STATUTORY INSTRUMENTS

2024 No. 685

FOOD, ENGLAND

The Food Additives and Novel Foods (Authorisations and Miscellaneous Amendments) and Food Flavourings (Removal of Authorisations) (England) Regulations 2024

Made - - - -	*22nd May 2024*
Laid before Parliament	*23rd May 2024*
Coming into force	*28th June 2024*

CONTENTS

The Secretary of State makes the following Regulations in exercise of the powers conferred by Articles 7(4), (5), and 14A(2)(b) of Regulation (EC) No. 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (**a**) and Articles 12(1) and 32A(3)(b) of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, etc.(**b**).

In relation to Parts 2 and 3, the Secretary of State sought, and had regard to, advice from the Food Standards Agency as required by Article 7(4) and (5) of Regulation 1331/2008.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the

(**a**) EUR 2008/1331, amended by S.I. 2019/860; there are other amending instruments but none is relevant. The terms "domestic list", "prescribe" and "appropriate authority" are defined in Article 2.

(**b**) EUR 2015/2283, amended by S.I. 2019/702; there are other amending instruments but none is relevant. The terms "prescribe", "appropriate authority", and "list" are defined in Article 3. Article 12(1) applies in accordance with Articles 9 and 27(1).

European Food Safety Authority and laying down procedures in matters of food safety(**a**), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

PART 1

Introduction

Citation, commencement, extent and application

1.—(1) These Regulations may be cited as the Food Additives and Novel Foods (Authorisations and Miscellaneous Amendments) and Food Flavourings (Removal of Authorisations) (England) Regulations 2024 and come into force on 28th June 2024.

(2) These Regulations extend to England and Wales, but apply in relation to England only.

PART 2

Food Additives

Amendment of Regulation (EC) No. 1333/2008

2.—(1) Annex 2 to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives(**b**) is amended as follows.

(2) In Part B, paragraph 2, in the table headed "Sweeteners" after the entry for "E 960a" (Steviol glycosides from Stevia) insert the following entry—

"E 960b	Steviol glycosides from fermentation".

(3) In Part C, paragraph 5—

(a) for "(v) E 960a and E 906c: Steviol glycosides" substitute "(v) E 960a – E 960c: Steviol glycosides"; and

(b) in the table at (v), after the entry for "E 960a" (Steviol glycosides from Stevia) insert the following entry —

"E 960b	Steviol glycosides from fermentation".

(4) In Part E, in the table—

(a) in each place in which it occurs, for "E 960a and E 960c" substitute "E 960a – E 960c";

(b) in category 03 (Edible ices), after the entry for "E 473-474" (Sucrose esters of fatty acids – sucroglycerides) insert the following entry—

"E 476	Polyglycerol polyricinoleate	4000	except sorbets".

(c) in category 05.1 (Cocoa and Chocolate products) after table footnote "(*)" (E 170, E 500-504, E 524-528 and E 530: 7 % on dry matter, without fat, expressed as potassium carbonates) insert the following footnote "(1): The additives may be added individually or in combination";

(d) in category 05.2 (Other confectionery including breath freshening microsweets)—

(i) in the third entry for "Group IV" (Polyols) for "only cocoa or dried fruit-based, milk or fat-based sandwich spreads, energy-reduced or with no added sugar" substitute

(**a**) EUR 2002/178, amended by S.I. 2019/641; there are other amending instruments but none is relevant.
(**b**) EUR 2008/1333; amended by S.I. 2019/860 and 2023/334; there are other amending instruments but none is relevant.

"sandwich spreads made with a base of cocoa, milk, dried fruit or fat; energy reduced or with no added sugar";

(ii) in the first entry for "E 960a and E 960c" (Steviol glycosides) for "only cocoa or dried-fruit-based, energy-reduced or with no added sugar" substitute "only cocoa or dried fruit based; energy reduced or with no added sugar";

(iii) in the second entry for "E 960a and E 960c" (Steviol glycosides) for "only cocoa, milk, dried-fruit-based or fat-based sandwich spreads, energy-reduced or with no added sugar" substitute "sandwich spreads made with a base of cocoa, milk, dried fruit or fat; energy reduced or with no added sugar";

(e) in category 05.4 (Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4), for the second entry for "E 960a and E 960c" (Steviol glycosides) for "only cocoa or dried-fruit-based, energy-reduced or with no added sugar" substitute "only cocoa or dried fruit based; energy reduced or with no added sugar"; and

(f) in category 12.6 (Sauces), for the entry for "E 476" (Polyglycerol polyricinoleate) substitute—

"E 476	Polyglycerol polyricinoleate	4000	only emulsified sauces with a fat content of less than 20%
E 476	Polyglycerol polyricinoleate	8000	only emulsified sauces with a fat content of 20% or more".

Amendment of Commission Regulation (EU) No. 231/2012

3.—(1) The Annex to Commission Regulation (EU) No. 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council(**a**) is amended as follows.

(2) In the first paragraph, for "Note: Ethylene oxide may not be used for sterilising purposes in food additives" substitute —

"Restrictions on ethylene oxide in food additives

Ethylene oxide may not be used for sterilising purposes in food additives.

Total residues of ethylene oxide (sum of ethylene oxide and 2-chloroethanol expressed as ethylene oxide (i.e., ethylene oxide + (0.55 x 2-chloroethanol))), irrespective of origin, in food additives listed in Annexes II and III to Regulation (EC) No 1333/2008, or mixtures of those food additives, must not exceed 0.1 mg/kg."

(3) In the following tables headed—

(a) "E 431 POLYOXYETHYLENE (40) STEARATE";

(b) "E 432 POLYOXYETHYLENE SORBITAN MONOLAURATE (POLYSORBATE 20)";

(c) "E 433 POLYOXYETHYLENE SORBITAN MONOOLEATE (POLYSORBATE 80)";

(d) "E 434 POLYOXYETHYLENE SORBITAN MONOPALMITATE (POLYSORBATE 40)";

(e) "E 435 POLYOXYETHYLENE SORBITAN MONOSTEARATE (POLYSORBATE 60)";

(**a**) EUR 2012/231; amended by S.I. 2019/860 and 2023/334; there are other amending instruments but none is relevant.

(f) "E 436 POLYOXYETHYLENE SORBITAN TRISTEARATE (POLYSORBATE 65)";

(g) "E 1209 POLYVINYL ALCOHOL-POLYETHYLENE GLYCOL-*GRAFT*-COPOLYMER"; and

(h) "E 1521 POLYETHYLENE GLYCOL";

omit "Ethylene oxide" and "Not more than 0,2 mg/kg".

(4) After the table for "E 960a" (Steviol glycosides from stevia), insert the heading and table in Schedule 1.

(5) In the heading for the table for "E 960c" (Rebaudioside M produced via enzyme modification of steviol glycosides from stevia) for "E 960c" substitute "E 960c(i)".

(6) In alphabetical order, insert the heading and table in Schedule 2.

PART 3

Food Flavourings

Amendment of Regulation (EC) No. 1334/2008

4.—(1) Annex 1 to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods etc(**a**) is amended as follows.

(2) In Part A, Section 2, Table 1 (the domestic list), the entries for the following are omitted in full—

(a) FL No. "07.030" chemical name "1-(4-Methoxyphenyl)pent-1-en-3-one";

(b) FL No. "07.046" chemical name "Vanillylidene acetone";

(c) FL No. "07.049" chemical name "1-(4-Methoxyphenyl)-4-methylpent-1-en-3-one";

(d) FL No. "07.206" chemical name "4-(2,3,6-Trimethylphenyl)but-3-en-2-one";

(e) FL No. "07.258" chemical name "6-Methyl-3-hepten-2-one";

(f) FL No. "10.034" chemical name "5,6-Dihydro-3,6-dimethylbenzofuran-2(4H)-one";

(g) FL No. "10.036" chemical name "5,6,7,7a-Tetrahydro-3,6-dimethylbenzofuran-2(4H)-one";

(h) FL No. "10.042" chemical name "3,4-Dimethyl-5-pentylidenefuran-2(5H)-one";

(i) FL No. "10.043" chemical name "2,7-Dimethylocta-5(trans),7-dieno-1,4-lactone";

(j) FL No. "10.046" chemical name "Hex-2-eno-1,4-lactone";

(k) FL No. "10.054" chemical name "Non-2-eno-1,4-lactone";

(l) FL No. "10.060" chemical name "2-Decen-1,4-lactone";

(m) FL No. "10.170" chemical name "5-Pentyl-3H-furan-2-one";

(n) FL No. "13.004" chemical name "Allyl 2-furoate";

(o) FL No. "13.034" chemical name "3-(2-furyl)acrylaldehyde";

(p) FL No. "13.043" chemical name "Furfurylidene-2-butanal";

(q) FL No. "13.044" chemical name "4-(2-Furyl)but-3-en-2-one";

(r) FL No. "13.046" chemical name "3-(2-Furyl)-2-methylprop-2-enal";

(s) FL No. "13.066" chemical name "3-Acetyl-2,5-dimethylfuran";

(t) FL No. "13.103" chemical name "2-Butylfuran";

(u) FL No. "13.137" chemical name "3-(2-Furyl)-2-phenylprop-2-enal"; and

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(**a**) EUR 2008/1334; amended by S.I. 2019/860; there are other amending instruments but none is relevant.

(v) FL No. "13.150" chemical name "3-(5-Methyl-2-furyl)prop-2-enal".

Transitional provision

5.—(1) The flavouring substances referred to in regulation 4(2)(a) to (v), and foods containing them may, until their date of minimum durability of a food or 'use by' date, be placed on the market and, as the case may be, added to other foods, if —

(a) present in the United Kingdom and were, or could have been, lawfully placed on the market in Great Britain before the end of 27th June 2024; or

(b) in transit to Great Britain before the end of 27th June 2024, and could have lawfully been imported, or moved into Great Britain, and placed on the market as at the date of dispatch.

(2) Foods containing one or more flavouring substances to which regulation 5(1)(a) or (b) applies may, until their date of minimum durability of a food or 'use by' date, be placed on the market and, as the case may be, added to other foods.

(3) The following expressions have the same meaning as they bear in Regulation (EU) No. 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers etc(**a**) —

(a) "date of minimum durability of a food"; and

(b) "'use by' date".

(4) Any expression used in both this regulation and Regulation (EC) No. 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods etc(**b**) has the meaning it bears in that Regulation.

PART 4

Novel Foods

Amendment of Commission Implementing Regulation (EU) 2017/2470

6.—(1) The Annex to Commission Implementing Regulation (EU 2017/2470 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(**c**) is amended as follows.

(2) In Table 1 (Authorised novel foods: England)—

(a) after the entry for "Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae" insert the entry in Schedule 3.

(b) for the entry for "Bovine milk basic whey protein isolate" substitute the entry in Schedule 4;

(c) after the entry for "*Calanus finmarchicus* oil" insert the entry in Schedule 5;

(d) after the entry for "2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL') (microbial source)" insert the entry in Schedule 6; and

(e) after the entry for "Lactitol" insert the entry in Schedule 7.

(3) In Table 2 (Specifications: England)—

(a) after the entry for "Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae" insert the entry in Schedule 8;

(b) after the entry for "*Calanus finmarchicus* oil" insert the entry in Schedule 9;

(**a**) EUR 2011/1169; to which there are amendments not relevant to these Regulations.
(**b**) EUR 2008/1334; amended by S.I. 2019/860; there are other amending instruments but none is relevant.
(**c**) EUR 2017/2470; amended by S.I. 2019/702; there are other amending instruments but none is relevant.

(c) after the entry for "2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL') (microbial source)" insert the entry in Schedule 10;

(d) after the entry for "Lactitol" insert the entry in Schedule 11; and

(e) in the entry for "Xylo-oligosaccharides", in the second column (Specifications), after the row for "Moisture (%)" insert the following row—

"Dry material (%)	-	-	70-75".

Andrea Leadsom
Parliamentary Under Secretary of State
Department of Health and Social Care

22nd May 2024

SCHEDULE 1

Regulation 3(4)

Insertion of entry in the Annex to Commission Regulation (EU) 231/2012 for E 960b for Steviol Glycosides from Fermentation (*Yarrowia Lipolytica)*

"E 960b STEVIOL GLYCOSIDES FROM FERMENTATION (*YARROWIA LIPOLYTICA*)

Synonyms	
Definition	Steviol glycosides from *Yarrowia lipolytica* consist of a mixture predominantly composed of rebaudioside M, with some rebaudioside D, and smaller amounts of rebaudioside A and rebaudioside B. The manufacturing process comprises two main phases. The first phase involves fermentation of a non-toxigenic non-pathogenic strain of *Yarrowia. lipolytica* VRM that has been genetically modified with heterologous genes to overexpress steviol glycosides. Removal of biomass by solid-liquid separation and heat treatment is followed by concentration of the steviol glycosides. The second phase involves purification by employing ion-exchange chromatography, followed by recrystallisation of the steviol glycosides resulting in a final product containing not less than 95% of rebaudiosides M, D, A, and B. Viable cells or the DNA of *Yarrowia Lipolytica* VRM must not be detected in the food additive.
Chemical name	Rebaudioside A: 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester Rebaudioside B: 13-[(2-*O*-β–D-glucopyranosyl-3-*O*-β– D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid Rebaudioside D: 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl ester

	Rebaudioside M: 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl ester		
Molecular formula	**Trivial name**	**Formula**	**Conversion factor**
	Rebaudioside A	$C_{44}H_{70}O_{23}$	0.33
	Rebaudioside B	$C_{38}H_{60}O_{18}$	0.40
	Rebaudioside D	$C_{50}H_{80}O_{28}$	0.29
	Rebaudioside M	$C_{56}H_{90}O_{33}$	0.25
Molecular weight and CAS No.	**Trivial name**	**CAS Number**	**Molecular weight (g/mol)**
	Rebaudioside A	58543-16-1	967.01
	Rebaudioside B	58543-17-2	804.88
	Rebaudioside D	63279-13-0	1129.15
	Rebaudioside M	1220616-44-3	1291.29
Assay	Not less than 95% of rebaudioside M, rebaudioside D, rebaudioside A, and rebaudioside B on the dried basis.		
Description	White to light yellow powder, approximately between 200 and 350 times sweeter than sucrose (at 5% sucrose equivalency).		
Identification			
Solubility	Freely soluble to slightly soluble in water.		
pH	Between 4.5 and 7.0 (1 in 100 solution)		
Purity			
Total ash	Not more than 1%		
Loss on drying	Not more than 6 % (105 °C, 2h)		
Residual solvent	Not more than 5000 mg/kg ethanol		
Arsenic	Not more than 0.1 mg/kg		
Lead	Not more than 0.1 mg/kg		
Cadmium	Not more than 0.01 mg/kg		
Mercury	Not more than 0.05 mg/kg		
Residual protein	Not more than 20 mg/kg		
Microbiological criteria			
Total (aerobic) plate count	Not more than 1000 CFU/g		
Yeast	Not more than 100 CFU/g		
Moulds	Not more than 100 CFU/g		
Escherichia coli	Negative in 1g		
***Salmonella* spp.**	Negative in 25g"		

SCHEDULE 2

Regulation 3(6)

Insertion of entry in the Annex to Commission Regulation (EU) 231/2012 for E 960c(ii) for Rebaudioside M, AM and D Produced via Enzymatic Conversion of Highly Purified Steviol Glycosides from Stevia Leaf Extracts

"E 960c(ii) REBAUDIOSIDE M, AM AND D PRODUCED VIA ENZYMATIC CONVERSION OF HIGHLY PURIFIED STEVIOL GLYCOSIDES FROM STEVIA LEAF EXTRACTS

Synonyms

Definition

Steviol glycosides produced via enzymatic conversion of highly purified steviol glycosides (rebaudioside A or stevioside) stevia leaf extracts are composed predominantly of rebaudioside M, rebaudioside D, and rebaudioside AM.

Rebaudiosides D, M and AM are produced via enzymatic conversion of highly purified steviol glycoside (rebaudioside A or stevioside) extracts (95% steviol glycosides) obtained from *Stevia rebaudiana* Bertoni plant using UDP-glucosyltransferase and sucrose synthase enzymes produced by genetically modified strains of *Escherichia coli* (pPM294, pFAH170, and pSK041) that facilitate the transfer of glucose from sucrose and UDP-glucose to steviol glycosides via glycosidic bonds. After removal of the enzymes by solid-liquid separation and heat treatment, the purification involves concentration of the steviol glycosides by resin adsorption, followed by recrystallisation of the steviol glycosides resulting in a final product containing not less than 95 % of total steviol glycosides, including one or more of rebaudiosides D, M and AM.

Viable cells or DNA of *Escherichia coli* (pPM294, pFAH170, and pSK041) must not be detected in the food additive.

Chemical name

Rebaudioside M: 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl ester

Rebaudioside D: 13-[(2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl ester

Rebaudioside AM: 13-[(2-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-*O*-β-D-glucopyranosyl-3-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl ester

Molecular formula

Trivial name	**Formula**	**Conversion factor**
Rebaudioside M	$C_{56}H_{90}O_{33}$	0.25
Rebaudioside D	$C_{50}H_{80}O_{28}$	0.29
Rebaudioside AM	$C_{50}H_{80}O_{28}$	0.29

Molecular weight and CAS No

Trivial name	**CAS Number**	**Molecular weight (g/mol)**
Rebaudioside M	1220616-44-3	1291.29
Rebaudioside D	63279-13-0	1129.15
Rebaudioside AM	2222580-26-7	1129.15

Assay

Not less than 95 % of steviol glycosides on the dried basis, including one or more of rebaudiosides D, M and AM.

Description

White to light yellow powder, approximately between 200 and 350 times sweeter than sucrose (at 5 % sucrose equivalency).

Identification

Solubility

Freely soluble to slightly soluble in water.

pH

Between 4.5 and 7.0 (1 in 100 solution)

Purity

Total ash

Not more than 1 %

Loss on drying

Not more than 6 % (105 °C, 2h)

Residual solvent

Not more than 5000 mg/kg ethanol

Arsenic

Not more than 0.015 mg/kg

Lead

Not more than 0.2 mg/kg

Cadmium

Not more than 0.015 mg/kg

Mercury

Not more than 0.07 mg/kg

Residual protein	Not more than 5 mg/kg”

SCHEDULE 3

Regulation 6(2)(a)

Insertion of entry in Table 1 in the Annex to Commission Implementing Regulation (EU) 2017/2470 for Partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*)

“Partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*)	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of food containing it is “partially hydrolysed protein from spent barley and rice”.	Included in the list on 28 June 2024. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Evergrain LLC, 1 Busch Place, St. Louis, Missouri 63118 USA. During the period of data protection, partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) is authorised for placing on the market, within England, only by Evergrain LLC unless a subsequent applicant obtains
	Bread and similar products	15 g/100 g		
	Fine bakery wares	15 g/100 g		
	Breakfast cereals	30 g/100 g		
	Margarines and similar	10 g/100 g		
	Butter and margarine/oil blends	10 g/100 g		
	Pasta and rice (or other cereal)-based dishes	30 g/100 g		
	Fried or extruded cereal, seed, and root-based products	30 g/100 g		
	Fruit/vegetables spreads and similar	30 g/100 g		
	Confectionary including chocolate	15 g/100 g		
	Dairy imitates	50 g/100 ml (beverages)		
		50 g/100 g (products other than beverages)		
	Milk and dairy products	50 g/100 ml (beverages)		
		50 g/100 g (products other than beverages)		
	Dessert sauces/toppings	15 g/100 g		
	Syrups (molasses and other syrups)	15 g/100 g		

Meat analogues	30 g/100 g	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 Evergrain LLC. The data protection will expire at the end of 27 June 2029.
Soups (marketed as such or reconstituted as instructed by the manufacturer)	15 g/100 g	
Stock cubes and granules (bouillon base)	15 g/100 g	
Gravy ingredients	10 g/100 g	
Savoury sauces	10 g/100 g	
Condiments (including table-top formats)	10 g/100 g	
Hummus	30 g/100 g	
Nut/seeds paste emulsion/mass	20 g/100 g	
Energy drinks	90 g/100 ml	
Carbohydrate-rich energy food products for sports people	30 g/100 g	
Protein and protein components for sports people	90 g/100 g	
Meal replacement for weight control	90 g/100 g ”	

SCHEDULE 4

Regulation 6(2)(b)

Substitution of entry in Table 1 in the Annex to Commission Implementing Regulation (EU) 2017/2470 for Bovine milk basic whey protein isolate

“Bovine milk basic whey protein isolate	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of food containing it is “Milk whey protein isolate”. The labelling of food supplements must bear a statement, as appropriate, that they should not be consumed by infants (persons under the age of 1 year)/infants or
	Infant formula as defined in Regulation (EU) No. 609/2013(**a**)	30 mg/ 100g (powder 3.9 mg/100 ml (reconstituted)	
	Follow-on formula as defined in Regulation (EU) No.	30 mg/ 100 g (powder) 4.2 mg/100 ml (reconstituted)	

(**a**) EUR 2013/609, amended by S.I. 2019/651; there are other amending instruments but none are relevant.

609/2013		
Total diet replacement for weight control as defined in Regulation (EU) No. 609/2013	300 mg/day	young children (persons under the age of 3 years)/infants, children or adolescents (persons under the age of 18 years).
Foods for special medical purposes as defined in Regulation (EU) No. 609/2013	30 mg/100 g (powder formula for infants (persons under the age of 1 year (12 months)) during 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 (persons aged between 1 year (12 months) up to the age of 3 years (36 months))	

		380 mg/day for children and adolescents (aged 3 years (36 months) to 18 years of age) 610 mg/day for persons aged 18 years or above		
	Food supplements as defined in the Food Supplements (England) Regulations 2003	25 mg/day for infants (persons under the age of 1 year (12 months)) 58 mg/day for young children (persons aged 1 year (12 months) up to the age of 3 years (36 months)) 250 mg/day for children and adolescents (aged 3 years (36 months) to 18 years of age) 610 mg/day for persons aged 18 years or above"		

SCHEDULE 5

Regulation 6(2)(c)

Insertion of entry in Table 1 in the Annex to Commission Implementing Regulation (EU) 2017/2470 for Cetylated fatty acids

"Cetylated fatty acids	Specified food category Food supplements as defined in the Food Supplements (England) Regulations 2003(**a**) for persons aged 18 years or above	Maximum levels 2.1 g/day"	The designation of the novel food on the labelling of food containing it is "cetylated fatty acids preparation". The labelling of food supplements must bear a statement that they should not be	Included in the list on 28 June 2024. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance

(**a**) S.I. 2003/1387; to which there are amendments not relevant to these Regulations.

	consumed by persons under 18 years of age.	with Article 26 of Regulation (EU) 2015/2283. Applicant: Pharmanutra S.p.A, Via Delle Lenze 216/b, 56122 Pisa, Italy. During the period of data protection, cetylated fatty acids is authorised for placing on the market, within England, only by Pharmanutra S.p.A 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 Pharmanutra S.p.A. The data protection will expire at the end of 27 June 2029.

SCHEDULE 6

Regulation 6(2)(d)

Insertion of entry in Table 1 in the Annex to Commission Implementing Regulation (EU) 2017/2470 for 3-Fucosyllactose (produced by a derivative strain of *Escherichia coli* K-12 DH1)

"3-Fucosyllactose (3-FL) (produced by a derivative strain of *Escherichia coli* K-12 DH1)	*Specified food category* Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	*Maximum levels* 2.0 g/l	The designation of the novel food on the labelling of food containing it is "3-fucosyllactose". The labelling of food supplements for infants and young children must bear a statement that they should not be consumed if breast milk or food with added 3-fucosyllactose is consumed on the same day.	Included in the list on 28 June 2024. 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, 3-fucosyllactose is authorised for placing on the market, within England, 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
	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		
	Infant formula and follow-on formula as defined in Regulation (EU) No. 609/2013	2.0 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Milk-based drinks and similar products intended for young children (persons aged 1 year (12 months) up to the age of 3 years (36 months))	2.0 g/l (beverages) in the final product ready for use, marketed as such or reconstituted as instructed		

	by the manufacturer	26 of Regulation (EU) 2015/2283 or with the agreement of Glycom A/S. The data protection will expire at the end of 27 June 2029.
	12 g/kg (products other than beverages)	
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	2.0 g/l (beverages)	
	25.0 g/kg (products other than beverages)	
Flavoured drinks (excluding cola flavour and cola flavoured drinks)	1.25 g/l	
Food supplements as defined in the Food Supplements (England) Regulations 2003 for infants (persons under the age of 1 year (12 months)) and young children (persons aged 1 year (12 months) up to the age of 3	2.0 g/day	

	years (36 months))			
	Food supplements as defined in the Food Supplements (England) Regulations 2003 excluding food supplements for infants and young children	4.0 g/day”		

SCHEDULE 7

Regulation 6(2)(e)

Insertion of entry in Table 1 in the Annex to Commission Implementing Regulation (EU) 2017/2470 for Lacto-*N*-fucopentaose I and 2’-fucosyllactose mixture

“Lacto-*N*-fucopentaose I (LNFP-I) and 2’-fucosyllactose (2’-FL) mixture	*Specified food category*	*Maximum levels of LNFP-I*	The designation of the novel food on the labelling of food containing it is “lacto-*N*-fucopentaose I and 2’-fucosyllactose mixture”. The labelling of food supplements intended for infants and young children must bear a statement that they should not be consumed if breast milk or food with added lacto-*N*-fucopentaose I (LNFP-I) or 2’-fucosyllactose (2’-FL) is consumed on the same day. The labelling of food supplements must bear a statement that they should not be consumed if other food with added lacto-*N*-fucopentaose I (LNFP-I) or 2’-fucosyllactose (2’-	Included in the list on 28 June 2024. 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, lacto-*N*-fucopentaose I (LNFP-I) and 2’-fucosyllactose (2’-FL) is authorised for placing on the
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	1.0 g/l		
	Unflavoured fermented milk-based products	1.0 g/l (beverages)		
		2.0 g/kg (products other than beverages)		
	Flavoured fermented milk-based products including heat-treated products	1.0 g/l (beverages)		
		10.0 g/kg (products other than beverages)		
	Cereal bars	10.0 g/kg		
	Infant formula and follow-on formula as defined in Regulation (EU) No. 609/2013	1.5 g/l (in the final product ready for use, marketed as such or reconstituted by the manufactu		

	rer	FL) is consumed on the same day.	market, within England, 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. The data protection will expire at the end of 27 June 2029.
Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No. 609/2013	1.0 g/l (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 8.33 g/kg (products other than beverages)		
Milk-based drinks and similar products intended for young children (persons aged 1 year (12 months) up to the age of 3 years (36 months))	1.2 g/l (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 10.0 g/kg (products other than beverages)		
Foods for special medical purposes as defined in Regulation (EU)	In accordance with the particular		

No. 609/2013	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	2.0 g/l (beverages) 20.0 g/kg (products other than beverages)
Flavoured drinks (excluding cola flavour and cola flavoured drinks)	1.0 g/l
Food supplements as defined in the Food Supplements (England) Regulations 2003 for infants (persons under the age of 1 year (12 months)) and young children (persons aged between 1 year (12 months) up to the age of 3 years (36 months))	1.5 g/day
Food supplements as defined in the Food Supplements (England) Regulations 2003 excluding supplements for infants and young children	3.0 g/day"

SCHEDULE 8

Regulation 6(3)(a)

Insertion of entry in Table 2 in the Annex to Commission Implementing Regulation (EU) 2017/2470 for Partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*)

"Partially hydrolysed protein from spent barley	**Description/Definition**

(*Hordeum vulgare*) and rice (*Oryza sativa*)	Partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) is an off-white powder, produced by concentration of proteins from a mixture of barley and rice from the mash step of beer production using a series of enzymatic hydrolysis and mechanical purification steps. **Characteristics/Composition** Protein (dry basis): ≥ 85% Moisture: < 8% Total Carbohydrates: < 10% Fat: < 2% Ash: < 8% **Heavy metals** Arsenic: < 0.1 mg/kg Cadmium: < 0.1 mg/kg Lead: < 0.2 mg/kg Mercury: < 0.1 mg/kg **Microbiological criteria** Aerobic plate count: < 30,000 CFU/g Coliforms: < 10 CFU/g Yeast and Mould: < 50 CFU/g *Salmonella* spp: Negative in 25 g *Escherichia coli*: < 10 CFU/g *Staphylococcus aureus*: < 10 CFU/g *Listeria* spp.: Negative in 25 g CFU: Colony Forming Units”

SCHEDULE 9

Regulation 6(3)(b)

Insertion of entry in Table 2 in the Annex to Commission Implementing Regulation (EU) 2017/2470 for Cetylated fatty acids

“Cetylated fatty acids	**Description/Definition** The novel food is a mixture of 70 – 80% cetylated fatty acids which are produced from the reaction of cetyl alcohol with myristic acid and oleic acid. **Characteristics/Composition** Physical status at 25°C: Solid Colour (APHA Colour): ≤ 600 Acid value (mg KOH/g): ≤ 5

	Iodine value (I_2g/100 g): 30 – 50 Saponification value (mg KOH/g): 130 – 150 Hydroxyl value (mg KOH/g): ≤ 20 Ester content (%): 70 – 80 Cetyl oleate (%): 22 – 30 Cetyl myristate (%): 41 – 56 Triglycerides(%): 22 - 25 **Microbiological criteria** Total aerobic microbial count (CFU/g): ≤ 1000 Yeasts and moulds (CFU/g): ≤ 100 APHA: American Public Health Association KOH: potassium hydroxide CFU: Colony Forming Units"

SCHEDULE 10

Regulation 6(3)(c)

Insertion of entry in Table 2 in the Annex to Commission Implementing Regulation (EU) 2017/2470 for 3-Fucosyllactose (produced by a derivative strain of *Escherichia coli* K-12 DH1)

"3-Fucosyllactose (3-FL) (produced by a derivative strain of *Escherichia coli* K-12 DH1)	**Description/Definition** 3-Fucosyllactose (3-FL) (produced by a derivative strain of *Escherichia coli* K-12 DH1) is a purified carbohydrate powder or agglomerate containing at least 90% of 3-fucosyllactose on a dry matter basis obtained from microbial fermentation with a genetically modified strain of *Escherichia coli* K-12 DH1. Chemical name: β-D-Galactopyranosyl-(1→4)- [α-L-fucopyranosyl-(1→3)]- D-glucopyranose Chemical formula: $C_{18}H_{32}O_{15}$ Molecular mass: 488.44 Da CAS No: 41312-47-4 **Characteristics/Composition** Appearance: Powder, agglomerates, powder with agglomerates Colour: White to off-white Assay (water-free) – Specified saccharides (includes 3-FL, D-lactose, L-fucose and 3-fucosyllactulose): ≥ 92.0 w/w % Assay (water-free) – 3-FL: ≥ 90.0 w/w % L-Fucose: ≤ 1.0 w/w % D-Lactose: ≤ 5.0 w/w % 3-fucosyllactulose: ≤ 1.5 w/w % Sum of other carbohydrates: ≤ 5.0 w/w %

	pH in 5% solution (20°C): 3.2–7.0 Water: ≤ 6.0 w/w % Ash, sulphated: ≤ 0.5 w/w % Acetic acid (relevant only for crystallised 3-FL): ≤ 1.0 w/w % Residual protein by Bradford assay: ≤ 0.01 w/w % Residual endotoxins: ≤ 10 EU/mg **Heavy metals** Lead: ≤ 0.1 mg/kg Arsenic: ≤ 0.2 mg/kg **Mycotoxins** Aflatoxin M1: ≤ 0.025 µg/kg **Microbiological criteria** Aerobic mesophilic total plate count: ≤ 1000 CFU/g Enterobacteriaceae: absent in 10 g *Salmonella* spp: absent in 25 g *Bacillus cereus*: ≤ 50 CFU/g *Listeria monocytogenes*: absent in 25 g *Cronobacter* spp.: absent in 10 g Yeasts: ≤ 100 CFU/g Moulds: ≤ 100 CFU/g EU: Endotoxin Units CFU: Colony Forming Units"

SCHEDULE 11

Regulation 6(3)(d)

Insertion of entry in Table 2 in the Annex to Commission Implementing Regulation (EU) 2017/2470 for Lacto-*N*-fucopentaose I and 2'-fucosyllactose mixture

"Lacto-*N*-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) mixture	**Description/Definition** Lacto-*N*-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) mixture is a purified carbohydrate powder or agglomerate obtained from microbial fermentation with a genetically modified strain of *Escherichia coli* K-12 DH1 containing at least 75% of LNFP-I and 2'- FL of dry matter, where ≥ 50% is LNFP-I (dry weight) and ≥ 15% is 2'-FL (dry weight). **Characteristics/Composition** Appearance: Powder, agglomerates, powder with agglomerates

	Colour: White to off-white Assay (water-free) – Specified saccharides (includes LNFP-I, 2'-FL, lacto-*N*-tetraose, difucosyl-D-lactose, 3-fucosyllactose, D-lactose, L-fucose and 2'-fucosyl-lactitol, LNFP-I fructose isomer and 2'-fucosyl-D-lactulose): ≥ 90.0 w/w % Assay (water-free) – LNFP-I and 2'-FL: ≥ 75.0 w/w % Assay (water-free) – LNFP-I: ≥ 50.0 w/w % Assay (water-free) – 2'-FL: ≥ 15.0 w/w % Lacto-*N*-tetraose: ≤ 5.0 w/w % 3-Fucosyllactose: ≤ 1.0 w/w % Sum of L-Fucose and 2'-fucosyl-lactitol: ≤ 1.0 w/w % D-Lactose: ≤ 10.0 w/w % Difucosyl-D-lactose: ≤ 2.0 w/w % LNFP-I fructose isomer: ≤ 1.5 w/w % 2'-Fucosyl-D-lactulose: ≤ 1.0 w/w % Sum of other carbohydrates: ≤ 6.0 w/w % pH in 5% solution (20°C): 4.0–7.0 Water: ≤ 8.0 w/w % Ash, sulphated: ≤ 0.5 w/w % Residual protein by Bradford assay: ≤ 0.01 w/w % **Heavy metals** Arsenic: ≤0.2 mg/kg **Mycotoxins** Residual endotoxins: ≤ 10 EU/mg Aflatoxin M1: ≤ 0.025 µg/kg **Microbiological criteria** Aerobic mesophilic total plate count: ≤ 1000 CFU/g Enterobacteriaceae: Absent in 10g *Salmonella* spp: Absent in 25 g Yeasts: ≤ 100 CFU/g Moulds: ≤ 100 CFU/g *Bacillus cereus*: ≤ 50 CFU/g *Listeria monocytogenes*: Absent in 25g *Cronobacter* spp.: Absent in 10g EU: Endotoxin Units CFU: Colony Forming Units"

EXPLANATORY NOTE

(This note is not part of the Regulations)

Regulation 2 amends Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives (EUR 2008/1333) to add a new food additive, amend the conditions of use for an existing food additive, and makes consequential amendments and corrections.

Regulation 3 amends Commission Regulation (EU) No. 231/2012 laying down specifications for food additives listed in Annexes II and III of Regulation (EC) No. 1333/2008 of the European Parliament and of the Council (EUR 2012/231) to set a maximum limit for ethylene oxide in all food additives, add a new production method for an existing additive and makes a consequential change to subcategorise the E numbers for that additive.

Regulation 4 amends Regulation (EC) No. 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods etc. (EUR 2008/1334) to remove 22 flavouring substances from the authorised list of flavourings.

Regulation 5 creates a transitional measure to allow the 22 flavouring substances and foods containing them to remain on the market, and be added to foods, if already present in the United Kingdom or in transit to Great Britain before the authorisation was removed and to allow foods to which they are added to be placed on the market, and used, until they reach their date of minimum durability.

Regulation 6 amends Commission Implementing Regulation (EU) 2017/2470 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 (EUR 2017/2470) to add four new novel foods, amends the conditions of use for one existing novel food and correct the specifications for another existing novel food in the list of authorised novel foods.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the public, private or voluntary sector is foreseen.

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