#### 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

#### **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 rebaudioside 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)-1*H*-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 UVtreated 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 D<sub>2</sub> 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.

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	22 March 2023
Coming into force in regulation 1(3) and (4)	accordance with

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);

<sup>(1)</sup> 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).

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

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(4) (in relation to Parts 2 and 3) and section 48(4A) of the Food Safety Act 1990(5) (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(**6**) or, in the case of provisions relating to feed for non food-producing animals, of section 84(1) of the Agriculture Act 1970.

(3) 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.

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.

<sup>(2) 1990</sup> 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).

<sup>(4)</sup> The term "Authority" is defined in Article 2(3) of EUR 2008/1331.

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

<sup>(6)</sup> EUR 2002/178, amended by S.I. 2019/641; there are other amending instruments but none is relevant.

## 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(**1**) 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(**2**) is amended in accordance with Schedule 2.

#### **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.

<sup>(1)</sup> EUR 2008/1333, amended by S.I. 2019/860. S.I. 2019/860 was amended by S.I 2020/1504.

<sup>(2)</sup> EUR 2012/231, amended by S.I. 2019/860.

## 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(1) 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(**2**) 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(**3**), 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(4), in

<sup>(1)</sup> EUR 2008/1334; amended by S.I. 2019/860. S.I. 2019/860 was amended by S.I 2020/1504.

<sup>(2)</sup> EUR 2017/2470, amended by S.I. 2019/702 and 2022/575 (W. 133); there are other amending instruments but none is relevant.

<sup>(3)</sup> S.I. 2012/2705 (W. 291), amended by S.I. 2022/1362 (W. 273); there are other amending instruments but none is relevant.

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

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")";
- (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(**1**) 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

<sup>(1)</sup> S.I. 2016/386 (W. 120), amended by S.I. 2022/1362 (W. 273); there are other amending instruments but none is relevant.

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";

(b) in the appropriate place, insert the following entry—

"E 960c	Enzymatically produced steviol glycosides".

**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";

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

(d) in category 04.2.4.1 (fruit and vegetable preparations excluding compote), for the entry for "E 960" (Steviol glycosides) substitute—

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

(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";

(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";

(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";

WE 0(0 1	0, 1	250	(1) ((0)	1
"E 960a and	Steviol	350	(1) (60)	only
E 960c	glycosides			confectionery
				with no added
				sugar
				0
				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
				reduced nought
				1
				only energy-
				reduced
				marzipan";

(iii) for the third entry for "E 960" (Steviol glycosides) substitute-

(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—

	r	1	1	
"E 960a and	Steviol	3300	(1) (60)	only with no
E 960c	glycosides			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 "E 960" (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 "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";

(1) 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";

(m) in category 07.2 (fine bakery wares), for the entry for "E 960" (Steviol glycosides) substitute—

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

(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	Steviol	quantum satis(1)	(60)";	
E 960c	glycosides			

(p) in category 11.4.2 (table-top sweeteners in powder form), for the entry for "E 960" (Steviol glycosides) substitute—

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

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

"E 960a and	Steviol	quantum satis	(60)";	

(1)

"quantum satis" is defined in Article 3(2)(h) of EUR 2008/1333.

E 960c	glycosides		

(r) in category 12.4 (mustard), for the entry for "E 960" (Steviol glycosides) substitute—

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

(s) in category 12.5 (soups and broths), for the entry for "E 960" (Steviol glycosides) substitute—

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

(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)";

(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)";

(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	Steviol	330	(1) (60)";	
E 960c	glycosides			

(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	Steviol	270	(1) (60)";	
E 960c	glycosides			

(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—

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

(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
L 7000	grycosides			and instant
				cappuccino products, energy-
				reduced or with no added sugar";

(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";

(z) in category 14.2.1 (beer and malt beverages), for the entry for "E 960" (Steviol glycosides) substitute—

(T 0 6 0 1	~		(4) (50)	
"E 960a and	Steviol	70	(1) (60)	only alcohol-free
E 960c	glycosides			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 nonalcoholic drinks and spirits with less than 15% of alcohol), for the entry for "E 960" (Steviol glycosides) substitute—

"E 960a and Steviol 150 (1) (60)":			"E 960a and	Steviol	150	(1) (60)";	
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E 960c	glycosides		

(bb) in category 15.1 (potato-, cereal-, flour- or starch-based snacks), for the entry for "E 960" (Steviol glycosides) substitute—

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

(cc) in category 15.2 (processed nuts), for the entry for "E 960" (Steviol glycosides) substitute—

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

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

(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	Steviol	670	(1) (60)";	
E 960c	glycosides			

(ii) for the second entry for "E 960" (Steviol glycosides) substitute-

"E 960a and	Steviol	1800	(1) (60)	only food
E 960c	glycosides			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 "E 960" (Steviol glycosides) substitute-

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

(ii) for the second entry for "E 960" (Steviol glycosides) substitute-

"E 960a and E 960cSteviol glycosides	1800	(1) (60)	only food supplements in syrup form".
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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	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 <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.				
	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.				
Chemical name	Rebaudioside M: 13-[(2-O- $\beta$ -D-glucopyranosyl-3-O- $\beta$ -D-glucopyranosyl- $\beta$ -D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O- $\beta$ -D- glucopyranosyl-3-O- $\beta$ -D-glucopyranosyl- $\beta$ -D-glucopyranosyl ester				
Molecular formula	Trivial name	Formula	Conversion factor		
	Rebaudioside M	C56 H90 O33	0.25		
Molecular weight and CAS number	Trivial name	CAS Number	Molecular weight (g/mol)		
	Rebaudioside M	1220616-44-3	1291.29		
Assay	Not less than 95% reb	audioside M on the dried b	pasis		
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
рН	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 $\mu$ m (using a mesh #200 sieve with a particle size limit of 74 $\mu$ m)

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-((3,5dimethylisoxazol-4-yl)methyl)-1*H*-pyrazol-4-yl)-1-(3hydroxybenzyl)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—

"16.127	3-(1-	1119	2161	At least	Restrictions of	The
10.12/	((3,5-	831-		99%, assay	use as a	Authority
	dimethy	25-2		(HPLC/UV)	flavouring	(1)".
	lisoxazo	_		· · · · · /	substance:	
	1-4-				In category 1.4	
	yl)meth				– not more than	
	yl)-1 <i>H</i> -				4 mg/kg	
	pyrazol-				In category 1.8	
	4-yl)-1-				– not more than	
	(3-				8 mg/kg	
	hydroxy				In category 3 –	
	benzyl)i				not more than 4	
	midazol				mg/kg	
	idine-				In category 5.1	
	2,4-				– not more than	
	dione				15 mg/kg	
					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	

"Authority" is defined in Article 3(2)(l) of EUR 2008/1334.

(1)

		In asta some	
		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 20 mg/kg	
		In category 16,	
		dairy-based	
		desserts only –	
		not more than 4	
		mg/l	
		1115/1	

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 (Saccharomyc es cerevisiae)	Specified food category Yeast- leavened breads and rolls Yeast- leavened fine bakery wares Food supplements as defined in the Food Supplements (Wales) Regulations 2003(1)	Maximum levelsof $levels$ of $vitamin D_2$ $5 \mu g/100 g$ $5 \mu g/100 g$ $5 \mu g/100 g$ $5 \mu g/100 g$ In accordance $max$	The designation of the novel food on the labelling of food containing it is "vitamin D yeast" or "vitamin D <sub>2</sub> 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."
	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 $D_2$ yeast". The labelling of the novel food must bear a statement that the food is only intended for	

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

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

baking and should not be eaten raw.baking and 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 D2 in the final home- baked product is not exceeded.Dishes, including ready-to-eat meals3 µg/100 gThe designation of the novel food on the labeling of food containing it is "vitamin D yeast" or "vitamin D yeast" or "vitamin D yeast".Soups and salads)5 µg/100 g"witamin D yeast".Soups and salads5 µg/100 g"vitamin D yeast".Infant formula and follow-on formula as defined in (EU) No 609/2013In accordance with Regulation (EU) No 609/2013In accordance with Regulation (EU) No 609/2013Processed cereal-based food as (EU) No 609/2013In accordance with Regulation (EU) No 609/2013In accordance with Regulation (EU) No 609/2013	· · · · · · · · · · · · · · · · · · ·				•	
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009/201.3						
			1.5			
Processed $1.5 \mu g/100 g$			1.5 µg/100 g			
fruit products			2			
Processed $2 \mu g/100 g$			2 μg/100 g			
vegetables [7, (100]			<i>r</i> (100			
Bread and $5 \mu g/100 g$			5 μg/100 g			
similar						
products to the transmission of transmission of the transmission of transmission o			4 // 00			
Breakfast $4 \mu g/100 g$			4 μg/100 g			
cereals						
Pasta, doughs $5 \mu g/100 g$			5 μg/100 g			
and similar						
products		products				

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.

r				0
Oth	ner cereal-	3 μg/100 g		
bas	ed			
pro	ducts			
	ces,	10 µg/100 g		
	sonings,	10		
	diments,			
sau				
	redients,			
e	sert sauces/			
	pings	4.0 // 0.0		
	otein	10 µg/100 g		
	ducts			
Che	eese	2 μg/100 g		
Dai	iry desserts	2 μg/100 g		
	l similar			
	ducts			
	mented	1.5 μg/100 g		
	k or	1.5 µg/ 100 g		
	nented			
crea		25 (100		
	iry powders	25 µg/100 g		
and				
con	centrates			
Mil	lk-based	0.5 μg/100 g		
pro	ducts,			
whe	ey and			
crea	-			
Me	at and	2.5 μg/100 g		
daii				
	logues			
	al diet	5 u a/100 a		
		5 μg/100 g		
	lacement			
	weight			
	trol as			
	ined in			
	gulation			
	J) No			
	0/2013			
Me	al	5 μg/100 g		
rep	lacement			
	weight			
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	od for	In accordance		
	cial	with the		
	dical	particular		
		nutritional		
	poses as			
	ined in	requirements of		
	gulation	the persons for		
	J) No	whom the		
609	0/2013	products are		
		intended		

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

"UV-treated baker's	Description/Definition
yeast (Saccharomyces	
cerevisiae)	Baker's yeast ( <i>Saccharomyces cerevisiae</i> ) is treated with ultraviolet light to induce the conversion of ergosterol to vitamin $D_2$ (ergocalciferol). Vitamin $D_2$ content in the yeast concentrate varies between 800,000 - 3,500,000 IU vitamin D/100 g (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 in 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 <sub>2</sub>
	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: $\leq 10^3$ CFU/g
	<i>Escherichia coli</i> : $\leq 10$ CFU/g
	Salmonella spp.: Absence in 25 g
	CFU: Colony Forming Units".

Regulation 6

# Amendments to the list of novel foods in the Annex to Commission Implementing Regulation (EU) 2017/2470 for the authorisation of vitamin D<sub>2</sub> 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  $D_2$  mushroom powder" insert the following entry—

"Vitamin D <sub>2</sub> mushroom powder	Specified food category Breakfast cereals Yeast- leavened bread and similar pastries Grain products and pasta and	Maximum levels   of     2.1 μg/100 g   2.1 μg/100 g     2.1 μg/100 g   2.1 μg/100 g	The designation of the novel food on the labelling of food containing it is "UV- treated mushroom powder containing vitamin D <sub>2</sub> ".	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.
	similar productsThe labelling of foodFruit / vegetable juices and nectars $1.1 \ \mu g/100 \ ml$ (marketed as such or reconstituted as instructed by the manufacturer)The labelling of food supplements, as defined in the Food Supplements (Wales) Regulations 2003, containing vitamin D2 mushroom powder must bear a	Applicant: MBio, Monaghan Mushrooms, Tullygony, Tyholland, Co. Monaghan, Ireland, H18 FW95. During the period of data protection, vitamin D <sub>2</sub> mushroom powder is authorised for placing on the		
	by the manufacturer)by the manufacturer)statement that they should not be consumed by infants and children under 3 years of age.Dairy products and analogues as beverages $1.1 \ \mu g/100 \ ml(marketed assuch orreconstitutedas instructedby themanufacturer)not beconsumed byinfants andchildrenunder 3 yearsof age.Milk anddairypowders21.3 \ \mu g/100 \ g(marketed assuch orreconstitutedas instructedby the$	statement that they should not be consumed by infants and children under 3 years	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	

		manufacturer)		Regulation (EU)
	/leat			2015/2283 or with
	nalogues	2.1 µg/100 g		the agreement of
	-	2.1		MBio, Monaghan
5	oups	2.1 µg/100 ml (marketed as		Mushrooms.
		such or		
		reconstituted		The data protection
		as instructed		will expire at the
		by the		end of 14 May
		manufacturer)		2028."
F	Extruded	2.1 μg/100 g		
	egetable	2.1 µg/100 g		
	nack			
	/leal	2.1 μg/100 g		
	eplacement	2.1 µg/100 g		
	or weight			
	ontrol			
F	food for	In accordance		
	pecial	with the		
	nedical	particular		
p	urposes as	nutritional		
d	efined in	requirements		
	Regulation	of the persons		
	EU) No	for whom the		
	09/2013	products are		
	xcluding	intended		
	nose			
	ntended for			
	nfants	1.5		
	Food	15 µg of		
	upplements	vitamin		
	s defined in	D <sub>2</sub> /day		
	he Food			
	wales)			
	Wales)			
	Regulations			
	xcluding			
	ood			
	upplements			
	or infants			
	nd children			
	nder 3 years			
	fage			

**3.** In Table 2, (specifications), after the entry for "Vitamin  $D_2$  mushroom powder" insert the following entry—

"Vitamin D <sub>2</sub> mushroom powder	Description/Definition
	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.
	Characteristics/Composition

Vitamin D <sub>2</sub> content: 580-595 $\mu$ g/g of mushroom powder
Ash: $\leq 13.5\%$
Water activity: $< 0.5$
Moisture content: $\leq 7.5\%$
Carbohydrates: $\leq 35\%$
Total dietary fibre: $\geq 15\%$
Crude protein (N x 6.25): $\geq 22\%$
Fat: ≤ 4.5%
Heavy metals
Lead: $\leq 0.5 \text{ mg/kg}$
Cadmium: $\leq 0.5 \text{ mg/kg}$
Mercury: $\leq 0.1 \text{ mg/kg}$
Arsenic: $\leq 0.3 \text{ mg/kg}$
Mycotoxins
Aflatoxin B1: $\leq 0.1  \mu g/kg$
Aflatoxins (sum of $B1 + B2 + G1 + G2$ ): < 4 $\mu$ g/kg
Microbiological criteria
Total plate county < 5000 CEU
Total plate count: $\leq$ 5000 CFU Total yeast and mould count: $\leq$ 100 CFU/g
Escherichia coli: $< 10$ CFU/g
Salmonella spp.: Absence in 25 g
Staphylococcus aureus: $\leq 10 \text{ CFU/g}$
$Suprytococcus unreas. \leq 10 \text{ CPO/g}$ Coliforms: $\leq 10 \text{ CFU/g}$
<i>Listeria</i> spp.: Absence in 25 g
Enterobacteriaceae: < 10 CFU/g
CFU: Colony Forming Units".