Queensland Government

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File Ref: QCHO/011194

17 January 2019

Standards Management Officer
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Dear Sir / Madam

Submission – Application A1155 - 2′-FL and LNnT in infant formula and other products

Thank you for the opportunity to provide a submission on the Call for Submissions paper for Proposal A1155.

This submission provides comment on the proposed changes to the *Australia New Zealand Food Standards Code* (the Code). The submission does not represent a Queensland Government position, which will be a matter for the Queensland Government should notification be made by the FSANZ Board to the Australia and New Zealand Ministerial Forum on Food Regulation.

Application A1155 has been prepared to consider permission to add 2′-FL and LNnT in infant formula and formulated supplementary food for young children (FSFYC) as a nutritive substance and a food produced using gene technology.

Summary

Queensland has concerns regarding the insufficiency of evidence provided by the Applicant to substantiate both bifidogenic effect and anti-campylobacteriosis claims related to addition of 2′-FL and LNnT to infant formula and other foods. Particularly with respect to compliance with the *Ministerial policy guideline on the regulation of infant formula products* (Policy Guideline) requirements for clearly substantiated evidence of specific health outcomes for use in infant-, and follow-on formulas. The anti-campylobacteriosis health claim additionally appears to constitute a therapeutic claim of prevention of (an infectious) disease, which is not permitted under Code 1.2.7-8(a).

Queensland seeks clarification from FSANZ regarding its position with respect to a bifidogenic effect *per se* as a substantiated beneficial health effect, and/or whether prebiotics whose physiological impact is indirect and which are specifically not directly absorbed or metabolized by

humans can be considered nutritive substances for the purposes of section 1.2.7 and Schedule 4 of the Code.

As outcomes of proposals regarding the revision of nutritive substances and novel foods (P1024) and infant formula (P1028) may impact on Application A1155, consideration should be given to delaying a decision on this Application until the outcomes of these proposals are known. Alternatively, this Application could be reviewed with respect to stakeholder input received on P1024 and P1028 to date.

Queensland therefore does not support the Application to permit the voluntary addition 2′-FL and LNnT in infant formula and FSFYC.

Queensland requests FSANZ respond to the issues and concerns raised in this submission, after which Queensland may reconsider its position with respect to permission for the voluntary addition 2′-FL and LNnT in infant formula and FSFYC.

Queensland supports the proposed labelling requirements, including restriction to use of names 2-fucosyllactose and Lacto-N-neotetraose, prohibition of health claims and indications of human breast milk equivalency of these substances. Queensland feels that these restrictions and prohibitions should extend to both infant formula and FSFYC/follow-on formula.

Code *Schedule 26 - Food Produced using gene technology* includes only GM plant-derived permitted foods. The Application proposes amendment representing the first addition of a GM microorganism-derived food. Due to potential public sensitivity regarding such amendment Queensland suggests FSANZ consider drafting an associated public communications strategy.

Please find below additional information and evidence below in relation to this summary.

Health Claims

The Applicant's health effects assessment of 2′-FL and LNnT indicates the plausibility of (a) an anti-infective effect against campylobacteriosis, and (b) bifidogenic effect (FSANZ-defined as the proliferation and increase in the relative abundance of bifidobacteria in intestinal microflora).

The Policy Guideline specifically prohibits any health claims associated with infant formula. In addition, Code 1.2.7-8 *Claims not to be therapeutic in nature* prohibits claims in all foods that "refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition;". The Applicant's anti-infective claim with respect to prevention of campylobacteriosis (an infectious disease) would therefore appear to represent a claim therapeutic in nature. Although the Policy Guideline prohibition refers to infant formula, the nature of the anti-campylobacteriosis claim as per Code 1.2.7-8(a) should also preclude such claims in all foods. Queensland also recommends the general prohibition on health claims for infant formula also apply to FSFYC.
Queensland seeks general clarification from FSANZ on whether the prohibition on claims *therapeutic in nature* under Code 1.2.7-8(a) is absolute, or whether high-level health claims may be made for such foods under the Code 1.2.7-18 subject to substantiation under Code Schedule 6 systematic review (and listing in Schedule 4-4.)

Although FSANZ applied a weight-of-evidence approach with respect to evaluation of the bifidogenic health claim of 2′-FL and LNnT at the levels specified by the applicant, we feel the scientific evidence presented is currently insufficient to warrant such a beneficial health claim. This is due to: (a) the low number of applicable peer-reviewed studies cited, (b) low numbers of study participants, (c) variable end-point determinants of health benefit between studies, (d) uncertainty regarding the precise definition of a bifidogenic effect, i.e. is this characterised by an increase in

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intestinal microflora total number of *Bifidobacterium* spp., or an increase in the population-relative proportion of this genus or specific *Bifidobacterium* species, or both.

In addition, although "FSANZ has previously recognized (under Proposal P306 and Application A1055) the dominance of *Bifidobacterium* in the intestinal microflora is generally considered to be beneficial to the host", the scientific evidence supporting this "general recognition" is frequently qualified in the indicated respective Proposal and Application, for similar reasons to those cited in a-d above. Therefore, Queensland does not support the bifidogenic health claim in the current Application at this time, and recommend FSANZ seek additional evidence from the Applicant to substantiate this claim.

The Policy Guideline requires clearly substantiated evidence of specific health outcomes for substances use in infant-, and follow-on formulas, including:

- "a substantiated beneficial role in the normal growth and development of infants or children" should be demonstrated for substances for use in infant and follow-on formula/FSFYC, and;

- "appropriate evidence to link the physiological, biochemical and/or functional effects of the substance to specific health outcomes for infants, in infancy or in childhood", and;

- "particular caution should be applied by the Authority where such links are less than clear."

Queensland recognises the weight-of-evidence approach used and recommend FSANZ proactively form an independent scientific expert group to review and provide advice regarding the status of prebiotics and probiotics "microbigenic"/"microbistatic" intestinal microflora effects (and the criteria for determination of same) as beneficial health effects for classification in the Code. This includes general criteria related to human normal flora indicative of an impact on same, i.e. increase/decrease in total population of an organism/class of organisms, their relative proportion of the total microbial population, or both. This should include examples of what may be considered positive health impacts, e.g. increase in body weight, nutrient absorption, specific immune effects, etc. FSANZ should review other countries assessment criteria in this regard (EU, US, Canada).

QLD recognises FSANZ did not support listing of "gut health" in Proposal 293 as an approved substantiated health effect from probiotics and prebiotics. Queensland seeks clarification as to FSANZ's current position regarding this issue. Considering the likelihood of future Proposals and/or Applications associated with health claims based on pre-, or pro-biotic effects assessed using metagenomic intestinal microbiome profiling, such expert scientific review is additionally warranted.

Nutritive substance claim(s)

Code 1.1.2-12 *Definition of use as a nutritive substance*, subsection 1(a) defines a nutritive substance in relation to a food if it is added to the food "to achieve a nutritional purpose" and "it is identified in the code as a nutritive substance" and (is) "any substance (other than an inulin-type fructan, a galacto-oligosaccharide or a substance normally consumed as a food) that has been concentrated, refined or synthesised, to achieve a nutritional purpose when added to a food" and "any substance (other than an inulin-type fructan, a galacto-oligosaccharide or a substance normally consumed as a food) that has been concentrated, refined or synthesised, to achieve a nutritional purpose when added to a food."

The Macquarie dictionary definition of nutritive is *serving to nourish; affording nutriment*, where nourish is defined as (1) *to sustain with food or nutriment/supply with what is necessary for maintaining life*, (2) *to foster or promote*. Nutriment is defined as "*any matter that, taken into a living organism, serves to sustain it in its existence, promoting growth, replacing loss, and providing energy*."

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FSANZ 1st call for submission (p 5) states:

"In addition, paragraph 1.1.1—10(6)(b) requires that, unless expressly permitted, a food for sale must not have as an ingredient or component a substance that was *used as a nutritive substance* (section 1.1.2—12). 2′-FL and LNnT are both also used as a nutritive substance because their addition to food is intended to achieve specific nutritional purposes."

It is unclear whether a claim for addition of 2′-FL and LNnT as a nutritive substance for a nutritive purpose in A1155 relates to a potential bifidogenic effect. As 2′-FL and LNnT are not directly absorbed or metabolized by humans, but rather exert a *potential indirect* nutritive effect via an impact on the lower GI tract bacterial population (specifically *Bifidobacterium* spp.), there is an issue of whether this specifically qualifies as a nutritive effect. Queensland notes that ITF and GOS, which *are* metabolized by humans, appear specifically excluded in the Code from classification as nutritive substances in Schedule 4 and addition for nutritive purposes.

Queensland recommends FSANZ undertake a review of its criteria for definition of - and associated claims as - *nutritive substances* and *nutritive purposes*, with a goal of potentially revising the Code definition to clarify and delineate criteria qualifying substances as same. Queensland seeks information as to whether this is currently part of Proposal 1024 assessment.

In this context, Queensland recommends a concurrent determination of whether prebiotic effects (such as the bifidogenic effect) qualify as a general nutritive impact (as distinct from any health claims), and thus as nutritive substances and/or purposes.

Queensland recommends FSANZ form an expert scientific and regulatory group to review and clearly delineate the status of prebiotics as nutritive substances for classification in the Code. This includes general criteria related to human normal flora indicative of an impact on same, i.e. increase/decrease in total population of an organism/class of organisms, their relative proportion of the total microbial population, or both. FSANZ should review other countries assessment criteria in this regard (EU, US, Canada).

Labelling

Code amendments should also endeavour to align with the NHMRC *Infant Feeding Guidelines* (2012), which recommends breastfeeding exclusively to around six months of age, and complimentary breastfeeding to 12 months or beyond.

It is acknowledged that some mothers may not be able to or may choose to not breastfeed their infants, and therefore use infant formula during the first six to 12 months. For some infants, infant formula may be the sole source of nutrition until solid foods are introduced. Therefore, Code amendments related to infant formula should align with the *WHO International Code of Marketing of Breast-milk Substitutes*.

Except for foods for special medical purposes as recommended by a suitably qualified health professional, infants older than 12 months do not require follow-on formulas and toddlers' milks (i.e. FSFYC). However, as FSFYC are widely available and marketed, it is important that their composition and labelling is also consistent with the WHO International Code of Marketing of Breast-milk Substitutes.

Queensland agrees with the restriction to use of 2′-O-fucosyllactose (2′-FL) and Lacto-N-neotetraose (LNnT) on the ingredients or nutrition information panel, where these ingredients are added.

To retain consistency with Code 2.9.1-21 *Declaration of nutrition information*, subsection 1(a)(iv) with respect to inulin-type fructans (ITF) and galacto-oligosacharides (GOS), Queensland

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recommends 2'FL and LNnT be subject to the same nutrition declaration requirements as ITF and GOS.

A1155 *First call for submissions* section 2.2.5.1 *Statement of ingredients* (p16 paragraph 1) suggests - but does not appear to specifically state - a prohibition of labelling "human milk identical", "human milk oligosaccharide(s)", "humanised" or "maternalised" (or a word or words having the same or similar effect implying human-derivation equivalency) in FSFYC as well as infant formula. The Code (2.9.1-24; *Prohibited representations*) and the Policy Guideline prohibit labelling with such terminology.

Prohibitions on labelling of infant formula and/or ingredients with respect to "human milk equivalency" should also extend to "follow-on" formula/FSFYC. As part of its review of Code requirements in this respect, FSANZ should also consider whether a prohibition on such terms is warranted more generally, i.e. foods for other purposes, e.g. sports supplements.

In the context of this Application, FSANZ should note the *International Codex Alimentarius* (Codex) Commission is currently discussing new food standards for commercial milk formulas targeting older infants and young children. Its deliberations are to be continued over the coming year and will shape global and national regulation and marketing of commercial baby food products going forward.

(First) permission for use of a GM-microorganism-derived food (ingredient)

Queensland note the Application would presumably include the first addition of a GM microorganism to *Schedule 26 - Food Produced using gene technology*; table in subsection S26-3(4), which currently includes only GM plant-derived permitted foods. The Code currently permits use of numerous processing aids produced using GM-microorganisms (S18[4](5)) *Permitted enzymes, enzymes of microbial origin*. Subsection S26(2) would presumably require amendment as it currently deals with plant derived GM foods only.

FSANZ' safety assessment and proposed labelling requirements appear satisfactory in relation to permission for GM-microorganism produced 2'-FL and LNnT as an ingredient in infant formula and other foods. However, given potential sensitivity regarding the first addition of a GM-*microorganism*-derived ingredient to infant formula and FSFYC specifically, it is suggested FSANZ consider drafting an associated public communications strategy.

Should you require further information in relation to this matter, please contact Food Safety Standards and Regulation, Health Protection Branch, Department of Health on (07) 3328 9310 or at foodsafety@health.qld.gov.au.

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