



**NOTIFICATION**

<p><b>1. Notifying Member:</b> <u>UNITED KINGDOM</u></p> <p><b>If applicable, name of local government involved:</b></p>
<p><b>2. Agency responsible:</b> The UK Food Safety Authorities comprising of the Food Standards Agency (FSA) and Food Standards Scotland (FSS)</p>
<p><b>3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable):</b></p> <p>Authorization of four novel food (NF) products and modification to the conditions of use of one novel food and specifications for its existing authorization.</p> <p>The four novel food products are:</p> <ul style="list-style-type: none"><li>• 3'-Sialyllactose (3'-SL) sodium salt</li><li>• 6'-Sialyllactose (6'-SL) sodium salt</li><li>• Schizochytrium sp. (WZU477) oil</li><li>• Schizochytrium sp. (FCC-3204) oil.</li></ul> <p>The modification of one novel food is:</p> <ul style="list-style-type: none"><li>• 2'-Fucosyllactose/difucosyllactose mixture (2'-FL/DFL) (note this consists of a change to the conditions of use and specifications, not a new authorization).</li></ul>
<p><b>4. Regions or countries likely to be affected, to the extent relevant or practicable:</b></p> <p><input checked="" type="checkbox"/> <b>All trading partners</b></p> <p><input type="checkbox"/> <b>Specific regions or countries:</b></p>
<p><b>5. Title of the notified document:</b> Authorization of four novel food products and a change to the conditions of use and specification for an existing authorization. <b>Language(s):</b> English. <b>Number of pages:</b></p> <p>Full text of the legislation made available for England, Scotland and Wales, respectively.</p> <p>England: <a href="https://www.legislation.gov.uk/uksi/2022/619/introduction/made">https://www.legislation.gov.uk/uksi/2022/619/introduction/made</a> Scotland: <a href="https://www.legislation.gov.uk/en/ssi/2022/168/introduction/made">https://www.legislation.gov.uk/en/ssi/2022/168/introduction/made</a> Wales: <a href="https://www.legislation.gov.uk/wsi/2022/575/made">https://www.legislation.gov.uk/wsi/2022/575/made</a></p>
<p><b>6. Description of content:</b> The UK Food Safety Authorities are notifying Members of an authorization of four novel food products for use in the GB market and a change to the conditions of use of one novel food and its specification for an existing authorization.</p> <p>The authorizations cover novel food products to be used as components in infant follow-on formula. The following products are classified as "human-identical milk oligosaccharides (HiMOs)". The manufactured HiMOs are identical in structure to the same molecules present in breast milk.</p> <ul style="list-style-type: none"><li>o 3'-Sialyllactose (3'-SL) sodium salt,</li><li>o 6'-Sialyllactose (6'-SL) sodium salt.</li></ul>

Terms for entry to the list of authorized novel foods:

- Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products
- Flavoured fermented milk-based products including heat-treated products
- Unflavoured fermented milk-based products
- Beverages (flavoured drinks, excluding drinks with a pH less than 5)
- Cereal bars
- Infant formula as defined under Retained EU Regulation 609/2013
- Follow-on formula as defined under Retained EU Regulation 609/2013
- Processed cereal-based drinks and baby food for infants and young children as defined under Retained EU Regulation 609/2013
- Milk-based drinks and similar products intended for young children
- Total diet replacement foods for weight control as defined in Retained EU Regulation 609/2013
- Food for special medical purposes as defined under Retained EU Regulation 609/2013 (*only applicable to 3'-Sialyllactose (3'-SL) sodium salt*)
- Food supplements as defined in the Food Supplements Regulation 2003 for England, excluding food supplements for infants and young children.

o 2'-Fucosyllactose/difucosyllactose mixture (2'-FL/DFL) (note this consists of a change to the conditions of use and specifications, not a new authorization)

- Milk-based drinks and similar products intended for young children.

The below products are Docosahexaenoic acid (DHA) rich oils derived from marine algae. DHA is mandatory in infant and follow-on formula in the UK under retained Commission Delegated Regulation 2016/127.

o Schizochytrium sp. (WZU477) oil

- Infant formula and follow-on formula as defined in retained Regulation (EU) No 609/2013.

o Schizochytrium sp. (FCC-3204) oil

- Food supplements as defined in The Food Supplements Regulations 2003 for England, excluding food supplements for infants and young children
- Infant and follow-on formula.

These authorizations are made on the basis of the uses and specifications set out in the consultations linked in section 9.

**7. Objective and rationale:  food safety,  animal health,  plant protection,  protect humans from animal/plant pest or disease,  protect territory from other damage from pests.**

**8. Is there a relevant international standard? If so, identify the standard:**

**Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):** CXG-62-2007 - Working Principles for Risk Analysis for Food Safety for Application by Governments.

**World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):**

**International Plant Protection Convention (e.g. ISPM number):**

**None**

**Does this proposed regulation conform to the relevant international standard?**

<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard:</p>	
9.	<p><b>Other relevant documents and language(s) in which these are available:</b> Full details of the applications for authorization of these Novel Food products are laid out in previous public consultations on the FSA and FSS websites, available here:</p> <p><a href="#">FSA consultation on NF uses</a> <a href="#">FSS consultation on NF uses</a></p> <p>The consultations also link to the FSA/FSS risk assessment on the uses.</p>
10.	<p><b>Proposed date of adoption (dd/mm/yy):</b> 20 May 2022 <b>Proposed date of publication (dd/mm/yy):</b> 20 May 2022</p>
11.	<p><b>Proposed date of entry into force:</b> <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): 30 June 2022 <input checked="" type="checkbox"/> Trade facilitating measure</p>
12.	<p><b>Final date for comments:</b> <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): Not applicable. <b>Agency or authority designated to handle comments:</b> <input checked="" type="checkbox"/> National Notification Authority, <input type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>UK SPS Contact Point, Defra, Nobel House, London SW1P 3JR E-mail: <a href="mailto:UKSPS@defra.gov.uk">UKSPS@defra.gov.uk</a></p>
13.	<p><b>Text(s) available from:</b> <input type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>UK SPS Contact Point, Defra, Nobel House, London SW1P 3JR E-mail: <a href="mailto:UKSPS@defra.gov.uk">UKSPS@defra.gov.uk</a></p>