WELSH STATUTORY INSTRUMENTS

2022 No. 575 (W. 133)

FOOD, WALES

The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022

Made - - - - 24 May 2022

Laid before Senedd Cymru 27 May 2022

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

The Welsh Ministers make the following Regulations in exercise of the powers conferred by Articles 12(1) and 32A(3) of, and in accordance with Articles 9 and 27(1) of, Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods(**1**); and Article 11(4) of Regulation (EC) No. 2065/2003 of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods(**2**).

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**), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

PART 1

Introduction

Title, extent, application and commencement

1.—(1) The title of these Regulations is the Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022.

(2) These Regulations—

(a) extend to England and Wales;

(b) apply in relation to Wales.

(**1**) EUR 2015/2283; relevant amending instruments are S.I. 2019/702 and 2020/1504. The terms "prescribe", "appropriate authority" and "list" are defined in Article 3 of Regulation 2015/2283.

(**2**) EUR 2065/2003; relevant amending instruments are S.I. 2019/860 and 2020/1504. The terms "prescribe" and "appropriate authority" are defined in Article 3 of Regulation 2065/2003.

(**3**) EUR 178/2002; relevant amending instruments are S.I. 2019/641 and 2020/1504.

(3) Parts 1 and 3 of these Regulations come into force on 18 June 2022.

(4) Part 2 of these Regulations comes into force on 30 June 2022.

PART 2

Novel Foods

Amendment of Commission Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods

2. In 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(**4**), the Annex (list of novel foods) is amended in accordance with Schedules 1 to 5.

PART 3

Smoke Flavourings

Amendment of Commission Implementing Regulation (EU) No. 1321/2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings

3. In Commission Implementing Regulation (EU) No. 1321/2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings(**5**), the Annex (domestic list of authorised smoke flavourings) is amended in accordance with regulations 4 to 8.

Modification of authorisation for "Scansmoke PB 1110"

4. In the authorisation for "Scansmoke PB 1110" (unique code "SF-001"), in column 2, for the entries corresponding to "Name of the authorisation holder" and "Address of the authorisation holder" substitute—

"proFagus GmbH
Uslarer Strasse 30 37194 Bodenfelde GERMANY"

Modification of authorisation for "Zesti Smoke Code 10"

5. In the authorisation for "Zesti Smoke Code 10" (unique code "SF-002"), in column 2, for the entries corresponding to "Name of the authorisation holder" and "Address of the authorisation holder" substitute—

(**4**) EUR 2017/2470, amended by S.I. 2019/702.
(**5**) EUR 1321/2013, amended by S.I. 2019/860.

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

Modification of authorisation for "SmokEz C-10"

6. In the authorisation for "SmokEz C-10" (unique code "SF-005"), in column 2, for the entries corresponding to "Name of the authorisation holder" and "Address of the authorisation holder" substitute—

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

Modification of authorisation for "SmokEz Enviro-23"

7. In the authorisation for "SmokEz Enviro-23" (unique code "SF-006"), in column 2, for the entries corresponding to "Name of the authorisation holder" and "Address of the authorisation holder" substitute—

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

Modification of authorisation for "Tradismoke™ A MAX"

8. In the authorisation for "Tradismoke™ A MAX" (unique code "SF-007"), in column 2, for the entries corresponding to "Name of the authorisation holder" and "Address of the authorisation holder" substitute—

"J. Rettenmaier & Söhne GmbH + CO KG
Holzmühle 1 73494 Rosenberg

GERMANY”

Lynne Neagle
Deputy Minister for Mental Health and Wellbeing, under the authority of the Minister for Health and Social Services

24 May 2022

SCHEDULE 1

Regulation 2

Amendment of the conditions of use and specifications of 2'-Fucosyllactose/Difucosyllactose mixture (2'FL/DFL) as a novel food

1. In Table 1 (authorised novel foods), in the entry for "2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL') (microbial source)", in column 2 (conditions under which the novel food may be used), at the end, insert the following condition of use—

"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".

2. In Table 2 (specifications), in the entry for "2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL') (microbial source)", in column 2 (specifications)—

(a) in the section headed "Description/Definition", for the wording from "amorphous powder" to "spray drying" substitute "powder or agglomerates thereof that is produced by a microbial process";

(b) in the section headed "Characteristics/Composition", for "Lactose and Fucose" substitute "D-Lactose, L-Fucose, and 3-Fucosyllactose".

SCHEDULE 2

Regulation 2

Authorisation of *Schizochytrium* sp. (FCC-3204) oil as a novel food

1. In Table 1 (authorised novel foods), after the entry for "*Schizochytrium* sp. (ATCC PTA-9695) oil", insert the following entry—

*"**"Schizochytrium* sp. (FCC-3204) oil**	*Specified food category*	*Maximum levels of DHA*	The designation of the novel food on the labelling of the foodstuffs containing it is "Oil from the microalgae *Schizochytrium* sp.". The labelling of food supplements containing *Schizochytrium* sp. (FCC-3204) oil must bear a statement that they should not be consumed by infants and		
	Food Supplements as defined in the Food Supplements (Wales) Regulations 2003(**6**), excluding food supplements for infants and children under 3 years of age	1g/day			

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

	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013(**7**)	In accordance with Regulation (EU) No 609/2013"	children under 3 years of age."		

2. In Table 2 (specifications), after the entry for "*Schizochytrium* sp. (ATCC PTA-9695) oil", insert the following entry—

"**"*Schizochytrium* sp. (FCC-3204) oil**	**Description/Definition:** The novel food is an oil produced from the strain FCC-3204 of the microalgae *Schizochytrium* sp. **Composition:** Acid value: ≤ 0.5 mg KOH (potassium hydroxide)/g Peroxide value (PV): ≤ 5.0 meq (milliequivalent)/kg oil Moisture and volatiles: ≤ 0.05 % Unsaponifiables: ≤ 4.5 % Trans-fatty acids: ≤ 1.0 % Docosahexaenoic acid (DHA): ≥ 32.0 % P-anisidine value: ≤ 10"".

SCHEDULE 3

Regulation 2

Authorisation of *Schizochytrium* sp. (WZU477) oil as a novel food

1. In Table 1 (authorised novel foods), after the entry for "*Schizochytrium* sp. (T18) oil", insert the following entry—

"**"*Schizochytrium* 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. This inclusion is based on proprietary
	Infant formula and	In accordance			

(**7**) EUR 2013/609, amended by S.I. 2019/651 and 2020/1476.

	follow-on formula as defined in Regulation (EU) No 609/2013	with Regulation (EU) No 609/2013"	is "Oil from the microalgae *Schizochytrium* sp.".		scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Progress Biotech BV, Canaalstaete, Kanaalweg 33, 2903LR Capelle aan den Ijssel, the Netherlands. During the period of data protection, *Schizochytrium* 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. The data protection ends at the end of 29 June 2027."

2. In Table 2 (specifications), after the entry for "*Schizochytrium* sp. (T18) oil", insert the following entry—

" ***"Schizochytrium* sp. (WZU477) oil**	**Description/Definition:**

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

SCHEDULE 4 Regulation 2

Authorisation for the placing on the market of 3'-Sialyllactose (3'-SL) sodium salt (microbial source) as a novel food

1. In Table 1 (authorised novel foods), after the entry for "Selenium-containing yeast (*Yarrowia lipolytica*) biomass", insert the following entry—

"**"3'-Sialyllactose (3'-SL) sodium salt (microbial source)**	*Specified food category*	*Maximum levels (expressed as 3'-Sialyllactose)*	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:		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
	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)			
	Unflavoured fermented	0.25 g/L (beverages)			

	milk-based products	0.5 g/kg (products other than beverages)	a) if foods containing added 3'-Sialyllactose sodium salt are consumed the same day; b) by infants and young children.		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."
	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	0.25 g/L			
	Cereal bars	2.5 g/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			

	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. In Table 2 (specifications), after the entry for “Selenium-containing yeast (*Yarrowia lipolytica*) biomass” insert the following entry—

“**"3’-Sialyllactose (3’-SL) sodium salt (microbial source)**	**Description:** 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 **Source:**

	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→3)-β-D-galactopyranosyl-(1→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

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

SCHEDULE 5 Regulation 2

Authorisation for the placing on the market of 6’-Sialyllactose (6’-SL) sodium salt (microbial source) as a novel food

1. In Table 1 (authorised novel foods), after the entry for “3’-Sialyllactose (3’-SL) sodium salt (microbial source)” (as inserted by Paragraph 1 of Schedule 4 to these Regulations), insert the following entry—

“**"6’-Sialyllactose (6’-SL) sodium salt (microbial source)**	*Specified food category*	*Maximum levels (expressed as 6’-Sialyllactose)*	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			

	defined in Regulation (EU) No 609/2013	ready for use, marketed as such or reconstituted as instructed by the manufacturer			Regulation (EU) 2015/2283 or with the agreement of Glycom A/S. The data protection ends at the end of 29 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	1.0 g/L (beverages) 10.0 g/kg (products other than beverages)			

	(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. In Table 2 (specifications), after the entry for “3’-Sialyllactose (3’-SL) sodium salt (microbial source)” (as inserted by Paragraph 2 of Schedule 4 to these Regulations), insert the following entry—

“**"6’-Sialyllactose (6’-SL) sodium salt (microbial source)**	**Description:** 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 **Source:** 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→6)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt Molecular mass: 655.53 Da

	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: ≤ 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.""

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision on regulated food product authorisations in relation to Wales. Part 2 and the Schedules are made pursuant to retained (EU) Regulation 2015/2283 on novel foods. Part 3 is made pursuant to retained Regulation (EC) No. 2065/2003 on smoke flavourings used or intended for use in or on foods.

Part 2 and the Schedules update, in relation to Wales, the list of authorised novel foods in Annex 1 to retained Regulation (EU) 2017/2470 establishing the Union list of novel foods—

- Schedule 1 amends the existing entry for 2'-Fucosyllactose/Difucosyllactose (2'FL/DFL) to authorise the placing on the market of that novel food for use in milk-based drinks and similar products intended for young children;
- Schedule 2 inserts a new entry, authorising the placing on the market of a specific strain of Schizochytrium sp. Oil (FCC-3204) as a novel food for use in food supplements, and for infant formula and follow-on formula;
- Schedule 3 inserts a new entry, authorising the placing on the market of a specific strain of Schizochytrium sp. Oil (WZU477) as a novel food for use in infant formula and follow-on formula;
- Schedule 4 inserts a new entry, authorising the placing on the market of 3'-Sialyllactose (3'-SL) sodium salt (microbial source) as a novel food for use in the specified food categories;
- Schedule 5 inserts a new entry, authorising the placing on the market of 6'-Sialyllactose (6'-SL) sodium salt (microbial source) as a novel food for use in the specified food categories.

Part 3 contains modifications to the authorisations for five smoke flavouring primary products within the Annex to retained Regulation (EC) No. 1321/2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods. The amendments change the names and the addresses of the authorisation holders of the respective product authorisations.

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.