
WELSH STATUTORY INSTRUMENTS

2023 No. 343 (W. 50)

**FOOD, WALES
AGRICULTURE, WALES**

The Food Additives, Food Flavourings, and
Novel Foods (Authorisations) and Food and Feed
(Miscellaneous Amendments) (Wales) Regulations 2023

Made - - - - 20 March 2023

Laid before Senedd Cymru 20 March 2023

*Coming into force in accordance with regulation 1(3)
and (4)*

The Welsh Ministers make these Regulations in exercise of the powers conferred by—

- Articles 7(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(1);
- Article 12(1) of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods(2);
- sections 16(1)(a) and (2)(b), and 48(1)(c) of the Food Safety Act 1990(3);
- sections 74A(1) and 84(1) of the Agriculture Act 1970(4).

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- (1) EUR 2008/1331, amended by S.I. 2019/860 and 2022/1351. S.I. 2019/860 was amended by S.I. 2020/1504. The terms “domestic list”, “prescribe” and “appropriate authority” are defined in Article 2 of EUR 2008/1331. The term “sectoral food law” is defined in Article 1(2) of EUR 2008/1331. In relation to Part 2 of these Regulations, Article 7(5) of EUR 2008/1331 applies in accordance with Articles 10(3), 14 and 30(4) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (EUR 2008/1333). In relation to Part 3 of these Regulations, Article 7(5) of EUR 2008/1331 applies in accordance with 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 (EUR 2008/1334).
- (2) EUR 2015/2283, amended by S.I. 2019/702 ; there are other amending instruments but none is relevant. S.I. 2019/702 was amended by S.I. 2020/1504. The terms “prescribe”, “appropriate authority” and “list” are defined in Article 3 of EUR 2015/2283. Article 12(1) of EUR 2015/2283 applies in accordance with Articles 9 and 27(1) of that Regulation.
- (3) 1990 c. 16. Sections 16(1) and (2), and 48(1) were amended by section 40(1) of, and paragraphs 7 and 8 of Schedule 5 to, the Food Standards Act 1999 (c. 28) (“the 1999 Act”). There are other amendments not relevant to these Regulations. Those functions, formerly exercisable by “the Ministers”, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act. Those functions are now exercisable by the Welsh Ministers by virtue of section 162 of, and paragraph 30 of Schedule 11 to, the Government of Wales Act 2006 (c. 32).
- (4) 1970 c. 40. Section 74A was inserted by paragraph 6 of Schedule 4 to the European Communities Act 1972 (c. 68); that section was subsequently amended by section 33(3) of the Agriculture Act 2020 (c. 21). Section 84 was amended by S.I. 2004/3254. The terms “the Ministers”, “prescribed” and “regulations” are defined in section 66(1) of the Agriculture Act 1970. Functions formerly exercisable by “the Ministers”, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672. Those functions are now exercisable by the Welsh Ministers by virtue of section 162 of, and paragraph 30 of Schedule 11 to, the Government of Wales Act 2006.

The Welsh Ministers have sought, and had regard to, advice from the Food Standards Agency as required by Article 7(5) of Regulation (EC) No 1331/2008⁽⁵⁾ (in relation to Parts 2 and 3) and section 48(4A) of the Food Safety Act 1990⁽⁶⁾ (in relation to regulations 7 and 8).

There has been open and transparent public consultation during the preparation of these Regulations in accordance with the requirements of 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⁽⁷⁾ or, in the case of provisions relating to feed for non food-producing animals, of section 84(1) of the Agriculture Act 1970.

PART 1

Introduction

Title, extent, application and coming into force

1.—(1) The title of these Regulations is the Food Additives, Food Flavourings, and Novel Foods (Authorisations) and Food and Feed (Miscellaneous Amendments) (Wales) Regulations 2023.

(2) These Regulations—

- (a) extend to England and Wales;
- (b) apply in relation to Wales.

(3) Parts 1 and 5 come into force on 14 April 2023.

(4) Parts 2, 3 and 4 come into force on 15 May 2023.

PART 2

Food Additives Authorisation

Amendment of Regulation (EC) No 1333/2008

2. Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives⁽⁸⁾ is amended in accordance with Schedule 1.

Amendment of Commission Regulation (EU) No 231/2012

3. 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⁽⁹⁾ is amended in accordance with Schedule 2.

(5) The term “Authority” is defined in Article 2(3) of EUR 2008/1331.

(6) Section 48(4A) was inserted by paragraph 21 of Schedule 5 to, the 1999 Act.

(7) EUR 2002/178, amended by S.I. 2019/641; there are other amending instruments but none is relevant.

(8) EUR 2008/1333, amended by S.I. 2019/860. S.I. 2019/860 was amended by S.I. 2020/1504.

(9) EUR 2012/231, amended by S.I. 2019/860.

Transitional provision

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

(2) Expressions used in paragraph (1) and in Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives have the same meaning as in that Regulation.

PART 3

Food Flavourings Authorisation

Amendment of Regulation (EC) No 1334/2008

5. 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(10) is amended in accordance with Schedule 3.

PART 4

Novel Foods Authorisation

Amendment of Commission Implementing Regulation (EU) 2017/2470

6. 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(11) is amended in accordance with Schedules 4 and 5.

PART 5

Miscellaneous Amendments

Amendment of the Materials and Articles in Contact with Food (Wales) Regulations 2012

7. In the Materials and Articles in Contact with Food (Wales) Regulations 2012(12), in regulation 12(2), for the words from “table 1” to the end substitute “Table 1 of Schedule 6 and subject to the restrictions in that Table”.

Amendment of the Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013

8. In the Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013(13), in regulation 2(1), in the definition of “the retained EU Regulations”—

- (a) in the Welsh language text, for “(“*the EU Regulations*”)” substitute “(“*the retained EU Regulations*”)”;

(10) EUR 2008/1334; amended by S.I. 2019/860. S.I. 2019/860 was amended by S.I. 2020/1504.

(11) EUR 2017/2470, amended by S.I. 2019/702 and 2022/575 (W. 133); there are other amending instruments but none is relevant.

(12) S.I. 2012/2705 (W. 291), amended by S.I. 2022/1362 (W. 273); there are other amending instruments but none is relevant.

(13) S.I. 2013/2591 (W. 255), amended by S.I. 2022/1362 (W. 273); there are other amending instruments but none is relevant.

- (b) in the English language text, after ““the retained EU Regulations”” insert “(“*Rheoliadau'r UE a ddargedwir*”)”.

Amendment of the Animal Feed (Composition, Marketing and Use) (Wales) Regulations 2016

9.—(1) The Animal Feed (Composition, Marketing and Use) (Wales) Regulations 2016⁽¹⁴⁾ are amended as follows.

(2) In Schedule 1B, in Table 1, in the Welsh language text, in the entry for “1. Arsenig”, in the second column, for “deunyddiau blawd”, in each place it occurs, substitute “deunyddiau bwyd anifeiliaid”.

Lynne Neagle
Deputy Minister for Mental Health and
Wellbeing, under the authority of the Minister
for Health and Social Services, one of the Welsh
Ministers

20 March 2023

⁽¹⁴⁾ S.I. 2016/386 (W. 120), amended by S.I. 2022/1362 (W. 273); there are other amending instruments but none is relevant.

SCHEDULE 1

Regulation 2

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

1. In Regulation (EC) No 1333/2008, Annex 2 (domestic list of food additives approved for use in foods) is amended as follows.

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

(a) for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a	Steviol glycosides from Stevia”;
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(b) in the appropriate place, insert the following entry—

“E 960c	Enzymatically produced steviol glycosides”.
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3. In Part C (definitions of groups of additives), in paragraph 5 (other additives that may be regulated combined), after sub-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”.

4. 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 “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	100	(1) (60)	only energy-reduced products or with no added sugar”;
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(b) in category 03 (edible ices), for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	200	(1) (60)	only energy-reduced products or with no added sugar”;
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(c) in category 04.2.2 (fruit and vegetables in vinegar, oil or brine), for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	100	(1) (60)	only sweet-sour preserves of fruit and vegetables”;
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(d) in category 04.2.4.1 (fruit and vegetable preparations excluding compote), for the entry for “E 960” (Steviol glycosides) substitute—

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“E 960a and E 960c	Steviol glycosides	200	(1) (60)	only energy-reduced”;
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- (e) in category 04.2.5.1 (extra jam and extra jelly), for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	200	(1) (60)	only energy-reduced jams, jellies and marmalades”;
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- (f) in category 04.2.5.2 (jam, jellies and marmalades and sweetened chestnut purée), for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	200	(1) (60)	only energy-reduced jams, jellies and marmalades”;
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- (g) in category 04.2.5.3 (other similar fruit or vegetable spreads), for the entry for “E 960” (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”;
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- (h) in category 05.1 (cocoa and chocolate products), for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	270	(1) (60)	only energy-reduced or with no added sugar”;
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- (i) in category 05.2 (other confectionery including breath freshening microsweets)—

(i) for the first entry for “E 960” (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”;
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(ii) for the second entry for “E 960” (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”;
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(iii) for the third entry for “E 960” (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”;
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(iv) for the fourth entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	2000	(1) (60)	only breath-freshening microsweets, energy-reduced or with no added sugar”;
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(v) for the fifth entry for “E 960” (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”;
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(j) in category 05.3 (chewing gum), for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	3300	(1) (60)	only with no added sugar”;
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(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 “E 960” (Steviol glycosides) substitute—

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“E 960a and E 960c	Steviol glycosides	330	(1) (60)	only confectionery with no added sugar”;
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(ii) for the second entry for “E 960” (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”;
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(l) in category 06.3 (breakfast cereals), for the entry for “E 960” (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”;
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(m) in category 07.2 (fine bakery wares), for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	330	(1) (60)	only essoblaten – wafer paper”;
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(n) in category 09.2 (processed fish and fishery products including molluscs and crustaceans), for the entry for “E 960” (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”;
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(o) in category 11.4.1 (table-top sweeteners in liquid form), for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	<i>quantum satis</i> (15)	(60)”;	
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(p) in category 11.4.2 (table-top sweeteners in powder form), for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	<i>quantum satis</i>	(60)”;	
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(15) “*quantum satis*” is defined in Article 3(2)(h) of EUR 2008/1333.

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- (q) in category 11.4.3 (table-top sweeteners in tablets), for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	<i>quantum satis</i>	(60)”;	
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- (r) in category 12.4 (mustard), for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	120	(1) (60)”;	
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- (s) in category 12.5 (soups and broths), for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	40	(1) (60)	only energy-reduced soups”;
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- (t) in category 12.6 (sauces)—

- (i) for the first entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	120	(1) (60)	except soy-bean sauce (fermented and non-fermented)”;
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- (ii) for the second entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	175	(1) (60)	only soy-bean sauce (fermented and non-fermented)”;
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- (u) in category 13.2 (dietary foods for special medical purposes (excluding products from food category 13.1.5))—

- (i) for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	330	(1) (60)”;	
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- (ii) in the entry for “E 960” (Advantame), for “E 960” substitute “E 969”;

- (v) in category 13.3 (dietary foods for weight control diets intended to replace total daily food intake or an individual meal)—

- (i) for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	270	(1) (60)”;	
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- (ii) in the entry for “E 960” (Advantame), for “E 960” substitute “E 969”;

- (w) in category 14.1.3 (fruit nectars and vegetable nectars and similar products), for the entry for “E 960” (Steviol glycosides) substitute—

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“E 960a and E 960c	Steviol glycosides	100	(1) (60)	only energy-reduced or with no added sugar
	(1): The additives may be added individually or in combination”;			

- (x) in category 14.1.4 (flavoured drinks), for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	80	(1) (60)	only energy-reduced or with no added sugar”;
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- (y) in category 14.1.5.2 (other)—

- (i) for the first entry for “E 960” (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”;
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- (ii) for the second entry for “E 960” (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”;
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- (iii) for the third entry for “E 960” (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”;
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- (z) in category 14.2.1 (beer and malt beverages), for the entry for “E 960” (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
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				“Obergäriges Einfachbier”; beers with a minimum acidity of 30 milliequivalents expressed as NaOH; Brown beers of the “oud bruin” type”;
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- (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 “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	150	(1) (60)”;	
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- (bb) in category 15.1 (potato-, cereal-, flour- or starch-based snacks), for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	20	(1) (60)”;	
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- (cc) in category 15.2 (processed nuts), for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	20	(1) (60)”;	
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- (dd) in category 16 (desserts excluding products covered in categories 1, 3 and 4), for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	100	(1) (60)	only energy-reduced or with no added sugar”;
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- (ee) in category 17.1 (food supplements supplied in a solid form, excluding food supplements for infants and young children)—

- (i) for the first entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	670	(1) (60)”;	
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- (ii) for the second entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	1800	(1) (60)	only food supplements in chewable form”;
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- (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 “E 960” (Steviol glycosides) substitute—

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“E 960a and E 960c	Steviol glycosides	200	(1) (60)”;	
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(ii) for the second entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	1800	(1) (60)	only food supplements in syrup form”.
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SCHEDULE 2

Regulation 3

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

1. In [Commission Regulation \(EU\) No 231/2012](#), the Annex (specifications for food additives including colours and sweeteners listed in Annexes 2 and 3 to [Regulation \(EC\) No 1333/2008](#)) is amended as follows.

2. For the heading of the entry for “E 960 STEVIOL GLYCOSIDES” substitute—

“E 960a STEVIOL GLYCOSIDES FROM STEVIA”

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

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

Synonyms	
Definition	<p>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.</p> <p>Rebaudioside M is obtained via enzymatic bioconversion of purified steviol glycoside leaf extracts (95% steviol glycosides) of the <i>Stevia rebaudiana</i> Bertoni plant using UDP-glucosyltransferase and sucrose synthase enzymes produced by the genetically modified yeasts <i>K. phaffi</i> (formerly known as <i>Pichia pastoris</i>) UGT-a and <i>K. phaffi</i> UGT-b that facilitate the transfer of glucose from sucrose and UDP-glucose to steviol glycosides via glycosidic bonds.</p> <p>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 <i>K. phaffi</i> UGT-a or <i>K. phaffi</i> UGT-b must not be detected in the food additive.</p>

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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	<i>Trivial name</i>	<i>Formula</i>	<i>Conversion factor</i>
	Rebaudioside M	C ₅₆ H ₉₀ O ₃₃	0.25
Molecular weight and CAS number	<i>Trivial name</i>	<i>CAS Number</i>	<i>Molecular weight (g/mol)</i>
	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)		
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		
Particle size	Not less than 74 µm (using a mesh #200 sieve with a particle size limit of 74 µm)”		

SCHEDULE 3

Regulation 5

Amendments to the domestic list of flavouring substances in Annex 1 to Regulation (EC) No 1334/2008 for the addition of 3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1H-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione

1. In Regulation (EC) No 1334/2008, Annex 1 (domestic list of flavourings and source materials) is amended as follows.

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

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"16.127	3-(1- (3,5- dimethylisoxazol-4- yl)methyl)-1H- pyrazol-4- yl)-1-(3- hydroxybenzyl)imidazolidine-2,4- dione	111983-2-0612			At least 99%, assay (HPLC/ UV)	<p>Restrictions of use as a flavouring substance:</p> <p>In category 1.4 – not more than 4 mg/kg</p> <p>In category 1.8 – not more than 8 mg/kg</p> <p>In category 3 – not more than 4 mg/kg</p> <p>In category 5.1 – not more than 15 mg/kg</p> <p>In category 5.2 – not more than 16 mg/kg</p> <p>In category 5.3 – not more than 30 mg/kg</p> <p>In category 5.4 – not more than 15 mg/kg</p> <p>In category 6.3 – not more than 25 mg/kg</p> <p>In category 12.1 – not more than 75 mg/kg</p> <p>In category 12.2 – not more than 100 mg/kg</p> <p>In category 12.3 – not more than 25 mg/kg</p> <p>In category 12.4 – not more than 25 mg/kg</p> <p>In category 12.5 – not more than 4 mg/kg</p>	The Authority(16)
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(16) "Authority" is defined in Article 3(2)(l) of EUR 2008/1334.

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						<p>In category 13.2 – not more than 4 mg/kg</p> <p>In category 13.3 – not more than 4 mg/kg</p> <p>In category 14.1.4, dairy-based drinks only – not more than 4 mg/l</p> <p>In category 14.1.5 – not more than 8 mg/kg</p> <p>In category 15.1 – not more than 20 mg/kg</p> <p>In category 16, dairy-based desserts only – not more than 4 mg/l”.</p>	
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SCHEDULE 4

Regulation 6

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 Commission Implementing Regulation (EU) 2017/2470, the Annex (list of novel foods) is amended as follows.
2. In Table 1 (authorised novel foods), for the entry for “UV-treated baker’s yeast (*Saccharomyces cerevisiae*)” substitute—

“UV-treated baker’s yeast (<i>Saccharomyces cerevisiae</i>)”	Specified food category	Maximum levels of vitamin D ₂		
	Yeast-leavened breads and rolls	5 µg/100 g	The designation of the novel food on the labelling of food containing it is “vitamin D yeast” or “vitamin D ₂ yeast”.	The novel food must be inactivated for use in infant formula, follow-on formula, processed cereal-based food and food for special medical purposes.
	Yeast-leavened fine bakery wares	5 µg/100 g		
	Food supplements as defined in the Food Supplements	In accordance with any relevant requirements contained in regulations		

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(Wales) Regulations 2003(17)	applying in relation to Wales and made under regulation 4 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019(18)	
Pre-packed fresh or dry yeast for home baking	45 µg/100 g for fresh yeast 200 µg/100 g for dry yeast	<p>The designation of the novel food on the labelling of food containing it is “vitamin D yeast” or “vitamin D₂ yeast”.</p> <p>The labelling of the novel food must bear a statement that the food is only intended for baking and should not be eaten raw.</p> <p>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 D₂ in the final home-baked product is not exceeded.</p>
Dishes, including ready-to-eat meals	3 µg/100 g	The designation of the novel food on the labelling

(17) S.I. 2003/1719 (W. 186), to which there are amendments not relevant to these Regulations.

(18) S.I. 2019/651, amended by S.I. 2020/1476 and 2023/28.

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(excluding soups and salads)		of food containing it is “vitamin D yeast” or “vitamin D ₂ yeast”.
Soups and salads	5 µg/100 g	
Fried or extruded cereal, seed or root-based products	5 µg/100 g	
Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 ⁽¹⁹⁾	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	

⁽¹⁹⁾ EUR 2013/609, amended by S.I. 2019/651 and 2023/28. S.I. 2019/651 was amended by S.I. 2020/1476 and 2023/28.

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

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

<p>“UV-treated baker’s yeast (<i>Saccharomyces cerevisiae</i>)”</p>	<p>Description/Definition</p> <p>Baker’s yeast (<i>Saccharomyces cerevisiae</i>) is treated with ultraviolet light to induce the conversion of ergosterol to vitamin D₂ (ergocalciferol). Vitamin D₂ content in the yeast concentrate varies between 800,000 - 3,500,000 IU vitamin D/100 g (200-875 µg/g).</p> <p>The yeast is inactivated for use in infant formula, follow-on formula, processed cereal-based food, and food for special</p>
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<p>medical purposes as defined in Regulation (EU) No 609/2013. The yeast can be active or inactive for use in other foods.</p> <p>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.</p> <p>Tan-coloured, free-flowing granules.</p> <p>Vitamin D₂</p> <p>Chemical name: (5Z,7E,22E)-(3S)-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol</p> <p>Synonym: Ergocalciferol</p> <p>CAS No.: 50-14-6</p> <p>Molecular weight: 396.65 g/mol</p> <p>Microbiological criteria for the yeast concentrate</p> <p>Coliforms: ≤ 10³ CFU/g</p> <p><i>Escherichia coli</i>: ≤ 10 CFU/g</p> <p><i>Salmonella</i> spp.: Absence in 25 g</p> <p>CFU: Colony Forming Units”.</p>

SCHEDULE 5

Regulation 6

Amendments to the list of novel foods in the Annex to Commission Implementing Regulation (EU) 2017/2470 for the authorisation of vitamin D₂ mushroom powder as a novel food

1. In Commission Implementing Regulation (EU) 2017/2470, the Annex (list of novel foods) is amended as follows.
2. In Table 1 (authorised novel foods), after the entry for “Vitamin D₂ mushroom powder” insert the following entry—

“ Vitamin D₂ mushroom powder ”	<i>Specified food category</i>	<i>Maximum levels of vitamin D₂</i>	The designation of the novel food on the labelling of food containing it is “UV-treated mushroom powder	Included in the list on 15 May 2023. This inclusion is based on proprietary scientific evidence and scientific data
	Breakfast cereals	2.1 µg/100 g		
	Yeast-leavened bread and similar pastries	2.1 µg/100 g		

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Grain products and pasta and similar products	2.1 µg/100 g	<p>containing vitamin D₂".</p> <p>The labelling of food supplements, as defined in the Food Supplements (Wales) Regulations 2003, containing vitamin D₂ mushroom powder must bear a statement that they should not be consumed by infants and children under 3 years of age.</p>	<p>protected in accordance with Article 26 of Regulation (EU) 2015/2283.</p> <p>Applicant: MBio, Monaghan Mushrooms, Tullygony, Tyholland, Co. Monaghan, Ireland, H18 FW95.</p> <p>During the period of data protection, vitamin D₂ mushroom powder is authorised for placing on the market, within Wales, 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,</p>
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)		
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	In accordance with the		

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<p>purposes as defined in Regulation (EU) No 609/2013 excluding those intended for infants</p>	<p>particular nutritional requirements of the persons for whom the products are intended</p>	<p>Monaghan Mushrooms.</p> <p>The data protection will expire at the end of 14 May 2028.</p>
<p>Food supplements as defined in the Food Supplements (Wales) Regulations 2003 excluding food supplements for infants and children under 3 years of age</p>	<p>15 µg of vitamin D₂/day”</p>	

3. In Table 2, (specifications), after the entry for “Vitamin D₂ mushroom powder” insert the following entry—

<p>“Vitamin D₂ mushroom powder</p>	<p>Description/Definition</p> <p>The novel food is mushroom powder produced from dried whole <i>Agaricus bisporus</i> mushrooms. The process includes drying, milling and the controlled exposure of the mushroom powder to ultraviolet light.</p> <p>Characteristics/Composition</p> <p>Vitamin D₂ content: 580-595 µg/g of mushroom powder</p> <p>Ash: ≤ 13.5%</p> <p>Water activity: < 0.5</p> <p>Moisture content: ≤ 7.5%</p> <p>Carbohydrates: ≤ 35%</p> <p>Total dietary fibre: ≥ 15%</p> <p>Crude protein (N x 6.25): ≥ 22%</p> <p>Fat: ≤ 4.5%</p> <p>Heavy metals</p>
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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 μ g/kg
Aflatoxins (sum of B1 + B2 + G1 + G2): < 4 μ g/kg
Microbiological criteria
Total plate count: ≤ 5000 CFU
Total yeast and mould count: ≤ 100 CFU/g
<i>Escherichia coli</i> : < 10 CFU/g
<i>Salmonella</i> spp.: Absence in 25 g
<i>Staphylococcus aureus</i> : ≤ 10 CFU/g
Coliforms: ≤ 10 CFU/g
<i>Listeria</i> spp.: Absence in 25 g
Enterobacteriaceae: < 10 CFU/g
CFU: Colony Forming Units”.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision, in relation to Wales, on regulated food product authorisations. They also make minor corrections to various Welsh subordinate instruments on food law and animal feed law.

Part 2 of these Regulations (regulations 2 to 4 and Schedules 1 and 2) is made in exercise of powers in Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (EUR 2008/1331). Together, the amendments made in Part 2 of these Regulations provide for the authorisation, in relation to Wales, of the placing on the market and use of the food additive E 960c rebudioside M produced via enzyme modification

of steviol glycosides from Stevia. The existing authorisation entries for food additive E 960 steviol glycosides are changed to reflect the amended name and E-number E 960a steviol glycosides from Stevia.

Regulation 2 and Schedule 1 update, in relation to Wales, the domestic list of food additives approved for use in foods in Annex 2 of Regulation (EC) No 1333/2008 on food additives (EUR 2008/1333). Schedule 1 also corrects the E-number in two entries in that Annex for the food additive E 969 Advantame.

Regulation 3 and Schedule 2 amend, in relation to Wales, Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 (EUR 2012/231).

Regulation 4 contains a transitional provision that allows for an 18-month period within which stocks of products may still be labelled as E 960 steviol glycosides, or as containing E 960 steviol glycosides. Stocks that are labelled within that timeframe may be placed on the market and used until those stocks are exhausted.

Part 3 of these Regulations (regulation 5 and Schedule 3) is also made in exercise of powers in EUR 2008/1331. Regulation 5 and Schedule 3 update, in relation to Wales, the domestic list of 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). These amendments provide for authorisation, in relation to Wales, of the placing on the market and use of the food flavouring 3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1H-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione.

Part 4 of these Regulations (regulation 6 and Schedules 4 and 5) is made in exercise of powers in Regulation (EU) 2015/2283 on novel foods (EUR 2015/2283). Regulation 6 and Schedules 4 and 5 update, in relation to Wales, the list of authorised novel foods in Annex 1 to Commission Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods (EUR 2017/2470):

- Schedule 4 substitutes the entry for UV-treated baker's yeast (*Saccharomyces cerevisiae*), extending the specified food categories for which that novel food is authorised.
- Schedule 5 inserts a new entry, authorising the placing on the market of a new vitamin D₂ mushroom powder as a novel food for use in the specified food categories.

Part 5 of these Regulations (regulations 7, 8 and 9) contains minor corrections to various Welsh Subordinate instruments on food law and animal feed law. Regulations 7 and 8 are made in exercise of powers in the Food Safety Act 1990 (c. 16). Regulation 9 is made in exercise of powers in the Agriculture Act 1970 (c. 40).

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, it was not considered necessary to carry out a regulatory impact assessment as to the likely costs and benefits of complying with these Regulations.