



OFFERYNNAU STATUDOL CYMRU

2024 Rhif 741 (Cy. 102)

BWYD, CYMRU

Rheoliadau Ychwanegion Bwyd a Bwydydd Newydd
(Awdurdodiadau a Diwygiadau Amrywiol) a Chyflasynnau Bwyd
(Dileu Awdurdodiadau) (Cymru) 2024

<i>Gwnaed</i>	<i>5 Mehefin 2024</i>
<i>Gosodwyd gerbron Senedd Cymru</i>	<i>7 Mehefin 2024</i>
<i>Yn dod i rym</i>	<i>28 Mehefin 2024</i>

WELSH STATUTORY INSTRUMENTS

2024 No. 741 (W. 102)

FOOD, WALES

The Food Additives and Novel Foods
(Authorisations and Miscellaneous Amendments) and Food
Flavourings (Removal of Authorisations) (Wales) Regulations 2024

<i>Made</i>	<i>5 June 2024</i>
<i>Laid before Senedd Cymru</i>	<i>7 June 2024</i>
<i>Coming into force</i>	<i>28 June 2024</i>



OFFERYNNAU STATUDOL
CYMRU

WELSH STATUTORY
INSTRUMENTS

2024 Rhif 741 (Cy. 102)

2024 No. 741 (W. 102)

BWYD, CYMRU

FOOD, WALES

Rheoliadau Ychwanegion Bwyd a
Bwydydd Newydd (Awdurdodiadau
a Diwygiadau Amrywiol) a
Chyflasynnau Bwyd (Dileu
Awdurdodiadau) (Cymru) 2024

The Food Additives and Novel
Foods (Authorisations and
Miscellaneous Amendments) and
Food Flavourings (Removal of
Authorisations) (Wales)
Regulations 2024

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.

Gwneir Rhan 2 o'r Rheoliadau hyn (rheoliadau 2 a 3 ac Atodlenni 1 i 3) 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). Mae rheoliad 2 ac Atodlen 1 yn diweddarau, 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 rheoliad 3 ac Atodlenni 2 a 3 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'r diwygiadau a wneir yn Rhan 2 o'r Rheoliadau hyn yn darparu ar gyfer—

- awdurdodi, o ran Cymru, osod ar y farchnad a defnyddio'r ychwanegyn bwyd E 960b glycosidau steviol o eplesu (*Yarrowia lipolytica*);

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision, in relation to Wales, on regulated food product authorisations.

Part 2 of these Regulations (regulations 2 and 3 and Schedules 1 to 3) 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). 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). Regulation 3 and Schedules 2 and 3 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).

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 960b steviol glycosides from fermentation (*Yarrowia lipolytica*);

- awdurdodi, o ran Cymru, ddull cynhyrchu newydd ar gyfer ychwanegyn awdurdodedig sy'n bodoli eisoes: E 960c glycosidau stefiol a gynhyrchir yn ensymatig. Mae'r fanyleb ar gyfer y dull cynhyrchu sy'n bodoli eisoes yn yr Atodiad i EUR 2012/231 wedi ei hailrifo'n E 960c(i). Mae'r fanyleb ar gyfer y dull cynhyrchu newydd wedi ei mewnosod fel "E 960c(ii) rebaudioside M, AM and D produced via enzymatic conversion of highly purified steviol glycosides from Stevia leaf extracts";
- awdurdodi, o ran Cymru, ddefnydd newydd (iâ bwytdwy) ar gyfer yr ychwanegyn bwyd E 476 polyglyserol polyrisinolead, a diwygio defnydd awdurdodedig sy'n bodoli eisoes (sawsiau);
- cyflwyno uchafswm terfyn gweddillion o 0.1 mg/kg ar gyfer gweddillion ethylen ocsid sy'n gymwys i bob ychwanegyn bwyd awdurdodedig;
- mân gywiriadau amrywiol i Atodiad 2 i EUR 2008/1333.
- the authorisation, in relation to Wales, of a new production method for an existing authorised additive: E 960c enzymatically produced steviol glycosides. The specification for the existing production method in the Annex to EUR 2012/231 is renumbered as E 960c(i). The specification for the new production method is inserted as "E 960c(ii) rebaudioside M, AM and D produced via enzymatic conversion of highly purified steviol glycosides from Stevia leaf extracts";
- the authorisation, in relation to Wales, of a new use (edible ices) for the food additive E 476 polyglycerol polyricinoleate, and an amendment to an existing authorised use (sauces);
- the introduction of a maximum residue limit of 0.1 mg/kg for residues of ethylene oxide applying to all authorised food additives;
- minor miscellaneous corrections to Annex 2 to EUR 2008/1333.

Gwneir Rhan 3 o'r Rheoliadau hyn hefyd drwy arfer pwerau yn EUR 2008/1331. Mae rheoliad 4 yn dileu, o ran Cymru, 22 o sylweddau cyflasu o'r rhestr ddomestig o sylweddau cyflasu awdurdodedig 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 rheoliad 5 yn gwneud darpariaeth drosiannol i ganiatáu i gynhyrchion sy'n bodoli eisoes sy'n cynnwys y sylweddau hyn barhau i gael eu marchnata a'u defnyddio tan eu dyddiad parhauster lleiaf (dyddiad 'ar ei orau cyn') neu ddyddiad 'defnyddio erbyn'.

Gwneir Rhan 4 o'r Rheoliadau hyn (rheoliad 6 ac Atodlenni 4 i 8) drwy arfer pwerau yn Rheoliad (EU) 2015/2283 ar fwydydd newydd (EUR 2015/2283). Mae Rhan 4 yn diweddarau, o ran Cymru, y rhestr o fwydydd newydd awdurdodedig yn yr Atodiad i Reoliad Gweithredu'r Comisiwn (EU) 2017/2470 sy'n sefydlu rhestr yr Undeb o fwydydd newydd (EUR 2017/2470)—

- Mae Atodlen 4 yn mewnosod cofnod newydd, sy'n awdurdodi rhoi ar y farchnad brotein wedi ei hydroleiddio'n rhannol o haidd a ddisbyddwyd (*Hordeum vulgare*) a reis a ddisbyddwyd (*Oryza sativa*) fel bwyd newydd i'w ddefnyddio yn y categorïau bwyd penodedig.
- Schedule 4 inserts a new entry, authorising the placing on the market of partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) as a novel food for use in the specified food categories.

- Mae Atodlen 5 yn mewnosod cofnod newydd, sy'n awdurdodi rhoi ar y farchnad asidau brasterog wedi eu setyleiddio fel bwyd newydd i'w ddefnyddio mewn atchwanegiadau bwyd ar gyfer oedolion yn unig.
- Mae Atodlen 6 yn mewnosod cofnod newydd, sy'n awdurdodi rhoi ar y farchnad 3-ffwcosyl-lactos (3-FL) (o straen o *Escherichia coli* K-12 DH1) fel bwyd newydd i'w ddefnyddio yn y categorïau bwyd penodedig.
- Mae Atodlen 7 yn mewnosod cofnod newydd, sy'n awdurdodi rhoi ar y farchnad gymysgedd lacto-*N*-ffwcopentaos I (LNFP-I) a 2'-ffwcosyl-lactos (2'-FL) fel bwyd newydd i'w ddefnyddio yn y categorïau bwyd penodedig.
- Mae Atodlen 8 yn cywiro gwallau mewn cofnodion presennol—
 - Yn Nhabl 1 yn unig, disodlir y cofnod presennol ar gyfer “bovine milk basic whey protein isolate” er mwyn mynd i'r afael â gwallau fformadu yn y cofnod presennol.
 - Yn Nhabl 2 yn unig, diwygir y fanyleb ar gyfer Sylo-oligosaccharidau er mwyn ychwanegu'r paramedr ar gyfer “Dry material (%)”, a oedd ar goll o'r cofnod presennol.
- Schedule 5 inserts a new entry, authorising the placing on the market of cetylated fatty acids as a novel food for use in food supplements for adults only.
- Schedule 6 inserts a new entry, authorising the placing on the market of 3-fucosyllactose (3-FL) (from a strain of *Escherichia coli* K-12 DH1) as a novel food for use in the specified food categories.
- Schedule 7 inserts a new entry, authorising the placing on the market of lacto-*N*-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) mixture as a novel food for use in the specified food categories.
- Schedule 8 corrects errors in existing entries—
 - In Table 1 only, the existing entry for “bovine milk basic whey protein isolate” is replaced to address formatting errors in the existing entry.
 - In Table 2 only, the specification for Xylo-oligosaccharides is amended to add the parameter for “Dry material (%)”, which was missing from the existing entry.

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

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.

2024 Rhif 741 (Cy. 102)

2024 No. 741 (W. 102)

BWYD, CYMRU

FOOD, WALES

Rheoliadau Ychwanegion Bwyd a
Bwydydd Newydd (Awdurdodiadau
a Diwygiadau Amrywiol) a
Chyflasynnau Bwyd (Dileu
Awdurdodiadau) (Cymru) 2024

The Food Additives and Novel
Foods (Authorisations and
Miscellaneous Amendments) and
Food Flavourings (Removal of
Authorisations) (Wales)
Regulations 2024

Gwnaed 5 Mehefin 2024

Made 5 June 2024

*Gosodwyd gerbron Senedd
Cymru* 7 Mehefin 2024

Laid before Senedd Cymru 7 June 2024

Yn dod i rym 28 Mehefin 2024

Coming into force 28 June 2024

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(4) a (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(4) and (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, 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(4) 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 cyflasu sydd i'w defnyddio mewn bwydydd ac ar fwydydd (EUR 2008/1334).

(1) EUR 2008/1331, amended by S.I. 2019/860, 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(4) 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).

- Erthyglau 12(1) a 32A(3)(b) o Reoliad (EU) 2015/2283 Senedd Ewrop a'r Cyngor ar fwydydd newydd(1).

- Articles 12(1) and 32A(3)(b) of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods(1).

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(4) a (5) o Reoliad (EC) Rhif 1331/2008 (mewn perthynas â Rhannau 2 a 3 o'r Rheoliadau hyn)(2).

The Welsh Ministers have sought, and had regard to, advice from the Food Standards Agency as required by Article 7(4) and (5) of Regulation (EC) No 1331/2008 (in relation to Parts 2 and 3 of these Regulations)(2).

Ymgynghorwyd fel sy'n ofynnol gan 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(3).

There has been consultation as required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(3).

RHAN 1

Cyflwyniad

PART 1

Introduction

Enwi, rhychwant, cymhwyso a dod i rym

1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau Ychwanegion Bwyd a Bwydydd Newydd (Awdurdodiadau a Diwygiadau Amrywiol) a Chyflasynnau Bwyd (Dileu Awdurdodiadau) (Cymru) 2024.

(2) Mae'r Rheoliadau hyn—

- yn rhychwantu Cymru a Lloegr;
- yn gymwys o ran Cymru;
- yn dod i rym ar 28 Mehefin 2024.

Title, extent, application and coming into force

1.—(1) The title of these Regulations is the Food Additives and Novel Foods (Authorisations and Miscellaneous Amendments) and Food Flavourings (Removal of Authorisations) (Wales) Regulations 2024.

(2) These Regulations—

- extend to England and Wales;
- apply in relation to Wales;
- come into force on 28 June 2024.

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

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

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

PART 2

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.—(1) Yn Rheoliad y Comisiwn (EU) Rhif 231/2012 sy'n gosod manylbau ar gyfer ychwanegion bwyd a restrir yn Atodiadau II a III i Reoliad (EC) Rhif 1333/2008 Senedd Ewrop a'r Cyngor(2), mae'r Atodiad wedi ei ddiwygio fel a ganlyn.

(2) Ar y dechrau, ar gyfer “*Note: Ethylene oxide may not be used for sterilising purposes in food additives*” rhodder—

“Restrictions on ethylene oxide in food additives

Ethylene oxide may not be used for sterilising purposes in food additives.

Total residues of ethylene oxide (sum of ethylene oxide and 2-chloroethanol expressed as ethylene oxide*), irrespective of origin, in food additives listed in Annexes 2 and 3 to Regulation (EC) No 1333/2008 or mixtures of those food additives, must not exceed 0.1 mg/kg.

* ethylene oxide + (0.55 × 2-chloroethanol)”.

(3) Yn y cofnodion ar gyfer pob un o'r ychwanegion a ganlyn, hepgorer y rhes sy'n ymwneud ag “Ethylene oxide” —

- (a) E 431 Polyocsiethylen (40) stearad;
- (b) E 432 Polyocsiethylen sorbitan monolawrad (Polysorbad 20);
- (c) E 433 Polyocsiethylen sorbitan monoolead (Polysorbad 80);
- (d) E 434 Polyocsiethylen sorbitan monopalmitad (Polysorbad 40);

(1) EUR 2008/1333; yr offerynnau diwygio perthnasol yw O.S. 2019/860, 2023/343 (Cy. 50). Diwygiwyd O.S. 2019/860 gan O.S. 2020/1504.

(2) EUR 2012/231; yr offerynnau diwygio perthnasol yw O.S. 2019/860, 2023/343 (Cy. 50). Diwygiwyd O.S. 2019/860 gan O.S. 2020/1504.

PART 2

Food Additives

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.—(1) In 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), the Annex is amended as follows.

(2) At the beginning, for “*Note: Ethylene oxide may not be used for sterilising purposes in food additives*” substitute—

“Restrictions on ethylene oxide in food additives

Ethylene oxide may not be used for sterilising purposes in food additives.

Total residues of ethylene oxide (sum of ethylene oxide and 2-chloroethanol expressed as ethylene oxide*), irrespective of origin, in food additives listed in Annexes 2 and 3 to Regulation (EC) No 1333/2008 or mixtures of those food additives, must not exceed 0.1 mg/kg.

* ethylene oxide + (0.55 × 2-chloroethanol)”.

(3) In the entries for each of the following additives, omit the row relating to “Ethylene oxide” —

- (a) E 431 Polyoxyethylene (40) stearate;
- (b) E 432 Polyoxyethylene sorbitan monolaurate (Polysorbate 20);
- (c) E 433 Polyoxyethylene sorbitan monooleate (Polysorbate 80);
- (d) E 434 Polyoxyethylene sorbitan monopalmitate (Polysorbate 40);

(1) EUR 2008/1333; relevant amending instruments are S.I. 2019/860, 2023/343 (W. 50). S.I. 2019/860 was amended by S.I. 2020/1504.

(2) EUR 2012/231; relevant amending instruments are S.I. 2019/860, 2023/343 (W. 50). S.I. 2019/860 was amended by S.I. 2020/1504.

- (e) E 435 Polyocsiethylen sorbitan monostearad (Polysorbad 60);
- (f) E 436 Polyocsiethylen sorbitan tristearad (Polysorbad 65);
- (g) E 1209 Copolymer impiedig o bolyfinyl alcohol-polyethylen glycol;
- (h) E 1521 Polyethylen glycol.

(4) Mae Atodlen 2 yn gwneud darpariaeth mewn perthynas â'r fanyleb ar gyfer E 960b glycosidau stefiol o eplesu (*Yarrowia lipolytica*).

(5) Mae Atodlen 3 yn gwneud darpariaeth mewn perthynas â'r fanyleb ar gyfer E 960c(ii) rebaudiosid M, AM a D a gynhyrchir drwy drosi glycosidau stefiol puredig iawn o echdyniad dail Stevia ag ensymau.

- (e) E 435 Polyoxyethylene sorbitan monostearate (Polysorbate 60);
- (f) E 436 Polyoxyethylene sorbitan tristearate (Polysorbate 65);
- (g) E 1209 Polyvinyl alcohol-polyethylene glycol-*graft*-copolymer;
- (h) E 1521 Polyethylene glycol.

(4) Schedule 2 makes provision in relation to the specification for E 960b steviol glycosides from fermentation (*Yarrowia lipolytica*).

(5) Schedule 3 makes provision in relation to the specification for E 960c(ii) rebaudioside M, AM and D produced via enzymatic conversion of highly purified steviol glycosides from Stevia leaf extracts.

RHAN 3

Cyflasynnau Bwyd

Diwygio Rheoliad (EC) Rhif 1334/2008

4.—(1) Yn 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), mae Atodiad 1 (rhestr ddomestig o gyflasynnau a deunyddiau ffynhonnell) wedi ei diwygio fel a ganlyn.

(2) Yn Rhan A (rhestr ddomestig o sylweddau cyflasu), yn Adran 2, yn Nhabl 1, hepgorer y cofnodion ar gyfer y sylweddau cyflasu a ganlyn—

- (a) Rhif FL(2) “07.030” enw cemegol “1-(4-Methoxyphenyl) pent-1-en-3-one”;
- (b) Rhif FL “07.046” enw cemegol “Vanillylidene acetone”;
- (c) Rhif FL “07.049” enw cemegol “1-(4-Methoxyphenyl)-4-methylpent-1-en-3-one”;
- (d) Rhif FL “07.206” enw cemegol “4-(2,3,6-Trimethylphenyl)but-3-en-2-one”;
- (e) Rhif FL “07.258” enw cemegol “6-Methyl-3-hepten-2-one”;
- (f) Rhif FL “10.034” enw cemegol “5,6-Dihydro-3,6-dimethylbenzofuran-2(4H)-one”;
- (g) Rhif FL “10.036” enw cemegol “5,6,7,7a-Tetrahydro-3,6-dimethylbenzofuran-2(4H)-one”;

(1) EUR 2008/1334; yr offerynnau diwygio perthnasol yw O.S. 2019/860, 2023/343 (Cy. 50). Diwygiwyd O.S. 2019/860 gan O.S. 2020/1504.

(2) Rhif adnabod unigryw a ddyrannwyd gan Awdurdod Diogelwch Bwyd Ewrop o dan system wybodaeth yr UE am gyflasynnau, “FLAVIS”.

PART 3

Food Flavourings

Amendment of Regulation (EC) No 1334/2008

4.—(1) In 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), 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, omit the entries for the following flavouring substances—

- (a) FL No.(2) “07.030” chemical name “1-(4-Methoxyphenyl)pent-1-en-3-one”;
- (b) FL No. “07.046” chemical name “Vanillylidene acetone”;
- (c) FL No. “07.049” chemical name “1-(4-Methoxyphenyl)-4-methylpent-1-en-3-one”;
- (d) FL No. “07.206” chemical name “4-(2,3,6-Trimethylphenyl)but-3-en-2-one”;
- (e) FL No. “07.258” chemical name “6-Methyl-3-hepten-2-one”;
- (f) FL No. “10.034” chemical name “5,6-Dihydro-3,6-dimethylbenzofuran-2(4H)-one”;
- (g) FL No. “10.036” chemical name “5,6,7,7a-Tetrahydro-3,6-dimethylbenzofuran-2(4H)-one”;

(1) EUR 2008/1334; relevant amending instruments are S.I. 2019/860, 2023/343 (W. 50). S.I. 2019/860 was amended by S.I. 2020/1504.

(2) Unique identification number allocated by the European Food Safety Authority under the EU flavouring information system “FLAVIS”.

- | | |
|---|--|
| <p>(h) Rhif FL “10.042” enw cemegol “3,4-Dimethyl-5-pentylidenefuran-2(5H)-one”;</p> <p>(i) Rhif FL “10.043” enw cemegol “2,7-Dimethylocta-5(trans),7-dieno-1,4-lactone”;</p> <p>(j) Rhif FL “10.046” enw cemegol “Hex-2-eno-1,4-lactone”;</p> <p>(k) Rhif FL “10.054” enw cemegol “Non-2-eno-1,4-lactone”;</p> <p>(l) Rhif FL “10.060” enw cemegol “2-Decen-1,4-lactone”;</p> <p>(m) Rhif FL “10.170” enw cemegol “5-Pentyl-3H-furan-2-one”;</p> <p>(n) Rhif FL “13.004” enw cemegol “Allyl 2-furoate”;</p> <p>(o) Rhif FL “13.034” enw cemegol “3-(2-furyl)acrylaldehyde”;</p> <p>(p) Rhif FL “13.043” enw cemegol “Furfurylidene-2-butanal”;</p> <p>(q) Rhif FL “13.044” enw cemegol “4-(2-Furyl)but-3-en-2-one”;</p> <p>(r) Rhif FL “13.046” enw cemegol “3-(2-Furyl)-2-methylprop-2-enal”;</p> <p>(s) Rhif FL “13.066” enw cemegol “3-Acetyl-2,5-dimethylfuran”;</p> <p>(t) Rhif FL “13.103” enw cemegol “2-Butylfuran”;</p> <p>(u) Rhif FL “13.137” enw cemegol “3-(2-Furyl)-2-phenylprop-2-enal”;</p> <p>(v) Rhif FL “13.150” enw cemegol “3-(5-Methyl-2-furyl)prop-2-enal”.</p> | <p>(h) FL No. “10.042” chemical name “3,4-Dimethyl-5-pentylidenefuran-2(5H)-one”;</p> <p>(i) FL No. “10.043” chemical name “2,7-Dimethylocta-5(trans),7-dieno-1,4-lactone”;</p> <p>(j) FL No. “10.046” chemical name “Hex-2-eno-1,4-lactone”;</p> <p>(k) FL No. “10.054” chemical name “Non-2-eno-1,4-lactone”;</p> <p>(l) FL No. “10.060” chemical name “2-Decen-1,4-lactone”;</p> <p>(m) FL No. “10.170” chemical name “5-Pentyl-3H-furan-2-one”;</p> <p>(n) FL No. “13.004” chemical name “Allyl 2-furoate”;</p> <p>(o) FL No. “13.034” chemical name “3-(2-furyl)acrylaldehyde”;</p> <p>(p) FL No. “13.043” chemical name “Furfurylidene-2-butanal”;</p> <p>(q) FL No. “13.044” chemical name “4-(2-Furyl)but-3-en-2-one”;</p> <p>(r) FL No. “13.046” chemical name “3-(2-Furyl)-2-methylprop-2-enal”;</p> <p>(s) FL No. “13.066” chemical name “3-Acetyl-2,5-dimethylfuran”;</p> <p>(t) FL No. “13.103” chemical name “2-Butylfuran”;</p> <p>(u) FL No. “13.137” chemical name “3-(2-Furyl)-2-phenylprop-2-enal”;</p> <p>(v) FL No. “13.150” chemical name “3-(5-Methyl-2-furyl)prop-2-enal”.</p> |
|---|--|

Darpariaeth drosiannol

5.—(1) Mae'r paragraff hwn yn gymwys i sylweddau cyflasu y cyfeirir atynt yn rheoliad 4(2)(a) i (v) ynghyd â bwyd sy'n eu cynnwys a oedd—

- (a) yn bresennol yn y Deyrnas Unedig ac a oedd wedi, neu y gallent fod wedi, eu gosod yn gyfreithlon ar y farchnad ym Mhrydain Fawr cyn diwedd 27 Mehefin 2024, neu
- (b) ar dramwy i Brydain Fawr cyn diwedd 27 Mehefin 2024, ac y gallent fod wedi eu mewnfurio neu eu symud i mewn i Brydain Fawr yn gyfreithlon a'u gosod ar y farchnad ar y dyddiad hwnnw.

(2) Caiff sylweddau cyflasu a bwyd y mae paragraff (1) yn gymwys iddynt, hyd at eu dyddiad parhauster lleiaf neu eu dyddiad 'defnyddio erbyn', gael eu rhoi ar y farchnad ac, yn ôl y digwydd, eu hychwanegu at fwyd arall.

Transitional provision

5.—(1) This paragraph applies to flavouring substances referred to in regulation 4(2)(a) to (v) and food containing them that were—

- (a) present in the United Kingdom and were, or could have been, lawfully placed on the market in Great Britain before the end of 27 June 2024, or
- (b) in transit to Great Britain before the end of 27 June 2024, and could have lawfully been imported or moved into Great Britain and placed on the market on that date.

(2) Flavouring substances and food to which paragraph (1) applies may, until their date of minimum durability or 'use by' date, be placed on the market and, as the case may be, added to other food.

(3) Caiff bwyd sy'n cynnwys un neu ragor o'r sylweddau cyflasu y mae paragraff (1) yn gymwys iddynt, hyd at ei ddyddiad parhauster lleiaf neu ei ddyddiad 'defnyddio erbyn', gael ei roi ar y farchnad ac, yn ôl y digwydd, ei ychwanegu at fwyd arall.

(4) Yn y rheoliad hwn—

mae i “dyddiad ‘defnyddio erbyn’” (“*use by date*”) yr un ystyr ag “‘use by’ date” yn Erthygl 24 o Reoliad (EU) Rhif 1169/2011 Senedd Ewrop a'r Cyngor ar ddarparu gwybodaeth am fwyd i ddefnyddwyr(1);

mae i “dyddiad parhauster lleiaf” (“*date of minimum durability*”) yr un ystyr â “date of minimum durability” yn Rheoliad (EU) Rhif 1169/2011 Senedd Ewrop a'r Cyngor ar ddarparu gwybodaeth am fwyd i ddefnyddwyr(2).

(5) Mae i ymadroddion Cymraeg eraill a ddefnyddir yn y rheoliad hwn sy'n cyfateb i ymadroddion Saesneg a ddefnyddir yn Rheoliad (EC) Rhif 1334/2008 Senedd Ewrop a'r Cyngor ar gyflwynnau a chynhwysion bwyd penodol â phriodoleddau cyflasu sydd i'w defnyddio mewn bwydydd ac ar fwydydd yr un ystyr â'r ymadroddion hynny yn y Rheoliad hwnnw.

(3) Food containing one or more flavouring substances to which paragraph (1) applies may, until its date of minimum durability or ‘use by’ date, be placed on the market and, as the case may be, be added to other food.

(4) In this regulation—

“date of minimum durability” (“*dyddiad parhauster lleiaf*”) has the same meaning as in Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers(1)(2);

“‘use by’ date” (“*dyddiad ‘defnyddio erbyn’*”) has the same meaning as in Article 24 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers.

(5) Other expressions used in this regulation and in 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 have the same meaning as in that Regulation.

RHAN 4

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(3) wedi ei ddiwygio yn unol ag Atodlenni 4 i 8.

PART 4

Novel Foods

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(3) is amended in accordance with Schedules 4 to 8.

Jayne Bryant

Y Gweinidog Iechyd Meddwl a'r Blynyddoedd Cynnar, o dan awdurdod Ysgrifennydd y Cabinet dros Iechyd a Gofal Cymdeithasol, un o Weinidogion Cymru
5 Mehefin 2024

Minister for Mental Health and Early Years, under the authority of the Cabinet Secretary for Health and Social Care, one of the Welsh Ministers

5 June 2024

(1) EUR 2011/1169; yr offerynnau diwygio perthnasol yw O.S. 2019/529, 778, 2020/1627. Diwygiwyd O.S. 2019/529 gan O.S. 2020/1501.

(2) Diffinnir y term “date of minimum durability of a food” yn Erthygl 2(2)(r) o EUR 2011/1169 ond gweler hefyd Erthyglau 9(1)(f) a 24.

(3) EUR 2017/2470; yr offerynnau diwygio perthnasol yw O.S. 2019/702, 2022/575 (Cy. 133), 2023/343 (Cy. 50).

(1) EUR 2011/1169; relevant amending instruments are S.I. 2019/529, 778, 2020/1627. S.I. 2019/529 was amended by S.I. 2020/1501.

(2) The term “date of minimum durability of a food” is defined in Article 2(2)(r) of EUR 2011/1169 but see also Articles 9(1)(f) and 24.

(3) EUR 2017/2470; relevant amending instruments are S.I. 2019/702, 2022/575 (W. 133), 2023/343 (W. 50).

Diwygio'r rhestr ddomestig o ychwanegion bwyd sydd wedi eu cymeradwyo i'w defnyddio mewn bwydydd yn Atodiad 2 i Reoliad (EC) Rhif 1333/2008

Diwygio Rheoliad (EC) Rhif 1333/2008

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.

Darpariaeth yn ymwneud ag ychwanegu E 960b (glycosidau stefiol o eplesu) ac E 960c(ii) (rebaudiosid M, AM a D a gynhyrchir drwy drosi glycosidau stefiol puredig iawn o echdyniad dail Stevia ag ensymau) at y rhestr ddomestig

2. Yn Rhan B (rhestr o'r holl ychwanegion), ym mharagraff 2 (melysyddion), yn y tabl, ar ôl y cofnod ar gyfer "E 960a" (glycosidau stefiol o Stevia) mewnosoder y cofnod a ganlyn—

"E 960b	Steviol glycosides from fermentation".
---------	--

3. Yn Rhan C (diffiniadau o grwpiau o ychwanegion), ym mharagraff 5 (ychwanegion eraill y caniateir eu rheoleiddio yn gyfun), yn is-baragraff (v)—

- (a) yn y testun o flaen y tabl, yn lle "E 960a and E 960c: Steviol Glycosides" rhodder "E 960a - E 960c: Steviol glycosides";
- (b) yn y tabl, ar ôl y cofnod ar gyfer "E 960a" (glycosidau stefiol o Stevia) mewnosoder y cofnod a ganlyn—

"E 960b	Steviol glycosides from fermentation".
---------	--

4. Yn Rhan E (ychwanegion bwyd awdurdodedig ac amodau defnyddio mewn categorïau bwyd), yn y tabl, yn lle "E 960a and E 960c", ym mhob lle y mae'n digwydd, rhodder "E 960a – E 960c".

Darpariaeth yn ymwneud â defnydd awdurdodedig newydd, a diwygio defnydd awdurdodedig presennol, ar gyfer E 476 (polyglyserol polyrisinolead)

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

- (a) yng nghategori 03 (iâ bwytdwy), ar ôl y cofnod ar gyfer "E 473-474" (esterau swcros o asidau brasterog – swcroglyseridau) mewnosoder y cofnod a ganlyn—

"E 476	Polyglycerol polyricinoleate	4000		except sorbets";
--------	------------------------------	------	--	------------------

- (b) yng nghategori 12.6 (sawsiau), yn lle'r cofnod ar gyfer "E 476" (polyglyserol polyrisinolead) rhodder—

"E 476	Polyglycerol polyricinoleate	4000		only emulsified sauces with a fat content of less than 20%
E 476	Polyglycerol polyricinoleate	8000		only emulsified sauces with a fat content of 20% or more".

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

- (a) ar ddiwedd categori 05.1 (cynhyrchion coco a siocled), yn y lle priodol, mewnosoder y troednodyn a ganlyn—

“(1): The additives may be added individually or in combination”;

- (b) yng nghategori 05.2 (melysion eraill gan gynnwys microfelysion ar gyfer puro'r anadl)—
- (i) yn y trydydd cofnod ar gyfer “Group IV” (polyolau), yn lle “only cocoa or dried fruit-based, milk or fat-based sandwich spreads,” rhodder “sandwich spreads made with a base of cocoa, milk, dried fruit or fat;”;
 - (ii) yn y cofnod cyntaf ar gyfer “E 960a – E 960c” (glycosidau stefiol) fel y'i diwygir gan baragraff 4 o'r Atodlen hon, yn lle “only cocoa or dried-fruit-based” rhodder “only cocoa or dried fruit based”;
 - (iii) yn yr ail gofnod ar gyfer “E 960a – E 960c” (glycosidau stefiol) fel y'i diwygir gan baragraff 4 o'r Atodlen hon, yn lle “only cocoa, milk, dried-fruit-based or fat-based sandwich spreads,” rhodder “sandwich spreads made with a base of cocoa, milk, dried fruit or fat;”;
- (c) yng nghategori 05.4 (addurniadau, caenau a llenwadau, ac eithrio llenwadau wedi eu seilio ar ffrwythau a gwmpesir gan gategori 4.2.4), yn yr ail gofnod ar gyfer “E 960a – E 960c” (glycosidau stefiol) fel y'i diwygir gan baragraff 4 o'r Atodlen hon, yn lle “only cocoa or dried-fruit-based,” rhodder “only cocoa or dried fruit based;”.

Diwygio'r Atodiad i Reoliad (EU) Rhif 231/2012 ar gyfer ychwanegu manyleb ar gyfer E 960b glycosidau steviol o eplesu (*Yarrowia lipolytica*)

1. Yn Rheoliad y Comisiwn (EU) Rhif 231/2012, mae'r Atodiad (manylebau ar gyfer ychwanegion bwyd) wedi ei ddiwygio fel a ganlyn.

2. Ar ôl y cofnod ar gyfer "E 960a" (glycosidau steviol o Stevia), mewnosoder y cofnod a ganlyn—

"E 960b STEVIOL GLYCOSIDES FROM FERMENTATION (YARROWIA LIPOLYTICA)

Synonyms																
Definition	<p>Steviol glycosides from <i>Yarrowia lipolytica</i> consist of a mixture predominantly composed of rebaudioside M, with some rebaudioside D, and smaller amounts of rebaudioside A and rebaudioside B. The manufacturing process comprises two main phases.</p> <p>The first phase involves fermentation of a non-toxicogenic non-pathogenic strain of <i>Yarrowia lipolytica</i> VRM that has been genetically modified with heterologous genes to overexpress steviol glycosides. Removal of biomass by solid-liquid separation and heat treatment is followed by concentration of the steviol glycosides.</p> <p>The second phase involves purification by employing ion-exchange chromatography, followed by recrystallisation of the steviol glycosides resulting in a final product containing not less than 95% of rebaudiosides M, D, A, and B.</p> <p>Viable cells or the DNA of <i>Yarrowia lipolytica</i> VRM must not be detected in the food additive.</p>															
Chemical name	<p>Rebaudioside A: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester</p> <p>Rebaudioside B: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid</p> <p>Rebaudioside D: 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-β-D-glucopyranosyl ester</p> <p>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</p>															
Molecular formula	<table border="1"> <thead> <tr> <th><i>Trivial name</i></th> <th><i>Formula</i></th> <th><i>Conversion factor</i></th> </tr> </thead> <tbody> <tr> <td>Rebaudioside A</td> <td>C₄₄H₇₀O₂₃</td> <td>0.33</td> </tr> <tr> <td>Rebaudioside B</td> <td>C₃₈H₆₀O₁₈</td> <td>0.40</td> </tr> <tr> <td>Rebaudioside D</td> <td>C₅₀H₈₀O₂₈</td> <td>0.29</td> </tr> <tr> <td>Rebaudioside M</td> <td>C₅₆H₉₀O₃₃</td> <td>0.25</td> </tr> </tbody> </table>	<i>Trivial name</i>	<i>Formula</i>	<i>Conversion factor</i>	Rebaudioside A	C ₄₄ H ₇₀ O ₂₃	0.33	Rebaudioside B	C ₃₈ H ₆₀ O ₁₈	0.40	Rebaudioside D	C ₅₀ H ₈₀ O ₂₈	0.29	Rebaudioside M	C ₅₆ H ₉₀ O ₃₃	0.25
<i>Trivial name</i>	<i>Formula</i>	<i>Conversion factor</i>														
Rebaudioside A	C ₄₄ H ₇₀ O ₂₃	0.33														
Rebaudioside B	C ₃₈ H ₆₀ O ₁₈	0.40														
Rebaudioside D	C ₅₀ H ₈₀ O ₂₈	0.29														
Rebaudioside M	C ₅₆ H ₉₀ O ₃₃	0.25														
Molecular weight and CAS number	<table border="1"> <thead> <tr> <th><i>Trivial name</i></th> <th><i>CAS Number</i></th> <th><i>Molecular weight (g/mol)</i></th> </tr> </thead> <tbody> <tr> <td>Rebaudioside A</td> <td>58543-16-1</td> <td>967.01</td> </tr> </tbody> </table>	<i>Trivial name</i>	<i>CAS Number</i>	<i>Molecular weight (g/mol)</i>	Rebaudioside A	58543-16-1	967.01									
<i>Trivial name</i>	<i>CAS Number</i>	<i>Molecular weight (g/mol)</i>														
Rebaudioside A	58543-16-1	967.01														

	Rebaudioside B	58543-17-2	804.88
	Rebaudioside D	63279-13-0	1129.15
	Rebaudioside M	1220616-44-3	1291.29
Assay	Not less than 95% of rebaudioside M, rebaudioside D, rebaudioside A, and rebaudioside B 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 0.1 mg/kg		
Lead	Not more than 0.1 mg/kg		
Cadmium	Not more than 0.01 mg/kg		
Mercury	Not more than 0.05 mg/kg		
Residual protein	Not more than 20 mg/kg		
Microbiological criteria			
Total (aerobic) plate count	Not more than 1000 CFU/g		
Yeast	Not more than 100 CFU/g		
Moulds	Not more than 100 CFU/g		
<i>Escherichia coli</i>	Negative in 1g		
<i>Salmonella</i> spp.	Negative in 25g".		

Diwygio'r Atodiad i Reoliad (EU) Rhif 231/2012 ynghylch ailrifo ychwanegyn E 960c(i) (E 960c yn flaenorol) ac ar gyfer ychwanegu manyleb ar gyfer E 960c(ii) rebaudiosid M, AM a D a gynhyrchir drwy drosi glycosidau stefiol puredig iawn o echdyniad dail Stevia ag ensymau

1. Yn Rheoliad y Comisiwn (EU) Rhif 231/2012, mae'r Atodiad (manylebau ar gyfer ychwanegion bwyd) wedi ei ddiwygio fel a ganlyn.

2. Ym mhennawd y cofnod ar gyfer "E 960c" (rebaudiosid M a gynhyrchir drwy addasu glycosidau stefiol o Stevia ag ensymau) yn lle "E 960c" rhodder "E 960c(i)".

3. Ar ôl y cofnod ar gyfer "E 960c(i)", fel y'i diwygir gan baragraff 2 o'r Atodlen hon, mewnosoder y cofnod a ganlyn—

"E 960c(ii) REBAUDIOSIDE M, AM AND D PRODUCED VIA ENZYMATIC CONVERSION OF HIGHLY PURIFIED STEVIOL GLYCOSIDES FROM STEVIA LEAF EXTRACTS

Synonyms			
Definition	<p>Steviol glycosides produced via enzymatic conversion of highly purified steviol glycosides (rebaudioside A or stevioside) from Stevia leaf extracts are composed predominantly of rebaudioside M, rebaudioside D, and rebaudioside AM.</p> <p>Rebaudiosides D, M and AM are produced via enzymatic conversion of highly purified steviol glycoside (rebaudioside A or stevioside) extracts (95% steviol glycosides) obtained from <i>Stevia rebaudiana</i> Bertoni plant using UDP-glucosyltransferase and sucrose synthase enzymes produced by genetically modified strains of <i>Escherichia coli</i> (pPM294, pFAH170, and pSK041) 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 steviol glycosides by resin adsorption, followed by recrystallisation of the steviol glycosides resulting in a final product containing not less than 95 % of total steviol glycosides, including one or more of rebaudiosides D, M and AM.</p> <p>Viable cells or DNA of <i>Escherichia coli</i> (pPM294, pFAH170, and pSK041) must not be detected in the food additive.</p>		
Chemical Name	<p>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</p> <p>Rebaudioside D: 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-β-D-glucopyranosyl ester</p> <p>Rebaudioside AM: 13-[(2-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</p>		
Molecular formula	<i>Trivial name</i>	<i>Formula</i>	<i>Conversion factor</i>
	Rebaudioside M	C ₅₆ H ₉₀ O ₃₃	0.25

	Rebaudioside D	$C_{50}H_{80}O_{28}$	0.29
	Rebaudioside AM	$C_{50}H_{80}O_{28}$	0.29
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
	Rebaudioside D	63279-13-0	1129.15
	Rebaudioside AM	2222580-26-7	1129.15
Assay	Not less than 95 % of steviol glycosides on the dried basis, including one or more of rebaudiosides D, M and AM.		
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".		

Diwygio’r rhestr o fwydydd newydd yn yr Atodiad i Reoliad Gweithredu’r Comisiwn (EU) 2017/2470 ar gyfer awdurdodi protein wedi ei hydroleiddio’n rhannol o haidd a ddisbyddwyd (*Hordeum vulgare*) a reis a ddisbyddwyd (*Oryza sativa*) 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 “Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae” mewnosoder y cofnod a ganlyn—

“Partially hydrolysed protein from spent barley (<i>Hordeum vulgare</i>) and rice (<i>Oryza sativa</i>)	Specified food category	Maximum levels	The designation of the novel food on the labelling of food containing it is “partially hydrolysed protein from spent barley and rice”.	Included in the list on 28 June 2024.	
	Bread and similar products	15 g/100 g			This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Evergrain LLC, 1 Busch Place, St. Louis, Missouri 63118, USA. During the period of data protection, partially hydrolysed protein from spent barley (<i>Hordeum vulgare</i>) and rice (<i>Oryza sativa</i>) is authorised for placing on the market, within Wales, only by Evergrain LLC unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence
	Fine bakery wares	15 g/100 g			
	Breakfast cereals	30 g/100 g			
	Margarines and similar	10 g/100 g			
	Butter and margarine/oil blends	10 g/100 g			
	Pasta and rice (and other cereal)-based dishes	30 g/100 g			
	Fried or extruded cereal, seed, and root-based products	30 g/100 g			
	Fruit/vegetable spreads and similar	30 g/100 g			
	Confectionary including chocolate	15 g/100 g			
	Dairy imitates	50 g/100 ml (beverages) 50 g/100 g (products other than beverages)			
	Milk and dairy products	50 g/100 ml (beverages) 50 g/100 g (products other than beverages)			

Dessert sauces/ toppings	15 g/100 g			<p>or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Evergrain LLC.</p> <p>The data protection will expire at the end of 27 June 2029.”</p>
Syrups (molasses and other syrups)	15 g/100 g			
Meat analogues	30 g/100 g			
Soups (marketed as such or reconstituted as instructed by the manufacturer)	15 g/100 g			
Stock cubes and granules (bouillon base)	15 g/100 g			
Gravy ingredients	10 g/100 g			
Savoury sauces	10 g/100 g			
Condiments (including table-top formats)	10 g/100 g			
Hummus	30 g/100 g			
Nut/seeds paste/emulsion/ mass	20 g/100 g			
Energy drinks	90 g/100 ml			
Carbohydrate-rich energy food products for sports people	30 g/100 g			
Protein and protein components for sports people	90 g/100 g			
Meal replacement for weight control	90 g/100 g			

3. Yn Nhabl 2 (manylebau), ar ôl y cofnod ar gyfer “Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae” mewnosoder y cofnod a ganlyn—

<p>“Partially hydrolysed protein from spent barley (<i>Hordeum vulgare</i>) and rice (<i>Oryza sativa</i>)</p>	<p>Description/Definition</p> <p>Partially hydrolysed protein from spent barley (<i>Hordeum vulgare</i>) and rice (<i>Oryza sativa</i>) is an off-white powder, produced by concentration of proteins from a mixture of barley and rice from the mash step of beer production using a series of enzymatic hydrolysis and mechanical purification steps.</p>
---	--

Characteristics/Composition

Protein (dry basis): $\geq 85\%$

Moisture: $< 8\%$

Total Carbohydrates: $< 10\%$

Fat: $< 2\%$

Ash: $< 8\%$

Heavy metals

Arsenic: < 0.1 mg/kg

Cadmium: < 0.1 mg/kg

Lead: < 0.2 mg/kg

Mercury: < 0.1 mg/kg

Microbiological criteria

Aerobic plate count: $< 30,000$ CFU/g

Coliforms: < 10 CFU/g

Yeast and mould: < 50 CFU/g

Salmonella spp.: Negative in 25 g

Escherichia coli: < 10 CFU/g

Staphylococcus aureus: < 10 CFU/g

Listeria spp.: Negative in 25 g

CFU: Colony Forming Units".

Diwygio'r rhestr o fwydydd newydd yn yr Atodiad i Reoliad Gweithredu'r Comisiwn (EU) 2017/2470 ar gyfer awdurdodi asidau brasterog wedi eu setyleiddio 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 "*Calanus finmarchicus* oil" mewnosoder y cofnod a ganlyn—

"Cetylated fatty acids"	<i>Specified food category</i>	<i>Maximum levels</i>		Included in the list on 28 June 2024.
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003(1) for persons aged 18 years or above	2.1 g/day	<p>The designation of the novel food on the labelling of food containing it is "cetylated fatty acids preparation".</p> <p>The labelling of food supplements must bear a statement that they should not be consumed by persons under 18 years of age.</p>	<p>This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.</p> <p>Applicant: Pharmanutra S.p.A, Via Delle Lenze 216/b, 56122 Pisa, Italy.</p> <p>During the period of data protection, cetylated fatty acids is authorised for placing on the market, within Wales, only by Pharmanutra S.p.A unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU)</p>

(1) O.S. 2003/1719 (Cy. 186), y mae diwygiadau iddo nad ydynt yn berthnasol i'r Rheoliadau hyn.

			<p>2015/2283 or with the agreement of Pharmanutra S.p.A.</p> <p>The data protection will expire at the end of 27 June 2029.”</p>
--	--	--	--

3. Yn Nhabl 2, (manylebau), ar ôl y cofnod ar gyfer “*Calanus finmarchicus* oil” mewnosoder y cofnod a ganlyn—

<p>“Cetylated Fatty Acids</p>	<p>Description/Definition</p> <p>The novel food is a mixture of 70 – 80% cetylated fatty acids which are produced from the reaction of cetyl alcohol with myristic acid and oleic acid.</p> <p>Characteristics/Composition</p> <p>Physical status at 25°C: Solid Colour (APHA Colour): ≤ 600 Acid value (mg KOH/g): ≤ 5 Iodine value (I₂/100g): 30 – 50 Saponification value (mg KOH/g): 130 – 150 Hydroxyl value (mg KOH/g): ≤ 20 Ester content (%): 70 – 80 Cetyl oleate (%): 22 – 30 Cetyl myristate (%): 41 – 56 Triglycerides (%): 22 – 25</p> <p>Microbiological criteria</p> <p>Total aerobic microbial count (CFU/g): ≤ 1000 Yeasts and moulds (CFU/g): ≤ 100</p> <p>APHA: American Public Health Association KOH: potassium hydroxide CFU: Colony Forming Units”.</p>
--------------------------------------	--

Diwygio'r rhestr o fwydydd newydd yn yr Atodiad i Reoliad Gweithredu'r Comisiwn (EU) 2017/2470 ar gyfer awdurdodi 3-ffwcosyl-lactos (3-FL) (a gynhyrchir gan straen deilliannol o *Escherichia coli* K-12 DH1) 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 "2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL') (microbial source)" mewnosoder y cofnod a ganlyn—

"3-Fucosyllactose (3-FL) (produced by a derivative strain of <i>Escherichia coli</i> K-12 DH1)	<i>Specified food category</i>	<i>Maximum levels</i>		
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	2.0 g/l	The designation of the novel food on the labelling of food containing it is "3-fucosyllactose".	Included in the list on 28 June 2024. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
	Unflavoured fermented milk-based products	2.0 g/l (beverages) 4.0 g/kg (products other than beverages)	The labelling of food supplements intended for infants and young children must bear a statement that they should not be consumed if breast milk or food with added 3-fucosyllactose is consumed on the same day.	Applicant: Glycom A/S, Kogle Allé 4, 2970 Hørsholm, Denmark.
	Flavoured fermented milk-based products including heat-treated products	2.0 g/l (beverages) 12.0 g/kg (products other than beverages)		
	Cereal bars	25.0 g/kg		During the period of data protection, 3-fucosyllactose is authorised for placing on the market, within Wales, only by Glycom A/S unless a subsequent
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013(1)	2.0 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Milk-based drinks and similar products intended for young children (persons aged 1 year (12 months) up to the age of 3	2.0 g/l (beverages) in the final product ready for use, marketed as such or reconstituted as		

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

	years (36 months))	instructed by the manufacturer 12.0 g/kg (products other than beverages)			<p>applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Glycom A/S.</p> <p>The data protection will expire at the end of 27 June 2029.”</p>
	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			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	2.0 g/l (beverages) 25.0 g/kg (products other than beverages)			
	Flavoured drinks (excluding cola flavour and cola flavoured drinks)	1.25 g/l			
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003 intended for infants (persons under the age of 1 year (12 months)) and young children (persons aged 1 year (12 months) up to the age of 3 years (36 months))	2.0 g/day			
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003 excluding food supplements for infants and young children	4.0 g/day			

3. Yn Nhabl 2 (manylebau), ar ôl y cofnod ar gyfer “2’-Fucosyllactose/Difucosyllactose mixture (‘2’-FL/DFL’) (microbial source)” mewnosoder y cofnod a ganlyn—

<p>“3-Fucosyllactose (3-FL) (produced by a derivative strain of <i>Escherichia coli</i> K-12 DH1)</p>	<p>Description/Definition</p> <p>3-Fucosyllactose (3-FL) (produced by a derivative strain of <i>Escherichia coli</i> K-12 DH1) is a purified carbohydrate powder or agglomerate containing at least 90% of 3-fucosyllactose on a dry matter basis obtained from microbial fermentation with a genetically modified strain of <i>Escherichia coli</i> K-12 DH1.</p> <p>Chemical name: β-D-Galactopyranosyl-(1\rightarrow4)- [α-L-fucopyranosyl-(1\rightarrow3)]- D-glucopyranose Chemical formula: C₁₈H₃₂O₁₅ Molecular mass: 488.44 Da CAS No: 41312-47-4</p> <p>Characteristics/Composition</p> <p>Appearance: Powder, agglomerates, powder with agglomerates Colour: White to off-white Assay (water-free) – Specified saccharides (includes 3-FL, D-lactose, L-fucose, and 3-fucosyllactulose): ≥ 92.0 % (w/w) Assay (water-free) – 3-FL: ≥ 90.0 % (w/w) L-Fucose: ≤ 1.0 % (w/w) D-Lactose: ≤ 5.0 % (w/w) 3-Fucosyllactulose: ≤ 1.5 % (w/w) Sum of other carbohydrates: ≤ 5.0 % (w/w) pH in 5% solution (20°C): 3.2 – 7.0 Water: ≤ 6.0 % (w/w) Ash, sulphated: ≤ 0.5 % (w/w) Acetic acid (relevant for crystallised 3-FL): ≤ 1.0 % (w/w) Residual protein by Bradford assay: ≤ 0.01 % (w/w) Residual endotoxins: ≤ 10 EU/mg</p> <p>Heavy metals</p> <p>Lead: ≤ 0.1 mg/kg Arsenic: ≤ 0.2 mg/kg</p> <p>Mycotoxins</p> <p>Aflatoxin M1: ≤ 0.025 μg/kg</p> <p>Microbiological criteria</p> <p>Aerobic mesophilic total plate count: ≤ 1000 CFU/g Enterobacteriaceae: absent in 10g <i>Salmonella</i> spp.: absent in 25g <i>Bacillus cereus</i>: ≤ 50 CFU/g <i>Listeria monocytogenes</i>: absent in 25g <i>Cronobacter</i> spp.: absent in 10g Yeasts: ≤ 100 CFU/g Moulds: ≤ 100 CFU/g</p> <p>EU: Endotoxin Units CFU: Colony Forming Units”.</p>
--	---

Diwygio'r rhestr o fwydydd newydd yn yr Atodiad i Reoliad Gweithredu'r Comisiwn (EU) 2017/2470 ar gyfer awdurdodi cymysgedd lacto-*N*-ffwcopentaos I (LNFP-I) a 2'-ffwcosyl-lactos (2'-FL) 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 "Lactitol" mewnosoder y cofnod a ganlyn—

“Lacto-<i>N</i>-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) mixture	<i>Specified food category</i>	<i>Maximum levels of LNFP-I</i>		
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	1.0 g/l	The designation of the novel food on the labelling of food containing it is “lacto- <i>N</i> -fucopentaose I and 2'-fucosyllactose mixture”.	Included in the list on 28 June 2024. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
	Unflavoured fermented milk-based products	1.0 g/l (beverages) 2.0 g/kg (products other than beverages)	The labelling of food supplements intended for infants and young children must bear a statement that they should not be consumed if breast milk or food with added lacto- <i>N</i> -fucopentaose I (LNFP-I) or 2'-fucosyllactose (2'-FL) is consumed on the same day.	Applicant: Glycom A/S, Kogle Allé 4, 2970 Hørsholm, Denmark.
	Flavoured fermented milk-based products including heat-treated products	1.0 g/l (beverages) 10.0 g/kg (products other than beverages)	The labelling of food supplements must bear a statement that they should not be consumed if food with added lacto- <i>N</i> -fucopentaose I (LNFP-I) or 2'-fucosyllactose (2'-FL) is consumed on the same day.	During the period of data protection, lacto- <i>N</i> -fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) is authorised for placing on the market, within Wales, only by Glycom A/S unless a subsequent applicant obtains
	Cereal bars	10.0 g/kg		
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	1.5 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Processed cereal-based food and baby food for infants and young children as defined in	1.0 g/l (beverages) in the final product ready for use, marketed as such or reconstituted		

	Regulation (EU) No 609/2013	as instructed by the manufacturer 8.33 g/kg (products other than beverages)			<p>authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Glycom A/S.</p> <p>The data protection will expire at the end of 27 June 2029.”</p>
	Milk-based drinks and similar products intended for young children (persons aged 1 year (12 months) up to the age of 3 years (36 months))	1.2 g/l (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 10.0 g/kg (products other than beverages)			
	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			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	2.0 g/l (beverages) 20.0 g/kg (products other than beverages)			
	Flavoured drinks (excluding cola flavour and cola flavoured drinks)	1.0 g/l			
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003 for infants (persons	1.5 g/day			

	under the age of 1 year (12 months)) and young children (persons aged 1 year (12 months) up to the age of 3 years (36 months))				
	Food supplements as defined in the Food Supplements Regulations 2003 excluding supplements for infants and young children	3.0 g/day			

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

<p>“Lacto-<i>N</i>-fucopentaose I (LNFP-I) and 2’-fucosyllactose (2’-FL) mixture</p>	<p>Description/Definition</p> <p>Lacto-<i>N</i>-fucopentaose I (LNFP-I) and 2’-fucosyllactose (2’-FL) mixture is a purified carbohydrate powder or agglomerate obtained from microbial fermentation with a genetically modified strain of <i>Escherichia coli</i> K-12 DH1 containing at least 75% of LNFP-I and 2’-FL of dry matter, where $\geq 50\%$ is LNFP-I (dry weight) and $\geq 15\%$ is 2’-FL (dry weight).</p> <p>Characteristics/Composition</p> <p>Appearance: Powder, agglomerates, powder with agglomerates Colour: White to off-white Assay (water-free) Specified saccharides (includes LNFP-I, 2’-FL, lacto-<i>N</i>-tetraose, difucosyl-D-lactose, 3-fucosyllactose, D-lactose, L-fucose and 2’-fucosyl-lactitol, LNFP-I fructose isomer, and 2’-fucosyl-D-lactulose): $\geq 90.0\%$ (w/w) Assay (water-free) – LNFP-I and 2’-FL: $\geq 75.0\%$ (w/w) Assay (water-free) – LNFP-I: $\geq 50.0\%$ (w/w) Assay (water-free) – 2’-FL: $\geq 15.0\%$ (w/w) Lacto-<i>N</i>-tetraose: $\leq 5.0\%$ (w/w) 3-Fucosyllactose: $\leq 1.0\%$ (w/w) Sum of L-Fucose and 2’-fucosyl-lactitol: $\leq 1.0\%$ (w/w) D-Lactose: $\leq 10.0\%$ (w/w) Difucosyl-D-lactose: $\leq 2.0\%$ (w/w) LNFP-I fructose isomer: $\leq 1.5\%$ (w/w) 2’-Fucosyl-D-lactulose: $\leq 1.0\%$ (w/w) Sum of other carbohydrates: $\leq 6.0\%$ (w/w) pH in 5% solution (20°C): 4.0–7.0</p>
---	--

	<p>Water: ≤ 8.0 % (w/w) Ash, sulphated: ≤ 0.5 % (w/w) Residual protein by Bradford assay: ≤ 0.01 % (w/w)</p> <p>Heavy metals</p> <p>Arsenic: ≤ 0.2 mg/kg</p> <p>Mycotoxins</p> <p>Residual endotoxins: ≤ 10 EU/mg Aflatoxin M1: ≤ 0.025 μg/kg</p> <p>Microbiological criteria</p> <p>Aerobic mesophilic total plate count: ≤ 1000 CFU/g Enterobacteriaceae: Absent in 10g <i>Salmonella</i> spp.: Absent in 25 g Yeasts: ≤ 100 CFU/g Moulds: ≤ 100 CFU/g <i>Bacillus cereus</i>: ≤ 50 CFU/g <i>Listeria monocytogenes</i>: Absent in 25g <i>Cronobacter</i> spp.: Absent in 10g</p> <p>EU: Endotoxin Units CFU: Colony Forming Units”.</p>
--	---

Cywiro cofnodion presennol yn y rhestr o fwydydd newydd yn yr Atodiad i Reoliad Gweithredu'r Comisiwn (EU) 2017/2470

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

Cywiro'r cofnod yn Nhabl 1 ar gyfer "Bovine milk basic whey protein isolate"

2. Yn Nhabl 1 (bwydydd newydd awdurdodedig), yn lle'r cofnod ar gyfer "Bovine milk basic whey protein isolate" rhodder—

"Bovine milk basic whey protein isolate"	<i>Specified food category</i>	<i>Maximum levels</i>			
	Infant formula as defined in Regulation (EU) No 609/2013	30 mg/100 g (powder) 3.9 mg/100 ml (reconstituted)	The designation of the novel food on the labelling of food containing it is "Milk whey protein isolate". The labelling of food supplements must bear a statement, as appropriate, that they should not be consumed by infants (persons under the age of 1 year)/infants or young children (persons under the age of 3 years)/infants, children or adolescents (persons under the age of 18 years)."		
	Follow-on formula as defined in Regulation (EU) No 609/2013	30 mg/100 g (powder) 4.2 mg/100 ml (reconstituted)			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	300 mg/day			
	Food for special medical purposes as defined in Regulation (EU) No 609/2013	30 mg/100g (powder formula for infants (persons under the age of 1 year (12 months)) during first months of life until the introduction of appropriate complementary feeding) 3.9 mg/100ml (reconstituted formula for infants during the first months of life until the introduction of			

		<p>appropriate complementary feeding) 30 mg/100g (powder formula for infants when appropriate complementary feeding is introduced) 4.2 mg/100ml (reconstituted formula for infants when appropriate complementary feeding is introduced) 58 mg/day for young children (persons aged 1 year (12 months) up to the age of 3 years (36 months)) 380 mg/day for children and adolescents (persons aged 3 years (36 months) up to 18 years of age) 610 mg/day for persons aged 18 years or above</p>			
	<p>Food supplements as defined in the Food Supplements (Wales) Regulations 2003</p>	<p>25 mg/day for infants (persons under the age of 1 year (12 months)) 58 mg/day for young children (persons aged 1 year (12 months) up to the age of 3 years (36 months)) 250 mg/day for children and adolescents (persons aged 3 years (36 months) up to</p>			

		18 years of age) 610mg/day for persons aged 18 years or above			
--	--	--	--	--	--

Cywiro'r fanyleb yn Nhabl 2 ar gyfer "Xylo-oligosaccharides"

3. Yn Nhabl 2 (manylebau), yn y cofnod ar gyfer "Xylo-oligosaccharides", yng ngholofn 2 (nodweddion/cyfansoddiad), ar ôl y rhes yn ymwneud â "Moisture (%)" mewnosoder y rhes a ganlyn—

"Dry material (%)"	-	-	70 – 75".
--------------------	---	---	-----------

©Hawlfraint y Goron 2024

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

Amendment of Regulation (EC) No 1333/2008

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

Provision concerning addition to the domestic list of E 960b (steviol glycosides from fermentation) and E 960c(ii) (rebaudioside M, AM and D produced via enzymatic conversion of highly purified steviol glycosides from Stevia leaf extracts)

2. In Part B (list of all additives), in paragraph 2 (sweeteners), in the table, after the entry for “E 960a” (steviol glycosides from Stevia) insert the following entry—

“E 960b	Steviol glycosides from fermentation”.
---------	--

3. In Part C (definitions of groups of additives), in paragraph 5 (other additives that may be regulated combined), in sub-paragraph (v)—

- (a) in the text before the table, for “E 960a and E 960c: Steviol Glycosides” substitute “E 960a – E 960c: Steviol glycosides”;
- (b) in the table, after the entry for “E 960a” (steviol glycosides from Stevia) insert the following entry—

“E 960b	Steviol glycosides from fermentation”.
---------	--

4. In Part E (authorised food additives and conditions of use in food categories), in the table, for “E 960a and E 960c”, in each place it occurs, substitute “E 960a – E 960c”.

Provision concerning a new authorised use, and amendment to an existing authorised use, for E 476 (polyglycerol polyricinoleate)

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

- (a) in category 03 (edible ices), after the entry for “E 473-474” (sucrose esters of fatty acids – sucroglycerides) insert the following entry—

“E 476	Polyglycerol polyricinoleate	4000		except sorbets”;
--------	------------------------------	------	--	------------------

- (b) in category 12.6 (sauces), for the entry for “E 476” (polyglycerol polyricinoleate) substitute—

“E 476	Polyglycerol polyricinoleate	4000		only emulsified sauces with a fat content of less than 20%
E 476	Polyglycerol polyricinoleate	8000		only emulsified sauces with a fat content of 20% or more”.

Miscellaneous amendments

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

- (a) at the end of category 05.1 (cocoa and chocolate products), in the appropriate place, insert the following footnote—

“(1): The additives may be added individually or in combination”;

- (b) in category 05.2 (other confectionery including breath freshening microsweets)—
- (i) in the third entry for “Group IV” (polyols), for “only cocoa or dried fruit-based, milk or fat-based sandwich spreads,” substitute “sandwich spreads made with a base of cocoa, milk, dried fruit or fat;”;
 - (ii) in the first entry for “E 960a – E 960c” (steviol glycosides) as amended by paragraph 4 of this Schedule, for “only cocoa or dried-fruit-based,” substitute “only cocoa or dried fruit based;”;
 - (iii) in the second entry for “E 960a – E 960c” (steviol glycosides) as amended by paragraph 4 of this Schedule, for “only cocoa, milk, dried-fruit-based or fat-based sandwich spreads,” substitute “sandwich spreads made with a base of cocoa, milk, dried fruit or fat;”;
- (c) in category 05.4 (decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4), in the second entry for “E 960a – E 960c” (steviol glycosides) as amended by paragraph 4 of this Schedule, for “only cocoa or dried-fruit-based,” substitute “only cocoa or dried fruit based;”.

SCHEDULE 2

Regulation 3(4)

Amendment to the Annex to Regulation (EU) No 231/2012 for the addition of a specification for E 960b steviol glycosides from fermentation (*Yarrowia lipolytica*)

1. In Commission Regulation (EU) No 231/2012, the Annex (specifications for food additives) is amended as follows.

2. After the entry for “E 960a” (steviol glycosides from Stevia), insert the following entry—

“E 960b STEVIOL GLYCOSIDES FROM FERMENTATION (*YARROWIA LIPOLYTICA*)

Synonyms			
Definition	<p>Steviol glycosides from <i>Yarrowia lipolytica</i> consist of a mixture predominantly composed of rebaudioside M, with some rebaudioside D, and smaller amounts of rebaudioside A and rebaudioside B. The manufacturing process comprises two main phases.</p> <p>The first phase involves fermentation of a non-toxicogenic non-pathogenic strain of <i>Yarrowia lipolytica</i> VRM that has been genetically modified with heterologous genes to overexpress steviol glycosides. Removal of biomass by solid-liquid separation and heat treatment is followed by concentration of the steviol glycosides.</p> <p>The second phase involves purification by employing ion-exchange chromatography, followed by recrystallisation of the steviol glycosides resulting in a final product containing not less than 95% of rebaudiosides M, D, A, and B.</p> <p>Viable cells or the DNA of <i>Yarrowia lipolytica</i> VRM must not be detected in the food additive.</p>		
Chemical name	<p>Rebaudioside A: 13-[(2-<i>O</i>-β-D-glucopyranosyl-3-<i>O</i>-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester</p> <p>Rebaudioside B: 13-[(2-<i>O</i>-β-D-glucopyranosyl-3-<i>O</i>-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid</p> <p>Rebaudioside D: 13-[(2-<i>O</i>-β-D-glucopyranosyl-3-<i>O</i>-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-<i>O</i>-β-D-glucopyranosyl-β-D-glucopyranosyl ester</p> <p>Rebaudioside M: 13-[(2-<i>O</i>-β-D-glucopyranosyl-3-<i>O</i>-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-<i>O</i>-β-D-glucopyranosyl-3-<i>O</i>-β-D-glucopyranosyl-β-D-glucopyranosyl ester</p>		
Molecular formula	<i>Trivial name</i>	<i>Formula</i>	<i>Conversion factor</i>
	Rebaudioside A	C ₄₄ H ₇₀ O ₂₃	0.33
	Rebaudioside B	C ₃₈ H ₆₀ O ₁₈	0.40
	Rebaudioside D	C ₅₀ H ₈₀ O ₂₈	0.29
	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 A	58543-16-1	967.01
	Rebaudioside B	58543-17-2	804.88
	Rebaudioside D	63279-13-0	1129.15
	Rebaudioside M	1220616-44-3	1291.29
Assay	Not less than 95% of rebaudioside M, rebaudioside D, rebaudioside A, and rebaudioside B 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 0.1 mg/kg		
Lead	Not more than 0.1 mg/kg		
Cadmium	Not more than 0.01 mg/kg		
Mercury	Not more than 0.05 mg/kg		
Residual protein	Not more than 20 mg/kg		
Microbiological criteria			
Total (aerobic) plate count	Not more than 1000 CFU/g		
Yeast	Not more than 100 CFU/g		
Moulds	Not more than 100 CFU/g		
<i>Escherichia coli</i>	Negative in 1g		
<i>Salmonella</i> spp.	Negative in 25g".		

Amendment to Annex to Regulation (EU) No 231/2012 concerning the renumbering of additive E 960c(i) (formerly E 960c) and for the addition of a specification for E 960c(ii) rebaudioside M, AM and D produced via enzymatic conversion of highly purified steviol glycosides from Stevia leaf extracts

1. In Commission Regulation (EU) No 231/2012, the Annex (specifications for food additives) is amended as follows.

2. In the heading of the entry for “E 960c” (rebaudioside M produced via enzyme modification of steviol glycosides from Stevia) for “E 960c” substitute “E 960c(i)”.

3. After the entry for “E 960c(i)”, as amended by paragraph 2 of this Schedule, insert the following entry—

“E 960c(ii) REBAUDIOSIDE M, AM AND D PRODUCED VIA ENZYMATIC CONVERSION OF HIGHLY PURIFIED STEVIOL GLYCOSIDES FROM STEVIA LEAF EXTRACTS

Synonyms	
Definition	<p>Steviol glycosides produced via enzymatic conversion of highly purified steviol glycosides (rebaudioside A or stevioside) from Stevia leaf extracts are composed predominantly of rebaudioside M, rebaudioside D, and rebaudioside AM.</p> <p>Rebaudiosides D, M and AM are produced via enzymatic conversion of highly purified steviol glycoside (rebaudioside A or stevioside) extracts (95% steviol glycosides) obtained from <i>Stevia rebaudiana</i> Bertoni plant using UDP-glucosyltransferase and sucrose synthase enzymes produced by genetically modified strains of <i>Escherichia coli</i> (pPM294, pFAH170, and pSK041) 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 steviol glycosides by resin adsorption, followed by recrystallisation of the steviol glycosides resulting in a final product containing not less than 95 % of total steviol glycosides, including one or more of rebaudiosides D, M and AM.</p> <p>Viable cells or DNA of <i>Escherichia coli</i> (pPM294, pFAH170, and pSK041) must not be detected in the food additive.</p>
Chemical Name	<p>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</p> <p>Rebaudioside D: 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-β-D-glucopyranosyl ester</p> <p>Rebaudioside AM: 13-[(2-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</p>

Molecular formula	<i>Trivial name</i>	<i>Formula</i>	<i>Conversion factor</i>
	Rebaudioside M	C ₅₆ H ₉₀ O ₃₃	0.25
	Rebaudioside D	C ₅₀ H ₈₀ O ₂₈	0.29
	Rebaudioside AM	C ₅₀ H ₈₀ O ₂₈	0.29
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
	Rebaudioside D	63279-13-0	1129.15
	Rebaudioside AM	2222580-26-7	1129.15
Assay	Not less than 95 % of steviol glycosides on the dried basis, including one or more of rebaudiosides D, M and AM.		
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”.		

SCHEDULE 4

Regulation 6

Amendments to the list of novel foods in the Annex to Commission Implementing Regulation (EU) 2017/2470 for the authorisation of partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*) 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 “Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae” insert the following entry—

“Partially hydrolysed protein from spent barley (<i>Hordeum vulgare</i>) and rice (<i>Oryza sativa</i>)”	<i>Specified food category</i>	<i>Maximum levels</i>			
	Bread and similar products	15 g/100 g	The designation of the novel food on the labelling of food containing it is “partially hydrolysed protein from spent barley and rice”.	Included in the list on 28 June 2024.	This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
	Fine bakery wares	15 g/100 g			
	Breakfast cereals	30 g/100 g			
	Margarines and similar	10 g/100 g			
	Butter and margarine/oil blends	10 g/100 g			
	Pasta and rice (and other cereal)-based dishes	30 g/100 g			
	Fried or extruded cereal, seed, and root-based products	30 g/100 g			
	Fruit/vegetable spreads and similar	30 g/100 g			
	Confectionary including chocolate	15 g/100 g			
	Dairy imitates	50 g/100 ml (beverages) 50 g/100 g (products other than beverages)			
	Milk and dairy products	50 g/100 ml (beverages) 50 g/100 g (products other than beverages)			
					During the period of data protection, partially hydrolysed protein from spent barley (<i>Hordeum vulgare</i>) and rice (<i>Oryza sativa</i>) is authorised for placing on the market, within Wales, only by Evergrain LLC unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence

Dessert sauces/ toppings	15 g/100 g		<p>or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Evergrain LLC.</p> <p>The data protection will expire at the end of 27 June 2029.”</p>
Syrups (molasses and other syrups)	15 g/100 g		
Meat analogues	30 g/100 g		
Soups (marketed as such or reconstituted as instructed by the manufacturer)	15 g/100 g		
Stock cubes and granules (bouillon base)	15 g/100 g		
Gravy ingredients	10 g/100 g		
Savoury sauces	10 g/100 g		
Condiments (including table-top formats)	10 g/100 g		
Hummus	30 g/100 g		
Nut/seeds paste/emulsion/ mass	20 g/100 g		
Energy drinks	90 g/100 ml		
Carbohydrate-rich energy food products for sports people	30 g/100 g		
Protein and protein components for sports people	90 g/100 g		
Meal replacement for weight control	90 g/100 g		

3. In Table 2 (specifications), after the entry for “Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae” insert the following entry—

<p>“Partially hydrolysed protein from spent barley (<i>Hordeum vulgare</i>) and rice (<i>Oryza sativa</i>)”</p>	<p>Description/Definition</p> <p>Partially hydrolysed protein from spent barley (<i>Hordeum vulgare</i>) and rice (<i>Oryza sativa</i>) is an off-white powder, produced by concentration of proteins from a mixture of barley and rice from the mash step of beer production using a series of enzymatic hydrolysis and mechanical purification steps.</p>
--	--

Characteristics/Composition

Protein (dry basis): $\geq 85\%$

Moisture: $< 8\%$

Total Carbohydrates: $< 10\%$

Fat: $< 2\%$

Ash: $< 8\%$

Heavy metals

Arsenic: < 0.1 mg/kg

Cadmium: < 0.1 mg/kg

Lead: < 0.2 mg/kg

Mercury: < 0.1 mg/kg

Microbiological criteria

Aerobic plate count: $< 30,000$ CFU/g

Coliforms: < 10 CFU/g

Yeast and mould: < 50 CFU/g

Salmonella spp.: Negative in 25 g

Escherichia coli: < 10 CFU/g

Staphylococcus aureus: < 10 CFU/g

Listeria spp.: Negative in 25 g

CFU: Colony Forming Units".

Amendments to the list of novel foods in the Annex to Commission Implementing Regulation (EU) 2017/2470 for the authorisation of cetylated fatty acids 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 “*Calanus finmarchicus* oil” insert the following entry—

“Cetylated fatty acids	<i>Specified food category</i>	<i>Maximum levels</i>		Included in the list on 28 June 2024.
	Food supplements as defined in the Food Supplements Regulations 2003(1) for persons aged 18 years or above	2.1 g/day	<p>The designation of the novel food on the labelling of food containing it is “cetylated fatty acids preparation”.</p> <p>The labelling of food supplements must bear a statement that they should not be consumed by persons under 18 years of age.</p>	<p>This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.</p> <p>Applicant: Pharmanutra S.p.A, Via Delle Lenze 216/b, 56122 Pisa, Italy.</p> <p>During the period of data protection, cetylated fatty acids is authorised for placing on the market, within Wales, only by Pharmanutra S.p.A unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU)</p>

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

			<p>2015/2283 or with the agreement of Pharmanutra S.p.A.</p> <p>The data protection will expire at the end of 27 June 2029.”</p>
--	--	--	--

3. In Table 2, (specifications), after the entry for “*Calanus finmarchicus* oil” insert the following entry—

<p>“Cetylated Fatty Acids</p>	<p>Description/Definition</p> <p>The novel food is a mixture of 70 – 80% cetylated fatty acids which are produced from the reaction of cetyl alcohol with myristic acid and oleic acid.</p> <p>Characteristics/Composition</p> <p>Physical status at 25°C: Solid Colour (APHA Colour): ≤ 600 Acid value (mg KOH/g): ≤ 5 Iodine value (I₂/100g): 30 – 50 Saponification value (mg KOH/g): 130 – 150 Hydroxyl value (mg KOH/g): ≤ 20 Ester content (%): 70 – 80 Cetyl oleate (%): 22 – 30 Cetyl myristate (%): 41 – 56 Triglycerides (%): 22 – 25</p> <p>Microbiological criteria</p> <p>Total aerobic microbial count (CFU/g): ≤ 1000 Yeasts and moulds (CFU/g): ≤ 100</p> <p>APHA: American Public Health Association KOH: potassium hydroxide CFU: Colony Forming Units”.</p>
--------------------------------------	--

Amendments to the list of novel foods in the Annex to Commission Implementing Regulation (EU) 2017/2470 for the authorisation of 3-fucosyllactose (3-FL) (produced by a derivative strain of *Escherichia coli* K-12 DH1) 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 “2’-Fucosyllactose/Difucosyllactose mixture (‘2’-FL/DFL’) (microbial source)” insert the following entry—

“3-Fucosyllactose (3-FL) (produced by a derivative strain of <i>Escherichia coli</i> K-12 DH1)	<i>Specified food category</i>	<i>Maximum levels</i>		
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	2.0 g/l	The designation of the novel food on the labelling of food containing it is “3-fucosyllactose”.	Included in the list on 28 June 2024.
	Unflavoured fermented milk-based products	2.0 g/l (beverages) 4.0 g/kg (products other than beverages)	The labelling of food supplements intended for infants and young children must bear a statement that they should not be consumed if breast milk or food with added 3-fucosyllactose is consumed on the same day.	This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
	Flavoured fermented milk-based products including heat-treated products	2.0 g/l (beverages) 12.0 g/kg (products other than beverages)		Applicant: Glycom A/S, Kogle Allé 4, 2970 Hørsholm, Denmark.
	Cereal bars	25.0 g/kg		
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013(1)	2.0 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		During the period of data protection, 3-fucosyllactose is authorised for placing on the market, within Wales, only by Glycom A/S unless a subsequent applicant
	Milk-based drinks and similar products intended for young children (persons aged 1 year (12 months) up to the age of 3 years (36	2.0 g/l (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by		

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

	months))	the manufacturer 12.0 g/kg (products other than beverages)			<p>obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Glycom A/S.</p> <p>The data protection will expire at the end of 27 June 2029.”</p>
	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			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	2.0 g/l (beverages) 25.0 g/kg (products other than beverages)			
	Flavoured drinks (excluding cola flavour and cola flavoured drinks)	1.25 g/l			
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003 intended for infants (persons under the age of 1 year (12 months)) and young children (persons aged 1 year (12 months) up to the age of 3 years (36 months))	2.0 g/day			
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003 excluding food supplements for infants and young children	4.0 g/day			

3. In Table 2 (specifications), after the entry for “2’-Fucosyllactose/Difucosyllactose mixture (‘2’-FL/DFL’) (microbial source)” insert the following entry—

<p>“3-Fucosyllactose (3-FL) (produced by a derivative strain of <i>Escherichia coli</i> K-12 DH1)</p>	<p>Description/Definition</p> <p>3-Fucosyllactose (3-FL) (produced by a derivative strain of <i>Escherichia coli</i> K-12 DH1) is a purified carbohydrate powder or agglomerate containing at least 90% of 3-fucosyllactose on a dry matter basis obtained from microbial fermentation with a genetically modified strain of <i>Escherichia coli</i> K-12 DH1.</p> <p>Chemical name: β-D-Galactopyranosyl-(1\rightarrow4)- [α-L-fucopyranosyl-(1\rightarrow3)]- D-glucopyranose Chemical formula: C₁₈H₃₂O₁₅ Molecular mass: 488.44 Da CAS No: 41312-47-4</p> <p>Characteristics/Composition</p> <p>Appearance: Powder, agglomerates, powder with agglomerates Colour: White to off-white Assay (water-free) – Specified saccharides (includes 3-FL, D-lactose, L-fucose, and 3-fucosyllactulose): ≥ 92.0 % (w/w) Assay (water-free) – 3-FL: ≥ 90.0 % (w/w) L-Fucose: ≤ 1.0 % (w/w) D-Lactose: ≤ 5.0 % (w/w) 3-Fucosyllactulose: ≤ 1.5 % (w/w) Sum of other carbohydrates: ≤ 5.0 % (w/w) pH in 5% solution (20°C): 3.2 – 7.0 Water: ≤ 6.0 % (w/w) Ash, sulphated: ≤ 0.5 % (w/w) Acetic acid (relevant for crystallised 3-FL): ≤ 1.0 % (w/w) Residual protein by Bradford assay: ≤ 0.01 % (w/w) Residual endotoxins: ≤ 10 EU/mg</p> <p>Heavy metals</p> <p>Lead: ≤ 0.1 mg/kg Arsenic: ≤ 0.2 mg/kg</p> <p>Mycotoxins</p> <p>Aflatoxin M1: ≤ 0.025 μg/kg</p> <p>Microbiological criteria</p> <p>Aerobic mesophilic total plate count: ≤ 1000 CFU/g Enterobacteriaceae: absent in 10g <i>Salmonella</i> spp.: absent in 25g <i>Bacillus cereus</i>: ≤ 50 CFU/g <i>Listeria monocytogenes</i>: absent in 25g <i>Cronobacter</i> spp.: absent in 10g Yeasts: ≤ 100 CFU/g Moulds: ≤ 100 CFU/g</p> <p>EU: Endotoxin Units CFU: Colony Forming Units”.</p>
--	---

SCHEDULE 7

Regulation 6

Amendments to the list of novel foods in the Annex to Commission Implementing Regulation (EU) 2017/2470 for the authorisation of lacto-*N*-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) mixture 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 “Lactitol” insert the following entry—

“Lacto-<i>N</i>-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) mixture	<i>Specified food category</i>	<i>Maximum levels of LNFP-I</i>		
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	1.0 g/l	The designation of the novel food on the labelling of food containing it is “lacto- <i>N</i> -fucopentaose I and 2'-fucosyllactose mixture”.	<p>Included in the list on 28 June 2024.</p> <p>This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.</p> <p>Applicant: Glycom A/S, Kogle Allé 4, 2970 Hørsholm, Denmark.</p> <p>During the period of data protection, lacto-<i>N</i>-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) is authorised for placing on the market, within Wales, only by Glycom A/S unless a subsequent applicant obtains</p>
	Unflavoured fermented milk-based products	1.0 g/l (beverages) 2.0 g/kg (products other than beverages)	The labelling of food supplements intended for infants and young children must bear a statement that they should not be consumed if breast milk or food with added lacto- <i>N</i> -fucopentaose I (LNFP-I) or 2'-fucosyllactose (2'-FL) is consumed on the same day.	
	Flavoured fermented milk-based products including heat-treated products	1.0 g/l (beverages) 10.0 g/kg (products other than beverages)	The labelling of food supplements must bear a statement that they should not be consumed if food with added lacto- <i>N</i> -fucopentaose I (LNFP-I) or 2'-fucosyllactose (2'-FL) is consumed on the same day.	
	Cereal bars	10.0 g/kg		
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	1.5 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Processed cereal-based food and baby food for infants and young children as defined in	1.0 g/l (beverages) in the final product ready for use, marketed as such or reconstituted		

	Regulation (EU) No 609/2013	as instructed by the manufacturer 8.33 g/kg (products other than beverages)			<p>authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Glycom A/S.</p> <p>The data protection will expire at the end of 27 June 2029.”</p>
	Milk-based drinks and similar products intended for young children (persons aged 1 year (12 months) up to the age of 3 years (36 months))	1.2 g/l (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 10.0 g/kg (products other than beverages)			
	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			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	2.0 g/l (beverages) 20.0 g/kg (products other than beverages)			
	Flavoured drinks (excluding cola flavour and cola flavoured drinks)	1.0 g/l			
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003 for infants (persons	1.5 g/day			

	under the age of 1 year (12 months)) and young children (persons aged 1 year (12 months) up to the age of 3 years (36 months))				
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003 excluding supplements for infants and young children	3.0 g/day			

3. In Table 2 (specifications), after the entry for “Lactitol” insert the following entry—

<p>“Lacto-<i>N</i>-fucopentaose I (LNFP-I) and 2’-fucosyllactose (2’-FL) mixture</p>	<p>Description/Definition</p> <p>Lacto-<i>N</i>-fucopentaose I (LNFP-I) and 2’-fucosyllactose (2’-FL) mixture is a purified carbohydrate powder or agglomerate obtained from microbial fermentation with a genetically modified strain of <i>Escherichia coli</i> K-12 DH1 containing at least 75% of LNFP-I and 2’-FL of dry matter, where $\geq 50\%$ is LNFP-I (dry weight) and $\geq 15\%$ is 2’-FL (dry weight).</p> <p>Characteristics/Composition</p> <p>Appearance: Powder, agglomerates, powder with agglomerates Colour: White to off-white Assay (water-free) Specified saccharides (includes LNFP-I, 2’-FL, lacto-<i>N</i>-tetraose, difucosyl-D-lactose, 3-fucosyllactose, D-lactose, L-fucose and 2’-fucosyl-lactitol, LNFP-I fructose isomer, and 2’-fucosyl-D-lactulose): $\geq 90.0\%$ (w/w) Assay (water-free) – LNFP-I and 2’-FL: $\geq 75.0\%$ (w/w) Assay (water-free) – LNFP-I: $\geq 50.0\%$ (w/w) Assay (water-free) – 2’-FL: $\geq 15.0\%$ (w/w) Lacto-<i>N</i>-tetraose: $\leq 5.0\%$ (w/w) 3-Fucosyllactose: $\leq 1.0\%$ (w/w) Sum of L-Fucose and 2’-fucosyl-lactitol: $\leq 1.0\%$ (w/w) D-Lactose: $\leq 10.0\%$ (w/w) Difucosyl-D-lactose: $\leq 2.0\%$ (w/w) LNFP-I fructose isomer: $\leq 1.5\%$ (w/w) 2’-Fucosyl-D-lactulose: $\leq 1.0\%$ (w/w) Sum of other carbohydrates: $\leq 6.0\%$ (w/w) pH in 5% solution (20°C): 4.0–7.0</p>
---	--

	<p>Water: ≤ 8.0 % (w/w) Ash, sulphated: ≤ 0.5 % (w/w) Residual protein by Bradford assay: ≤ 0.01 % (w/w)</p> <p>Heavy metals</p> <p>Arsenic: ≤ 0.2 mg/kg</p> <p>Mycotoxins</p> <p>Residual endotoxins: ≤ 10 EU/mg Aflatoxin M1: ≤ 0.025 μg/kg</p> <p>Microbiological criteria</p> <p>Aerobic mesophilic total plate count: ≤ 1000 CFU/g Enterobacteriaceae: Absent in 10g <i>Salmonella</i> spp.: Absent in 25 g Yeasts: ≤ 100 CFU/g Moulds: ≤ 100 CFU/g <i>Bacillus cereus</i>: ≤ 50 CFU/g <i>Listeria monocytogenes</i>: Absent in 25g <i>Cronobacter</i> spp.: Absent in 10g</p> <p>EU: Endotoxin Units CFU: Colony Forming Units”.</p>
--	---

SCHEDULE 8

Regulation 6

Corrections to existing entries in the list of novel foods in the Annex to Commission Implementing Regulation (EU) 2017/2470

1. In Commission Implementing Regulation (EU) 2017/2470, the Annex (list of novel foods) is amended as follows.

Correction to the entry in Table 1 for “Bovine milk basic whey protein isolate”

2. In Table 1 (authorised novel foods), for the entry for “Bovine milk basic whey protein isolate” substitute—

“Bovine milk basic whey protein isolate	<i>Specified food category</i>	<i>Maximum levels</i>			
	Infant formula as defined in Regulation (EU) No 609/2013	30 mg/100 g (powder) 3.9 mg/100 ml (reconstituted)	The designation of the novel food on the labelling of food containing it is “Milk whey protein isolate”. The labelling of food supplements must bear a statement, as appropriate, that they should not be consumed by infants (persons under the age of 1 year)/infants or young children (persons under the age of 3 years)/infants, children or adolescents (persons under the age of 18 years).”		
	Follow-on formula as defined in Regulation (EU) No 609/2013	30 mg/100 g (powder) 4.2 mg/100 ml (reconstituted)			
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	300 mg/day			
	Food for special medical purposes as defined in Regulation (EU) No 609/2013	30 mg/100g (powder formula for infants (persons under the age of 1 year (12 months)) during first months of life until the introduction of appropriate complementary feeding) 3.9 mg/100ml (reconstituted formula for infants during the first months of life until the introduction of			

		<p>appropriate complementary feeding) 30 mg/100g (powder formula for infants when appropriate complementary feeding is introduced) 4.2 mg/100ml (reconstituted formula for infants when appropriate complementary feeding is introduced) 58 mg/day for young children (persons aged 1 year (12 months) up to the age of 3 years (36 months)) 380 mg/day for children and adolescents (persons aged 3 years (36 months) up to 18 years of age) 610 mg/day for persons aged 18 years or above</p>			
	<p>Food supplements as defined in the Food Supplements (Wales) Regulations 2003</p>	<p>25 mg/day for infants (persons under the age of 1 year (12 months)) 58 mg/day for young children (persons aged 1 year (12 months) up to the age of 3 years (36 months)) 250 mg/day for children and adolescents (persons aged 3 years (36 months) up to</p>			

		18 years of age) 610mg/day for persons aged 18 years or above			
--	--	--	--	--	--

Correction to the specification in Table 2 for “Xylo-oligosaccharides”

3. In Table 2 (specifications), in the entry for “Xylo-oligosaccharides”, in column 2 (characteristics/composition), after the row relating to “Moisture (%)” insert the following row—

“Dry material (%)	-	-	70 – 75”.
-------------------	---	---	-----------

© Crown copyright 2024

Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Jeff James,
Controller of His Majesty’s Stationery Office and King’s Printer of Acts of Parliament.



a Williams Lea company

Cyhoeddwyd gan TSO (Y Llyfrfa), cwmni Williams Lea,
ac ar gael o:

Arlein

www.tsoshop.co.uk

Post, Ffôn ac E-bost

TSO

Blwch Post 29, Norwich, NR3 1GN

Archebionf ffôn/ Ymholiadau cyffredinol 0333 202 5070

E-bost: customer.services@tso.co.uk

Ffôn Testun: 0333 202 5077

Published by TSO (The Stationery Office), a Williams Lea company,
and available from:

Online

www.tsoshop.co.uk

Mail, Telephone & E-mail

TSO

PO Box 29, Norwich, NR3 1GN

Telephone orders/General enquiries: 0333 202 5070

E-mail: customer.services@tso.co.uk

Textphone: 0333 202 5077

ISBN 978-0-348-39572-3



9 780348 395723