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OFFERYNNAU STATUDOL  
CYMRU

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**2022 Rhif 575 (Cy. 133)**

**BWYD, CYMRU**

**Rheoliadau Bwydydd Newydd  
(Awdurdodiadau) a Chyflasynnau  
Mwg (Addasu Awdurdodiadau)  
(Cymru) 2022**

**NODYN ESBONIADOL**

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

Mae'r Rheoliadau hyn yn gwneud darpariaeth ynghylch awdurdodiadau cynhyrchion bwyd rheoleiddiedig o ran Cymru. Gwneir Rhan 2 a'r Atodlenni yn unol â Rheoliad (EU) 2015/2283 a ddargedwir ar fwydydd newydd. Gwneir Rhan 3 yn unol â Rheoliad (EC) Rhif 2065/2003 a ddargedwir ar gyflasynnau mwg a ddefnyddir neu y bwriedir iddynt gael eu defnyddio mewn bwydydd neu arnynt.

Mae Rhan 2 a'r Atodlenni yn diweddar, o ran Cymru, y rhestr o fwydydd newydd awdurdodedig yn Atodiad 1 i Reoliad (EU) 2017/2470 a ddargedwir sy'n sefydlu rhestr yr Undeb o fwydydd newydd—

- mae Atodlen 1 yn diwygio'r cofnod presennol ar gyfer 2'-Ffwcosyl-lactos/Deuffwcosyl-lactos (2'FL/DFL) er mwyn awdurdodi rhoi ar y farchnad y bwyd newydd hwnnw i'w ddefnyddio mewn diodydd wedi eu seilio ar laeth a chynhyrchion tebyg a fwriedir ar gyfer plant ifanc;
- mae Atodlen 2 yn mewnosod cofnod newydd, sy'n awdurdodi rhoi ar y farchnad straen penodol o Olew Schizochytrium sp. (FCC-3204) fel bwyd newydd i'w ddefnyddio mewn atchwanegiadau bwyd, ac ar gyfer fformiwla babanod a fformiwla ddilynol;
- mae Atodlen 3 yn mewnosod cofnod newydd, sy'n awdurdodi rhoi ar y farchnad straen penodol o Olew Schizochytrium sp. (WZU477) fel bwyd newydd i'w ddefnyddio mewn fformiwla babanod a fformiwla ddilynol;

- mae Atodlen 4 yn mewnosod cofnod newydd, sy'n awdurdodi rhoi ar y farchnad halen sodiwm 3'-Sialyl-lactos (3'-SL) (ffynhonnell fibrobaid) fel bwyd newydd i'w ddefnyddio yn y categorïau o fwyd penodedig;
- mae Atodlen 5 yn mewnosod cofnod newydd, sy'n awdurdodi rhoi ar y farchnad halen sodiwm 6'-Sialyl-lactos (6'-SL) (ffynhonnell fibrobaid) fel bwyd newydd i'w ddefnyddio yn y categorïau o fwyd penodedig.

Mae Rhan 3 yn cynnwys addasiadau i'r awdurdodiadau ar gyfer pum cynnyrch cynradd sy'n creu cyflas mwg yn yr Atodiad i Reoliad (EU) Rhif 1321/2013 a ddargedwir sy'n sefydlu rhestr yr Undeb o gynhyrchion cynradd a awdurdodir i greu cyflas mwg i'w defnyddio yn y modd hwnnw mewn bwydydd neu arnynt. Mae'r diwygiadau'n newid enwau a chyfeiriadau deiliaid awdurdodiad awdurdodiadau'r priod gynhyrchion.

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.

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**2022 Rhif 575 (Cy. 133)**

**BWYD, CYMRU**

**Rheoliadau Bwydydd Newydd  
(Awdurdodiadau) a Chyflasynnau  
Mwg (Addasu Awdurdodiadau)  
(Cymru) 2022**

*Gwnaed* 24 Mai 2022

*Gosodwyd* gerbron *Senedd*  
*Cymru* 27 Mai 2022

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

Mae Gweinidogion Cymru yn gwneud y Rheoliadau a ganlyn drwy arfer y pwerau a roddir gan Erthyglau 12(1) a 32A(3) o, ac yn unol ag Erthyglau 9 a 27(1) o, Reoliad (EU) 2015/2283 Senedd Ewrop a'r Cyngor ar fwydydd newydd(1); ac Erthygl 11(4) o Reoliad (EC) Rhif 2065/2003 Senedd Ewrop a'r Cyngor ar gyflasynnau mwg a ddefnyddir neu y bwriedir iddynt gael eu defnyddio mewn bwydydd neu arnynt(2).

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), ymgynghorwyd yn agored ac yn dryloyw â'r cyhoedd wrth lunio a gwerthuso'r Rheoliadau hyn.

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- (1) EUR 2015/2283; yr offerynnau diwygio perthnasol yw O.S. 2019/702 a 2020/1504. Mae'r termau "prescribe", "appropriate authority" a "list" wedi eu diffinio yn Erthygl 3 o Reoliad 2015/2283.
- (2) EUR 2065/2003; yr offerynnau diwygio perthnasol yw O.S. 2019/860 a 2020/1504. Mae'r termau "prescribe" ac "appropriate authority" wedi eu diffinio yn Erthygl 3 o Reoliad 2065/2003.
- (3) EUR 178/2002; yr offerynnau diwygio perthnasol yw O.S. 2019/641 a 2020/1504.

## RHAN 1

### Cyflwyniad

#### **Enwi, rhychwant, cymhwyso a chychwyn**

1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau Bwydydd Newydd (Awdurdodiadau) a Chyflasynnau Mwg (Addasu Awdurdodiadau) (Cymru) 2022.

(2) Mae'r Rheoliadau hyn—

(a) yn rhychwantu Cymru a Lloegr;

(b) yn gymwys o ran Cymru.

(3) Daw Rhannau 1 a 3 o'r Rheoliadau hyn i rym ar 18 Mehefin 2022.

(4) Daw Rhan 2 o'r Rheoliadau hyn i rym ar 30 Mehefin 2022.

## RHAN 2

### Bwydydd Newydd

#### **Diwygio Rheoliad Gweithredu'r Comisiwn (EU) 2017/2470 sy'n sefydlu rhestr yr Undeb o fwydydd newydd yn unol â Rheoliad (EU) 2015/2283 Senedd Ewrop a'r Cyngor ar fwydydd newydd**

2. Yn 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(1), mae'r Atodiad (rhestr o fwydydd newydd) wedi ei ddiwygio yn unol ag Atodlenni 1 i 5.

## RHAN 3

### Cyflasynnau Mwg

#### **Diwygio Rheoliad Gweithredu'r Comisiwn (EU) Rhif 1321/2013 sy'n sefydlu rhestr yr Undeb o gynhyrchion cynradd a awdurdodir i greu cyflas mwg i'w defnyddio yn y modd hwnnw mewn bwydydd neu arnynt a/neu i gynhyrchu cyflasynnau mwg deilliedig**

3. Yn Rheoliad Gweithredu'r Comisiwn (EU) Rhif 1321/2013 sy'n sefydlu rhestr yr Undeb o gynhyrchion cynradd a awdurdodir i greu cyflas mwg i'w defnyddio yn y modd hwnnw mewn bwydydd neu arnynt a/neu i gynhyrchu cyflasynnau mwg deilliedig(2), mae'r Atodiad (rhestr ddomestig o gyflasynnau mwg

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(1) EUR 2017/2470, a ddiwygiwyd gan O.S. 2019/702.

(2) EUR 1321/2013, a ddiwygiwyd gan O.S. 2019/860.

awdurdodedig) wedi ei ddiwygio yn unol â rheoliadau 4 i 8.

**Addasu'r awdurdodiad ar gyfer "Scansmoke PB 1110"**

4. Yn yr awdurdodiad ar gyfer "Scansmoke PB 1110" (cod unigryw "SF-001"), yng ngholofn 2, yn lle'r cofnodion sy'n cyfateb i "Name of the authorisation holder" ac "Address of the authorisation holder" rhodder—

"proFagus GmbH
Uslarer Strasse 30 37194 Bodenfelde GERMANY"

**Addasu'r awdurdodiad ar gyfer "Zesti Smoke Code 10"**

5. Yn yr awdurdodiad ar gyfer "Zesti Smoke Code 10" (cod unigryw "SF-002"), yng ngholofn 2, yn lle'r cofnodion sy'n cyfateb i "Name of the authorisation holder" ac "Address of the authorisation holder" rhodder—

"Kerry Group Plc
Prince's Street Tralee Co. Kerry, V92 EH11 IRELAND"

**Addasu'r awdurdodiad ar gyfer "SmokeEz C-10"**

6. Yn yr awdurdodiad ar gyfer "SmokeEz C-10" (cod unigryw "SF-005"), yng ngholofn 2, yn lle'r cofnodion sy'n cyfateb i "Name of the authorisation holder" ac "Address of the authorisation holder" rhodder—

"Kerry Group Plc
Prince's Street Tralee Co. Kerry, V92 EH11 IRELAND"

**Addasu'r awdurdodiad ar gyfer "SmokeEz Enviro-23"**

7. Yn yr awdurdodiad ar gyfer "SmokeEz Enviro-23" (cod unigryw "SF-006"), yng ngholofn 2, yn lle'r cofnodion sy'n cyfateb i "Name of the authorisation holder" ac "Address of the authorisation holder" rhodder—

“Kerry Group Plc
Prince’s Street
Tralee
Co. Kerry, V92 EH11
IRELAND”

**Addasu’r awdurdodiad ar gyfer “Tradismoke™ A MAX”**

8. Yn yr awdurdodiad ar gyfer “Tradismoke™ A MAX” (cod unigryw “SF-007”), yng nghlofn 2, yn lle’r cofnodion sy’n cyfateb i “Name of the authorisation holder” ac “Address of the authorisation holder” rhodder—

“J. Rettenmaier & Söhne GmbH + CO KG
Holzmühle 1
73494 Rosenberg
GERMANY”

*Lynne Neagle*

Y Dirprwy Weinidog Iechyd Meddwl a Llesiant, o dan awdurdod y Gweinidog Iechyd a Gwasanaethau Cymdeithasol, un o Weinidogion Cymru  
24 Mai 2022

## ATODLEN 1

Rheoliad 2

### Diwygio amodau defnyddio a manylebau cymysgedd 2'-Ffwcosyl-lactos/Deuffwcosyl-lactos (2'FL/DFL) fel bwyd newydd

1. Yn Nhabl 1 (bwydydd newydd awdurdodedig), yn y cofnod ar gyfer “2'-Fucosyllactose/Difucosyllactose mixture (‘2'-FL/DFL’) (microbial source)”, yng nghlofn 2 (yr amodau y caniateir defnyddio'r bwyd newydd odanynt), ar y diwedd mewnosoder yr amod defnyddio a ganlyn—

“Milk-based drinks and similar products intended for young children	1.2 g/L in the final product ready for use marketed as such or reconstituted as instructed by the manufacturer”.
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2. Yn Nhabl 2 (manylebau), yn y cofnod ar gyfer “2'-Fucosyllactose/Difucosyllactose mixture (‘2'-FL/DFL’) (microbial source)”, yng nghlofn 2 (manylebau)—

- (a) yn yr adran sydd â'r pennawd “Description/Definition”, yn lle'r geiriau o “amorphous powder” hyd at “spray drying” rhodder “powder or agglomerates thereof that is produced by a microbial process”;
- (b) yn yr adran sydd â'r pennawd “Characteristics/Composition”, yn lle “Lactose and Fucose” rhodder “D-Lactose, L-Fucose, and 3-Fucosyllactose”.

ATODLEN 2

Rheoliad 2

Awdurdodi olew *Schizochytrium* sp. (FCC-3204) fel bwyd newydd

1. Yn Nhabl 1 (bwydydd newydd awdurdodedig), ar ôl y cofnod ar gyfer “*Schizochytrium* sp. (ATCC PTA-9695) oil” mewnosoder y cofnod a ganlyn—

<b>“<i>Schizochytrium</i> sp. (FCC-3204) oil</b>	<i>Specified food category</i>	<i>Maximum levels of DHA</i>	<p>The designation of the novel food on the labelling of the foodstuffs containing it is “Oil from the microalgae <i>Schizochytrium</i> sp.”.</p> <p>The labelling of food supplements containing <i>Schizochytrium</i> sp. (FCC-3204) oil must bear a statement that they should not be consumed by infants and children under 3 years of age.”</p>		
	Food Supplements as defined in the Food Supplements (Wales) Regulations 2003(1), excluding food supplements for infants and children under 3 years of age	1g/day			
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013(2)	In accordance with Regulation (EU) No 609/2013			

2. Yn Nhabl 2 (manylebau), ar ôl y cofnod ar gyfer “*Schizochytrium* sp. (ATCC PTA-9695) oil” mewnosoder y cofnod a ganlyn—

<b>“<i>Schizochytrium</i> sp. (FCC-3204) oil</b>	<p><b>Description/Definition:</b></p> <p>The novel food is an oil produced from the strain FCC-3204 of the microalgae <i>Schizochytrium</i> sp.</p> <p><b>Composition:</b></p> <p>Acid value: ≤ 0.5 mg KOH (potassium hydroxide)/g                  Peroxide value (PV): ≤ 5.0 meq (milliequivalent)/kg oil                  Moisture and volatiles: ≤ 0.05 %</p>
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(1) O.S. 2003/1719 (Cy. 186), y mae diwygiadau iddo nad ydynt yn berthnasol i'r Rheoliadau hyn.  
 (2) EUR 2013/609, a ddiwygiwyd gan O.S. 2019/651 a 2020/1476.



	Unsaponifiabiles: $\leq 4.5\%$ Trans-fatty acids: $\leq 1.0\%$ Docosahexaenoic acid (DHA): $\geq 32.0\%$ P-anisidine value: $\leq 10''$ .
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ATODLEN 3

Rheoliad 2

Awdurdodi olew *Schizochytrium* sp. (WZU477) fel bwyd newydd

1. Yn Nhabl 1 (bwydydd newydd awdurdodedig), ar ôl y cofnod ar gyfer “*Schizochytrium* sp. (T18) oil” mewnosoder y cofnod a ganlyn—

“ <i>Schizochytrium</i> sp. (WZU477) oil	<i>Specified food category</i>	<i>Maximum levels of DHA</i>	The designation of the novel food on the labelling of the foodstuffs containing it is	Included in the list on 30 June 2022.
	<p>Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013</p>	<p>In accordance with Regulation (EU) No 609/2013</p>	<p>“Oil from the microalgae <i>Schizochytrium</i> sp.”.</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: Progress Biotech BV, Canaalstaete, Kanaalweg 33, 2903LR Capelle aan den IJssel, the Netherlands.</p> <p>During the period of data protection, <i>Schizochytrium</i> sp. (WZU477) oil is authorised for placing on the market within Wales only by Progress Biotech BV unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Progress Biotech BV.</p> <p>The data protection ends at the end of 29</p>

				June 2027.”
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2. Yn Nhabl 2 (manylebau), ar ôl y cofnod ar gyfer “*Schizochytrium* sp. (T18) oil” mewnosoder y cofnod a ganlyn—

<p><b>“<i>Schizochytrium</i> sp. (WZU477) oil</b></p>	<p><b>Description/Definition:</b></p> <p>The novel food is an oil produced from the strain WZU477 of the microalgae <i>Schizochytrium</i> sp.</p> <p><b>Composition:</b></p> <p>Acid value: ≤ 0.5 mg KOH (potassium hydroxide)/g  Peroxide value (PV): ≤ 5.0 meq (milliequivalent)/kg oil  Moisture and volatiles: ≤ 0.05 %  Unsaponifiabiles: ≤ 4.5 %  Trans-fatty acids: ≤ 1.0 %  Docosahexaenoic acid (DHA): ≥ 32.0 %  P-anisidine value: ≤ 10”.</p>
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ATODLEN 4

Rheoliad 2

Awdurdodi rhoi ar y farchnad halen sodiwm 3’-Sialyl-lactos (3’-SL)  
(ffynhonnell ficrobaidd) fel bwyd newydd

1. Yn Nhabl 1 (bwydydd newydd awdurdodedig), ar ôl y cofnod ar gyfer “Selenium-containing yeast (*Yarrowia lipolytica*) biomass” mewnosoder y cofnod a ganlyn—

“3’-Sialyllactose (3’-SL) sodium salt (microbial source)	<i>Specified food category</i>	<i>Maximum levels (expressed as 3’-Sialyllactose)</i>	The designation of the novel food on the labelling of the foodstuffs containing it is “3’-Sialyllactose sodium salt”.  The labelling of food supplements containing 3’-Sialyllactose sodium salt must bear a statement that they should not be consumed:  a) if foods containing added 3’-Sialyllactose sodium salt are consumed the same day;  b) by infants and young children.	Included in the list on 30 June 2022.  This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.  Applicant: Glycom A/S, Kogle Alle 4, DK-2970 Horsholm, Denmark.  During the period of data protection, 3’-Sialyllactose sodium salt is authorised for placing on the market within Wales only by Glycom A/S unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Glycom A/S.  The data protection ends at the end of 29 June 2027.”
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0.25 g/L		
	Flavoured fermented milk-based products including heat-treated products	0.25 g/L (beverages)  2.5g/kg (products other than beverages)		
	Unflavoured fermented milk-based products	0.25 g/L (beverages)  0.5 g/kg (products other than beverages)		
	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	0.25 g/L		
	Cereal bars	2.5g/kg		
	Infant formula as defined in Regulation (EU) No 609/2013	0.2 g/L in the final product ready for use, marketed as such or reconstituted as instructed		

		by the manufacturer			
	Follow-on formula as defined in Regulation (EU) No 609/2013	0.15 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 Regulation (EU) No 609/2013	0.15 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.  1.25 g/kg (products other than beverages)			
	Milk-based drinks and similar products intended for young children	0.15 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013	0.5 g/L (beverages)  5g/kg (products other than beverages)			
	Food for special medical purposes as defined in Regulation	In accordance with the particular nutritional requirements			

	(EU) No 609/2013	of the persons for whom the products are intended			
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003, excluding food supplements for infants and young children	0.5 g/day			

2. Yn Nhabl 2 (manylebau), ar ôl y cofnod ar gyfer “Selenium-containing yeast (*Yarrowia lipolytica*) biomass” mewnosoder y cofnod a ganlyn—

<p><b>“3’-Sialyllactose (3’-SL) sodium salt (microbial source)</b></p>	<p><b>Description:</b></p> <p>3’-Sialyllactose (3’-SL) sodium salt is a purified, white to off-white powder or agglomerate that is produced by a microbial process and contains limited levels of lactose, 3’-sialyl-lactulose, and sialic acid</p> <p><b>Source:</b></p> <p>Genetically modified strain of <i>Escherichia coli</i> K-12 DH1</p> <p><b>Definition:</b></p> <p>Chemical formula: C<sub>23</sub>H<sub>38</sub>NO<sub>19</sub>Na  Chemical name: N-Acetyl-<math>\alpha</math>-D-neuraminy-(2→3)-<math>\beta</math>-D-galactopyranosyl-(1→4)-Dglucose, sodium salt  Molecular mass: 655.53 Da  CAS No 128596-80-5</p> <p><b>Characteristics/Composition:</b></p> <p>Appearance: White to off-white powder or agglomerate  Sum of 3’-Sialyllactose sodium salt, D-Lactose, and Sialic acid (% of dry matter): <math>\geq 90.0</math> % (w/w)  3’-Sialyllactose sodium salt (% of dry matter): <math>\geq 88.0</math> % (w/w)  D-Lactose: <math>\leq 5.0</math> % (w/w)  Sialic acid: <math>\leq 1.5</math> % (w/w)  3’-Sialyl-lactulose: <math>\leq 5.0</math> % (w/w)  Sum of other carbohydrates: <math>\leq 3.0</math> % (w/w)  Moisture: <math>\leq 8.0</math> % (w/w)  Sodium: 2.5 – 4.5 % (w/w)  Chloride: <math>\leq 1.0</math> % (w/w)  pH (20 °C, 5 % solution): 4.5 -6.0</p>
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	<p>Residual protein: <math>\leq 0.01</math> % (w/w)</p> <p><b>Microbiological criteria:</b></p> <p>Aerobic mesophilic bacteria total plate count: <math>\leq 1000</math> CFU/g <i>Enterobacteriaceae</i>: <math>\leq 10</math> CFU/g <i>Salmonella</i> sp.: Absence in 25 g Yeast: <math>\leq 100</math> CFU/g Mould: <math>\leq 100</math> CFU/g Residual endotoxins: <math>\leq 10</math> EU/mg</p> <p>CFU: Colony Forming Units; EU: Endotoxin Units.”</p>
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ATODLEN 5

Rheoliad 2

Awdurdodi rhoi ar y farchnad halen sodiwm 6'-Sialyl-lactos (6'-SL)  
(ffynhonnell ficrobaidd) fel bwyd newydd

1. Yn Nhabl 1 (bwydydd newydd awdurdodedig), ar ôl y cofnod ar gyfer “3'-Sialyllactose (3'-SL) sodium salt (microbial source)” (fel y'i mewnosodir gan baragraff 1 o Atodlen 4 i'r Rheoliadau hyn) mewnosoder y cofnod a ganlyn—

<b>“6'-Sialyllactose (6'-SL) sodium salt (microbial source)</b>	<i>Specified food category</i>	<i>Maximum levels (expressed as 6'-Sialyllactose)</i>	The designation of the novel food on the labelling of the foodstuffs containing it is “6'-Sialyllactose sodium salt”.		Included in the list on 30 June 2022.
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0.5 g/L	The labelling of food supplements containing 6'-Sialyllactose sodium salt must bear a statement that they should not be consumed:		This inclusion is authorised based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
	Unflavoured fermented milk-based products	0.5 g/L (beverages) 2.5 g/kg (products other than beverages)	a) if foods containing added 6'-Sialyllactose sodium salt are consumed the same day; b) by infants and young children.		Applicant: Glycom A/S, Kogle Alle 4, DK-2970 Horsholm, Denmark.
	Flavoured fermented milk-based products including heat-treated products	0.5 g/L (beverages) 5.0 g/kg (products other than beverages)			During the period of data protection, 6'-Sialyllactose sodium salt is authorised for placing on the market within Wales only by Glycom A/S unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Glycom A/S.
	Beverages (flavoured drinks, excluding drinks with a PH less than 5)	0.5 g/L			
	Cereal bars	5.0 g/kg			
	Infant formula as defined in Regulation	0.4 g/L in the final product ready for use, marketed as			The data protection ends at the end of 29



	(EU) No 609/2013	such or reconstituted as instructed by the manufacturer			June 2027.”
	Follow-on formula as defined in Regulation (EU) No 609/2013	0.3 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 Regulation (EU) No 609/2013	0.3 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer  2.5 g/kg (products other than beverages)			
	Milk based drinks and similar products intended for young children	0.3 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013	1.0 g/L (beverages)  10.0 g/kg (products other than beverages)			
	Food for special medical	In accordance with the particular			

	purposes as defined under Regulation (EU) No 609/2013	nutritional requirements of the persons for whom the products are intended			
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003, excluding food supplements for infants and young children	1.0 g/day			

2. Yn Nhabl 2 (manylebau), ar ôl y cofnod ar gyfer “3’-Sialyllactose (3’-SL) sodium salt (microbial source)” (fel y’i mewnosodir gan baragraff 2 o Atodlen 4 i’r Rheoliadau hyn) mewnosoder y cofnod a ganlyn—

<p><b>“6’-Sialyllactose (6’-SL) sodium salt (microbial source)”</b></p>	<p><b>Description:</b></p> <p>6’-Sialyllactose (6’-SL) sodium salt is a purified, white to off-white powder or agglomerate that is produced by a microbial process and contains limited levels of lactose, 6’-sialyllactulose, and sialic acid</p> <p><b>Source:</b></p> <p>Genetically modified strain of <i>Escherichia coli</i> K-12 DH1</p> <p><b>Definition:</b></p> <p>Chemical formula: C<sub>23</sub>H<sub>38</sub>NO<sub>19</sub>Na  Chemical name: N-Acetyl-<math>\alpha</math>-D-neuraminyl-(2→6)-<math>\beta</math>-D-galactopyranosyl-(1→4)-D-glucose, sodium salt  Molecular mass: 655.53 Da  CAS No 157574-76-0</p> <p><b>Characteristics/Composition:</b></p> <p>Appearance: White to off-white powder or agglomerate  Sum of 6’-Sialyllactose sodium salt, D-Lactose and Sialic acid (% of dry matter): <math>\geq 94.0</math> % (w/w)  6’-Sialyllactose sodium salt (% of dry matter): <math>\geq 90.0</math> % (w/w)  D-Lactose: <math>\leq 5.0</math> % (w/w)  Sialic acid: <math>\leq 2.0</math> % (w/w)</p>
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	<p>6'-Sialyl-lactulose: <math>\leq 3.0</math> % (w/w)  Sum of other carbohydrates: <math>\leq 3.0</math> % (w/w)  Moisture: <math>\leq 6.0</math> % (w/w)  Sodium: 2.5-4.5 % (w/w)  Chloride: <math>\leq 1.0</math> % (w/w)  pH (20 °C, 5 % solution): 4.5-6.0  Residual protein: <math>\leq 0.01</math> % (w/w)</p> <p><b>Microbiological criteria:</b></p> <p>Aerobic mesophilic bacteria total plate count: <math>\leq 1\ 000</math> CFU/g  <i>Enterobacteriaceae</i>: <math>\leq 10</math> CFU/g  <i>Salmonella</i> sp.: Absence in 25 g  Yeast: <math>\leq 100</math> CFU/g  Mould: <math>\leq 100</math> CFU/g  Residual endotoxins: <math>\leq 10</math> EU/mg</p> <p>CFU: Colony Forming Units; EU: Endotoxin Units.”</p>
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