SCOTTISH STATUTORY INSTRUMENTS

2024 No. 156

FOOD

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

Made - - - -	*28th May 2024*
Laid before the Scottish Parliament	*30th May 2024*
Coming into force - -	*28th June 2024*

The Scottish Ministers make these Regulations in exercise of the powers conferred by Articles 7(4) and (5)(**a**) 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(**b**), and Articles 12(1) and 32A(3)(b) of Regulation (EU) 2015/2283 of the European Parliament and of the Council 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(**c**), and all other powers enabling them to do so.

In relation to Parts 2 and 4, the Scottish Ministers have sought the advice of Food Standards Scotland in accordance with Article 7(4) and (5) 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.

There has been consultation 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 European Food Safety Authority and laying down procedures in matters of food safety(**d**).

(**a**) Article 2 makes provision as to how the regulation-making power in Article 7(5) is to be exercised.

(**b**) EUR 2008/1331, as relevantly amended by S.I. 2019/860. The terms "domestic list", "authority", "prescribe" and "appropriate authority" are defined in Article 2. In relation to Part 2 of these Regulations, Articles 7(5) and 14(2)(b) of EUR 2008/1331 are applied by Articles 10(3), 14 and 30(4) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives as relevantly amended by S.I. 2019/860. In relation to Part 3 of these Regulations, Articles 7(5) and 14(2)(b) of EUR 2008/1331 are applied by Article 11(3) of 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 as relevantly amended by S.I. 2019/860.

(**c**) EUR 2015/2283, as relevantly amended by S.I. 2019/702. The terms "list", "prescribe" and "appropriate authority" are defined in Article 3. Article 9 makes provision as regards how the regulation-making power in Article 12(1) is to be exercised and Article 27(1) lays down requirements as regards the information to be included in the entry for a novel food on the list set out in Commission Implementing Regulation (EU) 2017/2470 where it is authorised based in proprietary scientific evidence or scientific data. In accordance with Article 12(1), the appropriate authority must prescribe updates to that list within seven months of the date of publication of the Food Safety Authority's opinion.

(**d**) EUR 2002/178, as relevantly amended by S.I. 2019/641.

PART 1

Introduction

Citation, commencement and extent

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

(2) These Regulations extend to Scotland only.

Interpretation

2.—(1) In these Regulations—

"Regulation (EC) No 1333/2008" means Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives(**a**),

"Regulation (EC) No 1334/2008" means 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 and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC(**b**),

"Commission Regulation (EU) No 231/2012" means 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(**c**),

"Regulation (EU) No 609/2013" means Regulation (EU) No 609/2013 of the European Parliament and of the Council 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(**d**),

"Regulation (EU) 2015/2283" means Regulation (EU) 2015/2283 of the European Parliament and of the Council 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,

"Commission Implementing Regulation (EU) 2017/2470" means 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(**e**).

(2) Unless the contrary intention appears, any expression used both in these Regulations and in Regulation (EC) No 1333/2008, Regulation (EC) No 1334/2008, Commission Regulation (EU) No 231/2012 or Commission Implementing Regulation (EU) 2017/2470 has the same meaning as it has in Regulation (EC) No 1333/2008, Regulation (EC) No 1334/2008, Commission Regulation (EU) No 231/2012 or Commission Implementing Regulation (EU) 2017/2470, as the case may be.

(**a**) EUR 2008/1333, as relevantly amended by S.I. 2019/860.
(**b**) EUR 2008/1334, as relevantly amended by S.I. 2019/860.
(**c**) EUR 2012/231.
(**d**) EUR 2013/609, as relevantly amended by S.I. 2019/651.
(**e**) EUR 2017/2470, as relevantly amended by S.I. 2019/702.

PART 2

Food Additives Authorisations

Amendment of Regulation (EC) No 1333/2008

3. Annex 2 (domestic list of food additives approved for use in foods and conditions for use) to Regulation (EC) No 1333/2008 is amended in accordance with schedule 1.

Amendment of Commission Regulation (EU) No 231/2012

4.—(1) The Annex to Commission Regulation (EU) No 231/2012 is amended in accordance with paragraphs (2) to (6).

(2) At the beginning, 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))), regardless 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 entries for the following food additives—

(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),

(f) E 436 Polyoxyethylene Sorbitan Tristearate (Polysorbate 65),

(g) E 1209 Polyvinyl Alcohol-Polyethylene Glycol-*Graft*-Copolymer,

(h) E 1521 Polyethylene Glycol,

omit the row for "Ethylene oxide".

(4) After the table for E 960a (Steviol glycosides from Stevia), insert the heading and table in schedule 2.

(5) In the heading for the entry for E 960c (rebaudioside M produced via enzyme modification of steviol glycosides from Stevia) for "E 960c" substitute "E 960c(i)".

(6) After the table for E 960c(i)(**a**), (Rebaudioside M produced via enzyme modification of steviol glycosides from Stevia) insert the heading and table in schedule 3.

PART 3

Novel Foods Authorisations

Amendment of Commission Implementing Regulation (EU) 2017/2470

5. The Annex (domestic list of novel foods authorised to be placed on the market within Great Britain) to Commission Implementing Regulation (EU) 2017/2470 is amended in accordance with schedules 4 to 8.

(**a**) The food additive rebaudioside M produced via enzyme modification of steviol glycosides from Stevia E 960c(i) (formerly E 960c) was re-numbered by paragraph 4(5) of these Regulations.

PART 4

Food Flavourings Authorisations

Amendment of Regulation (EC) No 1334/2008

6.—(1) Annex 1 (domestic list of flavourings and source materials approved for use in and on foods) to Regulation (EC) No 1334/2008 is amended in accordance with paragraph (2).

(2) In Part A (domestic list of flavouring substance), Section 2, in Table 1, the following entries are omitted—

(a) FL No.(**a**) 07.030, chemical name 1-(4-Methoxyphenyl)pent-1-en-3-one, CAS No. 104-27-8(**b**),

(b) FL No. 07.046, chemical name Vanillylidene acetone, CAS No. 1080-12-2,

(c) FL No. 07.049, chemical name 1-(4-Methoxyphenyl)-4-methylpent-1-en-3-one, CAS No. 103-13-9,

(d) FL No. 07.206, chemical name 4-(2,3,6-Trimethylphenyl)but-3-en-2-one, CAS No. 56681-06-2,

(e) FL No. 07.258, chemical name 6-Methyl-3-hepten-2-one, CAS No. 2009-74-7,

(f) FL No. 10.034, chemical name 5,6-Dihydro-3,6-dimethylbenzofuran-2(4H)-one, CAS No. 80417-97-6,

(g) FL No. 10.036, chemical name 5,6,7,7a-Tetrahydro-3,6-dimethylbenzofuran-2(4H)-one, CAS No. 13341-72-5,

(h) FL No. 10.042, chemical name 3,4-Dimethyl-5-pentylidenefuran-2(5H)-one, CAS No. 774-64-1,

(i) FL No. 10.043, chemical name 2,7-Dimethylocta-5(trans),7-dieno-1,4-lactone, CAS No. 78548-56-8,

(j) FL No. 10.046, chemical name Hex-2-eno-1,4-lactone, CAS No. 2407-43-4,

(k) FL No. 10.054, chemical name Non-2-eno-1,4-lactone, CAS No. 21963-26-8,

(l) FL No. 10.060, chemical name 2-Decen-1,4-lactone, CAS No. 2518-53-8,

(m) FL No. 10.170, chemical name 5-Pentyl-3H-furan-2-one, CAS No. 51352-68-2,

(n) FL No. 13.004, chemical name Allyl 2-furoate, CAS No. 4208-49-5,

(o) FL No. 13.034, chemical name 3-(2-furyl)acrylaldehyde, CAS No. 623-30-3,

(p) FL No. 13.043, chemical name Furfurylidene-2-butanal, CAS No. 770-27-4,

(q) FL No. 13.044, chemical name 4-(2-Furyl)but-3-en-2-one, CAS No. 623-15-4,

(r) FL No. 13.046, chemical name 3-(2-Furyl)-2-methylprop-2-enal, CAS No. 874-66-8,

(s) FL No. 13.066, chemical name 3-Acetyl-2,5-dimethylfuran, CAS No. 10599-70-9,

(t) FL No. 13.103, chemical name 2-Butylfuran, CAS No. 4466-24-4,

(u) FL No. 13.137, chemical name 3-(2-Furyl)-2-phenylprop-2-enal, CAS No. 65545-81-5,

(v) FL No. 13.150, chemical name 3-(5-Methyl-2-furyl)prop-2-enal, CAS No. 5555-90-8.

Transitional provision

7.—(1) The flavouring substances referred to in regulation 6(2) 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**) The FL No. is the unique identification number of the substance.
(**b**) The CAS Registry Number assigned to the substance by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

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

(b) in transit to Great Britain before the end of 27 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 paragraph (1) 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) In this regulation—

"date of minimum durability of a food" has the same meaning as provided in Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC of the European Parliament and of the Council, Commission Directives 2022/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004(**a**) (see Articles 2(2)(r) and 24),

"'use by' date" has the same meaning as in Article 24 of Regulation (EU) 1169/2011.

JENNI MINTO
Authorised to sign by the Scottish Ministers

St Andrew's House,
Edinburgh
28th May 2024

(**a**) EUR 2011/1169, as relevantly amended by S.I. 2019/778.

SCHEDULE 1

Regulation 3

Amendments to Annex 2 (domestic list of food additives approved for use in foods and conditions for use) to Regulation (EC) No 1333/2008 concerning steviol glycosides from Stevia (E 960a – E 960c) and the extension of use of polyglycerol polyricinoleate (E 476)

1. In Part B (list of all additives), in paragraph 2 (sweeteners) after the entry for E 960a (Steviol glycosides from Stevia), insert—

"E 960b	Steviol glycosides from fermentation".

2. In Part C (definitions of groups of additives), in sub-part 5 (other additives that may be regulated combined), in paragraph (v)—

(a) for the heading of the paragraph, substitute "E 960a – E 960c: Steviol glycosides",

(b) after the entry for E 960a (Steviol glycosides from Stevia), insert—

"E 960b	Steviol glycosides from fermentation".

3. In Part E (authorised food additives and conditions of use in food categories), in the table—

(a) in each place 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—

"E 476	Polyglycerol polyricinoleate	4000	except sorbets",

(c) in category 05.1 (cocoa and chocolate products), at the end, insert the following footnote—

"(1) The additives may be added individually or in combination.",

(d) in category 05.2 (other confectionary 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 "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 – E960c Steviol glycosides(**a**) 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 – E960c 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 – 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",

(**a**) The entries for E 960a to E 960c were re-named by paragraph 3(a) of this schedule.

(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".

SCHEDULE 2

Regulation 4(4)

Amendment to the Annex to Commission Regulation (EU) No 231/2012 for the authorisation of steviol glycosides from fermentation (*Yarrowia lipolytica*) (E 960b)

1. In the appropriate place, insert the following entry—

"**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 A, rebaudioside B, rebaudioside D and rebaudioside M 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 3

Regulation 4(6)

Amendment to the Annex to Commission Regulation (EU) No 231/2012 for the re-numbering of rebaudioside M produced via enzyme modification of steviol glycosides from Stevia E 960c(i) (formerly E 960c) and for the addition of a specification for rebaudioside M, AM and D produced via enzymatic conversion of highly purified steviol glycosides from Stevia leaf extracts (E 960c(ii))

1. In the appropriate place, insert the following entry—

"**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) from 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 4

Regulation 5

Amendments to the Annex (domestic list of novel foods authorised to be placed on the market within Great Britain) to Commission Implementing Regulation (EU) 2017/2470 for the authorisation of partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) as a novel food

1. In Table 1 (authorised novel foods), after the entry for Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae insert the following entry—

"**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 Scotland, only by Evergrain LLC 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 Evergrain LLC.
	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			
	Pastas and rice (or other cereal)-based dishes	30 g/100 g			
	Fried or extruded cereal, seed, or 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			
	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			The data protection will expire at the end of 27 June 2029."
	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			

2. In Table 2 (specifications), after the entry for Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae insert the following entry—

"**Partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*)**	**Description/Definition:**
	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 5

Regulation 5

Amendments to the Annex (domestic list of novel foods authorised to be placed on the market within Great Britain) to Commission Implementing Regulation (EU) 2017/2470 for the authorisation of cetylated fatty acids as a novel food

1. In Table 1 (authorised novel foods), after the entry for *Calanus finmarchicus* oil insert the following entry—

"**Cetylated fatty acids**	*Specified food category*	*Maximum levels*	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 consumed by persons under 18 years of age.		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: 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 Scotland, 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."
	Food supplements as defined in the Food Supplements (Scotland) Regulations 2003(**a**) for persons aged 18 years or above	2.1g/day			

(**a**) S.S.I. 2003/278, as relevantly amended by S.S.I. 2019/54.

2. In Table 2 (specifications), after the entry for *Calanus finmarchicus* oil insert the following entry—

"**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/100g): 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 CFU: Colony Forming Units KOH: potassium hydroxide".

SCHEDULE 6

Regulation 5

Amendments to the Annex (domestic list of novel foods authorised to be placed on the market within Great Britain) to Commission Implementing Regulation (EU) 2017/2470 for the authorisation of 3-fucosyllactose (3-FL) (produced by a derivative strain of *Escherichia coli* K-12 DH1) as a novel food

1. In Table 1 (authorised novel foods), after the entry for 2'-Fucosyllactose / Difucosyllactose mixture ('2'-FL/DFL') (microbial source) insert the following entry—

"**3-Fucosyllactose (3-FL) (produced by a derivative strain of *Escherichia coli* K-12 DH1)**	*Specified food category*	*Maximum levels*	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 Scotland, 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
	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			
	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			
		12.0 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			Regulation (EU) 2015/2283 or with the agreement of Glycom A/S. The data protection will expire at the end of 27 June 2029."
	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 (Scotland) 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 years (36 months))	2.0 g/day			
	Food supplements as defined in the Food Supplements (Scotland) Regulations 2003 excluding food supplements for infants and young children	4.0 g/day			

2. In Table 2 (specifications), after the entry for 2'-Fucosyllactose / Difucosyllactose mixture ('2'-FL/DFL') (microbial source) insert the following entry—

"**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-fucosyllactose): ≥ 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 10g *Salmonella* spp: absent in 25g *Bacillus cereus*: ≤ 50 CFU/g *Listeria monocytogenes*: absent in 25g *Cronobacter* spp.: absent in 10g Yeasts: ≤ 100 CFU/g Moulds: ≤ 100 CFU/g EU: Endotoxin Units CFU: Colony Forming Units".

SCHEDULE 7

Regulation 5

Amendments to the Annex (domestic list of novel foods authorised to be placed on the market within Great Britain) to Commission Implementing Regulation (EU) 2017/2470 for the authorisation of lacto-*N*-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) mixture as a novel food

1. In Table 1 (authorised novel foods), after the entry for Lactitol insert the following entry—

<table>
<tr>
<td rowspan="11">"Lacto-N-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) mixture</td>
<td>Specified food category</td>
<td>Maximum levels of LNFP -I</td>
<td rowspan="11">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 other foods 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'-FL) is consumed on the same day.</td>
<td rowspan="11"></td>
<td rowspan="11">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) mixture is authorised for placing on the market, within Scotland, 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</td>
</tr>
<tr><td rowspan="2">Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products</td><td rowspan="2">1.0 g/L</td></tr>
<tr></tr>
<tr><td rowspan="2">Unflavoured fermented milk-based products</td><td>1.0 g/L (beverages)</td></tr>
<tr><td>2.0 g/kg (products other than beverages)</td></tr>
<tr><td rowspan="2">Flavoured fermented milk-based products including heat-treated products</td><td>1.0 g/L (beverages)</td></tr>
<tr><td>10.0 g/kg (products other than beverages)</td></tr>
<tr><td>Cereal bars</td><td>10.0 g/kg</td></tr>
<tr><td>Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013</td><td>1.5 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer</td></tr>
<tr><td rowspan="2">Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013</td><td rowspan="2">1.0 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer</td></tr>
<tr></tr>
<tr><td></td><td>8.33 g/kg (products other than beverages)</td></tr>
</table>

	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			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."
		10.0 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)			
		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 (Scotland) Regulations 2003, for infants (persons under the age of 1 year (12 months)) and young children (persons	1.5 g/day			

	aged 1 year (12 months) up to the age of 3 years (36 months))				
	Food supplements as defined in the Food Supplements (Scotland) Regulations 2003 excluding food supplements for infants and young children	3.0 g/day			

2. In Table 2 (specifications), after the entry for Lactitol insert the following entry—

"**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 25g Yeasts: ≤ 100 CFU/g Moulds: ≤ 100 CFU/g *Bacillus cereus*: ≤ 50 CFU/g *Listeria monocytogenes*: Absent in 25g *Cronobacter* spp.: Absent in 10g CFU: Colony Forming Units EU: Endotoxin Units".

SCHEDULE 8

Regulation 5

Corrections to existing entries in the Annex (domestic list of novel foods authorised to be placed on the market within Great Britain) to Commission Implementing Regulation (EU) 2017/2470 concerning the authorisation of bovine milk basic whey protein isolate and xylo-oligosaccharides

1. In Table 1 (authorised novel foods), for the entry for bovine milk basic whey protein isolate substitute the following entry—

"**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 young children (persons under the age of 3 years) / infants, children or adolescents (persons under the age of 18 years)."		
	Infant formula as defined in Regulation (EU) No 609/2013	30 mg/100 g (powder)			
		3.9 mg/100 ml (reconstituted)			
	Follow-on formula as defined in Regulation (EU) No 609/2013	30 mg/100 g (powder)			
		4.2mg/100 ml (reconstituted)			
	Total diet replacement 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 (persons under the age of 1 year (12 months)) 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 complimentary feeding is introduced)			
		58 mg/day for young children (persons aged 1 year (12 months) up the age of 3 years (36 months))			
		380 mg/day for children and adolescents (aged 3 years (36 months) up to 18 years of age)			
		610 mg/day for persons aged 18 years or above			
	Food supplements as defined in the Food Supplements (Scotland) 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) up to 18 years of age)			
		610 mg/day for persons aged 18 years or above			

2. In Table 2 (specifications), for the entry for Xylo-oligosaccharides, in column 2 (description/definition), after the row specifying the moisture (%) content, insert—

"Dry Material (%)	-	-	70 -75"

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision regarding the authorisation of—

- food additives under 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 (EUR 2008/1331),
- food flavourings under EUR 2008/1331, and
- novel foods under Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (EUR 2015/2283).

Regulation 3 and schedule 1 amends the list of authorised food additives set out in Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (EUR 2008/1333) to add an entry thereby authorising the placing on the market and use of the food additive steviol glycosides from fermentation (*Yarrowia lipolytica*) (E 960b). Amendments are made to the list of authorised food additives consequential to that addition, and further amendments correct errors in that Regulation concerning steviol glycosides. Entries are added in that Regulation extending the use of the authorised food additive polyglycerol polyricinoleate (E 476).

Regulation 4 and schedules 2 and 3 amend the Annex to Commission Regulation (EU) No 231/2012 (EUR 2012/231) laying down specifications for food additives listed in Annexes II and III of EUR 2008/1333 to—

- provide a maximum limit for residues of ethylene oxide applicable to all food additives,
- add an entry concerning the authorisation of steviol glycosides from fermentation (*Yarrowia lipolytica*) (E 960b), and
- authorise rebaudioside M, AM and D produced via enzymatic conversion of highly purified steviol glycosides from Stevia leaf extracts (E 960c(ii)), which is a new production method for an existing food additive rebaudioside M produced via enzyme modification of steviol glycosides from Stevia E 960c(i) (formerly E 960c).

Regulation 5 and schedules 4 to 8 amend the list of authorised novel foods set out in the Annex to Commission Implementing Regulation (EU) 2017/2470 (EUR 2017/2470). Schedule 8 corrects errors to existing entries in the list concerning bovine milk basic whey protein isolate and xylo-oligosaccharides. Schedules 4 to 7 authorise the placing on the market of 4 new novel foods—

- partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*),
- cetylated fatty acids,
- 3-fucosyllactose (3-FL) (produced by a derivative strain of *Escherichia coli* K-12 DH1), and
- lacto-*N*-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) mixture.

Regulation 6 removes 22 flavouring substances from the domestic list of authorised flavouring substances in Annex 1 to Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (EUR 2008/1334).

Regulation 7 is a transitional measure allowing the 22 flavouring substances, the authorisation of which is removed by regulation 6, and foods containing them to be placed on the market, and be added to other foods, if already present in the United Kingdom or in transit to Great Britain before the removal of the authorisations. Foods to which such substances are added may be placed on the market, and used, until their date of minimum durability ('best before' date) or 'use by' date.

No business and regulatory impact assessment has been prepared for these Regulations as no impact upon business, charities or voluntary bodies is foreseen.

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