

OFFERYNNAU STATUDOL CYMRU

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.

RHAN 1

Cyflwyniad

Enwi, rychwant, 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 rychwantu Cymru a Lloegr;
(b) yn gymwys o ran Cymru.

(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.

- (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(4), 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(5), mae'r Atodiad (rhestr ddomestig o gyflasynnau mwg 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—

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

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

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

Addasu'r awdurdodiad ar gyfer “SmokEz C-10”

6. Yn yr awdurdodiad ar gyfer “SmokEz 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 “SmokEz Enviro-23”

7. Yn yr awdurdodiad ar gyfer “SmokEz 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 ngholofn 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
Holzühle 1
73494 Rosenberg

Statws This is the original version (as it was originally made). Dim ond ar
ei ffurf wreiddiol y mae'r eitem hon o ddeddfwriaeth ar gael ar hyn o bryd.

GERMANY”

24 Mai 2022

Lynne Neagle
Y Dirprwy Weinidog Iechyd Meddwl a
Llesiant, o dan awdurdod y Gweinidog Iechyd a
Gwasanaethau Cymdeithasol, un o Weinidogion
Cymru

Statws This is the original version (as it was originally made). Dim ond ar ei ffurf wreiddiol y mae'r eitem hon o ddeddfwriaeth ar gael ar hyn o bryd.

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 ngholofn 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 ngholofn 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—

“ <i>Schizochytrium</i> sp. (FCC-3204) 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 “Oil from the microalgae <i>Schizochytrium</i> sp.”. The labelling of food supplements containing <i>Schizochytrium</i> sp. (FCC-3204) oil must bear a statement that they		
	Food Supplements as defined in the Food Supplements Regulations 2003(6), excluding food supplements for infants and children under 3 years of age	1g/day			

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

Statws This is the original version (as it was originally made). Dim ond ar ei ffurf wreiddiol y mae'r eitem hon o ddeddfwriaeth ar gael ar hyn o bryd.

Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013(7)	In accordance with Regulation (EU) No 609/2013”	should not be consumed by infants and children under 3 years of age.”		
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2. Yn Nhabl 2 (manylebau), ar ôl y cofnod ar gyfer “*Schizochytrium* sp. (ATCC PTA-9695) oil” mewnosoder y cofnod a ganlyn—

<p>“<i>Schizochytrium</i> sp. (FCC-3204) oil</p>	<p>Description/Definition:</p> <p>The novel food is an oil produced from the strain FCC-3204 of the microalgae <i>Schizochytrium</i> sp.</p> <p>Composition:</p> <p>Acid value: ≤ 0.5 mg KOH (potassium hydroxide)/g</p> <p>Peroxide value (PV): ≤ 5.0 meq (milliequivalent)/kg oil</p> <p>Moisture and volatiles: ≤ 0.05 %</p> <p>Unsaponifiables: ≤ 4.5 %</p> <p>Trans-fatty acids: ≤ 1.0 %</p> <p>Docosahexaenoic acid (DHA): ≥ 32.0 %</p> <p>P-anisidine value: ≤ 10””.</p>
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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	Specified food category	Maximum levels of DHA	The designation of the novel food on the labelling of the foodstuffs containing it	Included in the list on 30 June 2022.
	Infant formula and	In accordance		

(7) EUR 2013/609, a ddiwygiwyd gan O.S. 2019/651 a 2020/1476.

Statws This is the original version (as it was originally made). Dim ond ar ei ffurf wreiddiol y mae'r eitem hon o ddeddfwriaeth ar gael ar hyn o bryd.

	<p>follow-on formula as defined in Regulation (EU) No 609/2013</p>	<p>with Regulation (EU) No 609/2013</p>	<p>is “Oil from the microalgae <i>Schizochytrium</i> sp.”.</p>	<p>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 June 2027."</p>
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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>“<i>Schizochytrium</i> sp. (WZU477) oil</p>	<p>Description/Definition:</p>
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Statws This is the original version (as it was originally made). Dim ond ar ei ffurf wreiddiol y mae'r eitem hon o ddeddfwriaeth ar gael ar hyn o bryd.

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

Rheoliad 2

Awdurdodi rhoi ar y farchnad halen sodiwm 3'-Sialyllactos (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".	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.
	Unflavoured pasteurised and sterilised (including UHT) milk products	0.25 g/L unflavoured		
	Flavoured fermented milk-based products including heat-treated products	0.25 g/L (beverages) 2.5g/kg (products other than beverages)	The labelling of food supplements containing 3'-Sialyllactose sodium salt must bear a statement that they should not be consumed:	Applicant: Glycom A/S, Kogle Alle 4, DK-2970 Horsholm, Denmark.
	Unflavoured fermented	0.25 g/L (beverages)		During the period of data protection, 3'-Sialyllactose

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milk-based products	0.5 g/kg (products other than beverages)	<p>a) if foods containing added 3'-Sialyllactose sodium salt are consumed the same day;</p> <p>b) by infants and young children.</p>	<p>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.</p> <p>The data protection ends at the end of 29 June 2027."</p>
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	0.15 g/L in the final product		

Statws This is the original version (as it was originally made). Dim ond ar ei ffurf wreiddiol y mae'r eitem hon o ddeddfwriaeth ar gael ar hyn o bryd.

products intended for young children	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 (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended		
Food supplements as defined in the Food Supplements (Wales) Regulations 2003, excluding food supplements for infants and 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—

“3'-Sialyllactose (3'-SL) sodium salt (microbial source)	<p>Description:</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'-sialyllactulose, and sialic acid</p> <p>Source:</p>
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Statws This is the original version (as it was originally made). Dim ond ar ei ffurf wreiddiol y mae'r eitem hon o ddeddfwriaeth ar gael ar hyn o bryd.

Genetically modified strain of *Escherichia coli* K-12 DH1

Definition:

Chemical formula: $C_{23}H_{38}NO_{19}Na$

Chemical name: N-Acetyl- α -D-neuraminyl-(2 \rightarrow 3)- β -D-galactopyranosyl-(1 \rightarrow 4)-Dglucose, sodium salt

Molecular mass: 655.53 Da

CAS No 128596-80-5

Characteristics/Composition:

Appearance: White to off-white powder or agglomerate

Sum of 3'-Sialyllactose sodium salt, D-Lactose, and Sialic acid (% of dry matter): ≥ 90.0 % (w/w)

3'-Sialyllactose sodium salt (% of dry matter): ≥ 88.0 % (w/w)

D-Lactose: ≤ 5.0 % (w/w)

Sialic acid: ≤ 1.5 % (w/w)

3'-Sialyl-lactulose: ≤ 5.0 % (w/w)

Sum of other carbohydrates: ≤ 3.0 % (w/w)

Moisture: ≤ 8.0 % (w/w)

Sodium: 2.5 – 4.5 % (w/w)

Chloride: ≤ 1.0 % (w/w)

pH (20 °C, 5 % solution): 4.5 -6.0

Residual protein: ≤ 0.01 % (w/w)

Microbiological criteria:

Aerobic mesophilic bacteria total plate count: ≤ 1000 CFU/g

Enterobacteriaceae: ≤ 10 CFU/g

Salmonella sp.: Absence in 25 g

Yeast: ≤ 100 CFU/g

Mould: ≤ 100 CFU/g

Residual endotoxins: ≤ 10 EU/mg

Statws This is the original version (as it was originally made). Dim ond ar ei ffurf wreiddiol y mae'r eitem hon o ddeddfwriaeth ar gael ar hyn o bryd.

CFU: Colony Forming Units; EU: Endotoxin Units.""

ATODLEN 5

Rheoliad 2

Awdurdodi rhoi ar y farchnad halen sodiwm 6'-Sialyllactos (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—

"6'-Sialyllactose (6'-SL) sodium salt (microbial source)"	<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". The labelling of food supplements containing 6'-Sialyllactose sodium salt must bear a statement that they should not be consumed: a) if foods containing added 6'-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 authorised 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, 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
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0.5 g/L		
	Unflavoured fermented milk-based products	0.5 g/L (beverages) 2.5 g/kg (products other than beverages)		
	Flavoured fermented milk-based products including heat-treated products	0.5 g/L (beverages) 5.0 g/kg (products other than beverages)		
	Beverages (flavoured drinks, excluding drinks with a PH less than 5)	0.5 g/L		
	Cereal bars	5.0 g/kg		
	Infant formula as	0.4 g/L in the final product		

Statws This is the original version (as it was originally made). Dim ond ar ei ffurf wreiddiol y mae'r eitem hon o ddeddfwriaeth ar gael ar hyn o bryd.

<p>defined in Regulation (EU) No 609/2013</p>	<p>ready for use, marketed as such or reconstituted as instructed by the manufacturer</p>	<p>Regulation (EU) 2015/2283 or with the agreement of Glycom A/S.</p>
<p>Follow-on formula as defined in Regulation (EU) No 609/2013</p>	<p>0.3 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer</p>	<p>The data protection ends at the end of 29 June 2027."</p>
<p>Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013</p>	<p>0.3 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer</p> <p>2.5 g/kg (products other than beverages)</p>	
<p>Milk based drinks and similar products intended for young children</p>	<p>0.3 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer</p>	
<p>Total diet replacement foods for weight control as defined in Regulation</p>	<p>1.0 g/L (beverages)</p> <p>10.0 g/kg (products other than beverages)</p>	

Statws This is the original version (as it was originally made). Dim ond ar ei ffurf wreiddiol y mae'r eitem hon o ddeddfwriaeth ar gael ar hyn o bryd.

(EU) No 609/2013				
Food for special medical purposes as defined under Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
Food supplements as defined in the Food Supplements (Wales) Regulations 2003, excluding food supplements for infants and 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—

“6’-Sialyllactose (6’-SL) sodium salt (microbial source)	<p>Description:</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’-sialyl-lactulose, and sialic acid</p> <p>Source:</p> <p>Genetically modified strain of <i>Escherichia coli</i> K-12 DH1</p> <p>Definition:</p> <p>Chemical formula: C₂₃H₃₈NO₁₉Na</p> <p>Chemical name: N-Acetyl-α-D-neuraminyl-(2→6)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt</p> <p>Molecular mass: 655.53 Da</p>
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Statws This is the original version (as it was originally made). Dim ond ar ei ffurf wreiddiol y mae'r eitem hon o ddeddfwriaeth ar gael ar hyn o bryd.

CAS No 157574-76-0

Characteristics/Composition:

Appearance: White to off-white powder or agglomerate

Sum of 6'-Sialyllactose sodium salt, D-Lactose and Sialic acid (% of dry matter): ≥ 94.0 % (w/w)

6'-Sialyllactose sodium salt (% of dry matter): ≥ 90.0 % (w/w)

D-Lactose: ≤ 5.0 % (w/w)

Sialic acid: ≤ 2.0 % (w/w)

6'-Sialyl-lactulose: ≤ 3.0 % (w/w)

Sum of other carbohydrates: ≤ 3.0 % (w/w)

Moisture: ≤ 6.0 % (w/w)

Sodium: 2.5-4.5 % (w/w)

Chloride: ≤ 1.0 % (w/w)

pH (20 °C, 5 % solution): 4.5-6.0

Residual protein: ≤ 0.01 % (w/w)

Microbiological criteria:

Aerobic mesophilic bacteria total plate count: $\leq 1\ 000$ CFU/g

Enterobacteriaceae: ≤ 10 CFU/g

Salmonella sp.: Absence in 25 g

Yeast: ≤ 100 CFU/g

Mould: ≤ 100 CFU/g

Residual endotoxins: ≤ 10 EU/mg

CFU: Colony Forming Units; EU: Endotoxin Units.""

Statws This is the original version (as it was originally made). Dim ond ar ei ffurf wreiddiol y mae'r eitem hon o ddeddfwriaeth ar gael ar hyn o bryd.

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 diweddarau, 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 ddilydol;
- 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 ddilydol;
- mae Atodlen 4 yn mewnosod cofnod newydd, sy'n awdurdodi rhoi ar y farchnad halen sodiwm 3'-Sialyl-lactos (3'-SL) (ffynhonnell ficrobaidd) 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 ficrobaidd) 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.