SCOTTISH STATUTORY INSTRUMENTS

2023 No. 78

FOOD

The Food Additives, Food Flavourings and Novel Foods (Authorisations) (Scotland) Regulations 2023

Made - - - -	*14th March 2023*
Laid before the Scottish Parliament - - - -	*16th March 2023*
Coming into force - -	*15th May 2023*

The Scottish Ministers make these Regulations in exercise of the powers conferred by Articles 7(5)(**1**) 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(**2**), Article 12(1)(**3**) 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(**4**), and all other powers enabling them to do so.

In relation to Parts 2 and 3, the Scottish Ministers have sought the advice of Food Standards Scotland in accordance with Article 7(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(**5**).

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

(**2**) 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.

(**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 on 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.

(**4**) EUR 2015/2283, as relevantly amended by S.I. 2019/702. The terms "list", "prescribe" and "appropriate authority" are defined in Article 3.

(**5**) EUR 2002/178, as relevantly amended by S.I. 2019/641 and 2020/1504.

PART 1

Introduction

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Food Additives, Food Flavourings and Novel Foods (Authorisations) (Scotland) Regulations 2023 and come into force on 15 May 2023.

(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(**6**),

"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(**7**),

"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(**8**),

"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(**9**).

(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.

PART 2

Food Additives Authorisations

Amendment of Regulation (EC) No. 1333/2008

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

(2) Part E of Annex 2 to Regulation (EC) No. 1333/2008 is further amended as follows—

(a) in category 13.2 (dietary foods for special medical purposes), in the entry for "Advantame", for "E 960" substitute "E 969",

(**6**) EUR 2008/1333, as amended by S.I. 2019/860.
(**7**) EUR 2008/1334, as amended by S.I. 2019/860.
(**8**) EUR 2012/231, as amended by S.I. 2019/860.
(**9**) EUR 2017/2470, as amended by S.I. 2019/702.

(b) in category 13.3 (dietary foods for weight control diets), in the entry for "Advantame", for "E 960" substitute "E 969",

(c) in category 14.1.3 (fruit nectars and vegetable nectars and similar products) at the end at the appropriate place add the following footnote—

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

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

4. The specifications for food additives set out in the Annex to Commission Regulation (EU) No. 231/2012 are amended in accordance with schedule 2.

Transitional provision

5. Any food additive or food labelled before the end of 14 November 2024 as steviol glycosides (E 960) or as containing steviol glycosides (E 960), that is otherwise compliant with the conditions of use and specification for steviol glycosides from Stevia (E 960a), may continue to be placed on the market and used until stocks are exhausted.

PART 3

Food Flavourings Authorisations

Amendment of Regulation (EC) No. 1334/2008

6. The domestic list of flavourings and source materials set in out Annex 1 to Regulation (EC) No. 1334/2008 is amended in accordance with schedule 3.

PART 4

Novel Foods Authorisations

Amendment of Commission Implementing Regulation (EU) 2017/2470

7. The list of authorised novel foods set out in the Annex to Commission Implementing Regulation (EU) 2017/2470 is amended in accordance with schedules 4 and 5.

St Andrew's House,
Edinburgh
14th March 2023

MAREE TODD
Authorised to sign by the Scottish Ministers

SCHEDULE 1

Regulation 3

Amendments to the domestic list of food additives approved for use in foods in Annex 2 to Regulation (EC) No. 1333/2008 concerning steviol glycosides from Stevia (E 960a) (formerly steviol glycosides (E 960)) and for the addition of rebaudioside M produced by enzyme modification of steviol glycosides from Stevia (E 960c)

1. In Part B (list of all additives), in paragraph 2 (sweeteners)—

(a) For the entry for "Steviol glycosides" substitute—

"E 960a	Steviol glycosides from Stevia",

(b) after the entry referred to in paragraph (a) of this schedule insert—

"E 960c	Enzymatically produced steviol glycosides".

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

"(v) E 960a and E 960c: Steviol glycosides

E-number	*Name*
E 960a	Steviol glycosides from Stevia
E 960c	Enzymatically produced steviol glycosides".

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

(a) in category 01.4 (flavoured fermented milk products including heat-treated products), for the entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	100	(1) (60)	only energy-reduced products or with no added sugar",

(b) in category 03 (edible ices), for the entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	200	(1) (60)	only energy-reduced products or with no added sugar",

(c) in category 04.2.2 (fruit and vegetables in vinegar, oil, or brine), for the entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	100	(1) (60)	only sweet-sour preserves of fruit and vegetables",

(d) in category 04.2.4.1 (fruit and vegetable preparations excluding compote), for the entry "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	200	(1) (60)	only energy-reduced",

(e) in category 04.2.5.1 (extra jam and extra jelly), for the entry "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	200	(1) (60)	only energy-reduced jams, jellies and marmalades",

(f) in category 04.2.5.2 (jams, jellies and marmalades and sweetened chestnut purée), for the entry "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	200	(1) (60)	only energy-reduced jams, jellies and marmalades",

(g) in category 04.2.5.3 (other similar fruit or vegetable spreads), for the entry "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	200	(1) (60)	only energy-reduced fruit or vegetable spreads and dried-fruit-based sandwich spreads, energy-reduced or with no added sugar",

(h) in category 05.1 (cocoa and chocolate products), for the entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	270	(1) (60)	only energy-reduced or with no added sugar",

(i) in category 05.2 (other confectionery including breath freshening microsweets)—

(i) for the first entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	270	(1) (60)	only cocoa or dried-fruit-based, energy-reduced or with no added sugar",

(ii) for the second entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	330	(1) (60)	only cocoa, milk, dried-fruit-based or fat-based sandwich spreads, energy-reduced or with no added sugar",

(iii) for the third entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	350	(1) (60)	only confectionery with no added sugar only energy-reduced hard confectionery, such as candies and lollies only energy-reduced soft confectionery, such as chewy candies, fruit gums and foam sugar products/ marshmallows only energy-reduced liquorice only energy-reduced nougat only energy-reduced marzipan",

(iv) for the fourth entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	2000	(1)(60)	only breath-freshening microsweets, energy-reduced or with no added sugar",

(v) for the fifth entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	670	(1) (60)	only strongly flavoured freshening throat pastilles, energy-reduced or with no added sugar",

(j) in category 05.3 (chewing gum), for the entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	3300	(1) (60)	only with no added sugar",

(k) in category 05.4 (decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4)—

(i) for the first entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	330	(1) (60)	only confectionery with no added sugar",

(ii) for the second entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	270	(1) (60)	only cocoa or dried-fruit-based, energy-reduced or with no added sugar",

(l) in category 06.3 (breakfast cereals), for the entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	330	(1) (60)	only breakfast cereals with a fibre content of more than 15%, and containing at least 20% bran, energy-reduced or with no added sugar",

(m) in category 07.2 (fine bakery wares), for the entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	330	(1) (60)	only essoblaten – wafer paper",

(n) in category 09.2 (processed fish and fishery products including molluscs and crustaceans), for the entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	200	(1) (60)	only sweet-sour preserves and semi preserves of fish and marinades of fish, crustaceans and molluscs",

(o) in category 11.4.1 (table-top sweeteners in liquid form), for the entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	*quantum satis*(**10**)	(60)",	

(p) in category 11.4.2 (table-top sweeteners in powder form), for the entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	*quantum satis*	(60)",	

(q) in category 11.4.3 (table-top sweeteners in tablets), for the entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	*quantum satis*	(60)",	

(r) in category 12.4 (mustard), for the entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	120	(1) (60)",	

(s) in category 12.5 (soups and broths), for the entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	40	(1) (60)	only energy-reduced soups",

(t) in category 12.6 (sauces)—

(i) for the first entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	120	(1) (60)	except soy-bean sauce (fermented and non-fermented)",

(ii) for the second entry for "Steviol glycosides" substitute—

(**10**) "Quantum satis" is defined in Article 3(2)(h) of EUR 2008/1333 to mean that no maximum numerical level is specified and substances shall be used in accordance with good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose and provided the consumer is not misled.

"E 960a and E 960c	Steviol glycosides	175	(1) (60)	only soy-bean sauce (fermented and non-fermented)",

(u) in category 13.2 (dietary foods for special medical purposes (excluding products form food category 13.1.5)), for the entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	330	(1) (60)",	

(v) in category 13.3 (dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)), for the entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	270	(1) (60)",	

(w) in category 14.1.3 (fruit nectars and vegetable nectars and similar products), for the entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	100	(1) (60)	only energy-reduced or with no added sugar",

(x) in category 14.1.4 (flavoured drinks), for the entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	80	(1) (60)	only energy-reduced or with no added sugar",

(y) in category 14.1.5.2 (other)—

(i) for the first entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	30	(1) (60) (93)	only coffee, tea and herbal infusion beverages, energy-reduced or with no added sugar",

(ii) for the second entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	30	(1) (60) (93)	only flavoured instant coffee and instant cappuccino products,

				energy-reduced or with no added sugar”,

(iii) for the third entry for “Steviol glycosides” substitute—

“E 960a and E 960c	Steviol glycosides	20	(1) (60) (93)	only malt-based and chocolate/ cappuccino flavoured drinks, energy-reduced or with no added sugar”,

(z) in category 14.2.1 (beer and malt beverages), for the entry for “Steviol glycosides” substitute—

“E 960a and E 960c	Steviol glycosides	70	(1) (60)	only alcohol-free beer or with an alcohol content not exceeding 1.2% volume; ‘Bière de table/ Tafelbier/Table beer’ (original wort content less than 6%) except for ‘Obergäriges Einfachbier’; beers with a minimum acidity of 30 milli-equivalents expressed as NaOH; Brown beers of the ‘oud bruin’ type”,

(aa) in category 14.2.8 (other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15% of alcohol), for the entry for “Steviol glycosides” substitute—

“E 960a and E 960c	Steviol glycosides	150	(1) (60)”,	

(bb) in category 15.1 (potato-, cereal-, flour-, or starch-based snacks), for the entry for “Steviol glycosides” substitute—

"E 960a and E 960c	Steviol glycosides	20	(1) (60)",	

(cc) in category 15.2 (processed nuts), for the entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	20	(1) (60)",	

(dd) in category 16 (desserts excluding products covered in categories 1, 3 and 4), for the entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	100	(1) (60)	only energy-reduced or with no added sugar",

(ee) in category 17.1 (food supplements supplied in solid form, excluding food supplements for infants and young children)—

(i) for the first entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	670	(1) (60)",	

(ii) for the second entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	1800	(1) (60)	only food supplements in chewable form",

(ff) in category 17.2 (food supplements supplied in a liquid form, excluding food supplements for infants and young children)—

(i) for the first entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	200	(1) (60)",	

(ii) for the second entry for "Steviol glycosides" substitute—

"E 960a and E 960c	Steviol glycosides	1800	(1)(60)	Only food supplements in syrup form".

SCHEDULE 2

Regulation 4

Amendments to the Annex to Commission Regulation (EU) No. 231/2012 concerning the specification of steviol glycosides (E 960a) (formerly E 960) and for the addition of a specification for rebaudioside M produced via enzyme modification of steviol glycosides from Stevia (E 960c)

1. In the entry for steviol glycosides, for the heading "E 960 STEVIOL GLYCOSIDES" substitute—

"**E 960a STEVIOL GLYCOSIDES FROM STEVIA".**

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

"**E 960c REBAUDIOSIDE M PRODUCED VIA ENZYME MODIFICATION OF STEVIOL GLYCOSIDES FROM STEVIA**

Synonyms			
Definition	Rebaudioside M is a steviol glycoside composed predominantly of rebaudioside M with minor amounts of other steviol glycosides such as rebaudioside A, rebaudioside B, rebaudioside D, rebaudioside I, and stevioside. Rebaudioside M is obtained via enzymatic bioconversion of purified steviol glycoside leaf extracts (95% steviol glycosides) of the *Stevia rebaudiana* Bertoni plant using UDP-glucosyltransferase and sucrose synthase enzymes produced by the genetically modified yeasts *K. phaffi* (formerly known as *Pichia pastoris*) UGT-a and *K. phaffi* UGT-b 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 rebaudioside M by resin adsorption, followed by recrystallisation of rebaudioside M resulting in a final product containing not less than 95 % of rebaudioside M. Viable cells or the DNA of the yeasts *K. phaffii* UGT-a or *K. phaffii* UGT-b 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		
Molecular formula	Trivial name	Formula	Conversion factor
	Rebaudioside M	C_{56} H_{90} O_{33}	0.25
Molecular weight and CAS No	Trivial name	CAS Number	Molecular weight (g/mol)
	Rebaudioside M	1220616-44-3	1291.29
Assay	Not less than 95% 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)		

Synonyms	
Residual solvent	Not more than 5,000 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
Particle size	Not less than 74µm (using a mesh #200 sieve with a particle size limit of 74 µm)".

SCHEDULE 3

Regulation 6

Amendment to the domestic list of flavourings and source materials in Annex 1 to Regulation (EC) No. 1334/2008 for the addition of 3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1*H*-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione

1. In Part A (domestic list of flavouring substances), in sub-part 2, in Table 1, in the appropriate place insert the following entry—

"16.127	3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1*H*-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione	1119831-26-2			At least 99 %, assay (HPLC/UV)	Restrictions of use as a flavouring substance: In category 1.4 – not more than 4 mg/kg In category 1.8 – not more than 8 mg/kg In category 3 – not more than 4 mg/kg In category 5.1 – not more than 15 mg/kg		The Authority (**11**)

(**11**) "Authority" is defined in Article 3(2)(l) of EUR 2008/1334 to mean Food Standards Scotland as regards Scotland. The definition of "Authority" was inserted by S.I. 2019/860.

						In category 5.2 – not more than 16 mg/kg In category 5.3 – not more than 30 mg/kg In category 5.4 – not more than 15 mg/kg In category 6.3 – not more than 25 mg/kg In category 12.1 – not more than 75 mg/kg In category 12.2 – not more than 100 mg/kg In category 12.3 – not more than 25 mg/kg In category 12.4 – not more than 25 mg/kg In category 12.5 – not more than 4 mg/kg In category 13.2 – not more than 4 mg/kg In category 13.3 – not		

						more than 4 mg/kg In category 14.1.4, dairy-based drinks only – not more than 4 mg/l In category 14.1.5 – not more than 8 mg/kg In category 15.1 – not more than 20mg/kg In category 16, dairy-based desserts only – not more than 4mg/l		

SCHEDULE 4 Regulation 7

Amendments to the list of novel foods in the Annex to Commission Implementing Regulation (EU) 2017/2470 for the authorisation of UV-treated baker's yeast *(Saccharomyces cerevisiae)* as a novel food

1. In Table 1 (authorised novel foods), for the entry for UV-treated baker's yeast *(Saccharomyces cerevisiae)* substitute the following entry—

"**UV-treated baker's yeast (*Saccharomyces cerevisiae*)**	*Specified food category*	*Maximum levels of Vitamin D#*	The designation of the novel food on the labelling of food containing it is "vitamin D yeast" or "vitamin D# yeast".	The novel food must be inactivated for use in infant formula, follow-on formula, processed cereal-based food and food for special	
	Yeast- leavened breads and rolls	5 µg/100 g			
	Yeast-leavened fine bakery wares	5 µg/100 g			
	Food supplements as defined in the Food Supplements (Scotland)	In accordance with any relevant requirements contained in regulations			

	Regulations 2003(**12**)	applying in relation to Scotland and made under regulation 4 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019(**13**)		medical purposes.	
	Pre-packed fresh or dry yeast for home baking	45 µg/100 g for fresh yeast 200 µg/100 g for dry yeast	The designation of the novel food on the labelling of food containing it is "vitamin D yeast" or "vitamin D# yeast". The labelling of the novel food must bear a statement that the food is only intended for baking and it should not be eaten raw. The labelling of the novel food must bear instructions for use for the final consumer to ensure a maximum concentration of 5µg/100g of vitamin D# in the final home-baked product is not exceeded.		
	Dishes, including ready-to-eat meals (excluding soups and salads)	3 µg/100 g	The designation of the novel food on the labelling of food containing it is "vitamin D		
	Soups and salads	5 µg/100 g			

(**12**) S.S.I. 2003/278, to which there are amendments not relevant to these Regulations.
(**13**) S.I. 2019/651, as relevantly amended by S.I. 2020/1476.

	Fried or extruded cereal, seed or root-based products	5 µg/100 g	yeast" or "vitamin D# yeast".		
	Infant formula and follow-on formula as defined in Regulation (EU) No. 609/2013(**14**)	In accordance with Regulation (EU) No. 609/2013			
	Processed cereal-based food as defined in Regulation (EU) No. 609/2013	In accordance with Regulation (EU) No. 609/2013			
	Processed fruit products	1.5 µg/100 g			
	Processed vegetables	2 µg/100 g			
	Bread and similar products	5 µg/100 g			
	Breakfast cereals	4 µg/100 g			
	Pasta, doughs and similar products	5 µg/100 g			
	Other cereal-based products	3 µg/100 g			
	Spices, seasonings, condiments, sauce ingredients, dessert sauces/ toppings	10 µg/100 g			
	Protein products	10 µg/100 g			
	Cheese	2 µg/100 g			
	Dairy desserts and similar products	2 µg/100 g			
	Fermented milk or fermented cream	1.5 µg/100 g			
	Dairy powders and concentrates	25 µg/100 g			
	Milk-based products, whey and cream	0.5 µg/100 g			

(**14**) EUR 2013/609, as relevantly amended by S.I. 2019/651.

	Meat and dairy analogues	2.5 µg/100 g			
	Total diet replacement for weight control as defined by Regulation (EU) No. 609/2013	5 µg/100 g			
	Meal replacement for weight control	5 µg/100 g			
	Food for special medical purposes as defined by Regulation (EU) No. 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended”			

2. In Table 2 (specifications) for the entry for UV-treated baker’s yeast (Saccharomyces cerevisiae) substitute the following entry—

“**UV-treated baker’s yeast (*Saccharomyces cerevisiae*)**	**Description/Definition** Baker’s yeast *(Saccharomyces cerevisiae)* is treated with ultraviolet light to induce the conversion of ergosterol to vitamin D# (ergocalciferol). Vitamin D# content in the yeast concentrate varies between 800,000 - 3,500,000 IU vitamin D/100g (200-875 µg/g). The yeast is inactivated for use in infant formula, follow-on formula, processed cereal-based food, and food for special medical purposes as defined by Regulation (EU) No. 609/2013. The yeast can be active or inactive for use in other foods. The yeast concentrate is blended with regular baker’s yeast in order not to exceed the maximum level in the pre-packed fresh or dry yeast for home baking. Tan-coloured, free-flowing granules. **Vitamin D#** Chemical name: (5Z,7E,22E)-(3S)-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol Synonym: Ergocalciferol CAS No.: 50-14-6 Molecular weight: 396.65 g/mol

	Microbiological criteria for the yeast concentrate Coliforms: ≤ 10^3 CFU/g *Escherichia coli*: ≤ 10 CFU/g *Salmonella* spp: Absence in 25 g CFU: Colony Forming Units.”.

SCHEDULE 5 Regulation 7

Amendments to the list of novel foods in the Annex to Commission Implementing Regulation (EU) 2017/2470 for the authorisation of vitamin D# mushroom powder as a novel food

1. In Table 1 (authorised novel foods), after the existing entry for Vitamin D# mushroom powder insert the following entry—

“**Vitamin D# mushroom powder**	*Specified food category*	*Maximum levels of vitamin D#*	The designation of the novel food on the labelling of food containing it is “UV-treated mushroom powder containing vitamin D#”. The labelling of food supplements, as defined by the Food Supplements (Scotland) Regulations 2003, containing vitamin D# mushroom powder must bear a statement that they should not be consumed by infants and children under 3 years of age.		Included in the list on 15 May 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: MBio, Monaghan Mushrooms, Tullygony, Tyholland, Co. Monaghan, Ireland, H18 FW95. During the period of data protection, vitamin D# mushroom powder is authorised for placing on
	Breakfast cereals	2.1 µg/100 g			
	Yeast leavened bread and similar pastries	2.1 µg/100 g			
	Grain products and pasta and similar products	2.1 µg/100 g			
	Fruit/vegetable juices and nectars	1.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)			
	Dairy products and analogues other than beverages	2.1 µg/100 g (marketed as such or reconstituted as instructed by the manufacturer)			
	Dairy products and analogues as beverages	1.1 µg/100 ml (marketed as such or			

		reconstituted as instructed by the manufacturer)			the market, within Scotland, only by MBio, Monaghan Mushrooms 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 MBio, Monaghan Mushrooms. The data protection will expire at the end of 14 May 2028.
	Milk and dairy powders	21.3 µg/100 g (marketed as such or reconstituted as instructed by the manufacturer)			
	Meat analogues	2.1 µg/100 g			
	Soups	2.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)			
	Extruded vegetable snack	2.1 µg/100 g			
	Meal replacement for weight control	2.1 µg/100 g			
	Food for special medical purposes as defined in Regulation (EU) 609/2013 excluding those intended for infants	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Food supplements as defined in the Food Supplements (Scotland) Regulations 2003 excluding food supplements for infants and	15 µg of vitamin D#/ day”			

	children under 3 years of age				

2. In Table 2 (specifications), after the entry for Vitamin D# mushroom powder insert the following entry—

"**Vitamin D# mushroom powder**	**Description/Definition** The novel food is mushroom powder produced from dried whole *Agaricus bisporus* mushrooms. The process includes drying, milling and the controlled exposure of the mushroom powder to ultraviolet light. **Characteristics/Composition** Vitamin D# content: 580-595 µg/g of mushroom powder Ash: ≤ 13.5% Water activity: < 0.5 Moisture content: ≤ 7.5% Carbohydrates: ≤ 35% Total dietary fibre: ≥ 15% Crude protein (N x 6.25): ≥ 22% Fat: ≤ 4.5% **Heavy metals** Lead: ≤ 0.5 mg/kg Cadmium: ≤ 0.5 mg/kg Mercury: ≤ 0.1 mg/kg Arsenic: ≤ 0.3 mg/kg **Mycotoxins** Aflatoxin B1: ≤ 0.1 µg/kg Aflatoxins (sum of B1 + B2 + G1 + G2): < 4 µg/kg **Microbiological criteria** Total plate count: ≤ 5000 CFU 14 Total yeast and mould count: ≤ 100 CFU/g

	Escherichia coli: < 10 CFU/g *Salmonella* spp.: Absence in 25 g *Staphylococcus aureus*: ≤ 10 CFU/g Coliforms: ≤ 10 CFU/g *Listeria* spp.: Absence in 25 g Enterobacteriaceae: < 10 CFU/g CFU: Colony Forming Units.”.

EXPLANATORY NOTE

(This note is not part of the Regulations)

Regulation 3 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 to change the name and E number of the existing food additive steviol glycosides (E 960) to steviol glycosides from Stevia (E 960a), and to add the new food additive enzymatically produced steviol glycosides (E 960c). It also makes additional amendments to correct exisiting errors in that Regulation.

Regulation 4 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 to change the heading of the specification for E 960 to refer to E 960a and to add a specification for E 960c.

Regulation 5 provides for a transitional measure to allow stocks of the food additive and any food containing it labelled with the existing E number E 960 to be exhausted.

Regulation 6 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 and amending Council Regulation (EEC) No. 1601/91, Regulations (EC) No. 2232/96 and (EC) No. 110/2008 and Directive 2000/13 to add a new food flavouring to the list of authorised flavourings and source materials.

Regulation 7 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 to add a new novel food and to substitute a new entry for an existing novel food so as to extend the specified food categories for which it is authorised and to provide for a new specification for it.

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