STATUTORY INSTRUMENTS

# 2022 No. 560

# FOOD, ENGLAND

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

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| *Made - - - -* | *19th May 2022* |
| *Laid before Parliament* | *20th May 2022* |
| *Coming into force in accordance with regulation 1* | |

The Secretary of State makes the following Regulations in exercise of the powers conferred by Articles 12(1) and 32A(3), 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, etc. ("Regulation 2015/2283")(**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.

### Citation, commencement, extent and application

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

(2) This regulation and regulation 3 come into force on 18th June 2022.

(3) Regulation 2 comes into force on 30th June 2022.

(4) These Regulations extend to England and Wales, but apply in relation to England only.

### Amendment of Commission Implementing Regulation (EU) 2017/2470

**2.**—(1) The Annex to 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**) is amended as follows.

(**1**) EUR 2015/2283, amended by S.I. 2019/702. The terms "prescribe" and "appropriate authority" are defined in Article 3.
(**2**) EUR 2003/2065, amended by S.I. 2019/860. The terms "prescribe" and "appropriate authority" are defined in Article 3.
(**3**) EUR 2002/178, amended by S.I. 2019/641.
(**4**) EUR 2017/2470, amended by S.I. 2019/702.

(2) In Table 1—

(a) in the entry for "2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL') (microbial source)"—

(i) in the second column (specified food category) insert "Milk-based drinks and similar products intended for young children";

(ii) in the third column (maximum levels) insert "1.2 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer";

(b) after the entry for "Schizochytrium sp. (ATCC PTA-9695) oil" insert the entry in Schedule 1;

(c) after the entry for "Schizochytrium sp. (T18) oil" insert the entry in Schedule 2;

(d) after the entry for "Selenium-containing yeast (Yarrowia lipolytica) biomass" insert the entries in Schedule 3.

(3) In Table 2—

(a) for the entry "2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL') (microbial source)" substitute the entry in Schedule 4;

(b) after the entry for "Schizochytrium sp. (ATCC PTA-9695) oil" insert the entry in Schedule 5;

(c) after the entry for "Schizochytrium sp. (T18) oil" insert the entry in Schedule 6;

(d) after the entry for "Selenium-containing yeast (Yarrowia lipolytica) biomass" insert the entries in Schedule 7.

**Amendment of Commission Implementing Regulation (EU) No 1321/2013**

**3.**—(1) The Annex to 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**) is amended as follows.

(2) In the entry for unique code "SF-001"—

(a) for "Azelis Denmark A/S" substitute "proFagus GmbH";

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

(3) In the entry for unique code "SF-002"—

(a) for "Mastertaste" substitute "Kerry Group plc";

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

(4) In the entry for unique code "SF-005"—

(a) for "Red Arrow Products Company LLC" substitute "Kerry Group plc";

(b) for "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 unique code "SF-006"—

(a) for "Red Arrow Products Company LLC" substitute "Kerry Group plc";

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

(6) In the entry for unique code "SF-007"—

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

(a) for “Nactis” substitute “J. Rettenmaier & Söhne GmbH + CO KG”;

(b) for “36, rue Gutenberg – ZI La Marinière, 91070 Bondoufle FRANCE” substitute “Holzmühle 1, 73494 Rosenberg, GERMANY”.

*Maggie Throup*
Parliamentary Under-Secretary of State,
Department of Health and Social Care

19th May 2022

SCHEDULE 1

Regulation 2(2)(b)

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| "Schizochytrium sp. strain (FCC-3204) oil | *Specified food category*<br><br>Food supplements as defined in the Food Supplements (England) Regulations 2003 (**6**), excluding food supplements for infants and children under the age of 3.<br><br>Infant formula and follow-on formula as defined in Regulation 609/2013 (**7**) | *Maximum levels of DHA*<br><br>1000mg/day<br><br>In accordance with Regulation 609/2013." | The designation of the novel food on the labelling of the foodstuffs containing it is 'Oil from the microalgae Schizochytrium sp.'.<br><br>The labelling of food supplements containing Schizochytrium sp. strain (FCC-3204) oil must bear a statement that they should not be consumed by infants and children under the age of 3. |

SCHEDULE 2

Regulation 2(2)(c)

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| "Schizochytrium sp. (WZU477) oil | *Specified food category*<br><br>Infant formula and follow-on formula as defined in Regulation 609/2013 | *Maximum levels of DHA*<br><br>In accordance with Regulation 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 30th June 2022.<br><br>This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation 2015/2283.<br><br>Applicant: Progress Biotech BV of Canaalstaete, Kanaalweg 33, 2903LR Capelle |

(**6**) S.I. 2003/1387, to which there are amendments not relevant to these Regulations.
(**7**) EUR 2013/609, amended by S.I. 2019/651.

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| | aan den Ijssel, The Netherlands. |
| | During the period of data protection, Schizochytrium sp. (WZU477) oil is authorised for placing on the market within England 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 2015/2283 or with the agreement of Progress Biotech BV. |
| | The data protection will expire at the end of 29th June 2027. |

SCHEDULE 3 Regulation 2(2)(d)

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| "3'-Sialyllactose (3'-SL) sodium salt **(microbial source)** | Specified food category | Maximum levels | The designation of the novel food on the labelling of the foodstuffs containing it is '3'-Sialyllactose sodium salt'. | Included in the list on 30th June 2022. |
| | Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products | 0.25 g/L | | This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation 2015/2283. |
| | Flavoured fermented milk-based products including heat-treated products | 0.25 g/L (beverages)<br>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:<br>(a) if foods containing added 3'-Sialyllactose sodium salt are consumed the same day<br>(b) by infants and young children. | Applicant: Glycom A/S of Kogle Allé 4, DK-2970 Hørsholm, Denmark. |
| | Unflavoured fermented milk-based products | 0.25 g/L (beverages)<br>0.5g/kg (products other than beverages) | | During the period of data protection, 3'-Sialyllactose sodium salt is authorised for placing on the market within England 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 |
| | 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 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 609/2013 | 0.15 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer | | |

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| Processed cereal-based food and baby food for infants and young children as defined in Regulation 609/2013 | 0.15 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.<br><br>1.25 g/kg for products other than beverages | protected in accordance with Article 26 of Regulation 2015/2283 or with the agreement of Glycom A/S.<br><br>The data protection will expire at the end of 29th June 2027. |
| 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 609/2013 | 0.5 g/L (beverages)<br><br>5g/ kg (products other than beverages) | |
| Food for special medical purposes as defined in Regulation 609/2013 | In accordance with the particular nutritional requirements of the persons for whom the products are intended | |
| Food Supplements as defined the Food Supplements (England) Regulations 2003, excluding food supplements for infants and young children | 0.5 g/day | |

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| 6'-Sialyllactose (6'-SL) sodium salt **(microbial source)** | Specified food category | Maximum levels | The designation of the novel food on the labelling of the foodstuffs containing it is '6'-Sialyllactose sodium salt'.<br><br>The labelling of food supplements containing 6'-Sialyllactose sodium salt must bear a statement that they should not be consumed:<br><br>(a) if foods containing added 6'-Sialyllactose sodium salt are consumed the same day<br><br>(b) by infants and young children. | Included in the list on 30th June 2022.<br><br>This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation 2015/2283.<br><br>Applicant: Glycom A/S of Kogle Allé 4, DK-2970 Hørsholm, Denmark.<br><br>During the period of data protection, 6'-Sialyllactose sodium salt is authorised for placing on the market within England 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 |
| | Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products | 0.5 g/L | | |
| | Unflavoured fermented milk-based products | 0.5 g/L (beverages)<br><br>2.5g/ kg (products other than beverages) | | |
| | Flavoured fermented milk-based products including heat-treated products | 0.5 g/L (beverages)<br><br>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 defined in Regulation 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 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 | 0.3 g/L (beverages) in the final | | |

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| infants and young children as defined in Regulation 609/2013 | product ready for use, marketed as such or reconstituted as instructed by the manufacturer<br><br>kg for products other than beverages | with Article 26 of Regulation 2015/2283 or with the agreement of Glycom A/S.<br><br>The data protection will expire at the end of 29th June 2027. |
| 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 609/2013 | 1.0 g/L (beverages)<br><br>10.0 g/kg (products other than beverages) | |
| Food for special medical purposes as defined in Regulation 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 (England) Regulations 2003, excluding food supplements for infants and young children | 1.0 g/day” | |

SCHEDULE 4 Regulation 2(3)(a)

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| "2'-Fucosyllactose/ Difucosyllactose mixture ('2'-FL/DFL') **(microbial source)** | **Description:**<br><br>2'-Fucosyllactose/Difucosyllactose mixture is a purified, white to off-white powder or agglomerate thereof that is produced by a microbial process.<br><br>**Source:**<br><br>Genetically modified strain of Escherichia coli K-12 DH1<br><br>**Characteristics/Composition:**<br><br>Appearance: White to off white powder or agglomerates<br><br>Sum of 2′-Fucosyllactose, Difucosyllactose, D-Lactose, L-Fucose, and 3-Fucosyllactose (% of dry matter): ≥ 92.0 % (w/w)<br><br>Sum of 2′-Fucosyllactose and Difucosyllactose (% of dry matter): ≥ 85.0 % (w/w)<br><br>2′-Fucosyllactose (% of dry matter): ≥ 75.0 % (w/w)<br><br>Difucosyllactose (% of dry matter): ≥ 5.0 % (w/w)<br><br>D-Lactose: ≤ 10.0 % (w/w)<br><br>L-Fucose: ≤ 1.0 % (w/w)<br><br>2′-Fucosyl-D-lactulose: ≤ 2.0 (w/w)<br><br>Sum of other carbohydrates(**8**) (11): ≤ 6.0 % (w/w)<br><br>Moisture: ≤ 6.0 % (w/w)<br><br>Ash, sulfated: ≤ 0.8 % (w/w)<br><br>pH (20 °C, 5 % solution): 4.0 -6.0<br><br>Residual protein: ≤ 0.01 % (w/w)<br><br>**Microbiological criteria:**<br><br>Aerobic mesophilic total plate count: ≤ 1000 CFU/g<br>Enterobacteriaceae: ≤ 10 CFU/g<br><br>Salmonella sp.: Negative/25 g<br><br>Yeast: ≤ 100 CFU/g |

(**8**) 2'-Fucosyl-galactose, Glucose, Galactose, Mannitol, Sorbitol, Galactitol, Trihexose, Allo-lactose and other structurally related carbohydrates.

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| | Mould: ≤ 100 CFU/g<br><br>Residual endotoxins: ≤ 10 EU/mg<br><br>CFU: Colony Forming Units; EU: Endotoxin Units” |

SCHEDULE 5 Regulation 2(3)(b)

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

SCHEDULE 6 Regulation 2(3)(c)

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| “Schizochytrium sp. (WZU477) oil | **Description/Definition:**<br><br>The novel food is an oil produced from the strain WZU477 of the microalgae Schizochytrium sp.<br><br>**Composition:**<br><br>Acid value: ≤ 0.5 mg KOH (potassium hydroxide)/g<br><br>Peroxide value (PV): ≤ 5.0 meq (milliequivalent)/kg oil<br><br>Moisture and volatiles: ≤ 0.05 %<br><br>Unsaponifiables: ≤ 4.5 %<br><br>Trans-fatty acids: ≤ 1.0 % |

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| | Docosahexaenoic acid (DHA): ≥ 32.0 %<br><br>P-anisidine value: ≤ 10” |

SCHEDULE 7 Regulation 2(3)(d)

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| “3’-Sialyllactose (3’-SL) sodium salt **(microbial source)** | **Description:**<br><br>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<br><br>**Source:**<br><br>Genetically modified strain of Escherichia coli K-12 DH1<br><br>**Definition:**<br><br>Chemical formula: $C_{23}H_{38}NO_{19}Na$<br><br>Chemical name: N-Acetyl-α-D-neuraminyl-(2→3)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt<br><br>Molecular mass: 655.53 Da<br><br>CAS No 128596-80-5<br><br>**Characteristics/Composition:**<br><br>Appearance: White to off-white powder or agglomerate<br><br>Sum of 3’-Sialyllactose sodium salt, D-Lactose, and Sialic acid (% of dry matter): ≥ 90.0 % (w/w)<br><br>3’-Sialyllactose sodium salt (% of dry matter): ≥ 88.0 % (w/w)<br><br>D-Lactose: ≤ 5.0 % (w/w)<br><br>Sialic acid: ≤ 1.5 % (w/w)<br><br>3’-Sialyl-lactulose: ≤ 5.0 % (w/w)<br><br>Sum of other carbohydrates: ≤ 3.0 % (w/w)<br><br>Moisture: ≤ 8.0 % (w/w)<br><br>Sodium: 2.5 – 4.5 % (w/w)<br><br>Chloride: ≤ 1.0 % (w/w) |

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| | pH (20 °C, 5 % solution): 4.5 -6.0<br><br>Residual protein: ≤ 0.01 % (w/w)<br><br>**Microbiological criteria:**<br><br>Aerobic mesophilic bacteria total plate count: ≤ 1000 CFU/g<br><br>Enterobacteriaceae: ≤ 10 CFU/g<br><br>Salmonella sp.: Absence in 25 g<br><br>Yeast: ≤ 100 CFU/g<br><br>Mould: ≤ 100 CFU/g<br><br>Residual endotoxins: ≤ 10 EU/mg<br><br>CFU: Colony Forming Units; EU: Endotoxin Units |
| 6'-Sialyllactose (6'-SL) sodium salt **(microbial source)** | **Description:**<br><br>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'-sialy-llactulose, and sialic acid<br><br>**Source:**<br><br>Genetically modified strain of Escherichia coli K-12 DH1<br><br>**Definition:**<br><br>Chemical formula: $C_{23}H_{38}NO_{19}Na$<br><br>Chemical name: N-Acetyl-α-D-neuraminyl-(2→6)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt<br><br>Molecular mass: 655.53 Da<br><br>CAS No 157574-76-0<br><br>**Characteristics/Composition:**<br><br>Appearance: White to off-white powder or agglomerate<br><br>Sum of 6'-Sialyllactose sodium salt, D-Lactose and Sialic acid (% of dry matter): ≥ 94.0 % (w/w)<br><br>6'-Sialyllactose sodium salt (% of dry matter): ≥ 90.0 % (w/w)<br><br>D-Lactose: ≤ 5.0 % (w/w)<br><br>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)*

Regulation 2 amends 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 to add four novel foods and amend the conditions of use and specifications of one novel food on the list of authorised novel foods.

Regulation 3 amends 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 to modify the authorisation holder and addresses for five smoke flavouring primary product authorisations.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the public, private or voluntary sector is foreseen.