



OFFERYNNAU STATUDOL CYMRU

2023 Rhif 343 (Cy. 50)

BWYD, CYMRU

AMAETHYDDIAETH, CYMRU

Rheoliadau Ychwanegion Bwyd, Cyflasynnau Bwyd,
a Bwydydd Newydd (Awdurdodiadau) a Bwyd
a Bwyd Anifeiliaid (Diwygiadau Amrywiol) (Cymru) 2023

Gwnaed

20 Mawrth 2023

Gosodwyd gerbron Senedd Cymru

22 Mawrth 2023

Yn dod i rym yn unol â rheoliad 1(3) a (4)

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 accordance with regulation 1(3) and (4)

£11.50



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CYMRU

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INSTRUMENTS

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Rheoliadau Ychwanegion Bwyd,
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Newydd (Awdurdodiadau) a Bwyd
a Bwyd Anifeiliaid (Diwygiadau
Amrywiol) (Cymru) 2023

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

NODYN ESBONIADOL

(Nid yw'r nodyn hwn yn rhan o'r Rheoliadau)

Mae'r Rheoliadau hyn yn gwneud darpariaeth, o ran Cymru, ynghylch awdurdodiadau cynhyrchion bwyd rheoleiddiedig. Maent hefyd yn gwneud mân gywiriadau i is-offerynnau Cymreig amrywiol ar gyfraith bwyd a chyfraith bwyd anifeiliaid.

Gwneir Rhan 2 o'r Rheoliadau hyn (rheoliadau 2 i 4 ac Atodlenni 1 a 2) drwy arfer pwerau yn Rheoliad (EC) Rhif 1331/2008 sy'n sefydlu gweithdrefn awdurdodi gyffredin ar gyfer ychwanegion bwyd, ensymau bwyd a chyflasynnau bwyd (EUR 2008/1331). Gyda'i gilydd, mae'r diwygiadau a wneir yn Rhan 2 o'r Rheoliadau hyn yn darparu ar gyfer awdurdodi, o ran Cymru, roi ar y farchnad a defnyddio'r ychwanegyn bwyd E 960c rebaudiosid M a gynhyrchir drwy addasu glycosidau stefiol o Stevia ag ensymau. Mae'r cofnodion awdurdodi presennol ar gyfer yr ychwanegyn bwyd E 960 glycosidau stefiol yn cael eu newid i adlewyrchu'r enw a'r E-rif diwygiedig E 960a glycosidau stefiol o Stevia.

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.

Mae rheoliad 2 ac Atodlen 1 yn diweddar, o ran Cymru, y rhestr ddomestig o ychwanegion bwyd sydd wedi eu cymeradwyo i'w defnyddio mewn bwydydd yn Atodiad 2 i Reoliad (EC) Rhif 1333/2008 ar ychwanegion bwyd (EUR 2008/1333). Mae Atodlen 1 hefyd yn cywiro'r E-rif mewn dau gofnod yn yr Atodiad hwnnw ar gyfer yr ychwanegyn bwyd E 969 Advantame.

Mae rheoliad 3 ac Atodlen 2 yn diwygio, o ran Cymru, Reoliad y Comisiwn (EU) Rhif 231/2012 sy'n gosod manylebau ar gyfer ychwanegion bwyd a restrir yn Atodiadau II a III i Reoliad (EC) Rhif 1333/2008 (EUR 2012/231).

Mae rheoliad 4 yn cynnwys darpariaeth drosiannol sy'n caniatáu ar gyfer cyfnod o 18 mis pan ganiateir i stociau o gynhyrchion barhau i gael eu labelu fel E 960 glycosidau stefiol, neu fel eu bod yn cynnwys E960 glycosidau stefiol. Caniateir i stociau sy'n cael eu labelu o fewn yr amserlen honno gael eu rhoi ar y farchnad a'u defnyddio hyd nes y bydd y stociau hynny wedi eu dihysbyddu.

Gwneir Rhan 3 o'r Rheoliadau hyn (rheoliad 5 ac Atodlen 3) hefyd drwy arfer pwerau yn EUR 2008/1331. Mae rheoliad 5 ac Atodlen 3 yn diweddar, o ran Cymru, y rhestr ddomestig o sylweddau cyflasu yn Atodiad 1 i Reoliad (EC) Rhif 1334/2008 ar gyflwynnau a chynhwysion bwyd penodol â phriodoleddau cyflasu sydd i'w defnyddio mewn bwydydd ac ar fwydydd (EUR 2008/1334). Mae'r diwygiadau hyn yn darparu ar gyfer awdurdodi, o ran Cymru, roi ar y farchnad a defnyddio'r cyflasin bwyd 3-(1-((3,5-deumethylisocsasol-4-yl)methyl)-1H-pyrazol-4-yl)-1-(3-hydrocsybensyl)imidazolidin-2,4-dion.

Gwneir Rhan 4 o'r Rheoliadau hyn (rheoliad 6 ac Atodlenni 4 a 5) drwy arfer pwerau yn Rheoliad (EU) 2015/2283 ar fwydydd newydd (EUR 2015/2283). Mae rheoliad 6 ac Atodlenni 4 a 5 yn diweddar, o ran Cymru, y rhestr o fwydydd newydd awdurdodedig yn Atodiad 1 i Reoliad Gweithredu'r Comisiwn (EU) 2017/2470 sy'n sefydlu rhestr yr Undeb o fwydydd newydd (EUR 2017/2470):

- Mae Atodlen 4 yn amnewid y cofnod ar gyfer burum pobi sydd wedi ei drin ag UV (*Saccharomyces cerevisiae*), gan ymestyn y categorïau bwyd penodedig y mae'r bwyd newydd hwnnw wedi ei awdurdodi ar eu cyfer.
- Mae Atodlen 5 yn mewnosod cofnod newydd, sy'n awdurdodi rhoi ar y farchnad bowdr madarch fitamin D₂ newydd fel bwyd newydd i'w ddefnyddio yn y categorïau bwyd penodedig.

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.

Mae Rhan 5 o'r Rheoliadau hyn (rheoliadau 7, 8 a 9) yn cynnwys mân gywiriadau i is-offerynnau Cymreig amrywiol ar gyfraith bwyd a chyfraith bwyd anifeiliaid. Gwneir rheoliadau 7 ac 8 drwy arfer pwerau yn Neddf Diogelwch Bwyd 1990 (p. 16). Gwneir rheoliad 9 drwy arfer pwerau yn Neddf Amaethyddiaeth 1970 (p. 40).

Ystyriwyd Cod Ymarfer Gweinidogion Cymru ar gynnal Aseidiadau Effaith Rheoleiddiol mewn perthynas â'r Rheoliadau hyn. O ganlyniad, ystyriwyd nad oedd yn angenrheidiol cynnal aseiad effaith rheoleiddiol o'r costau a'r manteision sy'n debygol o ddeillio o gydymffurfio â'r Rheoliadau hyn.

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.

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

Gwnaed 20 Mawrth 2023

Made 20 March 2023

*Gosodwyd gerbron Senedd
Cymru* 22 Mawrth 2023

Laid before Senedd Cymru 22 March 2023

Yn dod i rym yn unol â rheoliad 1(3) a (4)

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

Mae Gweinidogion Cymru yn gwneud y Rheoliadau hyn drwy arfer y pwerau a roddir gan—

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

- Erthyglau 7(5) a 14A(2)(b) o Reoliad (EC) Rhif 1331/2008 Senedd Ewrop a'r Cyngor sy'n sefydlu gweithdrefn awdurdodi gyffredin ar gyfer ychwanegion bwyd, ensymau bwyd a chyflasynnau bwyd(1);

- 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);

(1) EUR 2008/1331, a ddiwygiwyd gan O.S. 2019/860 a 2022/1351. Diwygiwyd O.S. 2019/860 gan O.S. 2020/1504. Diffinnir y termau "domestic list", "prescribe" ac "appropriate authority" yn Erthygl 2 o EUR 2008/1331. Diffinnir y term "sectoral food law" yn Erthygl 1(2) o EUR 2008/1331. Mewn perthynas â Rhan 2 o'r Rheoliadau hyn, mae Erthygl 7(5) o EUR 2008/1331 yn gymwys yn unol ag Erthyglau 10(3), 14 a 30(4) o Reoliad (EC) Rhif 1333/2008 Senedd Ewrop a'r Cyngor ar ychwanegion bwyd (EUR 2008/1333). Mewn perthynas â Rhan 3 o'r Rheoliadau hyn, mae Erthygl 7(5) o EUR 2008/1331 yn gymwys yn unol ag Erthygl 11(3) o Reoliad (EC) Rhif 1334/2008 Senedd Ewrop a'r Cyngor ar gyflasynnau a chynhwysion bwyd penodol â phriodoleddau cyffasu sydd i'w defnyddio mewn bwydydd ac ar fwydydd (EUR 2008/1334).

(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).

- Erthygl 12(1) o Reoliad (EU) 2015/2283 Senedd Ewrop a'r Cyngor ar fwydydd newydd(1);
- adrannau 16(1)(a) a (2)(b), ac 48(1)(c) o Ddeddf Diogelwch Bwyd 1990(2);
- adrannau 74A(1) a 84(1) o Ddeddf Amaethyddiaeth 1970(3).
- 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).

Mae Gweinidogion Cymru wedi ceisio cyngor gan yr Asiantaeth Safonau Bwyd ac wedi rhoi sylw i'r cyngor hwnnw, fel sy'n ofynnol gan Erthygl 7(5) o Reoliad (EC) Rhif 1331/2008(4) (mewn perthynas â Rhannau 2 a 3) ac adran 48(4A) o Ddeddf Diogelwch Bwyd 1990(5) (mewn perthynas â rheoliadau 7 ac 8).

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).

Ymgynghorwyd yn agored ac yn dryloyw â'r cyhoedd wrth lunio'r Rheoliadau hyn yn unol â gofynion Erthygl 9 o Reoliad (EC) Rhif 178/2002 Senedd Ewrop a'r Cyngor sy'n gosod egwyddorion a gofynion cyffredinol cyfraith bwyd, yn sefydlu Awdurdod Diogelwch Bwyd Ewrop ac yn gosod gweithdrefnau o ran materion diogelwch bwyd(6) neu, yn achos darpariaethau sy'n ymwneud â bwyd anifeiliaid ar gyfer anifeiliaid nad ydynt yn cynhyrchu bwyd, adran 84(1) o Ddeddf Amaethyddiaeth 1970.

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.

(1) EUR 2015/2283, a ddiwygiwyd gan O.S. 2019/702; mae offerynnau diwygio eraill ond nid yw'r un ohonynt yn berthnasol. Diwygiwyd O.S. 2019/702 gan O.S. 2020/1504. Diffinnir y termau "prescribe", "appropriate authority" a "list" yn Erthygl 3 o EUR 2015/2283. Mae Erthygl 12(1) o EUR 2015/2283 yn gymwys yn unol ag Erthyglau 9 a 27(1) o'r Rheoliad hwnnw.

(2) 1990 p. 16. Diwygiwyd adrannau 16(1) a (2), ac 48(1) gan adran 40(1) o Ddeddf Safonau Bwyd 1999 (p. 28) ("Deddf 1999") a pharagraffau 7 ac 8 o Atodlen 5 iddi. Mae diwygiadau eraill nad ydynt yn berthnasol i'r Rheoliadau hyn. Trosglwyddwyd y swyddogaethau hynny, a oedd gynt yn arferadwy gan "the Ministers", i'r graddau y maent yn arferadwy o ran Cymru, i Gynulliad Cenedlaethol Cymru gan O.S. 1999/672 fel y'i darllenir gydag adran 40(3) o Ddeddf 1999. Mae'r swyddogaethau hynny bellach yn arferadwy gan Weinidogion Cymru yn rhinwedd adran 162 o Ddeddf Llywodraeth Cymru 2006 (p. 32) a pharagraff 30 o Atodlen 11 iddi.

(3) 1970 p. 40. Mewnosodwyd adran 74A gan baragraff 6 o Atodlen 4 i Ddeddf y Cymunedau Ewropeaidd 1972 (p. 68); diwygiwyd yr adran honno wedi hynny gan adran 33(3) o Ddeddf Amaethyddiaeth 2020 (p. 21). Diwygiwyd adran 84 gan O.S. 2004/3254. Diffinnir y termau "the Ministers", "prescribed" a "regulations" yn adran 66(1) o Ddeddf Amaethyddiaeth 1970. Trosglwyddwyd swyddogaethau a oedd gynt yn arferadwy gan "the Ministers", i'r graddau y maent yn arferadwy o ran Cymru, i Gynulliad Cenedlaethol Cymru gan O.S. 1999/672. Mae'r swyddogaethau hynny bellach yn arferadwy gan Weinidogion Cymru yn rhinwedd adran 162 o Ddeddf Llywodraeth Cymru 2006, a pharagraff 30 o Atodlen 11 iddi.

(4) Diffinnir y term "Authority" yn Erthygl 2(3) o EUR 2008/1331.

(5) Mewnosodwyd adran 48(4A) gan baragraff 21 o Atodlen 5 i Ddeddf 1999.

(6) EUR 2002/178, a ddiwygiwyd gan O.S. 2019/641; mae offerynnau diwygio eraill ond nid yw'r un ohonynt yn berthnasol.

(1) 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.

(2) 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).

(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

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

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

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

RHAN 1

Rhagarweiniad

Enwi, rhychwant, cymhwyso a dod i rym

1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau Ychwanegion Bwyd, Cyflasynnau Bwyd, a Bwydydd Newydd (Awdurdodiadau) a Bwyd a Bwyd Anifeiliaid (Diwygiadau Amrywiol) (Cymru) 2023.

(2) Mae'r Rheoliadau hyn—

- (a) yn rhychwantu Cymru a Lloegr;
- (b) yn gymwys o ran Cymru.

(3) Daw Rhannau 1 a 5 i rym ar 14 Ebrill 2023.

(4) Daw Rhannau 2, 3 a 4 i rym ar 15 Mai 2023.

RHAN 2

Awdurdodi Ychwanegion Bwyd

Diwygio Rheoliad (EC) Rhif 1333/2008

2. Mae Rheoliad (EC) Rhif 1333/2008 Senedd Ewrop a'r Cyngor ar ychwanegion bwyd⁽¹⁾ wedi ei ddiwygio yn unol ag Atodlen 1.

Diwygio Rheoliad y Comisiwn (EU) Rhif 231/2012

3. Mae Rheoliad y Comisiwn (EU) Rhif 231/2012 sy'n gosod manylebau ar gyfer ychwanegion bwyd a restrir yn Atodiadau II a III i Rheoliad (EC) Rhif 1333/2008 Senedd Ewrop a'r Cyngor⁽²⁾ wedi ei ddiwygio yn unol ag Atodlen 2.

Darpariaeth drosiannol

4.—(1) Caniateir i unrhyw ychwanegyn bwyd neu fwyd a labelir cyn diwedd 14 Tachwedd 2024 fel E 960 glycosidau stefiol, neu fel eu bod yn cynnwys E 960 glycosidiau stefiol, sydd fel arall yn cydymffurfio â'r amodau defnyddio a'r fanyleb ar gyfer E 960a glycosidau stefiol o Stevia, barhau i gael eu rhoi ar y farchnad a'u defnyddio hyd nes y bydd y stociau wedi eu dihysbyddu.

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.

(1) EUR 2008/1333, a ddiwygiwyd gan O.S. 2019/860. Diwygiwyd O.S. 2019/860 gan O.S. 2020/1504.

(2) EUR 2012/231, a ddiwygiwyd gan O.S. 2019/860.

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

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

(2) Mae i'r ymadroddion Cymraeg a ddefnyddir ym mharagraff (1) sy'n cyfateb i ymadroddion Saesneg a ddefnyddir yn Rheoliad (EC) Rhif 1333/2008 Senedd Ewrop a'r Cyngor ar ychwanegion bwyd yr un ystyr â'r ymadroddion hynny yn y Rheoliad hwnnw.

RHAN 3

Awdurdodi Cyflasynnau Bwyd

Diwygio Rheoliad (EC) Rhif 1334/2008

5. Mae Rheoliad (EC) Rhif 1334/2008 Senedd Ewrop a'r Cyngor ar gyflasynnau a chynhwysion bwyd penodol â phriodoleddau cyflasu sydd i'w defnyddio mewn bwydydd ac ar fwydydd(1) wedi ei ddiwygio yn unol ag Atodlen 3.

RHAN 4

Awdurdodi Bwydydd Newydd

Diwygio Rheoliad Gweithredu'r Comisiwn (EU) 2017/2470

6. Mae Rheoliad Gweithredu'r Comisiwn (EU) 2017/2470 sy'n sefydlu rhestr yr Undeb o fwydydd newydd yn unol â Rheoliad (EU) 2015/2283 Senedd Ewrop a'r Cyngor ar fwydydd newydd(2) wedi ei ddiwygio yn unol ag Atodlenni 4 a 5.

RHAN 5

Diwygiadau Amrywiol

Diwygio Rheoliadau Deunyddiau ac Eitemau mewn Cysylltiad â Bwyd (Cymru) 2012

7. Yn Rheoliadau Deunyddiau ac Eitemau mewn Cysylltiad â Bwyd (Cymru) 2012(3), yn rheoliad 12(2), yn lle'r geiriau o "nhabl 1" hyd at y diwedd rhodder "Nhabl 1 o Atodlen 6 ac yn ddarostyngedig i'r cyfyngiadau yn y Tabl hwnnw".

(1) EUR 2008/1334, a ddiwygiwyd gan O.S. 2019/860. Diwygiwyd O.S. 2019/860 gan O.S. 2020/1504.
(2) EUR 2017/2470, a ddiwygiwyd gan O.S. 2019/702 a 2022/575 (Cy. 133); mae offerynnau diwygio eraill ond nid yw'r un ohonynt yn berthnasol.
(3) O.S. 2012/2705 (Cy. 291), a ddiwygiwyd gan O.S. 2022/1362 (Cy. 273); mae offerynnau diwygio eraill ond nid yw'r un ohonynt yn berthnasol.

(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(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".

(1) EUR 2008/1334; amended by S.I. 2019/860. S.I. 2019/860 was amended by S.I. 2020/1504.
(2) EUR 2017/2470, amended by S.I. 2019/702 and 2022/575 (W. 133); there are other amending instruments but none is relevant.
(3) S.I. 2012/2705 (W. 291), amended by S.I. 2022/1362 (W. 273); there are other amending instruments but none is relevant.

Diwygio Rheoliadau Ychwanegion, Cyflasynnau, Ensymau a Thoddyddion Echdynnu Bwyd (Cymru) 2013

8. Yn Rheoliadau Ychwanegion, Cyflasynnau, Ensymau a Thoddyddion Echdynnu Bwyd (Cymru) 2013(1), yn rheoliad 2(1), yn y diffiniad o “Rheoliadau’r UE a ddargedwir”—

- (a) yn y testun Cymraeg, yn lle “(“*the EU Regulations*”)” rhodder “(“*the retained EU Regulations*”)”;
- (b) yn y testun Saesneg, ar ôl “the retained EU Regulations” mewnosoder “(“*Rheoliadau’r UE a ddargedwir*”)”.

Diwygio Rheoliadau Bwyd Anifeiliaid (Cyfansoddiad, Marchnata a Defnydd) (Cymru) 2016

9.—(1) Mae Rheoliadau Bwyd Anifeiliaid (Cyfansoddiad, Marchnata a Defnydd) (Cymru) 2016(2) wedi eu diwygio fel a ganlyn.

(2) Yn Atodlen 1B, yn Nhabl 1, yn y testun Cymraeg, yn y cofnod ar gyfer “1. Arsenig”, yn yr ail golofn, yn lle “deunyddiau blawd”, ym mhob lle y mae’n digwydd, rhodder “deunyddiau bwyd anifeiliaid”.

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(1), 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*”)”;
- (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(2) 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

Y Dirprwy Weinidog Iechyd Meddwl a Llesiant, o dan awdurdod y Gweinidog Iechyd a Gwasanaethau Cymdeithasol, un o Weinidogion Cymru
20 Mawrth 2023

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

(1) O.S. 2013/2591 (Cy. 255), a ddiwygiwyd gan O.S. 2022/1362 (Cy. 273); mae offerynnau diwygio eraill ond nid yw’r un ohonynt yn berthnasol.

(2) O.S. 2016/386 (Cy. 120), a ddiwygiwyd gan O.S. 2022/1362 (Cy. 273); mae offerynnau diwygio eraill ond nid yw’r un ohonynt yn berthnasol.

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

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

Diwygiadau i'r rhestr ddomestig o ychwanegion bwyd sydd wedi eu cymeradwyo i'w defnyddio mewn bwydydd yn Atodiad 2 i Reoliad (EC) Rhif 1333/2008 sy'n ymwneud â diwygio dynodiad yr ychwanegyn bwyd E 960a glycosidau stefiol o Stevia (E 960 glycosidau stefiol yn flaenorol) ac i ychwanegu E 960c rebaudiosid M a gynhyrchir drwy addasu glycosidau stefiol o Stevia ag ensymau

1. Yn Rheoliad (EC) Rhif 1333/2008, mae Atodiad 2 (rhestr ddomestig o ychwanegion bwyd sydd wedi eu cymeradwyo i'w defnyddio mewn bwydydd) wedi ei ddiwygio fel a ganlyn.

2. Yn Rhan B (rhestr o'r holl ychwanegion), ym mharagraff 2 (melysyddion), yn y tabl—

(a) yn lle'r cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a	Steviol glycosides from Stevia";
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(b) yn y lle priodol, mewnosoder y cofnod a ganlyn—

"E 960c	Enzymatically produced steviol glycosides".
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3. Yn Rhan C (diffiniadau o grwpiau o ychwanegion), ym mharagraff 5 (ychwanegion eraill y caniateir eu rheoleiddio yn gyfun), ar ôl is-baragraff (u) mewnosoder—

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

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

4. Yn Rhan E (ychwanegion bwyd awdurdodedig ac amodau defnyddio mewn categorïau bwyd), yn y tabl—

(a) yng nghategori 01.4 (cynhyrchion llaeth epleseidig â chyflas gan gynnwys cynhyrchion sydd wedi eu trin â gwres), yn lle'r cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and E 960c	Steviol glycosides	100	(1) (60)	only energy-reduced products or with no added sugar";
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(b) yng nghategori 03 (iâ bwytdwy), yn lle'r cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and E 960c	Steviol glycosides	200	(1) (60)	only energy-reduced products or with no added sugar";
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(c) yng nghategori 04.2.2 (ffrwythau a llysiau mewn finegr, olew neu heli), yn lle'r cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and E 960c	Steviol glycosides	100	(1) (60)	only sweet-sour preserves of fruit
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				and vegetables”;
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- (d) yng nghategori 04.2.4.1 (paratoadau ffrwythau a llysiau ac eithrio compot), yn lle’r cofnod ar gyfer “E 960” (glycosidau stefiol) rhodder—

“E 960a and E 960c	Steviol glycosides	200	(1) (60)	only energy-reduced”;
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- (e) yng nghategori 04.2.5.1 (jam ecstra a jeli ecstra), yn lle’r cofnod ar gyfer “E 960” (glycosidau stefiol) rhodder—

“E 960a and E 960c	Steviol glycosides	200	(1) (60)	only energy-reduced jams, jellies and marmalades”;
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- (f) yng nghategori 04.2.5.2 (jam, jeliâu a marmaledau a phiwri castan a felyswyd), yn lle’r cofnod ar gyfer “E 960” (glycosidau stefiol) rhodder—

“E 960a and E 960c	Steviol glycosides	200	(1) (60)	only energy-reduced jams, jellies and marmalades”;
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- (g) yng nghategori 04.2.5.3 (ffrwythau neu llysiau taenu tebyg eraill), yn lle’r cofnod ar gyfer “E 960” (glycosidau stefiol) rhodder—

“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) yng nghategori 05.1 (cynhyrchion coco a siocled), yn lle’r cofnod ar gyfer “E 960” (glycosidau stefiol) rhodder—

“E 960a and E 960c	Steviol glycosides	270	(1) (60)	only energy-reduced or with no added sugar”;
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- (i) yng nghategori 05.2 (melysion eraill gan gynnwys microfelysion ar gyfer puro’r anadl)—

- (i) yn lle’r cofnod cyntaf ar gyfer “E 960” (glycosidau stefiol) rhodder—

“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) yn lle’r ail gofnod ar gyfer “E 960” (glycosidau stefiol) rhodder—

“E 960a and E 960c	Steviol glycosides	330	(1) (60)	only cocoa, milk, dried-fruit-based or fat-based sandwich spreads, energy-
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				reduced or with no added sugar”;
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(iii) yn lle'r trydydd cofnod ar gyfer “E 960” (glycosidau stefiol) rhodder—

“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) yn lle'r pedwerydd cofnod ar gyfer “E 960” (glycosidau stefiol) rhodder—

“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) yn lle'r pumed cofnod ar gyfer “E 960” (glycosidau stefiol) rhodder—

“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) yng nghategori 05.3 (gwm cnoi), yn lle'r cofnod ar gyfer “E 960” (glycosidau stefiol) rhodder—

“E 960a and E 960c	Steviol glycosides	3300	(1) (60)	only with no added sugar”;
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(k) yng nghategori 05.4 (addurniadau, caenau a llenwadau, ac eithrio llenwadau wedi eu seilio ar ffrwythau a gwmpesir gan gategori 4.2.4)—

(i) yn lle'r cofnod cyntaf ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and E 960c	Steviol glycosides	330	(1) (60)	only confectionery with no added sugar";
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(ii) yn lle'r ail gofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"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) yng nghategori 06.3 (grawnfwydydd brecwast), yn lle'r cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"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) yng nghategori 07.2 (danteithion popty), yn lle'r cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and E 960c	Steviol glycosides	330	(1) (60)	only essoblaten – wafer paper";
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(n) yng nghategori 09.2 (pysgod a chynhyrchion pysgodfeydd wedi eu prosesu gan gynnwys molysgiaid a chramenogion), yn lle'r cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"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) yng nghategori 11.4.1 (melysyddion bwrdd ar ffurf hylif), yn lle'r cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and E 960c	Steviol glycosides	<i>quantum satis</i> (1)	(60)";	
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(p) yng nghategori 11.4.2 (melysyddion bwrdd ar ffurf powdr), yn lle'r cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and	Steviol	<i>quantum satis</i>	(60)";	
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(1) Diffinnir "*quantum satis*" yn Erthygl 3(2)(h) o EUR 2008/1333.

E 960c	glycosides			
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- (q) yng nghategori 11.4.3 (melysyddion bwrdd mewn tabledi), yn lle'r cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and E 960c	Steviol glycosides	<i>quantum satis</i>	(60)";	
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- (r) yng nghategori 12.4 (mwstard), yn lle'r cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and E 960c	Steviol glycosides	120	(1) (60)";	
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- (s) yng nghategori 12.5 (cawliau a photesau), yn lle'r cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and E 960c	Steviol glycosides	40	(1) (60)	only energy-reduced soups";
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- (t) yng nghategori 12.6 (sawsiau)—

- (i) yn lle'r cofnod cyntaf ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and E 960c	Steviol glycosides	120	(1) (60)	except soy-bean sauce (fermented and non-fermented)";
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- (ii) yn lle'r ail gofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and E 960c	Steviol glycosides	175	(1) (60)	only soy-bean sauce (fermented and non-fermented)";
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- (u) yng nghategori 13.2 (bwydydd deietegol at ddibenion meddygol arbennig (ac eithrio cynhyrchion o gategori bwyd 13.1.5))—

- (i) yn lle'r cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and E 960c	Steviol glycosides	330	(1) (60)";	
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- (ii) yn y cofnod ar gyfer "E 960" (Advantame), yn lle "E 960" rhodder "E 969";

- (v) yng nghategori 13.3 (bwydydd deietegol ar gyfer deietau rheoli pwysau y bwriedir iddynt gymryd lle cyfanswm y cymeriant bwyd dyddiol neu bryd unigol)—

- (i) yn lle'r cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and E 960c	Steviol glycosides	270	(1) (60)";	
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- (ii) yn y cofnod ar gyfer "E 960" (Advantame), yn lle "E 960" rhodder "E 969";

- (w) yng nghategori 14.1.3 (neithdarau ffirwythau a neithdarau llysiau a chynhyrchion tebyg), yn lle'r cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"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) yng nghategori 14.1.4 (diodydd â chyfflas), yn lle'r cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

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

(i) yn lle’r cofnod cyntaf ar gyfer “E 960” (glycosidau steviol) rhodder—

“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) yn lle’r ail gofnod ar gyfer “E 960” (glycosidau steviol) rhodder—

“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) yn lle’r trydydd cofnod ar gyfer “E 960” (glycosidau steviol) rhodder—

“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) yng nghategori 14.2.1 (cwrw a diodydd brag), yn lle’r cofnod ar gyfer “E 960” (glycosidau steviol) rhodder—

“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
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				bruin” type”;
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(aa) yng nghategori 14.2.8 (diodydd alcoholaidd eraill gan gynnwys cymysgeddau o ddiodydd alcoholaidd gyda diodydd dialcohol a gwirodydd â llai na 15% o alcohol), yn lle’r cofnod ar gyfer “E 960” (glycosidau stefiol) rhodder—

“E 960a and E 960c	Steviol glycosides	150	(1) (60)”;	
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(bb) yng nghategori 15.1 (byrbrydau wedi eu seilio ar datws, grawnfwyd, blawd neu startsh), yn lle’r cofnod ar gyfer “E 960” (glycosidau stefiol) rhodder—

“E 960a and E 960c	Steviol glycosides	20	(1) (60)”;	
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(cc) yng nghategori 15.2 (cnau wedi eu prosesu), yn lle’r cofnod ar gyfer “E 960” (glycosidau stefiol) rhodder—

“E 960a and E 960c	Steviol glycosides	20	(1) (60)”;	
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(dd) yng nghategori 16 (pwdinau ac eithrio cynhyrchion a gwmpesir yng nghategoriâu 1, 3 a 4), yn lle’r cofnod ar gyfer “E 960” (glycosidau stefiol) rhodder—

“E 960a and E 960c	Steviol glycosides	100	(1) (60)	only energy-reduced or with no added sugar”;
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(ee) yng nghategori 17.1 (atchwanegiadau bwyd a gyflenwir ar ffurf solet, ac eithrio atchwanegiadau bwyd ar gyfer babanod a phlant ifanc)—

(i) yn lle’r cofnod cyntaf ar gyfer “E 960” (glycosidau stefiol) rhodder—

“E 960a and E 960c	Steviol glycosides	670	(1) (60)”;	
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(ii) yn lle’r ail gofnod ar gyfer “E 960” (glycosidau stefiol) rhodder—

“E 960a and E 960c	Steviol glycosides	1800	(1) (60)	only food supplements in chewable form”;
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(ff) yng nghategori 17.2 (atchwanegiadau bwyd a gyflenwir ar ffurf hylif, ac eithrio atchwanegiadau bwyd ar gyfer babanod a phlant ifanc)—

(i) yn lle’r cofnod cyntaf ar gyfer “E 960” (glycosidau stefiol) rhodder—

“E 960a and E 960c	Steviol glycosides	200	(1) (60)”;	
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(ii) yn lle’r ail gofnod ar gyfer “E 960” (glycosidau stefiol) rhodder—

“E 960a and E 960c	Steviol glycosides	1800	(1) (60)	only food supplements in syrup form”.
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Diwygiadau i'r Atodiad i Reoliad (EU) Rhif 231/2012 sy'n ymwneud â'r fanyleb ar gyfer E 960a glycosidau steviol o Stevia (E 960 glycosidau steviol yn flaenorol) ac i ychwanegu manyleb ar gyfer E 960c rebaudiosid M a gynhyrchir drwy addasu glycosidau steviol o Stevia ag ensymau

1. Yn Rheoliad y Comisiwn (EU) Rhif 231/2012, mae'r Atodiad (manylebau ar gyfer ychwanegion bwyd gan gynnwys lliwiau a melysyddion a restrir yn Atodiadau 2 a 3 i Reoliad (EC) Rhif 1333/2008) wedi ei ddiwygio fel a ganlyn.

2. Yn lle pennawd y cofnod ar gyfer "E 960 STEVIOL GLYCOSIDES" rhodder—

"E 960a STEVIOL GLYCOSIDES FROM STEVIA"

3. Yn y lle priodol, mewnosoder y cofnod a ganlyn—

"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>		
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)

Diwygiadau i'r rhestr ddomestig o sylweddau cyflasau yn Atodiad 1 i Reoliad (EC) Rhif 1334/2008 ar gyfer ychwanegu 3-(1-((3,5-deumethylisocsasol-4-yl)methyl)-1*H*-pyrasol-4-yl)-1-(3-hydrocsybensyl)imidasolidin-2,4-dion

1. Yn Rheoliad (EC) Rhif 1334/2008, mae Atodiad 1 (rhestr ddomestig o gyflasynnau a deunyddiau ffynhonnell) wedi ei ddiwygio fel a ganlyn.

2. Yn Rhan A (rhestr ddomestig o sylweddau cyflasau), yn Adran 2, yn Nhabl 1, yn y lle priodol mewnosoder y cofnod a ganlyn—

"16.127	3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1 <i>H</i> -pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione	1119 831-25-2	2161		At least 99%, assay (HPLC/UV)	Restrictions of use as a flavouring substance: In category 1.4 – not more than 4 mg/kg In category 1.8 – not more than 8 mg/kg In category 3 – not more than 4 mg/kg In category 5.1 – not more than 15 mg/kg 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	The Authority (1)".
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(1) Diffinnir "Authority" yn Erthygl 3(2)(l) o EUR 2008/1334.

						<p>In category 12.4 – not more than 25 mg/kg</p> <p>In category 12.5 – not more than 4 mg/kg</p> <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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Diwygiadau i'r rhestr o fwydydd newydd yn yr Atodiad i Reoliad Gweithredu'r Comisiwn (EU) 2017/2470 ar gyfer awdurdodi burum pobi sydd wedi ei drin ag UV (*Saccharomyces cerevisiae*) fel bwyd newydd

1. Yn Rheoliad Gweithredu'r Comisiwn (EU) 2017/2470, mae'r Atodiad (rhestr o fwydydd newydd) wedi ei ddiwygio fel a ganlyn.

2. Yn Nhabl 1 (bwydydd newydd awdurdodedig), yn lle'r cofnod ar gyfer "UV-treated baker's yeast (*Saccharomyces cerevisiae*)" rhodder—

"UV-treated baker's yeast (<i>Saccharomyces cerevisiae</i>)"	<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 "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 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 (Wales) 2003(1)	In accordance with any relevant requirements contained in regulations applying in relation to Wales and made under regulation 4 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019(2)		
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) O.S. 2003/1719 (Cy. 186), y mae diwygiadau iddo nad ydynt yn berthnasol i'r Rheoliadau hyn.

(2) O.S. 2019/651, a ddiwygiwyd gan O.S. 2020/1476 a 2023/28.

			<p>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 (excluding soups and salads)	3 µg/100 g	<p>The designation of the novel food on the labelling of food containing it is “vitamin D yeast” or “vitamin D₂ yeast”.</p>		
	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(1)	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			

(1) EUR 2013/609, a ddiwygiwyd gan O.S. 2019/651 a 2023/28. Diwygiwyd O.S. 2019/651 gan O.S. 2020/1476 a 2023/28.

	Other cereal-based products	3 µg/100 g			
	Spices, seasonings, condiments, sauce ingredients, dessert sauces/toppings	10 µg/100 g			
	Protein products	10 µg/100 g			
	Cheese	2 µg/100 g			
	Dairy desserts and similar products	2 µg/100 g			
	Fermented milk or fermented cream	1.5 µg/100 g			
	Dairy powders and concentrates	25 µg/100 g			
	Milk-based products, whey and cream	0.5 µg/100 g			
	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. Yn Nhabl 2 (manylebau) yn lle'r cofnod ar gyfer “UV-treated baker’s yeast (*Saccharomyces cerevisiae*)” rhodder—

<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 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 Synonym: Ergocalciferol CAS No.: 50-14-6 Molecular weight: 396.65 g/mol</p> <p>Microbiological criteria for the yeast concentrate</p> <p>Coliforms: ≤ 10³ CFU/g <i>Escherichia coli</i>: ≤ 10 CFU/g <i>Salmonella</i> spp.: Absence in 25 g</p> <p>CFU: Colony Forming Units”.</p>
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**Diwygiadau i'r rhestr o fwydydd newydd yn yr Atodiad i Reoliad
Gweithredu'r Comisiwn (EU) 2017/2470 ar gyfer awdurdodi powdr madarch
fitamin D₂ fel bwyd newydd**

1. Yn Rheoliad Gweithredu'r Comisiwn (EU) 2017/2470, mae'r Atodiad (rhestr o fwydydd newydd) wedi ei ddiwygio fel a ganlyn.

2. Yn Nhabl 1 (bwydydd newydd awdurdodedig), ar ôl y cofnod ar gyfer "Vitamin D₂ mushroom powder" mewnosoder y cofnod a ganlyn—

"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 containing vitamin D ₂ ". The labelling of food supplements, as defined in the Food Supplements (Wales) Regulations 2003, containing vitamin D ₂ mushroom powder must bear a statement that they should not be consumed by infants and children under 3 years of age.	Included in the list on 15 May 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: MBio, Monaghan Mushrooms, Tullygony, Tyholland, Co. Monaghan, Ireland, H18 FW95. During the period of data protection, vitamin D ₂ 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
	Breakfast cereals	2.1 µg/100 g		
	Yeast-leavened bread and similar pastries	2.1 µg/100 g		
	Grain products and pasta and similar products	2.1 µg/100 g		
	Fruit / vegetable juices and nectars	1.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)		
	Dairy products and analogues other than beverages	2.1 µg/100 g (marketed as such or reconstituted as instructed by the manufacturer)		
	Dairy products and analogues as beverages	1.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)		
	Milk and dairy powders	21.3 µg/100 g (marketed as such or reconstituted as instructed by the		

		manufacturer)			Regulation (EU) 2015/2283 or with the agreement of MBio, Monaghan Mushrooms.
	Meat analogues	2.1 µg/100 g			The data protection will expire at the end of 14 May 2028.”
	Soups	2.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)			
	Extruded vegetable snack	2.1 µg/100 g			
	Meal replacement for weight control	2.1 µg/100 g			
	Food for special medical purposes as defined in Regulation (EU) No 609/2013 excluding those intended for infants	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003 excluding food supplements for infants and children under 3 years of age	15 µg of vitamin D ₂ /day			

3. Yn Nhabl 2 (manylebau), ar ôl y cofnod ar gyfer “Vitamin D₂ mushroom powder” mewnosoder y cofnod a ganlyn—

“Vitamin D₂ 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

	<p>Vitamin D₂ content: 580-595 µg/g of mushroom powder Ash: ≤ 13.5% Water activity: < 0.5 Moisture content: ≤ 7.5% Carbohydrates: ≤ 35% Total dietary fibre: ≥ 15% Crude protein (N x 6.25): ≥ 22% Fat: ≤ 4.5%</p> <p>Heavy metals</p> <p>Lead: ≤ 0.5 mg/kg Cadmium: ≤ 0.5 mg/kg Mercury: ≤ 0.1 mg/kg Arsenic: ≤ 0.3 mg/kg</p> <p>Mycotoxins</p> <p>Aflatoxin B1: ≤ 0.1 µg/kg Aflatoxins (sum of B1 + B2 + G1 + G2): < 4 µg/kg</p> <p>Microbiological criteria</p> <p>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</p> <p>CFU: Colony Forming Units”.</p>
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Argraffwyd a chyhoeddwyd yn y DU gan Y Llyfrfa Cyf dan awdurdod a goruchwyliaeth Jeff James, Rheolwr Llyfrfa Ei Fawrhydi ac Argraffydd Deddfau Senedd y Brenin.

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—

“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—

“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> (1)	(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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(q) in category 11.4.3 (table-top sweeteners in tablets), for the entry for “E 960” (Steviol glycosides) substitute—

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

E 960c	glycosides			
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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—

“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 “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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(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	Steviol	150	(1) (60)”;	
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E 960c	glycosides			
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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—

“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>		
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)-1*H*-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—

"16.127	3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1 <i>H</i> -pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione	1119 831- 25-2	2161		At least 99%, assay (HPLC/UV)	Restrictions of use as a flavouring substance: In category 1.4 – not more than 4 mg/kg In category 1.8 – not more than 8 mg/kg In category 3 – not more than 4 mg/kg In category 5.1 – not more than 15 mg/kg 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	The Authority (1)".
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(1) "Authority" is defined in Article 3(2)(l) of EUR 2008/1334.

						<p>In category 12.4 – not more than 25 mg/kg</p> <p>In category 12.5 – not more than 4 mg/kg</p> <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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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>)”	<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 “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 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 2003(1)	In accordance with any relevant requirements contained in regulations applying in relation to Wales and made under regulation 4 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019(2)		
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. The labelling of the novel food must bear instructions for use for the final consumer to ensure a maximum concentration of 5µg/100g of vitamin D ₂ 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 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(1)	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			

(1) 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.

	Other cereal-based products	3 µg/100 g			
	Spices, seasonings, condiments, sauce ingredients, dessert sauces/toppings	10 µg/100 g			
	Protein products	10 µg/100 g			
	Cheese	2 µg/100 g			
	Dairy desserts and similar products	2 µg/100 g			
	Fermented milk or fermented cream	1.5 µg/100 g			
	Dairy powders and concentrates	25 µg/100 g			
	Milk-based products, whey and cream	0.5 µg/100 g			
	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 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 Synonym: Ergocalciferol CAS No.: 50-14-6 Molecular weight: 396.65 g/mol</p> <p>Microbiological criteria for the yeast concentrate</p> <p>Coliforms: ≤ 10³ CFU/g <i>Escherichia coli</i>: ≤ 10 CFU/g <i>Salmonella</i> spp.: Absence in 25 g</p> <p>CFU: Colony Forming Units”.</p>
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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 containing vitamin D ₂ ”. The labelling of food supplements, as defined in the Food Supplements (Wales) Regulations 2003, containing vitamin D ₂ mushroom powder must bear a statement that they should not be consumed by infants and children under 3 years of age.	Included in the list on 15 May 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: MBio, Monaghan Mushrooms, Tullygony, Tyholland, Co. Monaghan, Ireland, H18 FW95. During the period of data protection, vitamin D ₂ 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
	Breakfast cereals	2.1 µg/100 g		
	Yeast-leavened bread and similar pastries	2.1 µg/100 g		
	Grain products and pasta and similar products	2.1 µg/100 g		
	Fruit / vegetable juices and nectars	1.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)		
	Dairy products and analogues other than beverages	2.1 µg/100 g (marketed as such or reconstituted as instructed by the manufacturer)		
	Dairy products and analogues as beverages	1.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)		
	Milk and dairy powders	21.3 µg/100 g (marketed as such or reconstituted as instructed by the		

		manufacturer)			Regulation (EU) 2015/2283 or with the agreement of MBio, Monaghan Mushrooms.
	Meat analogues	2.1 µg/100 g			The data protection will expire at the end of 14 May 2028.”
	Soups	2.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)			
	Extruded vegetable snack	2.1 µg/100 g			
	Meal replacement for weight control	2.1 µg/100 g			
	Food for special medical purposes as defined in Regulation (EU) No 609/2013 excluding those intended for infants	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003 excluding food supplements for infants and children under 3 years of age	15 µg of vitamin D ₂ /day			

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

“Vitamin D₂ 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

	<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> <p>Lead: ≤ 0.5 mg/kg</p> <p>Cadmium: ≤ 0.5 mg/kg</p> <p>Mercury: ≤ 0.1 mg/kg</p> <p>Arsenic: ≤ 0.3 mg/kg</p> <p>Mycotoxins</p> <p>Aflatoxin B1: ≤ 0.1 µg/kg</p> <p>Aflatoxins (sum of B1 + B2 + G1 + G2): < 4 µg/kg</p> <p>Microbiological criteria</p> <p>Total plate count: ≤ 5000 CFU</p> <p>Total yeast and mould count: ≤ 100 CFU/g</p> <p><i>Escherichia coli</i>: < 10 CFU/g</p> <p><i>Salmonella</i> spp.: Absence in 25 g</p> <p><i>Staphylococcus aureus</i>: ≤ 10 CFU/g</p> <p>Coliforms: ≤ 10 CFU/g</p> <p><i>Listeria</i> spp.: Absence in 25 g</p> <p>Enterobacteriaceae: < 10 CFU/g</p> <p>CFU: Colony Forming Units”.</p>
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