		

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xylohexaose (XOS DP6) (g/100 g)	1-5	1-5	1-5
Xyloheptaose (XOS DP7) (g/100 g) 0-7		2-7	2-6
Maltodextrin (g/100 g) ^b	$(g/100 g)^b$ 0 20-25		0
Copper (mg/kg)	< 5,0		
Lead (mg/kg)	< 0,5		
Arsenic (mg/kg)	< 0,3		
Salmonella (CFU°/25 g)	Negative		
E. coli (MPN ^d /100 g)	Negative		
Yeast (CFU/g)	< 10		
Mould (CFU/g)	< 10		

Other carbohydrates include monosaccharides (glucose, xylose and arabinose) and cellobiose.

Maltodextrin content is calculated according to the amount added in the process.

DP: Degree of polymerization

CFU: Colony Forming Units

MPN: Most Probable Number'

Correction of Implementing Regulation (EU) 2018/1648

Specification

ANNEX II

In point 2 of the Annex to Implementing Regulation (EU) 2018/1648, in Table 2 (Specifications), the entry for 'Xylo-oligosaccharide' is replaced by the following:

Authorised novel food

Xylo- ligosaccharides	Description: The novel food is a mixture of xylo-oligosaccharides (XOS) which are obtained from corncobs (<i>Zea mays</i> subsp. <i>mays</i>) via hydrolysis by a xylanase from <i>Trichoderm reesei</i> followed by a purification process. Characteristics/Composition:					
	Parameter	Powder form 1	Powder form 2	Syrup form		
	Moisture (%)	≤ 5,0	≤ 5,0	-		
	Dry material (%)	-	-	70-75		
	Protein (g/100 g)	< 0,2				
	Ash (%)	≤ 0,3				
	рН	3,5-5,0				
	Total carbohydrate content (g/100 g)	≥ 97	≥ 95	≥ 70		
	XOS content (dry basis) (g/100 g)	≥ 95	≥ 70	≥ 70		
	Other carbohydrates (g/100 g) ^a	2,5-7,5	2-16	1,5-31,5		
	Monosaccharides total (g/100 g)	0-4,5	0-13	0-29		
	Glucose (g/100 g)	0-2	0-5	0-4		
	Arabinose (g/100 g)	0-1,5	0-3	0-10		
	Xylose (g/100 g)	0-1,0	0-5	0-15		
	Disaccharides total (g/100 g)	27,5-48	25-43	26,5-42,5		
	Xylobiose (XOS DP2) (g/100 g)	25-45	23-40	25-40		
	Cellobiose (g/100 g)	2,5-3	2-3	1,5-2,5		
	Oligosaccharides total (g/100 g)	41-77	36-72	32-71		
	xylotriose (XOS DP3) (g/100 g)	27-35	18-30	18-30		
	xylotetraose (XOS DP4) (g/100 g)	10-20	10-20	8-20		

3-10

1-5

2-6

0

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Other carbohydrates include monosaccharides (glucose, xylose and arabinose) and cellobiose.
Maltodextrin content is calculated according to the amount added in the process.

3-10

1-5

0-7

0

< 5,0

< 0,5

< 0,3

Negative

Negative

< 10

< 10

5-10

1-5

2-7

20-25

xylopentaose (XOS DP5) (g/100 g)

xylohexaose (XOS DP6) (g/100 g)

Xyloheptaose (XOS DP7) (g/100 g)

Maltodextrin (g/100 g)^b

Copper (mg/kg)

Arsenic (mg/kg)

Salmonella (CFU^c/25 g)

E. coli (MPNd/100 g)

Lead (mg/kg)

Yeast (CFU/g)

Mould (CFU/g)

DP: Degree of polymerization
CFU: Colony Forming Units
MPN: Most Probable Number'

Correction of Implementing Regulation (EU) 2019/1686

In point 1 of the Annex to Implementing Regulation (EU) 2019/1686, in Table 1 (Authorised novel foods), the entry for 'Bovine milk basic whey protein isolate' 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
Bovine milk basic whey protein isolate	Specified food category Infant formulae as defined in Regulation (EU) No 609/2013 Follow-on formulae as defined in Regulation (EU) No 609/2013 Total diet replacement foods	Maximum levels 30 mg/100 g (powder) 3,9 mg/100 mL (reconstituted) 30 mg/100 g (powder) 4,2 mg/100 mL (reconstituted) 300 mg/day	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	requirements	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
	for weight control as defined in Regulation (EU) No 609/2013 Foods for special medical purposes as defined in Regulation (EU) No 609/2013	30 mg/100 g (powder formula for infants during the first months of life until the introduction of appropriate complementary feeding)	consumed by infants/children/ adolescents under the age of one/ three/eighteen (*) years" (*) Depending on the age group the food supplement is intended for.		data protection the novel food bovine milk basic whey 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
		3,9 mg/100 mL (reconstituted formula for infants during the first months of life until the introduction of appropriate complementary feeding)			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.'
		30 mg/100 g (powder formula for infants when appropriate complementary feeding is introduced)			

		4,2 mg/100 mL (reconstituted formula for infants when appropriate complementary feeding is introduced)
		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
	Food supplements as defined	25 mg/day for infants
in Directive 2002/46/EC	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

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Correction of Implementing Regulation (EU) 2021/96

In point 1 of the Annex to Implementing Regulation (EU) 2021/96, in Table 1 (Authorised novel foods), the entry for '3'-Sialyllactose (3'-SL) sodium salt (microbial source)' is replaced by the following:

Authorised novel food	Conditions under which the	ne novel food may be used	Additional specific labelling requirements	Other requirements	Data Protection
'3'-Sialyllactose (3'-SL) sodium salt (microbial source)	Specified food category	Maximum levels (expressed as 3'- Sialyllactose)	The designation of the novel food on the labelling of the foodstuffs containing it shall		Authorised on 18 February 2021. This inclusion is based on proprietary scientific
(microbiai source)	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0,25 g/L	be "3'-Sialyllactose sodium salt". The labelling of food supplements containing 3'-Sialyllactose sodium salt shall		evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Glycom A/S, Kogle
	Unflavoured fermented milk-based products	0,25 g/L (beverages)	bear a statement that they should not be consumed:		Allé 4, DK-2970 Hørsholm, Denmark. During the period of
	based products	0,5 g/kg (products other than beverages)	a) if foods containing added 3'-Sialyllactose sodium salt are consumed the		data protection, the novel food 3'-sialyllactose sodium salt is authorised for placing on the
	Flavoured fermented milk- based products including	0,25 g/L (beverages)	same day. b) by infants and young children		market within the Union only by Glycom A/S, unless a subsequent applicant obtains
	heat-treated products	2,5 g/kg (products other than beverages)	dren		authorisation for the novel food without reference to the proprietary scientific evidence
	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	0,25 g/L			or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Glycom
	Cereal bars	2,5 g/kg			A/S. End date of the data protection:
	Infant formula as defined in Regulation (EU) No 609/2013	0,2 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			18 February 2026.'

Follow-on formula as define in Regulation (EU) No 609/2013	d 0,15 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Processed cereal-based food and baby food for infants an young children as defined in Regulation (EU) No 609/201	
	1,25 g/kg for products other than beverages
Milk-based drinks and similar products intended for young children	0,15 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Total diet replacement foods	
for weight control as defined in Regulation (EU) No 609/2013	5 g/kg (products other than beverages)
Food for special medical purposes as defined in Regulation (EU) No 609/201	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Food Supplements as define in Directive 2002/46/EC, excluding food supplements for infants and young children	

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