Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 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 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2470

of 20 December 2017

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[(1)], and in particular Article 8 thereof,

Whereas:

(1) Regulation (EU) 2015/2283 lays down rules for the placing on the market and use of novel foods within the Union.

(2) Pursuant to Article 8 of Regulation (EU) 2015/2283, the Commission has to establish the Union list of novel foods authorised or notified under Regulation (EC) No 258/97 of the European Parliament and of the Council[(2)].

(3) The Union list of novel foods is to apply without prejudice to other provisions laid down in sector specific legislation.

(4) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Union list of authorised novel foods

The Union list of novel foods authorised to be placed on the market within the Union as referred to in Article 6(1) of Regulation (EU) 2015/2283 is hereby established and set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2470. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2470. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

[F1ANNEX

UNION LIST OF NOVEL FOODS

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2018/1023 of 23 July 2018 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods (Text with EEA relevance).

Content of the list

1. The Union list shall consist of Tables 1 and 2.

2. Table 1 includes the authorised novel foods and contains the following information:

Column 1 : Authorised novel food
Column 2 : Conditions under which the novel food may be used. This column is further subdivided into two: Specified food category and Maximum levels
Column 3 : Additional specific labelling requirements
Column 4 : Other requirements

3. Table 2 includes the specifications on novel foods and contains the following information:

Column 1 : Authorised novel food
Column 2 : Specifications

TABLE 1: AUTHORISED NOVEL FOODS

Authorised novel food	**Conditions under which the novel food may be used**		**Additional specific labelling requirements**	**Other requirements**	**[F6Data Protection]**
***N*-Acetyl-D-neuraminic acid**	***Specified food category***	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be '*N*-acetyl-D-neuraminic acid' Food supplements containing *N*-acetyl-D-neuraminic acid shall bear a statement		
	Infant and follow-on formulae as defined by Regulation (EU) No 609/2013[a]	0,05 g/L of reconstituted formula			
	Processed cereal-based foods and baby foods for infants and young children as defined by Regulation	0,05 g/kg for solid foods			

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2470. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(EU) No 609/2013		that the food supplement should not be given to infants, young children and children under 10 years of age where they consume breast milk or other foods with added *N*-acetyl-D-neuraminic acid within the same twenty four hour period.		
Foods for special medical purposes for infants and young children as defined by Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the infants and young children for whom the products are intended but in any case not higher than the maximum levels specified for the category mentioned in the table corresponding to the products.			
Total diet replacement foods for weight control as defined by Regulation (EU) No 609/2013	0,2 g/L (drinks) 1,7 g/kg (bars)			
Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014[b]	1,25 g/kg			
Unflavoured pasteurised	0,05 g/L			

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2470. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

and sterilised (including UHT) milk-based products				
Unflavoured fermented milk-based products, heat treated after fermentation, flavoured fermented milk products including heat-treated products	0,05 g/L (beverages) 0,4 g/kg (solids)			
Dairy analogues, including beverage whiteners	0,05 g/L (beverages) 0,25 g/kg (solids)			
Cereal bars	0,5 g/kg			
Table top sweeteners	8,3 g/kg			
Fruit and vegetable-based drinks	0,05 g/L			
Flavoured drinks	0,05 g/L			
Speciality coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions	0,2 g/kg			
Food Supplements as defined	300 mg/day for general population			