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Safety of the extension of use of galacto-oligosaccharides as a Novel food 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 extension of use of galacto-oligosaccharides (GOS) as a novel food (NF) pursuant to Regulation (EU) 2015/2283. The NF is a syrup containing ≥ 57% w/w GOS (w/w dry matter), consisting of different galactosyl residues linked to a terminal glucose by a β-glycosidic bond and also containing lactose and the constituent monomers of lactose (galactose and glucose). The NF is already authorised and included in the Union list of NFs and is produced according to the same production process. This application is limited to an assessment of the extension of use as a food ingredient in dairy confectionary, cheese and processed cheese, butter and spreads. There is a 10–30% increase in total GOS intake from the requested extension of use compared to the currently authorised uses at the highest 95th percentile. It is noted that the total intake at the highest mean (8.7–22.0 g/day) is below the adequate intake (AI) of 25 g/day for dietary fibre set to ensure a normal laxation in adults, while the highest 95th percentile (27.2–41.6 g/day) is higher than the AI. When the maximum use as a food supplement is added to the highest 95th percentile combined intake from all proposed and authorised food categories a total intake up to 58 g GOS/day is estimated. This highest intake level would exceed the AI for dietary fibre; however, no tolerable upper intake level for dietary fibre has been set and only transient gastrointestinal symptoms may be related to high intake of fibre. The Panel concludes that the NF, that is composed of ≥ 57% GOS dry matter, lactose and related saccharides, is safe under the proposed extension of use.

Keywords: Galacto-oligosaccharides, GOS, dietary fibre, novel food, food supplement, extension of use

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1. Introduction

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

On 19 November 2019, the company Dairy Crest Ltd trading as Saputo Dairy UK submitted a request to the European Commission in accordance with Article 10 of Regulation (EU) 2015/2283[1] to authorise an extension of use of galacto-oligosaccharide (GOS) as a novel food.

The application requests to extend the use of the novel food galacto-oligosaccharide (GOS) in additional foods.

In accordance with Article 10(3) of Regulation (EU) 2015/2283, the European Commission asks the European Food Safety Authority to provide a scientific opinion on the extension of use of galacto-oligosaccharide (GOS) as a novel food.

1.2. Interpretation of the Terms of Reference

The application is referring exclusively to a request for an extension of use for galacto-oligosaccharides (GOS) when used as a food ingredient in three additional food categories. GOS produced by the same production process using lactose and microbiologically produced β-galactosidases are already authorised to be added to several food categories and as a food supplement and included in the Union list of novel foods (Commission Implementing Regulation (EU) 2017/2470[2]).

Therefore, the current assessment is exclusively focussed on the proposed changes with respect to the possible impact on the safety and nutritional aspects of the novel food (NF).

1.3. Additional information

Information on existing evaluations and authorisations.

The original GOS were considered to be not novel due to their use in foods in the European Union (EU) prior to 15 May 1997. GOS are already permitted for use in the EU and their inclusion in the Union list was based on a substantial equivalence evaluation conducted in 2013 by the Food Safety Authority of Ireland (FSAI, 2013). This application seeks to extend the use of GOS to be added as an ingredient in three new food categories: dairy confectionary, cheese and processed cheese, butter and spreads. No changes in the production process, composition or final product specifications have been proposed with respect to the 2013 evaluation. For these reasons, no evaluations have been conducted by EFSA.

In 2021, EFSA published a scientific opinion on a change in the conditions of use of GOS when used as an ingredient in food supplements (EFSA NDA Panel, 2021).

2. Data and methodologies

2.1. Data

The safety assessment of this NF is based on data supplied in the application.

During the assessment, the Panel identified additional data which were not included in the application (Yamashita and Kobala, 1974; Toba et al., 1982; Saito et al., 1987; Gopala et al., 2003; Kimura et al., 2004; Matsumoto et al., 2004; Sar et al., 2004; Sumiyoshi et al., 2004; Mwenya et al., 2005; Villaluenga-Martinez et al., 2008; Ruiz-Matute et al., 2012; Kunz et al., 2014).

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) 2017/2469[3].

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,

[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, pp. 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, pp. 72–201.

[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, pp. 64–71.

confidential and published) scientific data (including both data in favour and not in favour) that are pertinent to the safety of the NF.

This NF application does not include a request for the protection of proprietary data.

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 NF under the proposed conditions of use and is not an assessment of the efficacy of the NF with regard to any claimed benefit.

3. Assessment

3.1. Introduction

The NF (called Promovita®) which is the subject of the application is mainly composed of GOS. The applicant stated that the NF is produced from milk lactose and that the production process and specifications have not been changed. This assessment concerns the risk that might be associated with the consumption of the NF when the use as food ingredient is extended to the proposed additional food categories. GOS are an established form of dietary fibre (EFSA NDA Panel, 2010). The target population is the general population.

According to Regulation (EU) 2015/2283, this NF falls under the following category:

i) 'food consisting of, isolated from or produced from microorganisms, fungi or algae'.

3.2. Identity of the NF

The NF which is subject of this application is in the form of a syrup containing ≥ 57% w/w GOS on a dry matter basis. The applicant stated that it is produced from refined lactose using β-galactosidases derived from *Aspergillus oryzae, Bifidobacterium bifidum* and *Bacillus circulans*.

GOS are oligosaccharides containing 2–9 galactosyl units linked to a terminal glucose via β-glycosidic bonds such as β (1→2), β (1→3), β (1→4), or β (1→6).

3.3. Production process

The Panel notes that an assessment of the production process for GOS when produced by microbial β-galactosidases was conducted by FSAI in 2013 (FSAI, 2013). This opinion supported the substantial equivalence with Vivinal®, GOS already permitted for use in foods. The production process has not changed since then with the exception of the microorganisms expressing β-galactosidases. In addition, the applicant also stated that no changes in the conditions of manufacture from the original assessed production process occurred.

3.4. Compositional data

The Panel notes that the composition of the NF meets the specifications of 'galacto-oligosaccharides' in term of GOS content as reported in the Union list of authorised novel foods (Commission Implementing Regulation (EU) 2017/2470) and previously reviewed by FSAI (2013).

The NF is a syrup containing ≥ 57% β-linked GOS (w/w dry matter, in addition to other saccharides). Since the NF contains a minimum of 75% dry matter, the GOS fraction comprises ≥ 42.75% GOS on a wet weight basis. The major saccharide in the GOS fraction of the NF is the trisaccharide 4′-galactosyllactose (*O*-β-D-galactopyranosyl-(1→4)-*O*-β-D-galactopyranosyl-(1→4)-D-glucose) (Sar et al., 2004; Mwenya et al., 2005). Other components in the NF include lactose and the constituent monomers of lactose (galactose and glucose).

Finally, the applicant states that there are no changes to chemical, physical and microbiological characteristics of the NF with respect to the original application.

3.5. History of use of the NF and/or of its source

3.5.1. History of use of the source

As previously stated (EFSA NDA Panel, 2021), GOS are naturally occurring in bovine colostrum and milk-related products such as fermented milk. Bovine colostrum has been reported to contain up to 8.5 mg/L GOS, while mature bovine milk contained only traces of oligosaccharides and no GOS at all (Saito et al., 1987; Kunz et al., 2000). However, fermented milk products (e.g. yoghurt) can contain a significant amount of GOS due to the enzymatic activity of microbial β-galactosidases on lactose. It is reported that commercial yoghurts may contain from 0.03% up to 0.58% of GOS, with the content being dependent on the microbial culture used to manufacture the product (Toba et al., 1982; Villaluenga-Martinez et al., 2008). Lactose-free milks can also contain GOS up to 0.43% as a result of lactose hydrolysis and subsequent GOS formation (Ruiz-Matute et al., 2012). GOS are not present in human milk (Kunz et al., 2014) or present only as a fraction up to 14.8 mg/L (Yamashita and Kobala, 1974; Sumiyoshi et al., 2004).

3.5.2. History of use of the NF

According to the applicant, GOS have a history of use in the food industry and industrial scale GOS production began in the 1980s. Currently, GOS are permitted for use in foods in several countries including Australia, Canada, the US and Japan. In the EU, GOS-containing products were marketed already before 1997. GOS are added to many products, including infant formulae, follow-on formulae, and baby foods.

The original GOS (Vivinal®) were not considered to be novel due to their use in foods in the EU prior to 15 May 1997. Other GOS-containing products which were subject to the NF regulation were deemed substantially equivalent to Vivinal® GOS in 2013 and have been marketed in the EU since the publication of that opinion (FSAI, 2013). Since then, other GOS products (including Dairy Crest Ltd's GOS) have been determined as substantially equivalent (FSAI, 2016, 2017a,b).

3.6. Proposed uses and use levels and anticipated intake

3.6.1. Target population

GOS are currently permitted in the EU for use in a number of foods, including infant formulae and follow-on formulae.

There is no indication of age restriction for the use of GOS-containing food supplements established in the Union List (Commission Implementing Regulation (EU) 2017/2470). However, when the maximum concentration is 45% GOS (instead of 33%) in the food supplement with a maximum recommended daily dose of 16.2 g GOS (divided in three servings) the use in infants and young children is excluded (Commission Implementing Regulation (EU) 2021/900[4]).

3.6.2. Proposed uses and use levels

GOS are already in the Union list of novel foods to be added in several food categories and also to be used as food supplement. The current proposed extension of use is referring to use in dairy confectionary, cheese and processed cheese, butter and spreads.[5] The proposed maximum use levels expressed as kg GOS/kg final food are as follows: 0.050 in dairy confectionary, 0.100 in cheese and processed cheese, butter and spreads.

EFSA carried out an assessment of GOS exposure from already authorised uses, and also an assessment of the cumulative GOS exposure upon inclusion of the food categories for which extension of use is proposed.

The NF is authorised to be used as an ingredient in several food categories. The applicant proposed the use in three additional food categories. These food categories, defined using the FoodEx2 hierarchy, and the maximum use levels are reported in Table 1.

[4] Commission implementing regulation (EU) 2021/900 of 3 June 2021 authorising a change of the conditions of use of the novel food 'galacto-oligosaccharide' under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470.

[5] Intended as 'spreadable fats' as defined by Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013. OJ L 347/671, 20.12.2013.

The NF is also marketed for use in food supplements in the general population, with the exclusion of infants and young children when the proposed maximum concentration is 45% GOS (instead of 33%) in the supplement. In this case, the maximum recommended daily dose is 16.2 g GOS, divided in three servings (Commission Implementing Regulation (EU) 2021/900).

Table 1: Food categories and maximum use levels of GOS including the extension of use proposed by the applicant (bolded)

FoodEx2 code	FoodEx2 level	Food category	Max use level (mg GOS/100 g)
A02LV	5	Cow milk	2,000
A0CXA	5	European buffalo milk	2,000
A02MC	5	Sheep milk	2,000
A02MB	4	Goat milk	2,000
A02MV	3	Butter milk	2,000
A02QD	4	Milkshakes	3,000
A02NQ	4	Yoghurt drinks	3,300
A02NR	4	Probiotic milk-like drinks	2,000
A02NE	4	Yoghurt	3,300
A03TH	4	Milk imitates	2,000
A02PT	3	Dairy dessert and similar	4,300
A02PV	3	Dairy desserts spoonable	4,300
A02PZ	4	Dairy ice creams and similar	4,300
A02QA	4	Ice cream, milk-based	4,300
A02QB	4	Ice cream, milk-imitate based	4,300
A02QC	4	Frozen yoghurt	4,300
A04NT	4	Other ice cream and similar	4,300
A065H	3	Baked milk and similar	4,300
A00EY	3	Cereal bars	12,500
A00EL	4	Cereals - mixed breakfast cereals	12,500
A03PZ	4	Infant formulae, powder	6,400
A03QE	4	Infant formulae, liquid	800
A03QK	4	Follow-on formulae, powder	6,400
A03QQ	4	Follow-on formulae, liquid	800
A03QY	3	Simple cereals which have to be reconstituted	18,900
A0BZE	3	Simple cereals for infants and children reconstituted	2,700
A03RA	3	Biscuits, rusks and cookies for children	2,700
A03RL	3	Other food for infants and children	1,200
A03RH	3	Ready-to-eat dairy-based meal for children	2,400
A03RE	3	Ready-to-eat cereal-based meal for children	14,300
A03RN	3	Fruit and vegetable juices and nectars specific for infants and young children	2,500
A03RT	4	Total daily diet replacement for weight reduction - liquid (drinks)	2,000
A0EQN	5	Soft drinks with minor amounts of fruits or flavours	2,100
A03EA	5	Soft drink with fruit juice (fruit content below the minimum for nectars)	2,100
A03GA	4	Energy drinks	2,100
A03GB	4	Isotonic and sport drinks	1,300
A0BX9	2	Fruit/vegetable juices and nectars	2,100
A00BZ	4	Fruit pie-tarts	12,500
A01QJ	4	Fruit or fruit-vegetable puree	12,500
A01QP	4	Fruit preparation for fillings and/or flavourings	5,900

FoodEx2 code	FoodEx2 level	Food category	Max use level (mg GOS/100 g)
A065Z	3	**Dairy snacks**	5,000
A02QE	2	**Cheese**	10,000
A039C	3	**Butter**	10,000
A0F1G	3	**Margarines and similar**	10,000

GOS: galacto-oligosaccharides.

3.6.3. Anticipated intake of the NF

EFSA performed an assessment of the anticipated daily intake of the NF based on the already authorised uses and the applicant's proposed uses at the maximum proposed use, using individual data from the EFSA Comprehensive European Food Consumption Database (EFSA, 2011). The lowest and highest mean and 95th percentile anticipated daily intake of the NF among the EU dietary surveys expressed on a g/day basis are presented in Table 3.

However, since an estimate of the intake for GOS was not previously available, for comparative purposes the Panel decided to perform first an assessment limited to the already authorised uses and use levels. This scenario is reported in Table 2.

Table 2: Intake estimate resulting from the use of the NF as an ingredient at the maximum proposed use levels in the already authorised food categories (expressed as g GOS/day)

Population group	Age (years)	Mean intake (g/day)		P95th intake (g/day)	
		Lowest[(a)]	Highest[(a)]	Lowest[(b)]	Highest[(b)]
Infants	< 1	2.84	7.66	6.92	24.77
Young children[(d)]	1 ≤ 3	6.28	14.08	12.72	24.00
Other children	3 ≤ 10	7.09	16.06	13.41	27.45
Adolescents	10 ≤ 18	3.78	17.70	13.13	32.55
Adults[(c)]	≥ 18	8.30	13.50	19.99	30.90

NF: novel food.
(a): Intakes are assessed for all EU dietary surveys available in the EFSA food comprehensive database on 29/3/2021. The lowest and the highest averages observed among all EU surveys are reported in these columns.
(b): Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 29/3/2021. The lowest and the highest P95th observed among all EU surveys are reported in these columns (P95th based on less than 60 individuals are not considered).
(c): Includes elderly, very elderly, pregnant and lactating women.
(d): Referred as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).

Table 3: Intake estimate resulting from the use of the NF as an ingredient at the maximum proposed use levels in all the authorised food categories combined with the food categories proposed for extension (expressed as g GOS/day)

Population group	Age (years)	Mean intake (g/day)		P95th intake (g/day)	
		Lowest[(a)]	Highest[(a)]	Lowest[(b)]	Highest[(b)]
Infants	< 1	2.88	8.70	6.96	27.23
Young children[(d)]	1 ≤ 3	8.86	18.48	17.21	31.13
Other children	3 ≤ 10	9.75	18.98	20.53	31.14
Adolescents	10 ≤ 18	7.31	22.03	18.74	39.99
Adults[(c)]	≥ 18	16.06	19.69	26.85	41.64

NF: novel food.
(a): Intakes are assessed for all EU dietary surveys available in the EFSA food comprehensive database on 29/3/2021. The lowest and the highest averages observed among all EU surveys are reported in these columns.
(b): Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 29/3/2021. The lowest and the highest P95th observed among all EU surveys are reported in these columns (P95th based on less than 60 individuals are not considered).
(c): Includes elderly, very elderly, pregnant and lactating women.
(d): Referred as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).

When considering the highest 95th percentile, the proposed extension of use accounts for an increase of GOS intake ranging from about 10% to 30%.

Finally, the total GOS intake from use as a food supplement (up to 16.2 g/day GOS) for the authorised population categories and the proposed use as a food ingredient (at the highest 95th percentile) is reported in Table 4.

Table 4: Total intake resulting from the NF use as an ingredient and as a food supplement (16.2 g at 45% GOS) expressed as g GOS/day

Population group	Age (years)	Highest P95th intake from the NF used as an ingredient (g/day)	Intake from the NF used as a food supplement (g/day)	Total intake (g/day)
Infants	< 1	27.23	ND	27.23
Young children[(a)]	1 ≤ 3	31.13	ND	31.13
Other children	3 ≤ 10	31.14	16.20	47.34
Adolescents	10 ≤ 18	39.99	16.20	56.19
Adults	≥ 18	41.64	16.20	57.84

NF: novel food; ND: not determined.
(a) Referred as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).

The lowest and highest mean and 95th percentile anticipated daily intake of the NF when expressed on a mg/kg body weight (bw) basis are included in Appendix A.

The estimated daily intake of the NF for each population group from each EU dietary survey is available in the excel file annexed to this scientific opinion (under 'Supporting Information').

3.7. Nutritional information

As previously noted (EFSA NDA Panel, 2021), dietary fibre is, by definition, resistant to hydrolysis and absorption in the small intestine and enters the colon substantially unmodified. Dietary fibre components may be subject to fermentation by the colonic microbiota. The extent of fermentation is also dependent on host factors (EFSA NDA Panel, 2010). Fermentable dietary fibre components (e.g. oligosaccharides) may play a role in modulating the intestinal microbiota (Tanaka et al., 1983; Gopala et al., 2003; Matsumoto et al., 2004). The Panel does not expect that the proposed increased intake of this non-digestible carbohydrate is of nutritional concern.

The Panel considers that, taking into account the characteristics of the NF and the proposed extension of use, its consumption is not nutritionally disadvantageous.

3.8. Allergenicity

According to data provided by the applicant (Kjeldahl analysis), the NF contains ≤ 0.1% of protein. The only potential source of protein would be β-galactosidases, the production enzymes that are expected to be removed during the purification steps.

The Panel considers that the likelihood of allergenic reactions to the NF is low.

4. Discussion

The NF which is the subject of the application is a syrup containing ≥ 57% β-linked GOS (w/w dry matter) and other substances such as lactose and related monomers (galactose and glucose). GOS are an established form of dietary fibre or non-digestible carbohydrate and are already authorised and included in the Union list of novel foods. GOS are used as food ingredients in several food categories, in infant formulae, follow-on formulae, baby foods and as food supplements.

The Panel noted that the current application is limited to an extension of use with GOS proposed to be added in additional food categories: dairy confectionary (0.050 kg GOS/kg final food), cheese and processed cheese, butter and spreads (0.100 kg GOS/kg final food). No changes in the manufacturing process and characteristics of the NF are reported.

As previously noted (EFSA NDA Panel, 2021), available evidence with regard to its effect on bowel function was the most suitable criterion for establishing an adequate intake (AI) of dietary fibre. EFSA considers dietary fibre intakes of 25 g/day to be adequate for normal laxation in adults (EFSA NDA Panel, 2010). However, the evidence available to set adequate intakes for children is limited, but it can

be extrapolated using the values set for adults, with appropriate adjustment for energy intake (a fibre intake of 2 g per megajoule is considered adequate for normal laxation in children from the age of 1 year). In addition, it is estimated that a breastfed infant would consume between 4 and 12 g/day of non-digestible oligosaccharides during the first half year of life (EFSA NDA Panel, 2014).

The NDA Panel noted that the increase in the total GOS exposure resulting from the requested extension of use in the new food categories is ranging approximately from 10% to 30% at the highest 95th percentile (Tables 2 and 3). It is also noted that the total intake at the highest mean (8.7–22.0 g/day) is below the adequate fibre intake of 25 g/day while it is higher when the highest 95th percentile is considered (27.2–41.6 g/day). When the maximum use as a food supplement is added to the highest 95th percentile combined intake from all proposed and authorised food categories, a maximum intake of around 58 g/day is estimated. These highest intake levels on their own would exceed the AI for dietary fibre intake. However, no tolerable upper intake level for dietary fibre has been set (EFSA NDA Panel, 2010) and, apart from gastrointestinal symptoms (e.g. borborygmus, flatus, transient diarrhoea), which in general may be related to high intake of fibre, no other adverse effects are known (Sako et al., 1999; Kimura et al., 2004). Occurrence of gastrointestinal symptoms or experience of gastrointestinal discomfort in relation to fibre intake differs among individuals and may limit its intakes.

The other constituents present in the NF (lactose, galactose, glucose) are the same as those evaluated in the previous assessment (FSAI, 2013) and are normal components of the standard diet.

The Panel considers that the proposed extension of use of GOS in additional food categories does not raise safety concerns.

5. Conclusions

The Panel concludes that the NF, that is composed of ≥ 57% GOS dry matter, lactose and related saccharides, is safe under the proposed extension of use.

6. Steps taken by EFSA

1) On 21/12/2020 EFSA received a letter from the European Commission with the request for a scientific opinion on the safety of the extension of use of galacto-oligosaccharides as a novel food pursuant to Article 10 of Regulation (EU) 2015/2283. Ref. Ares(2020)7829104.
2) On 21/12/2020, a valid application on GOS, which was submitted by Dairy Crest Ltd, was made available to EFSA by the European Commission through the Commission e-submission portal (NF 2020/1154) and the scientific evaluation procedure was initiated.
3) During its meeting on 14/09/2021, the NDA Panel, having evaluated the data, adopted a scientific opinion on the safety of the extension of use of galacto-oligosaccharides as a novel food pursuant to Regulation (EU) 2015/2283.

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Abbreviations

AI	Adequate intake
bw	body weight
FSAI	Food Safety Authority of Ireland
GOS	galacto-oligosaccharides
NDA	Scientific Panel on Nutrition, Novel Foods and Food Allergens
NF	Novel Food
w/w	weight for weight

Appendix A – NF intake estimate expressed as mg GOS/kg bw per day

Intake estimate resulting from the use of the NF as an ingredient at the maximum proposed use levels in the already authorised food categories (expressed as mg GOS/kg bw per day)

Population group	Age (years)	Mean intake (mg/kg bw per day)		P95th intake (mg/kg bw per day)	
		Lowest[(a)]	Highest[(a)]	Lowest[(b)]	Highest[(b)]
Infants	< 1	357	1,045	888	3,088
Young children[(d)]	1 ≤ 3	531	1,015	1,225	1,958
Other children	3 ≤ 10	286	874	645	1407
Adolescents	10 ≤ 18	71	342	237	710
Adults[(c)]	≥ 18	87	181	321	417

NF: novel food; bw: body weight.
(a): Intakes are assessed for all EU dietary surveys available in the EFSA food comprehensive database on 29/3/2021. The lowest and the highest averages observed among all EU surveys are reported in these columns.
(b): Intakes are assessed for all EU dietary surveys available in the EFSA food comprehensive database on 29/3/2021. The lowest and the highest P95th observed among all EU surveys are reported in these columns (P95th based on less than 60 individuals are not considered).
(c): Includes elderly, very elderly, pregnant and lactating women.
(d): Referred as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).

Intake estimate resulting from the use of the NF as an ingredient at the maximum proposed use levels in all the authorised food categories combined with the food categories proposed for extension (expressed as mg GOS/kg bw per day)

Population group	Age (years)	Mean intake (mg/kg bw per day)		P95th intake (mg/kg bw per day)	
		Lowest[(a)]	Highest[(a)]	Lowest[(b)]	Highest[(b)]
Infants	< 1	362	1,228	897	3,149
Young children[(d)]	1 ≤ 3	721	1,491	1,526	2,752
Other children	3 ≤ 10	425	1,033	796	1,648
Adolescents	10 ≤ 18	136	440	359	840
Adults[(c)]	≥ 18	250	257	413	548

NF: novel food; bw: body weight.
(a): Intakes are assessed for all EU dietary surveys available in the EFSA food comprehensive database on 29/3/2021. The lowest and the highest averages observed among all EU surveys are reported in these columns.
(b): Intakes are assessed for all EU dietary surveys available in the EFSA food comprehensive database on 29/3/2021. The lowest and the highest P95th observed among all EU surveys are reported in these columns (P95th based on less than 60 individuals are not considered).
(c): includes elderly, very elderly, pregnant and lactating women.
(d): Referred as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).

Appendix B – Dietary exposure estimates to the Novel Food for each population group from each EU dietary survey

Appendix B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2021.6844