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COMMISSION IMPLEMENTING REGULATION (EU) 2025/1549

of 30 July 2025

correcting Implementing Regulations (EU) 2023/2210 and (EU) 2022/1365 as regards the conditions of use of the novel foods 3-Fucosyllactose produced by a derivative strain of *Escherichia coli* K-12 DH1 and *Schizochytrium* sp. oil rich in DHA and EPA

(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.

(4) Pursuant to Article 4(2) of Regulation (EC) No 258/97, the competent authority of the United Kingdom authorised in 2012 *Schizochytrium* sp. oil rich in DHA and EPA to be placed on the market as a novel food for use in a number of foods, including food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([4]) intended for 'normal population' at levels of 250 mg/day, and in food supplements intended for pregnant and lactating women at 450 mg/day. The normal population is to be understood as the general population. However, the application included an intake assessment concerning the general population, excluding children below 18 months of age.

([1]) OJ L 327, 11.12.2015, p. 1, ELI: http://data.europa.eu/eli/reg/2015/2283/oj.
([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, ELI: http://data.europa.eu/eli/reg/1997/258/oj).
([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, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).
([4]) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51, ELI: http://data.europa.eu/eli/dir/2002/46/oj).

(5) In 2015, Commission Implementing Decision (EU) 2015/546 ([5]) authorised a change to the conditions of use of *Schizochytrium* sp. oil rich in DHA and EPA, increasing the maximum levels of DHA and EPA in food supplements for the adult population, with the exception of pregnant and lactating women, to 3 000 mg/day.

(6) When the initial Union list of novel foods was established by Implementing Regulation (EU) 2017/2470, the use of this novel food in food supplements for children from 18 months to 18 years of age at levels of 250 mg/day was erroneously omitted. In addition, when the conditions of use of *Schizochytrium* sp. oil rich in DHA and EPA were amended by Commission Implementing Regulation (EU) 2022/1365 ([6]), this amendment did not include the use of this novel food in food supplements for children from 18 months to 18 years of age at levels of 250 mg/day. It is therefore necessary to correct Implementing Regulation (EU) 2022/1365 to include the use of the novel food *Schizochytrium* sp. oil rich in DHA and EPA in food supplements for children from 18 months to 18 years of age at levels of 250 mg/day.

(7) The conditions of use of 3-Fucosyllactose (3-FL) produced by a derivative strain of *Escherichia coli* K-12 DH1 authorised as a novel food by Commission Implementing Regulation (EU) 2023/2210 ([7]) erroneously did not include foods for special medical purposes intended for infants and young children, as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([8]), that had been requested by the applicant and assessed by the European Food Safety Authority ('the Authority') in its opinion ([9]) on this novel food. In that opinion the Authority concluded that the maximum use levels of 3-FL in food for special medical purposes intended for infants and young children should not be higher than the maximum levels specified for the proposed uses in the corresponding food categories for this group of the population which would be the 1,75 g/L maximum levels authorised in infant formula and follow on formula. It is therefore appropriate that this use is added in the conditions of use of this novel food, and Implementing Regulation (EU) 2023/2210 is corrected accordingly.

(8) 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

Implementing Regulation (EU) 2022/1365 is corrected in accordance with Annex I to this Regulation.

Article 2

Implementing Regulation (EU) 2023/2210 is corrected in accordance with Annex II to this Regulation.

([5]) Commission Implementing Decision (EU) 2015/546 of 31 March 2015 authorising an extension of use of DHA and EPA-rich oil from the micro-algae *Schizochytrium* sp. as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 90, 2.4.2015, p. 11, ELI: http://data.europa.eu/eli/dec_impl/2015/546/oj).

([6]) Commission Implementing Regulation (EU) 2022/1365 of 4 August 2022 amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food *Schizochytrium* sp. oil rich in DHA and EPA (OJ L 205, 5.8.2022, p. 230, ELI: http://data.europa.eu/eli/reg_impl/2022/1365/oj).

([7]) Commission Implementing Regulation (EU) 2023/2210 of 20 October 2023 authorising the placing on the market of 3-Fucosyllactose produced by a derivative strain of *Escherichia coli* K-12 DH1 as a novel food and amending Implementing Regulation (EU) 2017/2470 (OJ L, 2023/2210, 23.10.2023, ELI: http://data.europa.eu/eli/reg_impl/2023/2210/oj).

([8]) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35, ELI: http://data.europa.eu/eli/reg/2013/609/oj).

([9]) Safety of 3-fucosyllactose (3-FL) produced by a derivative strain of *Escherichia coli* K-12 DH1 as a novel food pursuant to Regulation (EU) 2015/2283. *EFSA Journal*, 2023;21(6):8026.

Article 3

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, 30 July 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

CORRECTION TO IMPLEMENTING REGULATION (EU) 2022/1365

In Annex to Implementing Regulation (EU) 2022/1365, the table 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
'*Schizochytrium* sp. oil rich in DHA and EPA	*Specified food category*	*Maximum levels of DHA and EPA combined*	The designation of the novel food on the labelling of the foodstuffs containing it shall be "DHA and EPA-rich oil from the microalgae *Schizochytrium* sp."		
	Food supplements as defined in Directive 2002/46/EC for the adult population excluding pregnant and lactating women	3 000 mg/day			
	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 replacements for weight control	250 mg/meal			

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
	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 (1)				
	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 (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)			

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
	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			

([1]) Commission Implementing Regulation (EU) No 828/2014 of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food (OJ L 228, 31.7.2014, p. 5, ELI: http://data.europa.eu/eli/reg_impl/2014/828/oj).'

ELI: http://data.europa.eu/eli/reg_impl/2025/1549/oj

ANNEX II

CORRECTION TO IMPLEMENTING REGULATION (EU) 2023/2210

In point 1 of the Annex to Implementing Regulation (EU) 2023/2210, the table 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-Fucosyllactose ('3-FL') (produced by derivative strain of *E. coli* K-12 DH1)**	*Specified food category*	*Maximum levels (expressed as 3-Fucosyllactose)*	The designation of the novel food on the labelling of the foodstuffs containing it shall be "3-Fucosyllactose". The labelling of food supplements containing 3-Fucosyllactose (3-FL) shall bear a statement that (a) they should not be consumed by children under 3 years of age; (b) they should not be used if other foods containing added 3-Fucosyllactose are consumed on the same day.		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. 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 *E. coli* 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". End date of the data protection: 12 November 2028.'
	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			
	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)			

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
	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 excluding foods for infants and young children	In accordance with the 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			

ELI: http://data.europa.eu/eli/reg_impl/2025/1549/oj