

ATODLEN 1

Rheoliad 2

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

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

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

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

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

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

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

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

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

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

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

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

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

**Statws** This is the original version (as it was originally made).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.

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

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

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

"E 960a and E 960c	Steviol glycosides	200	(1) (60)	only energy-reduced fruit or vegetable spreads and dried-fruit-based sandwich spreads, energy-reduced or with no added sugar";
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- (h) yng nghategori 05.1 (cynhyrchion coco a siocled), yn lle'r cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

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

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

"E 960a and E 960c	Steviol glycosides	270	(1) (60)	only cocoa or dried-fruit-based, energy-reduced or with no added sugar";
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(ii) yn lle'r ail gofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and E 960c	Steviol glycosides	330	(1) (60)	only cocoa, milk, dried-fruit-based or fat-based sandwich spreads, energy-reduced or with no added sugar";
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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.

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

"E 960a and E 960c	Steviol glycosides	350	(1) (60)	only confectionery with no added sugar  only energy-reduced hard confectionery such as candies and lollies  only energy-reduced soft confectionery such as chewy candies, fruit gums and foam sugar products/ marshmallows  only energy-reduced liquorice  only energy-reduced nougat  only energy-reduced marzipan";
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(iv) yn lle'r pedwerydd cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and E 960c	Steviol glycosides	2000	(1) (60)	only breath-freshening microsweets, energy-reduced or with no added sugar";
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(v) yn lle'r pumed cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and E 960c	Steviol glycosides	670	(1) (60)	only strongly flavoured freshening throat pastilles, energy-reduced or with no added sugar";
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(j) yng nghategori 05.3 (gwm cnoi), yn lle'r cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

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

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

*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.

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

"E 960a and E 960c	Steviol glycosides	270	(1) (60)	only cocoa or dried-fruit-based, energy-reduced or with no added sugar";
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(l) yng nghategori 06.3 (grawnfwydydd brechwast), yn lle'r cofnod ar gyfer "E 960" (glycosidau steviol) rhodder—

"E 960a and E 960c	Steviol glycosides	330	(1) (60)	only breakfast cereals with a fibre content of more than 15%, and containing at least 20% bran, energy-reduced or with no added sugar";
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(m) yng nghategori 07.2 (danteithion popty), yn lle'r cofnod ar gyfer "E 960" (glycosidau steviol) rhodder—

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

"E 960a and E 960c	Steviol glycosides	200	(1) (60)	only sweet-sour preserves and semi preserves of fish and marinades of fish, crustaceans and molluscs";
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(o) yng nghategori 11.4.1 (melysyddion bwrdd ar ffurf hylif), yn lle'r cofnod ar gyfer "E 960" (glycosidau steviol) rhodder—

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

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

**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.

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

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

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

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

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

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

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

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

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

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

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

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

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

*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.

"E 960a and E 960c	Steviol glycosides	100	(1) (60)	only energy-reduced or with no added sugar
	(1): The additives may be added individually or in combination";			

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

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

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

"E 960a and E 960c	Steviol glycosides	30	(1) (60) (93)	only coffee, tea and herbal infusion beverages, energy-reduced or with no added sugar";
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(ii) yn lle'r ail gofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and E 960c	Steviol glycosides	30	(1) (60) (93)	only flavoured instant coffee and instant cappuccino products, energy-reduced or with no added sugar";
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(iii) yn lle'r trydydd cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and E 960c	Steviol glycosides	20	(1) (60) (93)	only malt-based and chocolate/cappuccino flavoured drinks, energy-reduced or with no added sugar";
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(z) yng nghategori 14.2.1 (cwrw a diodydd brag), yn lle'r cofnod ar gyfer "E 960" (glycosidau stefiol) rhodder—

"E 960a and E 960c	Steviol glycosides	70	(1) (60)	only alcohol-free beer or with an alcohol content not exceeding 1.2% volume; "Bière de table"/ "Tafelbier"/ "Table beer" (original wort content less than 6%) except for
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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.

				“Obergäriges Einfachbier”; beers with a minimum acidity of 30 milliequivalents expressed as NaOH; Brown beers of the “oud bruin” type”;
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- (aa) yng nghategori 14.2.8 (diodydd alcoholaidd eraill gan gynnwys cymysgeddau o ddiodydd alcoholaidd gyda diodydd dialcohol a gwirodydd â llai na 15% o alcohol), yn lle'r cofnod ar gyfer “E 960” (glycosidau stefiol) rhodder—

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

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

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

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

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

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

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

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

**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.

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

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

Rheoliad 3

Diwygiadau i'r Atodiad i Reoliad (EU) Rhif 231/2012 sy'n ymwneud â'r fanyleb ar gyfer E 960a glycosidau steviol o Stevia (E 960 glycosidau steviol yn flaenorol) ac i ychwanegu manyleb ar gyfer E 960c rebaudiosid M a gynhyrchir drwy addasu glycosidau steviol o Stevia ag ensymau

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

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

“E 960a STEVIOL GLYCOSIDES FROM STEVIA”

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

**“E 960c REBAUDIOSIDE M PRODUCED VIA ENZYME MODIFICATION OF STEVIOL GLYCOSIDES FROM STEVIA**

<b>Synonyms</b>	
<b>Definition</b>	<p>Rebaudioside M is a steviol glycoside composed predominantly of rebaudioside M with minor amounts of other steviol glycosides such as rebaudioside A, rebaudioside B, rebaudioside D, rebaudioside I, and stevioside.</p> <p>Rebaudioside M is obtained via enzymatic bioconversion of purified steviol glycoside leaf extracts (95% steviol glycosides) of the <i>Stevia rebaudiana</i> Bertoni plant using UDP-glucosyltransferase and sucrose synthase enzymes produced by the genetically modified yeasts <i>K. phaffi</i> (formerly known as <i>Pichia pastoris</i>) UGT-a and <i>K. phaffi</i> UGT-b that facilitate the transfer of glucose from sucrose and UDP-glucose to steviol glycosides via glycosidic bonds.</p> <p>After removal of the enzymes by solid-liquid separation and heat treatment, the purification involves concentration of the rebaudioside M by resin adsorption, followed by recrystallisation of rebaudioside M resulting in a final product containing not less than 95% of rebaudioside M. Viable cells or the DNA of the yeasts <i>K. phaffi</i> UGT-a or <i>K. phaffi</i> UGT-b must not be detected in the food additive.</p>
<b>Chemical name</b>	Rebaudioside M: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-



**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.

	O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester		
Molecular formula	<i>Trivial name</i>	<i>Formula</i>	<i>Conversion factor</i>
	Rebaudioside M	C <sub>56</sub> H <sub>90</sub> O <sub>33</sub>	0.25
Molecular weight and CAS number	<i>Trivial name</i>	<i>CAS Number</i>	<i>Molecular weight (g/mol)</i>
	Rebaudioside M	1220616-44-3	1291.29
Assay	Not less than 95% rebaudioside M on the dried basis		
<b>Description</b>	White to light yellow powder, approximately between 200 and 350 times sweeter than sucrose (at 5% sucrose equivalency)		
<b>Identification</b>			
Solubility	Freely soluble to slightly soluble in water		
pH	Between 4.5 and 7.0 (1 in 100 solution)		
<b>Purity</b>			
Total ash	Not more than 1%		
Loss on drying	Not more than 6% (105°C, 2h)		
Residual solvent	Not more than 5000 mg/kg ethanol		
Arsenic	Not more than 0.015 mg/kg		
Lead	Not more than 0.2 mg/kg		
Cadmium	Not more than 0.015 mg/kg		
Mercury	Not more than 0.07 mg/kg		
Residual protein	Not more than 5 mg/kg		
Particle size	Not less than 74 μm (using a mesh #200 sieve with a particle size limit of 74 μm)”		

## ATODLEN 3

Rheoliad 5

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

1. Yn Rheoliad (EC) Rhif 1334/2008, mae Atodiad 1 (rhestr ddomestig o gyflasynnau a deunyddiau ffynhonnell) wedi ei ddiwygio fel a ganlyn.
2. Yn Rhan A (rhestr ddomestig o sylweddau cyflasu), yn Adran 2, yn Nhabl 1, yn y lle priodol mewnosoder y cofnod a ganlyn—

*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.

"16.127	3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1H-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione	111983	121642		At least 99%, assay (HPLC/UV)	<p>Restrictions of use as a flavouring substance:</p> <p>In category 1.4 – not more than 4 mg/kg</p> <p>In category 1.8 – not more than 8 mg/kg</p> <p>In category 3 – not more than 4 mg/kg</p> <p>In category 5.1 – not more than 15 mg/kg</p> <p>In category 5.2 – not more than 16 mg/kg</p> <p>In category 5.3 – not more than 30 mg/kg</p> <p>In category 5.4 – not more than 15 mg/kg</p> <p>In category 6.3 – not more than 25 mg/kg</p> <p>In category</p>	The Authority <sup>(2)</sup>
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(2) Diffinnir "Authority" yn Erthygl 3(2)(l) o EUR 2008/1334.

**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.

									12.1 – not more than 75 mg/kg	
									In category	
									12.2 – not more than 100 mg/kg	
									In category	
									12.3 – not more than 25 mg/kg	
									In category	
									12.4 – not more than 25 mg/kg	
									In category	
									12.5 – not more than 4 mg/kg	
									In category	
									13.2 – not more than 4 mg/kg	
									In category	
									13.3 – not more than 4 mg/kg	
									In category	
									14.1.4, dairy-based drinks only – not more than 4 mg/l	
									In category	
									14.1.5 – not more than 8 mg/kg	

**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.

						In category 15.1 – not more than 20 mg/kg		
						In category 16, dairy-based desserts only – not more than 4 mg/l <sup>3</sup> .		

ATODLEN 4

Rheoliad 6

Diwygiadau i'r rhestr o fwydydd newydd yn yr Atodiad i Reoliad Gweithredu'r Comisiwn (EU) 2017/2470 ar gyfer awdurdodi burum pobi sydd wedi ei drin ag UV (*Saccharomyces cerevisiae*) fel bwyd newydd

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

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

"UV-treated baker's yeast ( <i>Saccharomyces cerevisiae</i> )"	Specified food category	Maximum levels of vitamin D <sub>2</sub>		The novel food must be inactivated for use in infant formula, follow-on formula, processed cereal-based food and food for special purposes.
	Yeast-leavened breads and rolls	5 µg/100 g	The designation of the novel food on the labelling of food containing it is "vitamin D yeast" or "vitamin D <sub>2</sub> yeast".	
	Yeast-leavened fine bakery wares	5 µg/100 g		
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003(3)	In accordance with any relevant requirements contained in regulations applying in relation to Wales and made under regulation 4 of the Nutrition (Amendment etc.) (EU Exit)		

(3) 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.

	Regulations 2019(4)	
Pre-packed fresh or dry yeast for home baking	45 µg/100 g for fresh yeast  200 µg/100 g for dry yeast	<p>The designation of the novel food on the labelling of food containing it is “vitamin D yeast” or “vitamin D<sub>2</sub> yeast”.</p> <p>The labelling of the novel food must bear a statement that the food is only intended for baking and should not be eaten raw.</p> <p>The labelling of the novel food must bear instructions for use for the final consumer to ensure a maximum concentration of 5µg/100g of vitamin D<sub>2</sub> in the final home-baked product is not exceeded.</p>
Dishes, including ready-to-eat meals (excluding soups and salads)	3 µg/100 g	The designation of the novel food on the labelling of food containing it is “vitamin
Soups and salads	5 µg/100 g	

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

*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.

Fried or extruded cereal, seed or root-based products	5 µg/100 g	D yeast” or “vitamin D <sub>2</sub> yeast”.
Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013(5)	In accordance with Regulation (EU) No 609/2013	
Processed cereal-based food as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013	
Processed fruit products	1.5 µg/100 g	
Processed vegetables	2 µg/100 g	
Bread and similar products	5 µg/100 g	
Breakfast cereals	4 µg/100 g	
Pasta, doughs and similar products	5 µg/100 g	
Other cereal-based products	3 µg/100 g	
Spices, seasonings, condiments, sauce ingredients, dessert sauces/toppings	10 µg/100 g	
Protein products	10 µg/100 g	
Cheese	2 µg/100 g	
Dairy desserts and similar products	2 µg/100 g	
Fermented milk or fermented cream	1.5 µg/100 g	

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

**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.

Dairy powders and concentrates	25 µg/100 g
Milk-based products, whey and cream	0.5 µg/100 g
Meat and dairy analogues	2.5 µg/100 g
Total diet replacement for weight control as defined in <a href="#">Regulation (EU) No 609/2013</a>	5 µg/100 g
Meal replacement for weight control	5 µg/100 g
Food for special medical purposes as defined in <a href="#">Regulation (EU) No 609/2013</a>	In accordance with the particular nutritional requirements of the persons for whom the products are intended".

**3. Yn Nhabl 2 (manylebau) yn lle'r cofnod ar gyfer "UV-treated baker's yeast (*Saccharomyces cerevisiae*)" rhodder—**

<p><b>"UV-treated baker's yeast (<i>Saccharomyces cerevisiae</i>)"</b></p>	<p><b>Description/Definition</b></p> <p>Baker's yeast (<i>Saccharomyces cerevisiae</i>) is treated with ultraviolet light to induce the conversion of ergosterol to vitamin D<sub>2</sub> (ergocalciferol). Vitamin D<sub>2</sub> content in the yeast concentrate varies between 800,000 - 3,500,000 IU vitamin D/100 g (200-875 µg/g).</p> <p>The yeast is inactivated for use in infant formula, follow-on formula, processed cereal-based food, and food for special medical purposes as defined in <a href="#">Regulation (EU) No 609/2013</a>. The yeast can be active or inactive for use in other foods.</p> <p>The yeast concentrate is blended with regular baker's yeast in order not to exceed the maximum level in the pre-packed fresh or dry yeast for home baking.</p> <p>Tan-coloured, free-flowing granules.</p> <p><b>Vitamin D<sub>2</sub></b></p>
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<p>Chemical name: (5Z,7E,22E)-(3S)-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol</p> <p>Synonym: Ergocalciferol</p> <p>CAS No.: 50-14-6</p> <p>Molecular weight: 396.65 g/mol</p> <p><b>Microbiological criteria for the yeast concentrate</b></p> <p>Coliforms: <math>\leq 10^3</math> CFU/g</p> <p><i>Escherichia coli</i>: <math>\leq 10</math> CFU/g</p> <p><i>Salmonella</i> spp.: Absence in 25 g</p> <p>CFU: Colony Forming Units”.</p>
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ATODLEN 5

Rheoliad 6

Diwygiadau i'r rhestr o fwydydd newydd yn yr Atodiad i Reoliad Gweithredu'r Comisiwn (EU) 2017/2470 ar gyfer awdurdodi powdr madarch fitamin D<sub>2</sub> fel bwyd newydd

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

2. Yn Nhabl 1 (bwydydd newydd awdurdodedig), ar ôl y cofnod ar gyfer “Vitamin D<sub>2</sub> mushroom powder” mewnosoder y cofnod a ganlyn—

“Vitamin D <sub>2</sub> mushroom powder	Specified food category	Maximum levels of vitamin D <sub>2</sub>	The designation of the novel food on the labelling of food containing it is “UV-treated mushroom powder containing vitamin D <sub>2</sub> ”.	Included in the list on 15 May 2023.
	Breakfast cereals	2.1 µg/100 g	The labelling of food supplements, as defined in the Food Supplements (Wales) Regulations 2003, containing vitamin D <sub>2</sub>	This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article
	Yeast-leavened bread and similar pastries	2.1 µg/100 g		
	Grain products and pasta and similar products	2.1 µg/100 g		
	Fruit / vegetable juices and nectars	1.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)		
	Dairy products and analogues	2.1 µg/100 g (marketed)		



**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.

other than beverages	as such or reconstituted as instructed by the manufacturer)	mushroom powder must bear a statement that they should not be consumed by infants and children under 3 years of age.	26 of Regulation (EU) 2015/2283.  Applicant: MBio, Monaghan Mushrooms, Tullygony, Tyholland, Co. Monaghan, Ireland, H18 FW95.  During the period of data protection, vitamin D <sub>2</sub> mushroom powder is authorised for placing on the market, within Wales, only by MBio, Monaghan Mushrooms unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or
Dairy products and analogues as beverages	1.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)		
Milk and dairy powders	21.3 µg/100 g (marketed as such or reconstituted as instructed by the manufacturer)		
Meat analogues	2.1 µg/100 g		
Soups	2.1 µg/100 ml (marketed as such or reconstituted as instructed by the manufacturer)		
Extruded vegetable snack	2.1 µg/100 g		
Meal replacement for weight control	2.1 µg/100 g		
Food for special medical purposes as defined in Regulation (EU) No 609/2013 excluding those intended for infants	In accordance with the particular nutritional requirements of the persons for whom the products are intended		
Food supplements as defined in the Food Supplements Regulations 2003 excluding food supplements for infants and	15 µg of vitamin D <sub>2</sub> /day”		

**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.

	children under 3 years of age			<p>scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of MBio, Monaghan Mushrooms.</p> <p>The data protection will expire at the end of 14 May 2028.</p>
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3. Yn Nhabl 2 (manylebau), ar ôl y cofnod ar gyfer “Vitamin D<sub>2</sub> mushroom powder” mewnosoder y cofnod a ganlyn—

<b>“Vitamin D<sub>2</sub> mushroom powder</b>	<p><b>Description/Definition</b></p> <p>The novel food is mushroom powder produced from dried whole <i>Agaricus bisporus</i> mushrooms. The process includes drying, milling and the controlled exposure of the mushroom powder to ultraviolet light.</p> <p><b>Characteristics/Composition</b></p> <p>Vitamin D<sub>2</sub> content: 580-595 µg/g of mushroom powder</p> <p>Ash: ≤ 13.5%</p> <p>Water activity: &lt; 0.5</p> <p>Moisture content: ≤ 7.5%</p> <p>Carbohydrates: ≤ 35%</p> <p>Total dietary fibre: ≥ 15%</p> <p>Crude protein (N x 6.25): ≥ 22%</p>
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Fat:  $\leq 4.5\%$

**Heavy metals**

Lead:  $\leq 0.5$  mg/kg

Cadmium:  $\leq 0.5$  mg/kg

Mercury:  $\leq 0.1$  mg/kg

Arsenic:  $\leq 0.3$  mg/kg

**Mycotoxins**

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

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

**Microbiological criteria**

Total plate count:  $\leq 5000$  CFU

Total yeast and mould count:  $\leq 100$  CFU/g

*Escherichia coli*:  $< 10$  CFU/g

*Salmonellaspp.*: Absence in 25 g

*Staphylococcus aureus*:  $\leq 10$  CFU/g

Coliforms:  $\leq 10$  CFU/g

*Listeria spp.*: Absence in 25 g

Enterobacteriaceae:  $< 10$  CFU/g

CFU: Colony Forming Units”.