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STATUTORY INSTRUMENTS

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**2023 No. 334**

**FOOD, ENGLAND**

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

<i>Made</i>	- - - -	<i>15th March 2023</i>
<i>Laid before Parliament</i>		<i>16th March 2023</i>
<i>Coming into force</i>	- -	<i>15th May 2023</i>

The Secretary of State makes the following 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 (“Regulation 1331/2008”)(1) and Article 12(1) of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, etc. (“Regulation 2015/2283”)(2).

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

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(3), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

**PART 1**

**Introduction**

**Citation, commencement extent and application**

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

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

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(1) EUR 2008/1331, amended by S.I. 2019/860; there are other amending instruments but none is relevant. The terms “domestic list”, “prescribe” and “appropriate authority” are defined in Article 2.  
(2) EUR 2015/2283, amended by S.I. 2019/702; there are other amending instruments but none is relevant. The terms “prescribe”, “appropriate authority”, and “list” are defined in Article 3. Article 12(1) applies in accordance with Articles 9 and 27(1).  
(3) EUR 2002/178, amended by S.I. 2019/641; there are other amending instruments but none is relevant.

## PART 2

### Food Additives

#### Amendment of Regulation (EC) No. 1333/2008

2.—(1) Annex 2 to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives<sup>(4)</sup> is amended as follows.

(2) In Part B, paragraph 2, in the table headed “Sweeteners”—

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

“E 960a	Steviol glycosides from Stevia
E 960c	Enzymatically produced steviol glycosides”.

(3) In Part C, paragraph 5, after paragraph (u) insert—

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

<i>E Number</i>	<i>Name</i>
E 960a	Steviol glycosides from Stevia
E 960c	Enzymatically produced steviol glycosides”.

(4) In Part E, the table is amended in accordance with Schedule 1.

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

3.—(1) The Annex to Commission Regulation (EU) No. 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council<sup>(5)</sup> is amended as follows.

(2) For the heading “E 960 STEVIOL GLYCOSIDES” substitute “E 960a STEVIOL GLYCOSIDES FROM STEVIA”.

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

#### Transitional provision

4.—(1) The food additive E 960a Steviol glycosides from Stevia, and any foods containing it, labelled before the end of 14th November 2024 may continue to be labelled as E 960 Steviol glycosides and placed on the market, and used, until stocks are exhausted.

(2) Any expression used in both paragraph (1) and Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives has the meaning it bears in that Regulation.

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(4) EUR 2008/1333; amended by S.I. 2019/860.

(5) EUR 2012/231; amended by S.I. 2019/860.

## PART 3

### Food Flavourings

#### **Amendment of Regulation (EC) No. 1334/2008**

5.—(1) Annex 1 to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods etc<sup>(6)</sup> is amended as follows.

(2) In Part A, Section 2, Table 1, after the entry for FL No. “16.126” (3-[(4-amino-2,2-dioxido-1H-2,1,3-benzothiadiazin-5-yl)oxy]-2,2-dimethyl-N-propylpropanamide) insert the entry in Schedule 3.

## PART 4

### Novel Foods

#### **Amendment of Commission Implementing Regulation (EU) 2017/2470**

6.—(1) The Annex to Commission Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods<sup>(7)</sup> is amended as follows.

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

- (a) for the entry for “UV-treated baker’s yeast (*Saccharomyces cerevisiae*)” substitute the entry in Schedule 4.
- (b) after the entry for “Vitamin D<sub>2</sub> mushroom powder” insert the entry in Schedule 5.

(3) In Table 2 (Specifications)—

- (a) for the entry for “UV-treated baker’s yeast (*Saccharomyces cerevisiae*)” substitute the entry in Schedule 6.
- (b) after the entry for “Vitamin D<sub>2</sub> mushroom powder” insert the entry in Schedule 7.

15th March 2023

*Neil O’Brien*  
Parliamentary Under Secretary of State,  
Department of Health and Social Care

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<sup>(6)</sup> EUR 2008/1334; amended by [S.I. 2019/860](#).

<sup>(7)</sup> EUR 2017/2470; amended by [S.I. 2019/702](#); there are other amending instruments but none is relevant.

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## SCHEDULE 1

Regulation 2(4)

## Amendment of the table in Part E of Annex 2 to Regulation (EC) No. 1333/2008

1. 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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2. 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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3. 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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4. In category 04.2.4.1 (Fruit and vegetable preparations excluding compote), for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	200	(1) (60)	only energy-reduced”
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5. 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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6. 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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7. In category 04.2.5.3 (Other similar fruit or vegetable spreads), 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 fruit or vegetable spreads and dried-fruit-based sandwich spreads, energy-reduced or with no added sugar”
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8. In category 05.1 (Cocoa and Chocolate products), for the entry for “E 960” (Steviol glycosides) substitute—

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“E 960a and E 960c	Steviol glycosides	270	(1) (60)	only energy-reduced or with no added sugar”
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9. In category 05.2 (Other confectionery including breath freshening microsweets) —

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

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

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

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“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

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confectionery  
such as chewy  
candies, fruit  
gums and foam  
sugar products/  
marshmallows

only energy-  
reduced  
liquorice

only energy-  
reduced nougat

only energy-  
reduced  
marzipan”

(d) 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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(e) 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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**10.** 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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**11.** In category 05.4 (Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4) —

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

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“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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12. 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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13. 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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14. 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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15. 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> (8)	(60)”	
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16. 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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(8) “quantum satis” is defined in Article 3(2)(h) of EUR 2008/1333.

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17. 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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18. 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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19. 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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20. In category 12.6 (Sauces) —

(a) 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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(b) 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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21. In category 13.2 (Dietary foods for special medical purposes (excluding products from food category 13.1.5))—

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

“E 960a and E 960c	Steviol glycosides	330	(1) (60)”
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(b) in the second entry for “E 960” (Advantame) for “E 960” substitute “E 969”.

22. 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))—

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

“E 960a and E 960c	Steviol glycosides	270	(1) (60)”
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(b) in the second entry for “E 960” (Advantame) for “E 960” substitute “E 969”.



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**23.** 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”				

**24.** 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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**25.** In category 14.1.5.2 (Other)—

(a) 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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(b) 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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(c) 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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**26.** In category 14.2.1 (Beer and malt beverages), for the entry for “E 960” (Steviol glycosides) substitute—

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“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”
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**27.** In category 14.2.8 (Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15% alcohol), for the entry for “E 960” (Steviol glycosides) substitute—

“E 960a and E 960c	Steviol glycosides	150	(1) (60)”	
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**28.** 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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**29.** 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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**30.** 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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**31.** In category 17.1 (Food supplements supplied in a solid form, excluding food supplements for infants and young children)—

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

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

“E 960a and E Steviol glycosides 960c	1800	(1) (60)	only food supplements in chewable form”
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**32.** In category 17.2 (Food supplements supplied in a liquid form, excluding food supplements for infants and young children)—

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

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

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

Regulation 3(3)

Amendment of the Annex to [Commission Regulation \(EU\) No. 231/2012](#)

### “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. phaffii* (formerly known as *Pichia pastoris*) UGT-a and *K. phaffii* 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

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	rebaudioside M. Viable cells or the DNA of the yeasts <i>K. phaffii</i> UGT-a or <i>K. phaffii</i> UGT-b must not be detected in the food additive.		
<b>Chemical name</b>	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		
<b>Molecular formula</b>	<b>Trivial name</b>	<b>Formula</b>	<b>Conversion factor</b>
	Rebaudioside M	C <sub>56</sub> H <sub>90</sub> O <sub>33</sub>	0.25
<b>Molecular weight and CAS No</b>	<b>Trivial name</b>	<b>CAS Number</b>	<b>Molecular weight (g/mol)</b>
	Rebaudioside M	1220616-44-3	1291.29
<b>Assay</b>	Not less than 95 % rebaudioside M on the dried basis.		
<b>Description</b>	White to light yellow powder, approximately between 200 and 350 times sweeter than sucrose (at 5 % sucrose equivalency).		
<b>Identification</b>			
<b>Solubility</b>	Freely soluble to slightly soluble in water		
<b>pH</b>	Between 4.5 and 7.0 (1 in 100 solution)		
<b>Purity</b>			
<b>Total ash</b>	Not more than 1 %		
<b>Loss on drying</b>	Not more than 6 % (105 °C, 2h)		
<b>Residual solvent</b>	Not more than 5000 mg/kg ethanol		
<b>Arsenic</b>	Not more than 0.015 mg/kg		
<b>Lead</b>	Not more than 0.2 mg/kg		
<b>Cadmium</b>	Not more than 0.015 mg/kg		
<b>Mercury</b>	Not more than 0.07 mg/kg		
<b>Residual protein</b>	Not more than 5 mg/kg		
<b>Particle size</b>	Not less than 74 µm (using a mesh #200 sieve with a particle size limit of 74 µm)”		

## SCHEDULE 3

Regulation 5(2)

Amendment of Table 1 in Part A, Section 2 of Annex 1 to Regulation (EC) No. 1334/2008

“16.127	3-(1- (3,5- dimethylisoxazol-4- yl)methyl)-1H- pyrazol-4- yl)-1-(3-	1119832125-2	At least 99 %, Restrictions assay (HPLC/ UV) of use as a flavouring substance	The Authority(9)
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(9) “Authority” is defined in Article 3(2)(l) of EUR 2008/1334.

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hydroxybenzyl)imidazolidine-2,4-dione

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

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

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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

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## SCHEDULE 4

Regulation 6(2)(a)

Substitution of entry in Table 1 in the Annex to  
Commission Implementing Regulation (EU) 2017/2470

“UV-treated baker’s yeast ( <i>Saccharomyces cerevisiae</i> )”	<b>Specified category</b>	<b>food</b>	<b>Maximum level of vitamin D<sub>2</sub></b>	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-up formula, processed cereal-based food and food for special medical purposes.
	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 Regulations (England) 2003 <sup>(10)</sup>		In accordance with any relevant requirements contained in regulations applying in relation to England and made under regulation 4 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 <sup>(11)</sup>		
	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 <sub>2</sub> 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

<sup>(10)</sup> S.I. 2003/1387, to which there are amendments not relevant to these Regulations.

<sup>(11)</sup> S.I. 2019/651, amended by S.I. 2020/1476; there are other amending instruments but none is relevant.

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		final consumer to ensure a maximum concentration of 5 µg/100 g of vitamin D <sub>2</sub> 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 yeast” or “vitamin D <sub>2</sub> 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(12)	In accordance with Regulation (EU) No. 609/2013	
Processed cereal-based food 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	

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



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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
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.”

SCHEDULE 5

Regulation 6(2)(b)

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

“Vitamin D <sub>2</sub> mushroom powder	<i>Specified food category</i>	<i>Maximum levels of vitamin D<sub>2</sub></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.
	Breakfast cereals	2.1 µg/100 g		This inclusion is based on proprietary scientific evidence and scientific data protected in
	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	containing vitamin D <sub>2</sub> ".  The labelling of food supplements, as defined in the Food Supplements (England) Regulations 2003,	accordance with Article 26 of Regulation 2015/2283.
Fruit/vegetable juices and nectars	1.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)		Applicant: MBio, Monaghan Mushrooms of Tullygony, Tyholland Co Monaghan, Ireland, H18 FW95.
Dairy products and analogues other than beverages	2.1 µg/100 g (marketed as such or reconstituted as instructed by the manufacturer)	containing vitamin D <sub>2</sub> mushroom powder must bear a statement that they should not be consumed by infants and children under 3 years of age.	During the period of data protection, Vitamin D <sub>2</sub> mushroom powder is authorised for placing on the market, within England, 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 2015/2283
Dairy products and analogues as beverages	1.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)		or with the agreement of MBio,
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 snacks	2.1 µg/100 g		
Meal replacement for weight control	2.1 µg/100 g		

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<p>Food for special medical purposes defined in Regulation (EU) No. 609/2013 excluding those intended for infants</p> <p>Food supplements as defined in the Food Supplements (England) Regulations 2003 excluding food supplements for infants and children under 3 years of age.</p>	<p>In accordance with the particular nutrients in of the persons for whom the products are intended.</p> <p>15 µg of vitamin D<sub>2</sub>/day”</p>	<p>Monaghan Mushrooms.</p> <p>The data protection will expire at the end of 14 May 2028.</p>
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SCHEDULE 6

Regulation 6(3)(a)

Substitution of entry in Table 2 in the Annex to Commission Implementing Regulation (EU) 2017/2470

<p>“UV-treated baker’s yeast (<i>Saccharomyces cerevisiae</i>)</p>	<p><b>Description/Definition</b></p> <p>Baker’s yeast (<i>Saccharomyces cerevisiae</i>) is treated with ultraviolet light to induce the conversion of ergosterol to vitamin D<sub>2</sub> (ergocalciferol). Vitamin D<sub>2</sub> 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 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</p>
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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

*Escherichia coli*:  $\leq 10$  CFU/g

*Salmonella* spp.: Absence in 25 g

CFU: Colony Forming Units

SCHEDULE 7

Regulation 6(3)(b)

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

“Vitamin D<sub>2</sub> 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<sub>2</sub> content: 580-595 µg/g of mushroom powder

Ash:  $\leq 13.5\%$

Water activity:  $< 0.5$

Moisture content:  $\leq 7.5\%$

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Carbohydrates:  $\leq 35\%$

Total dietary fibre:  $\geq 15\%$

Crude protein (N x 6.25):  $\geq 22\%$

Fat:  $\leq 4.5\%$

### **Heavy metals**

Lead:  $\leq 0.5$  mg/kg

Cadmium:  $\leq 0.5$  mg/kg

Mercury:  $\leq 0.1$  mg/kg

Arsenic:  $\leq 0.3$  mg/kg

### **Mycotoxins**

Aflatoxin B1:  $\leq 0.1$   $\mu\text{g}/\text{kg}$

Aflatoxins (sum of B1 + B2 + G1 + G2):  $< 4$   $\mu\text{g}/\text{kg}$

### **Microbiological criteria**

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*:  $\leq 10$  CFU/g

Coliforms:  $\leq 10$  CFU/g

*Listeria* spp.: Absence in 25 g

Enterobacteriaceae:  $< 10$  CFU/g

CFU: Colony Forming Units.”

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

Regulation 2 amends Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives to amend the name and E number for an existing food additive, correct the E number for another food additive, and add a new food additive to the list of authorised additives.

Regulation 3 amends Commission Regulation (EU) No. 231/2012 laying down specifications for food additives listed in Annexes II and III of Regulation (EC) No. 1333/2008 of the European Parliament and of the Council to amend the heading of the specification for an existing food additive and add a specification for a new food additive.

Regulation 4 creates a transitional measure to allow stocks of an amended food additive labelled with the existing name or E number to be exhausted.

Regulation 5 amends Regulation (EC) No. 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods etc. to add a new food flavouring to the list of authorised flavourings.

Regulation 6 amends Commission Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods to add one novel food and amend the conditions of use and specifications of one novel food on the list of authorised novel foods.

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