*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.*

**EN**

**ANNEX**

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

1. the following entry is inserted in Table 1 (Authorised novel foods) in alphabetical order:

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| --- | --- | --- | --- | --- | --- |
| **Authorised novel food** | **Conditions under which the novel food may be used** | | **Additional specific labelling requirements** | **Other requirements** | **Data Protection** |
| **2’-fucosyllactose/difucosyllactose mixture (‘2’-FL/DFL)**  **(Microbiological)** | **Specified food category** | **Maximum levels** | The designation of the novel food on the labelling of the foodstuffs containing it shall be “2’-fucosyllactose/difucosyllactose mixture”.  The labelling of food supplements containing the 2’-fucosyllactose/difucosyllactose mixture shall bear a statement that they should not be used if breast milk or other foods with added 2’-fucosyllactose/difucosyllactose mixture and/or added 2’-fucosyllactose are consumed the same day. |  | Authorised on dd.mm.yyyy [20th day following its publication]. 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 2’-fucosyllactose/difucosyllactose mixture is authorised for placing on the market within the Union 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 Glycom A/S.  End date of the data protection: dd.mm.yyyy (5 years). |
| Unflavoured pasteurised and unflavoured sterilised (including UHT) milk | 2.0 g/L |
| Unflavoured fermented milk-based products | 2.0 g/L (beverages)  20 g/kg (products other than beverages) |
| Flavoured fermented milk-bases products including heat-treated products | 2.0 g/L (beverages)  20 g/kg (products other than beverages) |
| Beverages (favoured drinks) | 2.0 g/L |
| Fine bakery wares (cereal bars only) | 20 g/kg |
| Infant formula as defined under Regulation (EU) No 609/2013 | 1.6 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer |
| Follow-on formula as defined under Regulation (EU) No 609/2013 | 1.2 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 under Regulation (EU) No 609/2013 | 1.2 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer  10 g/kg for products other than beverages |
| 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  10 g/kg for products other than beverages |
| Total diet replacement for weight control as defined under Regulation (EU) No 609/2013 | 4.0 g/L (beverages)  40 g/kg (products other than beverages) |
| Foods for Special Medical Purposes as defined under Regulation (EU) No 609/2013 for adults | On a case-by-case basis |
| Food Supplements as defined in Directive 2002/46/EC intended for the general population above the age of 1 year | 4.0 g/day |
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1. The following entry is inserted in Table 2 (Specifications) in alphabetical order:

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| --- | --- |
| **Authorised Novel Food** | **Specification** |
| **2’-fucosyllactose/difucosyllactose mixture (2’-FL/DFL)**  **(Microbioligical)** | **Description/Definition:**  2’-fucosyllactose/difucosyllactose mixture is obtained by microbial fermentation using a genetically modified strain of *Escherichia coli* K-12 using D-lactose and D-glucose as raw materials.  **Characteristics/Composition**  Appearance: White to off white powder or agglomerates  Identification : Retention time of standards ± 3.0%  Sum of 2’-fucosyllactose, difucosyllactose, lactose and fucose (% 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)  D-Fucose: ≤ 1.0 (w/w)  2’fucosyl-D-lactulose: ≤ 2.0 (w/w)  Sum or other carbohydrates[[1]](#footnote-1): ≤ 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: ≤ 1.0mg/g  **Microbiological criteria:** Aerobic mesophilic total plate count: ≤ 1000CFU/g  Coliforms: ≤ 10 CFU/g  *Salmonella* sp.: Negative/25 g  Yeast: ≤ 100 CFU/g  Mould: ≤ 100 CFU/g  Residual endotoxins: ≤ 100 EU/mg |

‘\*CFU: Colony Forming Units; EU: Endotoxin Units**’**

1. 3’-fucosyllactose, 2’-fucosyl-galactose, glucose, galactose, mannitol, sorbitol, galactitol, trihexose, allo-lactose and other structurally related carbohydrates [↑](#footnote-ref-1)