SCOTTISH STATUTORY INSTRUMENTS

2022 No. 168

FOOD

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

Made - - - -	*18th May 2022*
Laid before the Scottish Parliament	*20th May 2022*
Coming into force	
for the purpose of regulation 1(2)	*18th June 2022*
for the purpose of regulation 1(3)	*30th June 2022*

The Scottish Ministers make these Regulations in exercise of the powers conferred by Articles 12(1)(**a**) and 32A(3) of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, amending Regulation (EU) No. 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No. 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No. 1852/2001(**b**), 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(**c**), and all other powers enabling them to do so.

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

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Scotland) Regulations 2022 and come into force in accordance with paragraphs (2) and (3).

(2) Regulations 1, 2 and 4 come into force on 18 June 2022.

(3) Regulation 3 comes into force on 30 June 2022.

(4) These Regulations extend to Scotland only.

(**a**) Article 9 makes provision as regards how the regulation-making power in Article 12(1) is to be exercised and Article 27(1) lays down requirements as regards the information to be included in the entry for a novel food on the list set out in Regulation (EU) 2017/2470 where it is authorised based on proprietary scientific evidence or scientific data.
(**b**) EUR 2015/2283 as amended by S.I. 2019/702. The terms "prescribe" and "appropriate authority" are defined in Article 3.
(**c**) EUR 2065/2003 as amended by S.I. 2019/860. The terms "prescribe" and "appropriate authority" are defined in Article 3.
(**d**) EUR 178/2002 as amended by S.I. 2019/641.

Interpretation

2.—(1) In these Regulations—

"Regulation (EU) 1321/2013" means 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(**a**), and

"Regulation (EU) 2017/2470" means 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(**b**).

(2) Unless the contrary intention appears, any expression used both in these Regulations and in Regulation (EU) 1321/2013 or Regulation (EU) 2017/2470 has the same meaning as it bears in those Regulations.

Authorisation and change to conditions of use and specifications of novel foods

3. The list of authorised novel foods set out in the Annex to Regulation (EU) 2017/2470 is amended in accordance with schedules 1 to 5.

Modification of authorisation holders: authorised smoke flavouring primary products

4.—(1) The list of authorised smoke flavouring primary products set out in the Annex to Regulation (EU) 1321/2013 is amended in accordance with paragraphs (2) to (5).

(2) In the entry for Scansmoke PB 1110 for—

(a) "Azelis Denmark A/S" substitute "proFagus GmbH", and

(b) "Lundtoftegaardsvej 95, 2800, Lyngby, DENMARK" substitute "Uslarer Strasse 30, 37194 Bodenfelde, GERMANY".

(3) In the entry for Zesti Smoke Code 10 for—

(a) "Mastertaste" substitute "Kerry Group Plc", and

(b) "Draycott Mills, Cam, Dursley, Gloucestershire, GL11 5NA, UNITED KINGDOM" substitute "Prince's Street, Tralee, Co. Kerry, V92 EH11, IRELAND".

(4) In the entries for SmokeEz C-10 and SmokeEz Enviro-23 for—

(a) "Red Arrow Products Company LLC" substitute "Kerry Group Plc", and

(b) "P.O. Box 1537, 633 South 20th street, Manitowoc, WI 54221-1537, USA" substitute "Prince's Street, Tralee, Co. Kerry, V92 EH11, IRELAND".

(5) In the entry for Tradismoke™ A MAX for—

(a) "Nactis" substitute "J. Rettenmaier & Söhne GmbH + CO KG", and

(b) "36, rue Gutenberg - ZI La Marinière, 91070 Bondoufle, FRANCE" substitute "Holzmühle 1, 73494 Rosenberg, GERMANY".

MAREE TODD
Authorised to sign by the Scottish Ministers

St Andrew's House,
Edinburgh
18th May 2022

(**a**) EUR 1321/2013 as amended by S.I. 2019/860.
(**b**) EUR 2017/2470 as amended by S.I. 2019/702.

SCHEDULE 1

Regulation 3

Change to conditions of use and specifications of 2'-Fucosyllactose/Difucosyllactose mixture ('2'FL/DFL') (microbial source)

1. In the entry for 2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL') (microbial source) in Table 1 (authorised novel foods) insert at the end the following condition of use—

	"Specified food category Milk-based drinks and similar products intended for young children	*Maximum levels* 1.2 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer"			

2. For the entry for 2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL') (microbial source) in Table 2 (specifications) substitute the following—

"**2'-Fucosyllactose /Difucosyllactose mixture ('2'-FL/DFL') (microbial source)**	**Description/Definition:** 2'-Fucosyllactose/Difucosyllactose mixture is a purified, white to off-white powder or agglomerates thereof that is produced by a microbial process. **Source**: Genetically modified strain of *Escherichia coli* strain K-12 DH1 **Characteristics/Composition:** Appearance: White to off-white powder or agglomerates Sum of 2'-Fucosyllactose, Difucosyllactose, D-Lactose, L-Fucose, and 3-Fucosyllactose (% of dry matter): ≥ 92.0 % (w/w) Sum of 2'-fucosyllactose and difucosyllactose (% of dry matter): ≥ 85.0 % (w/w) 2'-Fucosyllactose (% of dry matter): ≥ 75.0 % (w/w) Difucosyllactose (% of dry matter): ≥ 5.0 % (w/w) D-Lactose: ≤ 10.0 % (w/w) L-Fucose: ≤ 1.0 % (w/w) 2'-Fucosyl-D-lactulose: ≤ 2.0 % (w/w) Sum of other carbohydrates(**a**): ≤ 6.0 % (w/w) Moisture: ≤ 6.0 % (w/w) Ash, sulfated: ≤ 0.8 % (w/w) pH (20 °C, 5 % solution): 4.0-6.0 Residual protein: ≤ 0.01 % (w/w) **Microbiological criteria:** Aerobic mesophilic bacteria total plate count: ≤ 1000 CFU/g Enterobacteriaceae: ≤ 10 CFU/g *Salmonella* sp.: Negative/25 g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units"

(**a**) 2′-Fucosyl-galactose, Glucose, Galactose, Mannitol, Sorbitol, Galactitol, Trihexose, Allo-lactose and other structurally related carbohydrates.

SCHEDULE 2

Regulation 3

Authorisation of *Schizochytrium* sp. (FCC-3204) oil

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*			
	Food supplements as defined in the Food Supplements (Scotland) Regulations 2003(**a**) excluding food supplements for infants and children under 3 years of age	1 g/day	The designation of the novel food on the labelling of the foodstuffs containing it is "Oil from the microalgae *Schizochytrium* sp.".		
	Infant formula and follow-on formula as defined in Regulation (EU) 609/2013(**b**)	In accordance with Regulation (EU) 609/2013	The labelling of food supplements containing *Schizochytrium* sp. (FCC-3204) oil must bear a statement that they should not be consumed by infants and children under 3 years of age."		

(**a**) S.S.I. 2003/278, as relevantly amended by S.S.I. 2019/54.
(**b**) EUR 609/2013 as amended by S.I. 2019/651.

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 3

Authorisation of *Schizochytrium* sp. (WZU477) oil

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* Infant formula and follow-on formula as defined in Regulation (EU) 609/2013	*Maximum levels of DHA* In accordance with Regulation (EU) 609/2013	The designation of the novel food on the labelling of the foodstuffs containing it is "Oil from the microalgae *Schizochytrium* sp.".		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: Progress Biotech BV of Canaalstaete, Kanaalweg 33, 2903LR Capelle aan den Ijssel, the Netherlands.

					During the period of data protection, the novel food *Schizochytrium* sp. (WZU477) oil is authorised for placing on the market within Scotland 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 will expire 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 3

Authorisation of 3'Sialyllactose (3'-SL) sodium salt (microbial source)

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* Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products Flavoured fermented milk-based products including heat-treated products Unflavoured fermented milk-based products	*Maximum levels (expressed as 3'-Sialyllactose)* 0.25 g/L 0.25 g/L (beverages) 2.5 g/kg (products other than beverages) 0.25 g/L (beverages) 0.5 g/kg (products other than beverages)	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 Allé 4, DK-2970 Hørsholm, Denmark. During the period of data protection, the novel food 3'-sialyllactose sodium salt is authorised for placing on the market within Scotland only by Glycom A/S, unless a subsequent applicant

	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	0.25 g/L			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 will expire at the end of 29 June 2027.
	Cereal bars	2.5 g/kg			
	Infant formula as defined in Regulation (EU) 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) 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) 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 for 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) 609/2013	0.5 g/L (beverages) 5 g/kg (products other than beverages)			
	Food for special medical purposes as defined in Regulation (EU) 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 (Scotland) 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)-D-glucose, 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 3

Authorisation of 6′-Sialyllactose (6′-SL) sodium salt (microbial source)

1. In Table 1 (authorised novel foods), after the entry for 3'Sialyllactose (3'-SL) sodium salt (microbial source)(**a**) insert the following entry—

"**6'-Sialyllactose (6'-SL) sodium salt (microbial source)**	*Specified food category* Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products Unflavoured fermented milk-based products Flavoured fermented milk-based products including heat-treated products Beverages (flavoured drinks, excluding drinks with a pH less than 5)	*Maximum levels (expressed as 6'-Sialyllactose)* 0.5 g/L 0.5 g/L (beverages) 2.5 g/kg (products other than beverages) 0.5 g/L (beverages) 5.0 g/kg (products other than beverages) 0.5 g/L	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 (6'-SL) sodium salt must bear a statement that they should not be consumed: (a) if foods containing added 6'-Sialyllactose sodium salt are consumed on 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 Allé 4, DK-2970 Hørsholm, Denmark. During the period of data protection, the novel food 6'-sialyllactose sodium salt is authorised for placing on the market

(**a**) Inserted by S.S.I. 2022/168.

	Cereal bars	5.0 g/kg			within Scotland 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 will expire at the end of 29 June 2027.
	Infant formula as defined in Regulation (EU) 609/2013	0.4 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) 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) 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 for products other than beverages			
	Milk based drinks and similar products intended for young children	0.3 g/L (beverages) 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) 609/2013 Food for special medical purposes as defined in Regulation (EU) 609/2013 Food supplements as defined in the Food Supplements (Scotland) Regulations 2003, excluding food supplements for infants and young children	1.0 g/L (beverages) 10.0 g/kg (products other than beverages) In accordance with the particular nutritional requirements of the persons for whom the products are intended 1.0 g/day.”			

2. In Table 2 (specifications), after the entry for 3'Sialyllactose (3'-SL) sodium salt (microbial source) 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 as regards the authorisation of novel foods under Regulation (EU) 2015/2283, and also substitute new authorisation holders for smoke flavourings already authorised under Regulation (EC) 2065/2003.

Regulation 3 and schedule 1 make changes to the conditions of use and specifications of a novel food already authorised under Regulation (EU) 2015/2283, 2'-Fucosyllactose/Difucosyllactose (2'FL/DFL).

Regulation 3 and schedules 2 to 5 authorise the placing on the market in Scotland of four novel foods by updating the list of novel foods (set out in Regulation (EU) 2017/2470) to add—

(a) Schizochytrium sp. (FCC-3204) oil,

(b) Schizochytrium sp. (WZU477) oil,

(c) 3'-Sialyllactose (3'-SL) sodium salt, and

(d) 6'-Sialyllactose (6'-SL) sodium salt.

Regulation 4 substitutes new authorisation holders for five smoke flavourings already authorised under Regulation (EC) 2065/2003—

(a) Scansmoke PB 1110,

(b) Zesti Smoke Code 10,

(c) SmokeEz C-10,

(d) SmokeEz Enviro-23, and

(e) Tradismoke™ A MAX.

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