NOTIFICATION

|  |  |
| --- | --- |
| **1.** | **Notifying Member:** UNITED KINGDOM**If applicable, name of local government involved:**  |
| **2.** | **Agency responsible:** The UK Food Safety Authorities comprising of the Food Standards Agency (FSA) and Food Standards Scotland (FSS) |
| **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):** Authorization of four novel food (NF) products and modification to the conditions of use of one novel food and specifications for its existing authorization.The four novel food products are:* 3'-Sialyllactose (3'-SL) sodium salt
* 6'-Sialyllactose (6'-SL) sodium salt
* Schizochytrium sp. (WZU477) oil
* Schizochytrium sp. (FCC-3204) oil.

The modification of one novel food is:* 2'-Fucosyllactose/difucosyllactose mixture (2'-FL/DFL) (note this consists of a change to the conditions of use and specifications, not a new authorization).
 |
| **4.** | **Regions or countries likely to be affected, to the extent relevant or practicable:****[****X]** **All trading partners** **[****]** **Specific regions or countries:**  |
| **5.** | **Title of the notified document:** Authorization of four novel food products and a change to the conditions of use and specification for an existing authorization.**Language(s):** English. **Number of pages:** Full text of the legislation made available for England, Scotland and Wales, respectively.England: <https://www.legislation.gov.uk/uksi/2022/619/introduction/made>Scotland: <https://www.legislation.gov.uk/en/ssi/2022/168/introduction/made>Wales: <https://www.legislation.gov.uk/wsi/2022/575/made> |
| **6.** | **Description of content:** 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.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.o 3'-Sialyllactose (3'-SL) sodium salt,o 6'-Sialyllactose (6'-SL) sodium salt.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-treaded 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: [****X]****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:****[****X]** **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?** **[****X]** **Yes [****]** **No****If no, describe, whenever possible, how and why it deviates from the international standard:**  |
| **9.** | **Other relevant documents and language(s) in which these are available:** 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:[FSA consultation on NF uses](https://www.food.gov.uk/news-alerts/consultations/applications-for-six-novel-foods)[FSS consultation on NF uses](https://consult.foodstandards.gov.scot/regulatory-policy/publication-of-fss-opinion-and-consultation-on-nf/)The consultations also link to the FSA/FSS risk assessment on the uses.  |
| **10.** | **Proposed date of adoption *(dd/mm/yy)*:** 20 May 2022**Proposed date of publication *(dd/mm/yy)*:** 20 May 2022 |
| **11.** | **Proposed date of entry into force: [****]****Six months from date of publication**, **and/or** ***(dd/mm/yy)*:** 30 June 2022**[****X]** **Trade facilitating measure**  |
| **12.** | **Final date for comments: [****]****Sixty days from the date of circulation of the notification and/or *(dd/mm/yy)*:** Not applicable.**Agency or authority designated to handle comments: [****X]****National Notification Authority, [****]****National Enquiry Point.** **Address, fax number and e‑mail address (if available) of other body:** UK SPS Contact Point, Defra, Nobel House, London SW1P 3JRE-mail: UKSPS@defra.gov.uk |
| **13.** | **Text(s) available from: [****]****National Notification Authority, [****X]****National Enquiry Point.** **Address, fax number and e‑mail address (if available) of other body:** UK SPS Contact Point, Defra, Nobel House, London SW1P 3JRE-mail: UKSPS@defra.gov.uk |