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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>	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘3-fucosyllactose’.		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. During the period of data protection, the novel food 3-Fucosyllactose is authorised for placing on the market within the
	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	The labelling of food supplements containing 3-Fucosyllactose (3-FL) shall bear a statement that		
	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	(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-		

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		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			

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	Foods for special medical purposes for infants and young children as defined under 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 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.			
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013 excluding foods	In accordance with the particular nutritional requirements of the persons for whom the products are intended			

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	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			