

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.

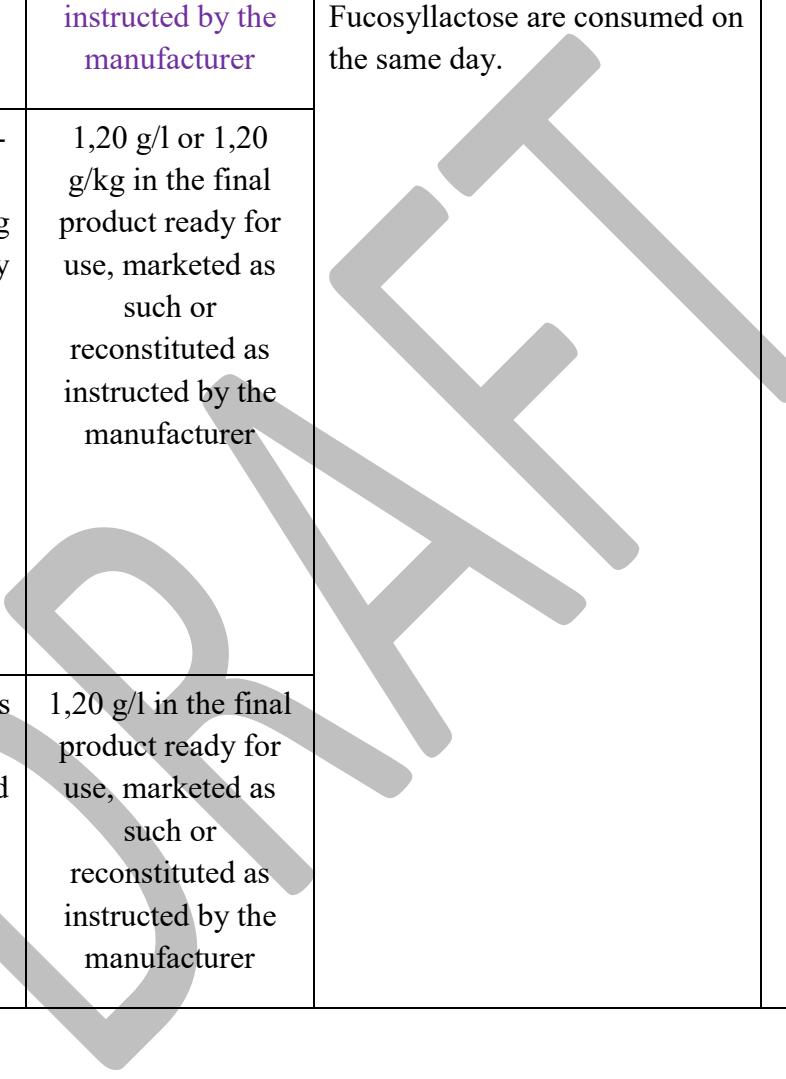
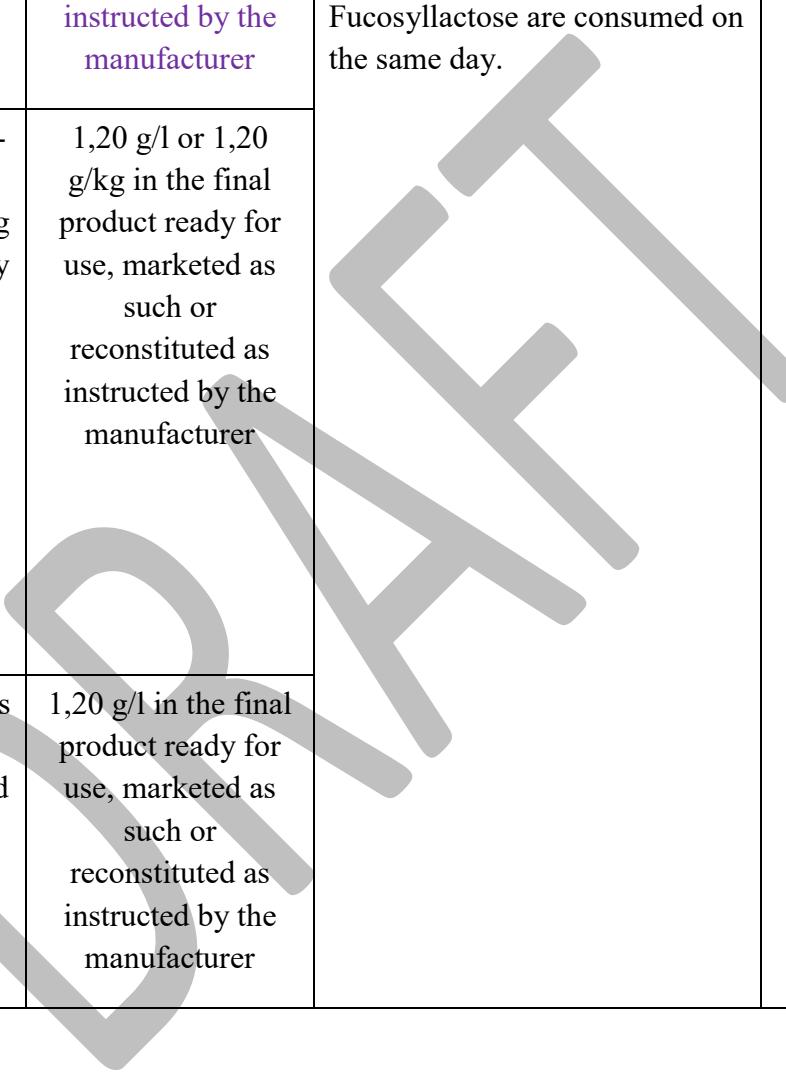
ANNEX

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

(1) in Table 1 (Authorised novel foods), the entry for ‘3-Fucosyllactose produced by a derivative strain of *Escherichia coli* BL21 (DE3)’ is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
3-Fucosyllactose ('3-FL') (produced by a derivative strain of <i>E. coli</i> BL21 (DE3))	<i>Specified food category</i>	<i>Maximum levels</i>			
	Infant formula as defined under Regulation (EU) No 609/2013	1,75 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	<p>The designation of the novel food on the labelling of the foodstuffs containing it shall be '3-fucosyllactose'.</p> <p>The labelling of food supplements containing 3-Fucosyllactose (3-FL) shall bear a statement that</p> <ul style="list-style-type: none"> (a) they should not be consumed by children under 3 years of age; (b) they should not be used if other foods containing added 3- 		<p>Authorised on 25.1.2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: "Chr. Hansen A/S", Bøge Allé 10-12, 2970 Hørsholm, Denmark.</p>
	Follow-on formula as defined under Regulation (EU) No 609/2013	1,75 g/l in the final product ready for use, marketed as such or reconstituted as			<p>During the period of data protection, the novel food 3-Fucosyllactose is authorised for placing on the market within the</p>

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.

		instructed by the manufacturer	Fucosyllactose are consumed on the same day.		Union only by Chr. Hansen 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 of “Chr. Hansen A/S”. End date of the data protection 25.1.2028.
	Processed cereal-based foods for infants and young children and baby foods for infants and young children as defined under Regulation (EU) No 609/2013	1,20 g/l or 1,20 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Milk based drinks and similar products intended for young children	1,20 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			

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.

	<p>Foods for special medical purposes for infants and young children as defined under Regulation (EU) No 609/2013</p>	<p>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 1.75 g/l or 1.75 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.</p>			
	<p>Foods for special medical purposes as defined under Regulation (EU) No 609/2013 excluding foods</p>	<p>In accordance with the particular nutritional requirements of the persons for whom the products are intended</p>			

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.

	for infants and young children			
	Food Supplements as defined in Directive 2002/46/EC, for the general population, excluding infants and young children	4 g/day		

DRAFT