

APPLICATION FOR THE AMENDMENT OF CONDITIONS OF USE FOR 2'-FUCOSYLLACTOSE

Regulation (EU) No 2015/2283 of the European Parliament and of the Council of 25 November 2015 Concerning Novel Foods and Novel Food Ingredients

SUMMARY

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2'-Fucosyllactose (2'-FL) is currently approved in the European Union (EU) within 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 (as amended)¹. 2'FL is approved in a wide variety of foods including infant and follow-on formula and milk-based drinks and similar products for young children as reproduced in Table 1 below:

Specified Food Category	Maximum Levels
Infant formula as defined in Regulation (EU) No 609/2013	1,2 g/l alone or in combination with up to 0,6 g/l of lacto- <i>N</i> -neotetraose at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Follow-on formula as defined in Regulation (EU) No 609/2013	1,2 g/l alone or in combination with up to 0,6 g/l of lacto- <i>N</i> -neotetraose at a ratio of 2:1 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	1,2 g/l for milk-based drinks and similar products added alone or in combination with up to 0,6 g/l lacto- <i>N</i> -neotetraose, at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer

In line with the most recent EFSA opinion on the safety of the extension of use of 2'-FL (and LNnT) as novel food in food supplements for infants², we seek to remove the requirement of the clause *alone or in combination with up to 0.6 g/l of lacto-N-neotetraose at a ratio of 2:1* for all foods for infants, since EFSA no longer bases their safety conclusion on this ratio. It is now predominantly simply based on the levels in breast milk.

Table 2 summarises the proposal.

Specified Food Category	Maximum Levels
Infant formula as defined in Regulation (EU) No 609/2013	1,2 g/l with up to 0,6 g/l of lacto-<i>N</i>-neotetraose at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Follow-on formula as defined in Regulation (EU) No 609/2013	1,2 g/l alone or in combination with up to 0,6 g/l of lacto-<i>N</i>-neotetraose at a ratio of 2:1 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	1,2 g/l alone or in combination with up to 0,6 g/l lacto-<i>N</i>-neotetraose, at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer

¹ 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 (as amended). Most recent consolidated Union List available online at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1599485966079&uri=CELEX:02017R2470-20200727>

² Safety of the extension of use of 2'-fucosyllactose (2'-FL) and lacto-*N*-neotetraose (LNnT) as novel foods in food supplements for infants pursuant to Regulation (EU) 2015/2283. Available online at: <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7257>

In its opinion on the safety of the extension of use of 2'-FL as novel food in food supplements for infants³ EFSA have provided their most recent estimations for the intake of 2'-FL from breast milk.

Specifically

For 2'-FL the daily intake ranges from 284 to 856 mg/kg bw, when considering mean and high concentrations in human milk in average (800 mL) and high (1,200 mL) milk intake scenarios, according to data reported by Erney et al. (2001)⁴ of 2.38 and 4.78 g 2'-FL/L as mean and high concentrations, respectively. In a recently published review (Soyyilmaz et al., 2021⁵), values of 2.28 and 4.28 g/L as mean of means and maximum mean, respectively, were reported from >4,000 samples of mature milk.

EFSA also stated:

The Panel notes that the maximum daily intakes of 2'-FL in FS for infants are lower than the estimated intake from the already authorised uses in IF (infants of 0–16 weeks) and in other food categories (infants of 4–11 months of age) [...] Moreover, the intake per kg bw of 2'-FL from the proposed maximum use levels in FS for infants is lower than the lowest estimated mean intake of naturally occurring 2'-FL from human milk. The intake per kg bw of LNnT is lower than the highest estimated mean intake of LNnT by breastfed infants [...] The Panel concludes that the use of the NFs containing 2'-FL or LNnT in FS for infants is safe under the proposed conditions of use.

In this EFSA Opinion, the proposed conditions of use do not mandate or mention a ratio with LNnT for infants based on referenced to upper levels in breast milk. Therefore, we request that this text is removed from the current Union List for all infant use categories.

There are no proposed changes to use levels, therefore exposures remain the same.

³ Safety of the extension of use of 2'-fucosyllactose (2'-FL) and lacto-N-neotetraose (LNnT) as novel foods in food supplements for infants pursuant to Regulation (EU) 2015/2283. Available online at: <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7257>

⁴ Erney R, Hilty M, Pickering L, Ruiz-Palacios G and Prieto P, 2001. Human milk oligosaccharides: a novel method provides insight into human genetics. In: Bioactive components of human milk. 8th International Conference of the International Society for Research on Human Milk and Lactation, October 25–29, 1997, Plymouth, MA. Newburg DS (ed.). Advances in Experimental Medicine and Biology. Kluwer Academic/Plenum Publishers, New York, vol 501, 285–297

⁵ Soyylmaz B, Miks MH, Röhrig CH, Matwiejuk M, Meszaros-Matwiejuk A and Vignæs LK, 2021. The mean of milk: a review of human milk oligosaccharide concentrations throughout lactation. *Nutrients*, 13, 2737. <https://doi.org/10.3390/nu13082737>