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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

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Abstract

Following a request from the European Commission, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) was asked to deliver an opinion on the safety of the extensions of use of the authorised novel foods (NFs) 2'-fucosyllactose (2'-FL) and lacto-*N*-neotetraose (LNnT) in food supplements (FS) for infants pursuant to Regulation (EU) 2015/2283. The NFs are produced by fermentation with genetically modified strains of *Escherichia coli* K-12 and already included in the EU list of NFs. The applicant stated that no changes in the production process or the identity of the NFs occurred. The applicant proposes an extension of use of the NF containing 2'-FL in FS intended for infants (< 1 year), at a maximum use level of 1.2 g/day. The applicant also proposes an extension of use of LNnT in FS intended for infants, at a maximum use level of 0.6 g/day. The intake of 2'-FL per kg body weight 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. Similarly, the intake of LNnT per kg body weight is lower than the highest estimated mean intake of naturally occurring 2'-FL from human milk. Furthermore, the Panel notes that the proposed uses of 2'-FL in FS for infants are lower than the estimated intake from the already authorised uses of the NF for the same population group. The Panel also notes that the proposed uses of LNnT in FS for infants are similar to the estimated intake from the already authorised uses of the NF for the same population group. 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.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

On 21 October 2019, the company Glycom A/S submitted a request to the European Commission in accordance with Article 10 of Regulation (EU) 2015/2283¹ to authorise the extension of use of the authorised novel food (NF) 2'-Fucosyllactose (2'-FL) in food supplements (FS) for infants.

Also, on 21 October 2019, the same company submitted a separate request to the European Commission in accordance with Article 10 of Regulation (EU) 2015/2283 to authorise the extension of use of the authorised NF lacto-N-neotetraose (LNnT) in FS for infants.

The applicant has not requested data protection under Article 26 of Regulation (EU) 2015/2283 for neither the data in support of the request concerning 2'-FL nor for the data in support of the request concerning LNnT.

In accordance with Article 10(3) of Regulation (EU) 2015/2283, the European Commission asks the European Food Safety Authority (EFSA) to provide a scientific opinion on the safety of the extension of use for each of the authorised NFs 2'-FL and LNnT to be used individually in FS for infants.

1.2. Interpretation of the Terms of Reference

The applications refer to an extension of use of the NFs 2'-FL and LNnT, whose respective use is already authorised in several food categories including: infant formulae (IF), follow-on formulae (FOF), milk-based drinks intended for young children (from 1 to < 3 years), processed cereal-based food and baby food for infants and young children and in FS for the general population, excluding infants. The applicant proposes to extend their use into FS for infants at the same maximum use levels as those individually authorised in FS for young children. Therefore, the current assessment is exclusively focused on the proposed extension of use with respect to the possible impact on safety and nutritional aspects.

1.3. Additional information

2'-FL is included in the Union list of authorised NFs (Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017²) when chemically synthesised or produced by fermentation with genetically modified strains of *Escherichia coli* K-12 or *E. coli* BL21. In 2015, EFSA published an opinion on the safety of the chemically synthesised 2'-FL as a NF (EFSA NDA, 2015a) and a statement on its use in FS for children, excluding infants (EFSA NDA Panel, 2015b). In addition, scientific opinions on the safety as a NF of the mixture of 2'-FL and difucosyllactose (DFL), produced by fermentation with a genetically modified strain of *E. coli* K-12, have been published (EFSA NDA Panel, 2019, 2022).

The NF containing 2'-FL (2'-FL \geq 83% w/w dry matter (DM)) is authorised for use in FS for young children up to the maximum use level of 1.2 g/day, and up to 3.0 g/day in FS for the general population.

LNnT is included in the Union list of authorised NFs (Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017²) when chemically synthesised or produced by fermentation with genetically modified strains of *E. coli* BL21 or *E. coli* K-12. In 2015, EFSA published an opinion on the safety of the chemically synthesised LNnT as a NF (EFSA NDA Panel, 2015c) and a statement on its use in FS for children, excluding infants (EFSA NDA Panel, 2015b). Moreover, a scientific opinion on the safety of LNnT as a NF when produced by fermentation with a genetically modified strain of *E. coli* BL21 has been published (EFSA NDA Panel, 2020).

The NF containing LNnT (LNnT \geq 80% w/w DM) is authorised for use in FS for young children up to the maximum use level of 0.6 g/day, and up to 1.5 g/day in FS for the general population.

According to the applicant, FS containing the NFs shall bear a statement that the corresponding FS should not be used if foods with added 2'-FL or LNnT or human milk are consumed on the same day.

¹ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 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; OJ L 327, 11.12.2015, p. 1–22.

² 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. OJ L 351, 30.12.2017, p. 72–201.

2. Data and methodologies

2.1. Data

The safety assessment of these NFs is based on data supplied in the applications.

Administrative and scientific requirements for NF applications referred to in Article 10 of Regulation (EU) 2015/2283 are listed in the Commission Implementing Regulation (EU) 2017/2469³.

A common and structured format on the presentation of NF applications is described in the EFSA guidance on the preparation and presentation of a NF application (EFSA NDA Panel, 2016). As indicated in this guidance, it is the duty of the applicant to provide all of the available (proprietary, confidential and published) scientific data (both in favour and not in favour) that are pertinent to the safety of the NF.

Although these applications do not include requests for the protection of proprietary data, the applications referred to proprietary data submitted by the applicant in support of the application of 2'-FL/DFL and used in the safety assessment (EFSA NDA Panel, 2019).

2.2. Methodologies

The assessment follows the methodology set out in the EFSA guidance on NF applications (EFSA NDA Panel, 2016) and the principles described in the relevant existing guidance documents from the EFSA Scientific Committee. The legal provisions for the assessment are laid down in Article 11 of Regulation (EU) 2015/2283 and in Article 7 of the Commission Implementing Regulation (EU) 2017/2469.

This assessment concerns only the risks that might be associated with consumption of the NFs under the proposed conditions of use and is not an assessment of the efficacy of the NFs with regard to any claimed benefit.

3. Assessment

3.1. Introduction

The NFs which are the subject of the application, are human identical milk oligosaccharides (HiMOs) composed of either 2'-FL or LNnT. As specified in the Union list², the NFs are produced by fermentation with genetically modified strains of *E. coli* K-12. They consist, respectively, of $\geq 83\%$ w/w DM 2'-FL or $\geq 80\%$ w/w DM LNnT. The remaining fraction of the NFs is composed of other saccharides (e.g. D-lactose).

The NFs are proposed to be used in FS for infants.

According to Regulation (EU) 2015/2283, these NFs fall under the following categories:

- i) 'food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997'; and
- ii) 'food consisting of, isolated from or produced from microorganisms, fungi or algae'.

3.2. Identity of the NF

The two NFs are composed of 2'-FL or LNnT.

The applicant stated that there is no change to the identity of 2'-FL and LNnT as currently approved in the Union list.

3.3. Production process

The applicant also stated that the manufacturing conditions for both NFs have not changed.

3.4. History of use of the NF and of its source

3.4.1. History of use of the NF

These NFs are authorised alone or in combination in IF and FOF and for use in several food categories intended for the general population, including infants.

³ Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. OJ L 351, 30.12.2017, p. 64–71.

In IF and FOF, the NFs are authorised up to the following maximum use levels²:

2'-FL – '1.2 g/L alone or in combination with up to 0.6 g/L of lacto-N-neotetraose at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer'.

LNnT – '0.6 g/L in combination with up to 1.2 g/L of 2'-fucosyllactose at a ratio of 1:2 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer'.

3.4.2. Intake of 2'-FL and LNnT from human milk

In previous EFSA opinions, the daily intake levels of these oligosaccharides from the consumption of human milk have been estimated for a 6.7-kg body weight (bw) infant (EFSA Scientific Committee, 2012), considering the average and high daily intake of human milk (800 and 1,200 mL, respectively) for infants from 0 to 6 months (EFSA NDA Panel, 2013).

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 (Table 1), according to data reported by Erney et al. (2001) (EFSA NDA Panel, 2019, 2022) of 2.38 and 4.78 g 2'-FL/L as mean and high concentrations, respectively. In a recently published review (Soyyilmaz et al., 2021), 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.

Table 1: Estimated daily intake levels of 2'-FL from average (800 mL) and high (1,200 mL) human milk intake for infants of 6.7 kg bw, based on mean and high concentration of 2.38 g/L and 4.78 g/L, respectively, of 2'-FL in human milk (Erney et al., 2001; EFSA NDA Panel, 2019, 2022)

	Daily intake levels (mg/kg bw) from 800 mL of human milk		Daily intake levels (mg/kg bw) from 1,200 mL of human milk	
	Mean concentration	High concentration	Mean concentration	High concentration
2'-FL	284	571	426	856

bw: body weight.

For LNnT, the daily intake ranges from 88 to 201 mg/kg bw, when considering mean and high concentrations in human milk in average (800 mL) and high (1,200 mL) milk intake scenarios (Table 2), according to data reported by Thurl et al. (2017) of 0.74 and 1.12 g LNnT/L as mean of means and maximum mean, respectively. Likewise, in the Soyylmaz et al. (2021) review, LNnT concentrations of 0.37 and 1.24 g/L from mature milk were recorded.

Table 2: Estimated daily intake levels of LNnT from average (800 mL) and high (1,200 mL) human milk intake for infants of 6.7 kg bw, based on mean and high concentration of 0.74 and 1.12 g/L, respectively, of LNnT in human milk (Thurl et al., 2017; term delivery)

	Daily intake levels (mg/kg bw) from 800 mL of human milk		Daily intake levels (mg/kg bw) from 1,200 mL of human milk	
	Mean concentration	High concentration	Mean concentration	High concentration
LNnT	88	134	133	201

bw: body weight.

3.5. Proposed uses and use levels and anticipated intake

3.5.1. Target population

The target population proposed by the applicant is infants.

3.5.2. Proposed uses and use levels

The applicant intends to market the NFs (2'-FL and LNnT) in FS for infants, at the proposed maximum use levels of 1.2 g/day for 2'-FL and 0.6 g/day for LNnT.

The Panel notes that 2'-FL and LNnT produced by the same applicant showed a purity > 96% (about 97 and 100% from the batch-to-batch analysis for 2'-FL and LNnT, respectively (EFSA NDA Panel, 2015a,c)).

3.5.3. Anticipated intake of the NF

The NFs are proposed to be used in FS for infants.

According to the maximum proposed use levels of 1.2 g/day for 2'-FL and 0.6 g/day for LNnT, and considering a bw of 5 kg (EFSA Scientific Committee, 2012), the estimated daily intakes amount to 240 and 120 mg per kg bw for 2'-FL and LNnT, respectively.

The Panel notes that the anticipated maximum daily intake of 2'-FL (expressed on a bw basis) from the proposed use of the NF in FS for infants (240 mg per kg bw) is below the lowest estimated daily intake of 2'-FL by infants (i.e. 284 mg/kg bw), considering average human milk intake (800 mL) and the mean concentration of 2'-FL in human milk (2.38 g/L) (Table 1).

The Panel also notes that the anticipated maximum daily intake of LNnT (expressed on a bw basis) from the proposed use of the NF in FS for infants (120 mg per kg bw) is below the estimated daily intake of LNnT by infants (i.e. 134 mg/kg bw), considering average human milk intake (800 mL) and the high concentration of LNnT in human milk (1.12 g/L) (Table 2).

Furthermore, the estimated intakes of 2'-FL and LNnT from their proposed uses in FS for infants are lower or similar to the estimated intakes from the already authorised uses of 2'-FL and LNnT in IF (infants of 0–16 weeks) and in other food categories (infants of 4–11 months of age) (EFSA NDA Panel, 2015a,c).

The applicant stated that FS containing the NFs are not intended to be used if human milk or foods with added 2'-FL or LNnT are consumed on the same day.

3.6. Nutritional information

The NFs are composed of non-digestible oligosaccharides, either 2'-FL or LNnT. The proposed use levels of the NFs in FS for infants are identical to those already authorised in FS for young children. In addition, the intakes from the proposed use of 2'-FL and LNnT in FS for infants are, respectively, lower than or similar to the estimated intake from the already authorised uses of the NFs in IF (infants of 0–16 weeks) and in other food categories (infants of 4–11 months of age) (EFSA NDA Panel, 2015a,c).

The Panel considers that consumption of the NFs at the proposed use levels is not nutritionally disadvantageous.

4. Discussion

The NFs which are the subject of the application, are the already authorised HiMOs 2'-FL and LNnT. As specified in the Union list², the NFs are produced by fermentation with genetically modified strains of *E. coli* K-12 and consist, respectively, of $\geq 80\%$ w/w DM LNnT or $\geq 83\%$ w/w DM 2'-FL. The remaining fraction of the NFs is composed of other saccharides (e.g. D-lactose).

2'-FL is proposed to be used at the maximum use level of 1.2 g/day in FS for infants. LNnT is proposed to be used at the maximum use level of 0.6 g/day in FS for infants.

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) (EFSA NDA Panel, 2015a).

The Panel notes that the maximum daily intakes of LNnT in FS for infants are similar to 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) (EFSA NDA Panel, 2015c).

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 applicant stated that FS containing the NFs are not intended to be used if human milk or foods with added 2'-FL or LNnT are consumed on the same day.

5. Conclusions

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.

6. Steps taken by EFSA

- 1) On 10 June 2021 EFSA received a letter from the European Commission with the request for a scientific opinion on the safety of the extension of use of the authorised novel foods 2'-FL and LNnT in FS for infants. Ref. Ares (2021)3810589.
- 2) On 10 June 2021, a valid application on 2'-FL and LNnT for use in FS for infants, which was submitted by Glycom A/S, was made available to EFSA by the European Commission through the Commission e-submission portal (NF 2019/1350 and NF 2019/1359) and the scientific evaluation procedure was initiated.
- 3) On 11 November 2021 EFSA received a letter from the European Commission with the updated request for a scientific opinion on the safety of the extension of use of the authorised novel foods 2'-FL and LNnT in FS for infants. Ref. Ares(2021)6943273.
- 4) On 11 November 2021, a valid application on 2'-FL and LNnT for use in FS for infants was made available to EFSA by the European Commission through the Commission e-submission portal and the scientific evaluation procedure was restarted.
- 5) During its meeting on 23 March 2022, the NDA Panel, having evaluated the data, adopted a scientific opinion on the safety of the extension of use of the authorized NFs 2'-FL and LNnT in FS for infants pursuant to Article 10 of Regulation (EU) 2015/2283 Novel food.

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Abbreviations

2'-FL	2'-fucosyllactose
bw	body weight
DFL	difucosyllactose
DM	dry matter
FOF	follow-on formulae
FS	food supplements
HiMO	human identical milk oligosaccharides
IF	infant formulae
LNnT	Lacto- <i>N</i> -neotetraose
NDA Panel	EFSA Panel on Nutrition, Novel Foods and Food Allergens
NF	novel food
w/w	weight per weight