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To FSANZ: submissions@foodstandards.gov.au.

SUBMISSION

FSANZ Application A1155 2nd Call for Submissions July 2019

2′-FL and LNnT in infant formula and other products

Submitter:

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Level at which submission authorised: authorised by General Manager Strategy and Commercial

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Information regarding the submitter:

Dairy Goat Co-operative (N.Z.) Ltd, (abbreviated as 'DGC'), is a New Zealand manufacturer, developer and exporter of premium consumer packaged nutritional powders primarily for infants and young children. It is a leading New Zealand exporter, and services over 25 international markets via its marketing partner and joint venture relationships. The markets are located primarily in Asia, Europe and Oceania.

Introduction

DGC supports regulatory changes that allow for voluntary addition of new substances that have been shown to be safe and have the potential to move the composition of infant formula products closer to that of human milk and/or the physiological outcomes of formula-fed babies closer to those of breast-fed infants. DGC therefore supports in principle the amendment of the Australia and New Zealand Food Standards Code ('the FSANZ Code") to permit the voluntary addition of 2′-FL alone, or in combination with LNnT in Infant Formula products and Formulated Supplementary Foods for Young Children (FSFYC). This is in line with permitted voluntary addition as novel foods in the EU and GRAS status for these product applications in the US.

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We appreciate the opportunity provided by this Call for Submissions to make comments on the conclusions reached by FSANZ and the proposed drafting variation developed for implementation. DGC seeks to assist FSANZ to achieve evidence-based, balanced and consistent food standards that protect the safety of consumers without being overly prescriptive.

DGC is an associate member of the Infant Nutrition Council (INC) and has participated in the preparation of the INC submission. This submission is therefore brief and serves to highlight the aspects of particular concern for DGC. We have some serious concerns about some aspects of the drafting variation and some suggestions on other aspects to improve consistency within the FSANZ code.

Key points

1. **The wording of the drafting variations to implement the proposed prohibition of the use of 2′-FL alone, or with LNnT, with already permitted galacto-oligosaccharides (GOS) and inulin-type fructans (ITF) is problematic.**

   Neither 2'FL or LNnt are detectable in cow milk, but goat milk naturally contains 2'FL (Leong et al, 2019; Oliveira et al, 2015). The proposed wording specifying, "may not contain any of the following added substances," is of concern based on previous experiences we have had with regulation interpretation. It is possible that goat milk based formulas with added GOS and/or ITF, that are fully compliant with the current regulations could be interpreted to be non-compliant on implementation of these drafting variations due to detection of 2'FL in these products.

   We query the need for these prohibitions at all. When formulas are manufactured from milks other than cow milk the natural oligosaccharides present need to be considered when contemplating addition of any oligosaccharides. Manufacturers are responsible for ensuring the safety of their products and it is simply not possible to regulate for every possible scenario. Further, as these prohibitions are not applied by other regulatory authorities they lead to non-alignment of international requirements.

   In the event that these prohibitions are retained, we recommend the wording is amended as follows:

   The drafting variations are as follows:
   2.9.1 7 (2) An infant formula product to which an inulin-type fructan or a galacto-oligosaccharide is added must not have ~~contain~~ any of the following ~~added~~ substances added:

   (a) 2′-O-fucosyllactose; or
   (b) a combination of 2′-O-fucosyllactose and lacto-N-neotetraose.

   2.9.2—7(3), substituting

   (3) If *inulin-type fructans or *galacto-oligosaccharides are added to a formulated supplementary food for young children:

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(a) the total amount of those substances, both added and naturally occurring, must not be more than 1.6 g/serving; and

(b) the food must not have ~~contain~~ any of the following ~~added~~ substances added:

(i) 2′-O-fucosyllactose; or

(ii) a combination of 2′-O-fucosyllactose and lacto-N-neotetraose.

2. Proposed labelling prohibitions

DGC considers that unwarranted prescription should be avoided and that the generic ingredient labelling requirements should apply to 2'FLand LNnt, consistent with the general approach of the Code. We recommend that the sections shown in blue in the drafting variation are deleted:

inserting after paragraph 2.9.1—24(1)(c)

(ca) the words 'human milk oligosaccharide', 'human milk identical oligosaccharide' or any word or words having the same or similar effect; or

(cb) the abbreviations 'HMO' or HiMO' or any abbreviation having the same or similar effect; or

omitting subsection 2.9.3—8(6), substituting

(6) The label on a package of a formulated supplementary food for young children must not contain:

(a) the words 'human milk oligosaccharide' or 'human milk identical oligosaccharide' or any word or words having the same or similar effect; or

(b) the abbreviations 'HMO' or HiMO' or any abbreviation having the same or similar effect; or

There are already adequate protections in the Code making the proposed prohibitions unnecessary. On page 39 of the 2nd CFS report it is stated that:

"Permitting 2′-FL and LNnT as proposed by FSANZ will promote greater compatibility between domestic and overseas food standards for infant formula products and FSFYC."

And,

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> "The proposed permission would support an internationally competitive food industry in relation to the addition of 2'-FL and LNnT to infant formula products and FSFYC."

These statements are not fulfilled if the proposed labelling prohibitions are applied. To our knowledge these prohibitions are not applied by any other country and as such are counter to achieving international harmonization of regulatory requirements and ensuring that domestic manufacturers can compete on an equal footing with international competitors. Banning the use of common names of substances is counter to providing consumers with terms that can be understood easily and to FSANZ's decision to apply generic ingredient labelling requirements consistent with the general approach of the Food Standards Code.

The extension of this proposed prohibition from infant formula products to FSFYC is especially concerning given that it undermines the policy process set out in the FSANZ Act. Such a move reduces confidence of food manufacturers and marketers in FSANZ.

Further, in relation to FSFYC, provision 1.2.1—23 in the Food Standards Code relating to the application of labelling provisions to advertising states that, "If this Code prohibits a label on or relating to food from including a statement, information, a design or a representation, an advertisement for that food must not include that statement, information, design or representation." If use of the term 'human identical milk oligosaccharides' and the abbreviation, 'HiMOs" are prohibited on labels this could be interpreted to extend to more comprehensive product information on websites for example. This makes it incredibly challenging for manufacturers to explain why these substances are added. In our experience consumers scrutinise these products very closely. Any observed changes in the appearance or physical properties of these products can cause caregivers to worry that the product may be defective. They want, and deserve, to be notified regarding any formulation changes. If manufacturers cannot explain the rationale for addition of these substances to the consumer, they could be accused of withholding information or misleading the consumer by remaining silent.

3. Identity and purity provisions

In Section 2.3.6 of the Call for Submissions FSANZ proposes to include the applicant's specifications in the FSANZ Code (excluding the methods of analysis). Between the first and second Call for Submissions for Application A1155 the applicant's specification was changed. DGC is aware of the prospect of future applications in this area and is concerned about the impact of handling such future applications on FSANZ proposal workflow. It may be more efficient to amend the specifications listed in Schedule 3 such that they might accommodate at least some future developments. We recommend that the specifications in the EU Novel Foods List for microbial sources of these substances be considered.

Further, in the interest of improving the consistency within the FSANZ Code, we recommend that more scrutiny is placed on the parameters that it are appropriate to include in the specifications included in Schedule 3. Suppliers' specifications typically include more parameters than are needed for the purpose of substance identification and purity

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provisions. We have suggested amendments to the proposed drafting variation below with rationale provided in *blue italics*.

S3—40 Specification for 2′-O-fucosyllactose

For 2′-O-fucosyllactose (2′-FL), the specifications are the following:

(a) chemical name——α-L-fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-D-glucopyranose;

(b) chemical formula—$C_{18}H_{32}O_{15}$;

(c) CAS number—41263-94-9;

(d) description— white to off white powder or agglomerates;

(e) ~~assay (water free) for sum of 2′-FL, lactose, difucosyllactose and fucose—not less than 96.0%;~~ *Not included in specifications for 2′FL from microbiological sources in EU Novel Food List.*

(f) assay (water free) 2′-FL——not less than ~~94.0~~ 90%*; Lowest minimum applied in specifications for 2′FL from microbial sources in EU Novel Foods List.*

(g) D-lactose——not more than ~~3.0~~ 5.0% *Highest maximum applied in specifications for 2′FL from microbial sources in EU Novel Foods List.*

(h) L-fucose——not more than ~~1.0~~ 3.0% *Highest maximum applied in specifications for 2′FL from microbial sources in EU Novel Foods lLst.*

(i) difucosyllactose——not more than 1.0%– *Refer to comment relating to (i) and (j) under (j).*

(j) 2′-fucosyl-D-lactulose——not more than 1.0% -*With regard to (i) and (j) we note that the two specifications for 2′FL from microbial sources in the EU Novel Foods List include provisions for different carbohydrates that may be present in small amounts. For the longevity of the specification we suggest that consideration is given to setting an upper limit for other carbohydrates.*

(k) ~~pH (20°C, 5% solution)——3.2 to 5.0~~ *Suggest deletion as not necessary; not included in nucleotide specs in S3, only included in one of the two specifications for 2′FL from microbial sources in EU novel foods list.*

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(l) water——not more than ~~5.0~~ 9.0% *Highest maximum applied in specifications for 2'FL from microbial sources in EU Novel Foods List and also applied for LNnT in this list.*

(m) ash, sulphated——not more than 1.5%

(n) ~~acetic acid (as free acid and/or sodium acetate)——not more than 1.0%~~ *Suggest deletion as not necessary; not included in nucleotide specs in S3, only included in one of the two specifications for 2'FL from microbial sources in EU Novel Foods List.*

(o) residual proteins——not more than 0.01%

(p~~)——lead——not more than 0.1 mg/kg~~ *Suggest deletion as default heavy metal criteria are covered by Schedule 3-4. We note that a maximum for lead is only included in one of the two specifications for 2'FL from microbiological sources in the EU Novel Foods list.*

(q) microbiological: *We suggest deleting the microbial parameters as these are not included in most of the specifications in Schedule 3. Further they are not consistent with the microbiological parameters for individual nucleotides listed is Schedule 3. If you look at the two sets of microbial criteria in the two specifications for 2'FL from microbial sources in the EU Novel Foods List these are very inconsistent.*

Alternatively, if it is preferred to retain some microbiological criteria then we recommend that these are aligned to the microbiological criteria for powdered infant formula in Schedule 27, Including the use of 'not detected' rather than 'absent.' The amendments below reflect this approach.

(i) salmonella——not detected ~~absent~~ in 25 g

(ii) ~~total plate count——not more than 500 cfu/g~~

(iii) ~~enterobacteriaceae——absent in 10 g~~

(iv) cronobacter (Enterobacter) sakazakii—— not detected absent ~~absent~~ in 10 g

(v) ~~listeria monocytogenes——absent in 25 g~~

(vi~~)——bacillus cereus——not more than 50 cfu/g~~

(vii~~)——yeasts——not more than 10 cfu/g~~

(viii) ~~moulds——not more than 10 cfu/g~~

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(ix) residual endotoxins——not more than ~~10~~ 100 EU/mg *We suggest considering this amendment, 100EU/mg being the highest maximum applied in specifications for 2'FL from microbial sources in the EU Novel Foods List.*

S3—41 Specification for lacto-N-neotetraose

For lacto-N-neotetraose (LNnT), the specifications are the following:

(a) chemical name——β-D-galactopyranosyl-(1→4)-2-acetamido-2-deoxy-β-D-glucopyranosyl-(1→3)-β-D-galactopyranosyl-(1→4)-D-glucopyranose

(b) chemical formula——$C_{26}H_{45}NO_{21}$

(c) CAS number——13007-32-4

(d) description——white to off white powder or agglomerates

(e) assay (water free) for sum of LNnT, lactose, lacto-N-triose II, and para-lacto-N-hexaose——not less than 95.0%

(f) assay (water free) LNnT——not less than 92.0%

(g) D-lactose——not more than 3.0%

(h) lacto-N-triose II——not more than 3.0%

(i) para-lacto-N-neohexaose——not more than 3.0%

(j) LNnT fructose isomer——not more than 1.0%

For the longevity of the specification we suggest that consideration is given to setting an upper limit for other carbohydrates rather than separate limits for some of these specific carbohydrates.

(k) ~~pH (20°C, 5% solution) ——4.0 to 7.0~~ *Not normally included in specifications in Schedule 3.*

(l) water——not more than 9.0%

(m) ash, sulphated——not more than 1.5%

(n) methanol——not more than 100 mg/kg–*Suggest checking with applicant on relevance for purity provisions within Schedule 3.*

(o) residual proteins——not more than 0.01%

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(p~~) lead——not more than 0.1 mg/kg~~ *Suggest deletion. Covered by Schedule 3-4.*

(q) microbiological: *Applied same rationale as for 2'FL above.*

(i) salmonella——not detected ~~absen~~t in 25 g

(ii~~) total plate count——not more than 500 cfu/g~~

(iii~~) enterobacteriaceae——absent in 10 g~~

(iv) cronobacter (Enterobacter) sakazakii—— not detected ~~absent~~ in 10 g

(v~~) listeria monocytogenes——absent in 25 g~~

(vi~~) bacillus cereus——not more than 50 cfu/g~~

(vii~~) yeasts——not more than 10 cfu/g~~

(viii) ~~moulds——not more than 10 cfu/g~~

(ix) residual endotoxins——not more than ~~10~~ 100 EU/mg *We suggest consideration is given to this change. As one of the specifications for 2'FL from microbial sources in the EU Novel Foods Lists states a maximum of 100, setting a maximum of 10 appears to be unnecessarily low.*

References:

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. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R2470

Leong et al, 2019. Oligosaccharides in goat's milk-based infant formula and their prebiotic and anti-infection properties. British Journal of Nutrition, June 2019, pp.1-26.

Oliveira et al, 2015. Milk Oligosaccharides: A Review. International Journal of Dairy Technology Vol 68 No 3 August 2015 pp. 305-321