SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 28 February 2022

doi: 10.2903/j.efsa.2022.7203

Safety of the extension of use of galacto-oligosaccharides (GOS) as a novel food in food for special medical purposes 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 (β-GOS) is produced from milk lactose using a β-galactosidase derived from *Bifidobacterium bifidum* and it is proposed to be used in food for special medical purposes (FSMP). The target population is the general population from 4 years of age onwards. GOS produced according to the same production process are already authorised and included in the EU Union list of novel foods. The applicant stated that the maximum daily intake from the use in FSMP is 8.25 g GOS. GOS are already authorised for use in food supplements up to a daily dose of 16.2 g. FSMP containing GOS are not intended to be used if food supplements containing GOS are consumed on the same day. The information provided on the proposed use levels and anticipated intake does not raise safety concerns. The Panel concludes that the proposed extension of use of GOS in FSMP is safe under the proposed conditions of use.

Keywords: Galacto-oligosaccharides, GOS, novel food, food for special medical purposes, FSMP, extension of use

Requestor: European Commission

Question number: EFSA-Q-2020-00747

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Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

Suggested citation: EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), Turck D, Bohn T, Castenmiller J, De Henauw S, Hirsch-Ernst KI, Maciuk A, Mangelsdorf I, McArdle HJ, Naska A, Pelaez C, Pentieva K, Siani A, Thies F, Tsabouri S, Vinceti M, Cubadda F, Frenzel T, Heinonen M, Marchelli R, Neuhäuser-Berthold M, Poulsen M, Prieto Maradona M, Schlatter JR, van Loveren H, Colombo P and Knutsen HK, 2022. Scientific Opinion on the safety of the extension of use of galacto-oligosaccharides (GOS) as a novel food in food for special medical purposes pursuant to Regulation (EU) 2015/2283. EFSA Journal 2022;20(3):7203, 7 pp. https://doi.org/10.2903/j.efsa.2022.7203

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

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1. Introduction

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

On 29 June 2020, the company G.K. Roozendaal, GLNP BV submitted a request to the European Commission for an extension of use of the novel food galacto-oligosaccharide within the meaning of Article 10(1) of Regulation (EU) 2015/2283.

The application requests to extend the use of galacto-oligosaccharide into an additional food category, namely foods for special medical purposes (FSMP) as defined in Regulation (EU) No 609/2013.

In accordance with Article 29(l)(a) of Regulation (EC) No 178/2002, the European Commission asks EFSA to provide a scientific opinion on the extension of use of galacto-oligosaccharide as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283.

1.2. Additional information

The original galacto-oligosaccharides (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 FSMP.

The Panel notes that an assessment on the effect of Bimuno-GOS in reducing gastro-intestinal discomfort has been carried out in the context of health claims in 2011 and 2014 with unfavourable outcomes (EFSA NDA Panel, 2011, 2014).

In 2021, EFSA published two scientific opinions on a change in the conditions of use of GOS when used as an ingredient in food supplements (EFSA NDA Panel, 2021a) or in three additional food categories (EFSA NDA Panel, 2021b).

It is noted from these assessments that the estimated mean intake of GOS is below the adequate intake (AI) of 25 g/day for dietary fibre, while the 95th percentile (31.1–41.6 g/day) is above the AI for dietary fibre. It is also noted that the maximum intake when used as a food supplement is up to 16.2 g GOS per day.

2. Data and methodologies

2.1. Data

The safety assessment of this NF is based on data supplied in the application and on additional data identified by the Panel (Tanaka et al., 1983; Gopala et al., 2003; Matsumoto et al., 2004; Commins and Platts-Mills, 2009).

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[1].

A common and structured format on the presentation of NF applications is described in the EFSA guidance on the preparation and presentation of an 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 (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.

[1] 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.

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. Furthermore, this assessment does not address whether an NF is a suitable FSMP pursuant to Article 9(3) of Regulation (EU) No 609/2013.

3. Assessment

3.1. Introduction

The NF (named Bimuno®, Bimuno-GOS or B-GOS by the applicant) which is the subject of the application is composed of β-GOS (hereinafter GOS). The NF is produced from milk lactose using a β-galactosidase derived from *Bifidobacterium bifidum* and is already included in the EU list of novel foods[1]. The applicant stated that there is no change regarding the production process and compositional data. GOS are non-digestible carbohydrates classified as dietary fibre by EFSA for the specific purpose of setting dietary reference values (DRV) for carbohydrates and dietary fibre (EFSA NDA Panel, 2010). GOS are currently permitted in the EU for use in a number of foods, including infant formulae, follow-on formulae, baby foods and as food supplements. The applicant seeks to extend the use of the NF to FSMP. The target population as proposed by the applicant is the general population from 4 years of age onwards.

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. Proposed uses and use levels and anticipated intake

3.2.1. Target population

The target population proposed by the applicant for the use of the NF in FSMP is the general population from the age of 4 years onwards.

3.2.2. Proposed uses and use levels

The applicant applies for an extension of use for the NF in FSMP at a maximum daily dose of 8.25 g GOS. The applicant stated that the maximum level of the GOS in the FSMP is 128 g/kg final product.

3.2.3. Combined intake from the NF and other sources

GOS are already authorised for use in several food categories and as food supplements as a source of non-digestible carbohydrates. Therefore, their use in FSMP might be in addition to the intake from other foods containing GOS.

It is noted that the maximum authorised use of GOS as a food supplement is up to 16.2 g per day.

The applicant stated that FSMP and food supplements containing GOS should not be consumed on the same day.

3.3. Nutritional information

As defined by EFSA for the purpose of setting DRV (EFSA NDA Panel, 2010), and as reported in previous GOS opinions (EFSA NDA Panel, 2021a,b), dietary fibre is 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 considers that, taking into account the characteristics of the NF and the proposed extension of use, its consumption is not nutritionally disadvantageous.

3.4. Allergenicity

According to data provided by the applicant, the NF contains ≤ 0.6% 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 applicant provided case reports of sporadic allergic reactions to GOS-containing dairy products that have been recorded in South East Asia (Vo et al., 2012; Soh et al., 2017). It has been proposed (Commins and Platts-Mills, 2009; Commins et al., 2011) that these reactions may have been due to cross reactivity with IgE in individuals sensitised to certain carbohydrate determinants (CCD) through tick bites, a condition similar to the so-called α-Gal syndrome. Noting the wide availability of GOS-supplemented foods in Europe and no reports of GOS-related allergy, the Panel considers that the likelihood of such reactions to occur is low.

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 composed of β-GOS produced from milk lactose using a β-galactosidase derived from *Bifidobacterium bifidum*. GOS are non-digestible carbohydrates and are already authorised and included in the Union list of novel foods. GOS are used as food ingredients in several food categories including 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 FSMP up to 128 g/kg final product. The proposed maximum use in FSMP results in a GOS intake of 8.25 g per day. The target population proposed by the applicant is the general population from the age of 4 years onwards.

EFSA considers dietary fibre intakes of 25 g/day to be adequate for normal laxation in adults (EFSA NDA Panel, 2010). As previously noted (EFSA NDA Panel, 2021a,b), the total intake from foods added with GOS at the highest mean (19.0–22.0 g/day) in the concerned population categories is below the adequate fibre intake of 25 g/day, while it is higher when the highest 95th percentile is considered (31.1–41.6 g/day). The maximum already authorised use as a food supplement is up to 16.2 g GOS per day. FSMP containing GOS are not intended to be used if food supplements containing GOS are consumed on the same day.

No tolerable upper intake level for dietary fibre has been established by EFSA (EFSA NDA Panel, 2010) and only transient gastrointestinal symptoms may be related to high intake of fibre (EFSA NDA Panel, 2021b).

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

The Panel considers that the proposed extension of use of GOS in FSMP intended for the general population from the age of 4 years onwards does not raise safety concerns.

5. Conclusions

The Panel concludes that the NF, β-GOS, is safe under the proposed conditions of use.

6. Steps taken by EFSA

1) On 12/07/2021 EFSA received a letter from the European Commission with the request for a scientific opinion on the safety of the extension of use of galacto-oligosaccharides as a novel food pursuant to Article 10 of Regulation (EU) 2015/2283. Ref. Ares(2021)4514488).
2) On 12/07/2021, a valid application on the extension of use of galacto-oligosaccharides, which was submitted by G.K. Roozendaal, GLNP BV, was made available to EFSA by the European Commission through the Commission e-submission portal (NF 2020/1606) and the scientific evaluation procedure was initiated.
3) On 13/12/2021, EFSA requested the applicant to provide additional information to accompany the application and the scientific evaluation was suspended.
4) On 17/12/2021, additional information was provided by the applicant through the Commission e-submission portal and the scientific evaluation was restarted.
5) During its meeting on 28/02/2022, the NDA Panel, having evaluated the data, adopted a scientific opinion on the safety of the extension of use of galacto-oligosaccharides as a NF pursuant to Regulation (EU) 2015/2283.

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Abbreviations

AI	adequate intake
bw	body weight
CCD	certain carbohydrate determinants
DRV	Dietary Reference Values
FSAI	Food Safety Authority of Ireland
FSMP	Food for special medical purposes
GOS	galacto oligosaccharides
IgE	Immunoglobulin E
NDA Panel	EFSA Panel on Nutrition, Novel Foods and Food Allergens
NF	novel food