

*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*

## ANNEX

### Correction of Implementing Regulation (EU) 2017/2470

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

(1) in Table 1 (Authorised novel foods), the entry for *Schizochytrium* sp. oil rich in DHA and EPA' 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
<b><i>Schizochytrium</i> sp. oil rich in DHA and EPA</b>	Food supplements as defined in Directive 2002/46/EC for the adult population excluding pregnant and lactating women	3 000 mg/day	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'DHA and EPA-rich oil from the microalgae <i>Schizochytrium</i> sp.'		
	Food supplements as defined in Directive 2002/46/EC for pregnant and lactating women	450 mg/day			
	Food supplements as defined in Directive 2002/46/EC for children from 18 months to 18 years of age	250 mg/day			
	Foods 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			
	Total diet replacement for weight control as defined in Regulation (EU)	250 mg/meal			

*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*

	No 609/2013 and meal replacements for weight control				
	Milk based drinks and similar products intended for young children	200 mg/100 g			
	Processed cereal based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013				
	Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen				
	Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014				
	Bakery products (breads, rolls and sweet biscuits)				
	Breakfast cereals	500 mg/100 g			
	Cooking fats	360 mg/100 g			
	Dairy analogues, except drinks	600 mg/100 g for cheese; 200 mg/100 g for soy and imitation			

*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*

		milk products (excluding drinks)			
	Dairy products except milk-based drinks	600 mg/100 g for cheese; 200 mg/100 g for milk products (including milk, fromage frais and yoghurt products; excluding drinks)			
	Non-alcoholic beverages (including dairy analogue and milk-based drinks)	80 mg/100 g			
	Cereal/nutrition bars	500 mg/100 g			
	Spreadable fats and dressings	600 mg/100 g			
	Fish analogues	300 mg/100 g			
	Meat analogues	300 mg/100 g			

*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 1 (Authorised novel foods), the entry for 3-Fucosyllactose ('3-FL') (produced by derivative strain of *E. coli* K-12 DH1) 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
<b>3-Fucosyllactose ('3-FL') (produced by derivative strain of <i>E. coli</i> K-12 DH1)</b>	<i>Specified food category</i>	<i>Maximum levels (expressed as 3-Fucosyllactose)</i>	<p>The designation of the novel food on the labelling of the foodstuffs containing it shall be '3-Fucosyllactose'.</p> <p>The labelling of food supplements containing 3-Fucosyllactose (3-FL) shall bear a statement that</p> <p>(a) they should not be consumed by children under 3 years of age;</p> <p>(b) they should not be used if other foods containing added 3-Fucosyllactose are consumed on the same day.</p>		<p>Authorised on 12 November 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.</p> <p>Applicant: 'Glycom A/S', Kogle Allé 4, 2970 Hørsholm, Denmark. During the period of data protection, the novel food 3-Fucosyllactose produced by derivative strain of <i>E. coli</i> K-12 DH1 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'.</p> <p>End date of the data protection: 12 November 2028.</p>
	Infant formula as defined under Regulation (EU) No 609/2013	1,75 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Follow-on formula as defined under Regulation (EU) No 609/2013	1,75 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	2,0 g/L			
	Unflavoured fermented milk-based products	2,0 g/L (beverages)			
		4,0 g/kg (products other than beverages)			
	Flavoured fermented milk-based products including heat-treated products	2,0 g/L (beverages)			
		12,0 g/kg (products other than beverages)			
	Cereal bars	25,0 g/kg			

*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*

	Milk based drinks and similar products	2,0 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
		12,0 g/kg (products other than beverages)			
	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	1,25 g/L			
	Total diet replacement foods for weight control as defined under Regulation (EU) No 609/2013	2,0 g/L (beverages)			
		25,0 g/kg (products other than beverages)			
	Foods for special medical purposes for infants and young children as defined under Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended but in any case not higher 1,75 g/L or 1,75 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.			
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended but in any case not			

*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*

	excluding foods for infants and young children	higher 4,0 g/L or 4,0 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.			
	Food Supplements as defined in Directive 2002/46/EC, for the general population, excluding infants and young children	4,0 g/day			

*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*

## Annex II

### Correction of Implementing Regulation (EU) 2022/1365

In point 1 of the Annex to Implementing Regulation (EU) 2022/1365, in Table 1 (Authorised novel foods), the entry for *Schizochytrium* sp. oil rich in DHA and EPA' 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
<b><i>Schizochytrium</i> sp. oil rich in DHA and EPA</b>	Food supplements as defined in Directive 2002/46/EC for the adult population excluding pregnant and lactating women	3 000 mg/day	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'DHA and EPA-rich oil from the microalgae <i>Schizochytrium</i> sp.'		
	Food supplements as defined in Directive 2002/46/EC for pregnant and lactating women	450 mg/day			
	Food supplements as defined in Directive 2002/46/EC for children from 18 months to 18 years of age	250 mg/day			
	Foods 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			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal	250 mg/meal			

*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*

	replacements for weight control				
	Milk based drinks and similar products intended for young children	200 mg/100 g			
	Processed cereal based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013				
	Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen				
	Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014				
	Bakery products (breads, rolls and sweet biscuits)				
	Breakfast cereals	500 mg/100 g			
	Cooking fats	360 mg/100 g			
	Dairy analogues, except drinks	600 mg/100 g for cheese; 200 mg/100 g for soy and imitation milk products			



*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*

		(excluding drinks)			
	Dairy products except milk-based drinks	600 mg/100 g for cheese; 200 mg/100 g for milk products (including milk, fromage frais and yoghurt products; excluding drinks)			
	Non-alcoholic beverages (including dairy analogue and milk-based drinks)	80 mg/100 g			
	Cereal/nutrition bars	500 mg/100 g			
	Spreadable fats and dressings	600 mg/100 g			
	Fish analogues	300 mg/100 g			
	Meat analogues	300 mg/100 g			

*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*

### Annex III

#### Correction of Implementing Regulation (EU) 2023/2210

In point 1 of the Annex to Implementing Regulation (EU) 2023/2210, in Table 1 (Authorised novel foods), the entry for ‘3-Fucosyllactose (‘3-FL’) (produced by derivative strain of *E. coli* K-12 DH) 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
<b>3-Fucosyllactose (‘3-FL’)</b> <b>(produced by derivative strain of <i>E. coli</i> K-12 DH1)</b>	<b><i>Specified food category</i></b>	<b><i>Maximum levels (expressed as 3-Fucosyllactose)</i></b>	<p>The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘3-Fucosyllactose’.</p> <p>The labelling of food supplements containing 3-Fucosyllactose (3-FL) shall bear a statement that</p> <p>(a) they should not be consumed by children under 3 years of age;</p> <p>(b) they should not be used if other foods containing added 3-Fucosyllactose are consumed on the same day.</p>		<p>Authorised on 12 November 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.</p> <p>Applicant: ‘Glycom A/S’, Kogle Allé 4, 2970 Hørsholm, Denmark. During the period of data protection, the novel food 3-Fucosyllactose produced by derivative strain of <i>E. coli</i> K-12 DH1 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’.</p>
	Infant formula as defined under Regulation (EU) No 609/2013	1,75 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Follow-on formula as defined under Regulation (EU) No 609/2013	1,75 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	2,0 g/L			
	Unflavoured fermented milk-based products	2,0 g/L (beverages)			
		4,0 g/kg (products other than beverages)			
	Flavoured fermented milk-based products	2,0 g/L (beverages)			

*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*

	including heat-treated products	12,0 g/kg (products other than beverages)			End date of the data protection: 12 November 2028.
	Cereal bars	25,0 g/kg			
	Milk based drinks and similar products	2,0 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
		12,0 g/kg (products other than beverages)			
	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	1,25 g/L			
	Total diet replacement foods for weight control as defined under Regulation (EU) No 609/2013	2,0 g/L (beverages)			
		25,0 g/kg (products other than beverages)			
	Foods for special medical purposes for infants and young children as defined under Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended but in any case not higher 1,75 g/L or 1,75 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.			
	Foods for special	In accordance with the			

*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*

	medical purposes as defined under Regulation (EU) No 609/2013 excluding foods for infants and young children	particular nutritional requirements of the persons for whom the products are intended but in any case not higher 4,0 g/L or 4,0 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.			
	Food Supplements as defined in Directive 2002/46/EC, for the general population, excluding infants and young children	4,0 g/day			