Application A1155
2'FL and LNnT in infant formula and other products
1st Call for submissions paper

Submission

The NSW Food Authority (NSWFA) welcomes the opportunity to comment on the 1st call for submissions on Application A1155 – 2'FL (2-fucosyllactose) and LNnT (Lacto-N-neotetraose), derived from a genetically modified organism using fermentation and chemical synthesis, in infant formula and formulated supplementary food for young children.

Summary position

NSW has concerns with the quality of current evidence supplied by the applicant in favour of the two health effects considered by FSANZ to have some potential to confer beneficial health outcomes.

The evidence in support of 'bifidogenic' health effect supplied by the applicant is equivocal. FSANZ when it assessed 'gut health' from probiotics and prebiotics for Proposal 293 (Nutrition, health and related claims) did not support listing of 'gut health' as a pre-approved substantiated health effect. NSW requests clarity from FSANZ as to why if this view has changed, given the certainty of evidence required for substantiation.

NSW considers that the evidence provided by the applicant in favour of the cited anti-infective health effect for *Campylobacter jejuni* is not satisfactory to permit claims. FSANZ to a certain degree agrees with this view as the extent of a health effect cannot be determined (pg 11 of 1st call for submissions - A 1155). NSW is very concerned about the possibility for therapeutic claims to be made about 2'FL and LNnT in this regard. NSW requests clarity from FSANZ concerning the nature of claims that could be made.

In combination, these matters raise concern as to whether the Ministerial Policy Guideline for Infant Formula products (the Policy Guideline) has been complied with. The Policy guideline (specific policy principle – composition j) is very clear that substances proposed for addition to infant formula should be subject to pre-market safety assessment by FSANZ and *'should have a substantiated beneficial role in the normal growth and development of infants'*. NSW has the preliminary view that the threshold of evidence provided by the applicant is insufficient. NSW requests that FSANZ seek further information from the applicant on this matter.

NSW also notes that Food Ministers on 29 June 2018, acknowledged regulatory and ethical complexities associated with the importation of human milk and its products and sought further consideration of this matter by the Clinical Principal Committee of the Australian Health Ministers Advisory Council (AHMAC).

NSW preliminary position on the addition of 2'FL and LNnT to FSFYC is to request further information on the nutritive purpose served by these substances to determine a clearer position. NSW does not consider current information sufficient to adequately define the nutritional benefit provided by these substances to toddlers. NSW also notes that the Policy Guideline for the intent of Part 2.9 of the Code provides that the composition of the special purpose food should be consistent with the intended purpose. Given that human milk oligosaccharides are not nutritionally required in the diets of persons above the age of 1 – what intended purpose will be served by the addition of 2'FL and LNnT to FSFYC and what evidence does FSANZ have to support this purpose? NSW considers there is potential for consumer exposure to false and misleading claims on food labels and associated advertising for products containing these substances. NSW requests that FSANZ respond to concerns expressed in this submission in this regard. NSW will then further consider its position on the addition of 2'FL and LNnT to FSFYC.

NSW supports FSANZ proposal to identify these substances as nutritive substances for the purposes of addition as it will allow the purpose of addition to be clear to industry and regulators. NSW further supports the proposal to provide for prescribed names and corresponding identity and compositional standards in Schedule 3 of the Code. This support is contingent on concerns expressed with regard to the above matters being satisfactorily addressed.

Further evidence in support of the above statements is provided below.

Specific issues – quality of evidence in support of a health effect

NSW is concerned by the current quality and certainty of evidence provided by the applicant compared to that required for substantiation according to page 22 of the First Review Report for Proposal 293 (Nutrition, Health and Related Claims Standard).

'To determine whether a causal relationship between the food or property of food and the health effect is established, consideration needs to be given to the totality and weight of evidence and thus whether the evidence is robust and therefore unlikely to be overturned by another well conducted study'.

'The degree of certainty required to establish food-health relationships underpinning all health claims will be the same'.

The evidence supplied in support of the bifidogenic health effect is equivocal. There is only one study cited where the gut microbiome of infants fed formula enriched with 2'FL or LNnT more closely resembled the microbiome of breast fed infants. One study is insufficient to meet the certainty of evidence required by substantiation.

NSW notes that 'substantiation' in a health claims context may not be perceived to mean that expressed by the Ministerial Policy Guideline for Infant Formula Products. The Macquarie Dictionary defines 'substantiate' as 'to establish by proof or competent evidence'. NSW does not consider that the applicant has met this threshold based on current evidence supplied.

NSW notes that FSANZ previously considered claims arising from probiotic of varying types on page 21 of the First Review Report for Proposal 293 (Nutrition, Health and Related Claims Standard).

'Some industry stakeholders have requested consideration of probiotic health claims approved overseas, in particular in Canada. Health Canada has four pre-approved non-strain specific probiotic claims. They are general claims that refer to the nature of probiotics and not their health effects or benefits and so they do not meet the definition of a general level health claim in Standard 1.2.7'.

'These products, or NHPs (natural health products) as they are referred to in Canada, are similar to complementary medicines or dietary supplements in Australia and New Zealand'.

Given the uncertainty of outcome from FSANZ in 2012, NSW requests clarity from FSANZ as to why such an effect now meets the definition of a health effect.

NSW queries the nature of the potential claim that may arise from the anti-infective health effect sited by FSANZ concerning *Campylobacter jejuni* in SD1 (pg 98) in FSFYC.

NSW would understand that any infant or young child aged 1-4 with positive diagnosis of *Campylobacter jejuni* infection is already under the care of a health professional, and depending on the severity of infection, possibly hospitalised. This would seem to position a possible health claim concerning 2'FL and LNnT about anti-infective effects of *Campylobacter jejuni* as a high level health claim (if not a therapeutic claim). NSW seeks FSANZ advice on this matter. NSW preferred position on this matter is that such a claim is permissible at all (i.e. it is not a therapeutic claim) that it is listed as a pre-approved food:health relationship in Schedule 4 of the Australia New Zealand Food Standards Code (the Code) for high level health claims. This will allow the line between a therapeutic claim and a high level health claim to be resolved centrally, providing national consistency and clarity on permissible health claims concerning this potential, but currently unsubstantiated claimed health effect.

NSW would not support delegation of this investigation to a jurisdictional level through a general level health claim as it is likely to run the risk of inconsistent outcome between jurisdictions.

NSW is also concerned about the lack of human clinical evidence concerning the bifidogenic health effect of 2'FL and LNnT on 1-4 year old children. SD1 cites a lack of evidence to support this claimed effect on this population group. NSW suggests that FSANZ request such information from the applicant. NSW would also express a preference that this health effect (if possible to substantiate as a health effect) is also

listed in Schedule 4 of the Code to ensure national consistency in the application of health claims concerning this claimed effect.

Infant Formula products

NSW re-iterates its support for maintaining a complete prohibition on nutrition and health claims for infant formula products (products regulated under Standard 2.9.1 of the Code). NSW notes that Standard 2.9.1 is under investigation by FSANZ through Proposal 1028.

NSW also re-iterates its support for pre-market safety assessment by FSANZ for all novel foods and nutritive substances intended for addition to infant formula products. Infants (under the age of 12 months) are a specific at-risk sub-population of the general community and should be managed through a prescriptive and conservative regulatory approach.

NSW supports FSANZ intention to consider claims and representations on infant formula product and/or advertising concerning 2'FL and LNnT as within scope of Standard 2.9.1-24 (prohibited presentations). This would prohibit attempts to present infant formula as 'human-milk identical', "HMO', 'Human milk oligosaccharides' or words of similar effect. Infant formula containing 2'FL and/or LnNT cannot replace the unique maternal bond between mother and baby arising from breastfeeding and should not be permitted to claim this status. NSW further suggests that claims such as 'HMO' or 'Human Milk Oligosaccharides' be prohibited on infant formula, such that the only legitimate way for industry to market this substance is via the proposed prescribed name.

NSW supports FSANZ proposal to identify 2'FL and LNnT as nutritive substances for Standard 2.9.1 using only the prescribed names as this will trigger mandatory listing in the nutrition information statement on infant formula products for 2'FL and LNnT and allow for uniform identification of these substances in these products.

Formulated Supplementary Foods for Young Children

NSW is concerned about the possibility of FSFYC containing 2'FL or LNnT to claim 'human milk identical' compositional status for these compounds on product labels or in advertising. NSW suggests that a similar prohibition on such representations that already exists for infant formula be extended to FSFYC. The argument in favour of such a proposal is a logical extension of existing policy of Food Ministers concerning infant formula products. Infant formula can be a complete source of nutrition for infants and prohibits such claims to ensure that infant formula may not be marketed as equivalent or superior to breast milk. Children above the age of 1 should source nutrients from a variety of dietary sources which may include breast milk but does not need to. It seems logical to extend the existing prohibition on such claims to the food targeted at the population where it is not and cannot be the sole source of nutrition for the same reason – the food should not be permitted to claim a status equivalent or superior to breast milk.

The lack of clear nutritional need for human milk oligosaccharides in populations above the age of 1 raises the issue of why they should be permitted at all, given the

FSFYC sit within Part 2.9 of the Code. NSW does not consider current information sufficient to adequately define the nutritional benefit provided by these substances to toddlers. NSW also notes that the Policy Guideline for the intent of Part 2.9 of the Code provides that the composition of the special purpose food should be consistent with the intended purpose. NSW requests that FSANZ seek further information from the applicant in this regard.

NSW notes that Standard 1.2.7 of the Code (nutrition, health and related claims) does not prevent application of nutrition and health claims to formulated supplementary foods for young children (FSFYC).

Given children in this age group (1-4 years) are still considered a vulnerable population, NSW advocates a pre-approved listing in Schedule 4 of the Code for any substantiated food:health relationships that would underpin any health claims that may appear on products marketed at this age group containing 2'FL or LNnT. NSW has similar concerns about nutrition content claims (i.e. contains 'HMO' or contains 'Xg of human milk oligosaccharides') appearing on products and would advocate a listing in Schedule 4 of the Code for any permissible claims that may arise.

NSW further suggests that FSANZ seek advice from the ACCC on the possibility of consumers being misled as the source of the human milk oligosaccharide that may appear in these products. The source is a genetically modified microorganism that produces compounds chemically like those found in human breast milk. Therefore, any claims that may appear on products concerning these substances should not create a misleading impression that the FSFYC is somehow related to human breast milk.

Concerning health claims NSW would appreciate advice from FSANZ on the following matters concerning health effects explored for addition of 2'FL and LNnT in FSFYC:

- Whether the strength of evidence provided by the applicant for the claimed bifidogenic health effect for FSFYC is sufficiently robust to permit addition to Schedule 4 of the Code.
- Whether a health claim concerning anti-infective effect for *Campylobacter jejuni* is a therapeutic claim. Claims concerning prevention or alleviation of a disease are considered therapeutic and may not be made. NSW considers campylobacteriosis as the disease associated with *Campylobacter* infection. The claimed effect, as it is anti-infective appears to very closely resemble a therapeutic claim (prevention or alleviation of a disease).
- If anti-infective effect is not considered a therapeutic claim, advice on whether a permissible health claim, based on a health effect associated with reduced incidence of campylobacterosis is a high-level health claim. NSW considers this to fall within the definition of 'serious disease' under Standard 1.2.7 of the Code as medical intervention is required to enable positive diagnosis of *Campylobacter jejuni* infection.

NSW has a clear preference for food:health relationships marketed on FSFYC to be listed in Schedule 4 of the Code. This will provide consistency and clarity in claims that may be made and ensure that the quality and quantity of evidence supporting each food:health relationship has been determined to be sufficiently rigorous to

substantiate each relationship to a degree that it is not unlikely to be overturned by a future study (i.e. substantiated to the following: NHMRC-General Grade A, WHO-High (++++), TGA-Grade A - strongly supports listable indication).

NSW also queries the status of declaration of presence of 2'FL and LNnT in FSFYC that do not bear a claim regulated by Standard 1.2.7 of the Code but make a claim according to the definition of claim under Standard 1.1.1 of the Code. NSW considers that any claim made concerning 2'FL and LNnT should trigger a requirement to declare the quantity of claimed substance in the NIP. This would provide a clear basis for consumers to make informed choices in the purchase of FSFYC.

Dose of 2'FL and LNnT required to provide for claimed health effect

The effective dose of 2'FL and LNnT required to provide for the claimed bifidogenic and anti-infective (invasive *Campylobacter jejuni)* health effects is not clear to NSW. Further clarity is requested on these amounts, so it may be demonstrated that the dose of substances to be delivered to infants through infant formula or toddlers through FSFYC is sufficient to enable these claimed effects to be realised. NSW notes that the 1st call for submissions report (pg 10) suggests that the extent of ant-infective effect cannot be established based on current information. NSW suggests that FSANZ request further information from the applicant on this matter. NSW also notes that no evidence has been supplied by the applicant in support of the claimed bifidogenic effect on toddlers. FSANZ is suggested to request this information from the applicant.

Exclusivity

NSW notes the applicant has requested exclusivity in marketing of products containing 2'FL and LNnT. Given this request NSW considers it of high importance that FSANZ review the evidence provided by the applicant for the claimed health effects to ensure it meets the degree of certainty required for the substantiation of a food:health relationship according to SD 8 for Proposal 293. Listing of these relationships in Schedule 4 of the Code would provide jurisdictions with a clear basis to then review products and product claims in the marketplace during the requested exclusivity period.

Prescribed name and proposed entry to Schedule 3 of the Code.

NSW supports FSANZ proposal to make '2-fucosyllactose and 'Lacto-N-neotetraose' prescribed names under the Code. Such status will make for simple identification of these substances on product labels. NSW considers this status accompanied by the proposed identity and purity entry in Schedule 3 of the Code will enable clear identification of these substances in products in the market.

ENDS

The views expressed in this submission may or may not accord with those of other NSW Government agencies. The NSW Food Authority has a policy which encourages the full range

of NSW agency views to be submitted during the standards development stages before final assessment. Other relevant NSW Government agencies are aware of and agree with this policy.