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 xylo-oligosaccharides 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).

([3]) 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 xylo-oligosaccharides 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

ANNEX I

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*	*Maximum levels*	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.		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.'
	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 in Regulation (EU) No 609/2013	300 mg/day			
	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)			
		3,9 mg/100 mL (reconstituted formula for infants during the first months of life until the introduction of appropriate complementary feeding)			
		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 in Directive 2002/46/EC	25 mg/day for infants			
		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			

(2) 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 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 in Regulation (EU) No 609/2013	0,5 g/L (beverages)			
		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	0,5 g/day			

(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 (*Zea mays* subsp. *mays*) via hydrolysis by a xylanase from *Trichoderma reesei* 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

	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]	0	20-25	0
	Copper (mg/kg)	< 5,0		
	Lead (mg/kg)	< 0,5		
	Arsenic (mg/kg)	< 0,3		
	Salmonella (CFU[c]/25 g)	Negative		
	E. coli (MPN[d]/100 g)	Negative		
	Yeast (CFU/g)	< 10		
	Mould (CFU/g)	< 10		

[a] Other carbohydrates include monosaccharides (glucose, xylose and arabinose) and cellobiose.
[b] Maltodextrin content is calculated according to the amount added in the process.
DP: Degree of polymerization
[c] CFU: Colony Forming Units
[d] MPN: Most Probable Number'

ANNEX II

Correction of Implementing Regulation (EU) 2018/1648

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	Specification			
'**Xylo-oligosaccharides**	**Description:** The novel food is a mixture of xylo-oligosaccharides (XOS) which are obtained from corncobs (*Zea mays* subsp. *mays*) via hydrolysis by a xylanase from *Trichoderma reesei* 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
	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]	0	20-25	0
	Copper (mg/kg)	< 5,0		
	Lead (mg/kg)	< 0,5		
	Arsenic (mg/kg)	< 0,3		
	Salmonella (CFU[c]/25 g)	Negative		
	E. coli (MPN[d]/100 g)	Negative		
	Yeast (CFU/g)	< 10		
	Mould (CFU/g)	< 10		

[a] Other carbohydrates include monosaccharides (glucose, xylose and arabinose) and cellobiose.
[b] Maltodextrin content is calculated according to the amount added in the process.
DP: Degree of polymerization
[c] CFU: Colony Forming Units
[d] MPN: Most Probable Number'

ANNEX III

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*	*Maximum levels*	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.		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.'
	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 in Regulation (EU) No 609/2013	300 mg/day			
	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)			
		3,9 mg/100 mL (reconstituted formula for infants during the first months of life until the introduction of appropriate complementary feeding)			
		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 in Directive 2002/46/EC	25 mg/day for infants			
		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			

ANNEX IV

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 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 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 in Regulation (EU) No 609/2013	0,5 g/L (beverages)			
		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	0,5 g/day			