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

### Submission

The NSW Food Authority (NSWFA) welcomes the opportunity to comment on the 2nd 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 does not support the addition of 2'-FL and LNnT to FSFYC on the basis that reliable evidence to support a beneficial health outcome has not been provided for populations above the age of 12 months.

NSW notes the safety assessment conducted by FSANZ has identified no health and safety concerns for 2'-FL and LNnT in infant formula products (or FSFYC) and notes these compounds when added to infant formula will likely result in a product more alike human breast milk than current infant formula on the market. This is desirable as all infant formula products are breast milk substitutes.

However NSW considers the health outcome assessment undertaken by FSANZ is not sufficiently rigorous and queries whether FSANZ has adequately complied with the Ministerial Policy Guideline for infant formula products *specific policy principle – composition j* as it suggests that 'particular caution should be applied by the Authority where such links are less clear'. Information provided in the 2nd CFS for the substantiation of the cited specific health outcomes concludes *'potential to confer beneficial health outcome'* and *'a biological and mechanistic plausibility'* of an anti-infective effect against *Campylobacter jejuni* and a bifidogenic effect may be attributed to 2'-FL and LNnT. This language could be interpreted to suggest that evidence on these matters is equivocal. NSW would appreciate a more comprehensive analysis of the cited health outcomes to remove doubt of compliance with this specific policy principle. NSW considers this especially important to this application as it is targeted at vulnerable populations (persons less than 47 months old) and exclusivity is sought by the applicant providing a 15 month commercial advantage over competing products.

NSW suggests that FSANZ may be well served to convene the Independent Scientific Expert Group proposed in the Ministerial Policy Guideline for Infant Formula Products to review evidence supplied by the applicant for the claimed health outcomes so they may be adequately substantiated.

NSW suggests that independent review of the health outcome evidence is especially important for 2'-FL and LNnT as the applicant will supply the product to the marketplace under the trade name 'Glycare'. This name is already likely to be a registered trademark of Glycom and could be applied to infant formula products and FSFYC alike, notwithstanding the prohibition of nutrition and health claims on infant formula products. Independent review and substantiation of the claimed health outcomes for 2'-FL and LNnT by an expert group would remove doubt as to the veracity of truthfulness surrounding any possible future marketing and advertising campaigns promoting the unique benefits of infant formula products and FSFYC bearing the trade name 'Glycare'.

**Addition of 2'-FL and LNnT to infant formula**

NSW notes the Ministerial Policy guideline for Infant Formula Products (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 is concerned that citing an anti-infective effect against the binding of *Campylobacter jejuni* may be implying that such infection should be interpreted as normal in the development of infants. This is clearly not intended. As raised in its submission to the 1st CFS, NSW considers a health outcome of this nature to be related to a high level health claim (serious disease) or a therapeutic or prophylactic effect or claim (prevention of a serious disease). NSW notes that health claims, therapeutic and prophylactic claims are not permitted by the Ministerial Policy Guidelines for Infant Formula Products.

NSW also notes that the human studies supplied by the applicant in support of this cited health outcome involves infants who were breast milk with a higher proportion of 2'-FL in their milk rather than fed infant formula supplemented with 2'-FL and LNnT. This raises doubt as to whether the health outcome cited may be consistently and reliably reproduced in healthy infants when 2'-FL and LNnT are delivered in infant formula. FSANZ acknowledges this doubt as the effect is cited as 'could occur' and 'the extent of the effect cannot be determined'.

The evidence for the cited bifidogenic health outcome and its alignment with oligosaccharides references previous work conducted by FSANZ in this area. Review of this work (Proposal 306 and Application 1055) suggests that neither examined this issue conclusively. Proposal 306 did not consider health benefits in its risk assessment - *'health benefits attributed to the substance when added to infant formula have not been considered in the risk assessment of this Proposal'*.
In Application 1055, FSANZ presented studies with formula using FOS (Fructooligosaccharides), many of which showed no effect on the levels of bifidobacteria in infants' guts. The health effect assigned to these ingredients was the ability to soften stools and reduce the incidence of constipation, rather than the bifidogenic effect.

NSW would request that FSANZ seek further information to provide greater certainty of a bifidogenic health outcome associated with the addition of 2'-FL and LNnT to infant formula so that doubt of compliance with *specific policy principle – composition j* may be removed. It may be prudent to refer consideration of this matter to the

Independent Scientific expert group proposed in the Ministerial Policy Guideline for Infant Formula Products for advice and decision, as independent experts may be aware of additional information on this matter.

**Addition of 2'FL and LNnT to FSFYC**

As outlined in its previous submission to FSANZ, NSW does not consider current information sufficient to adequately define the nutritional benefit provided by these substances to toddlers. NSW notes that FSFYC are designed to supplement children's (age 13 – 47 months) diet that are inadequate in energy and nutrients. Furthermore, as noted by FSANZ in CFS2, FSFYC are not considered breastmilk substitutes in Australia and New Zealand (p31). FSANZ also notes that the addition of 2'-FL and LNnT may not have strong alignment with the definition of FSFYC (p26). Therefore, NSW questions why 2'FL and LNnT should be added for FSFYC when doing so would not be consistent with supplementing an inadequate food intake for toddlers. NSW therefore considers that the addition of 2'FL and LNnT to toddler milks does not comply with the Ministerial Policy Guideline for the intent of Part 2.9 – Special Purpose Foods.

Concerns with regard to the certainty of evidence of the cited health outcomes stated for infant formula products are heightened when applied to FSFYC as it is permissible for such products to carry nutrition and health claims under Standard 1.2.7 of the Food Standards Code.

There are two specific elements of concern in this area that lend NSW to form the position that the presence of the 2'-FL and LNnT in FSFYC should not be permitted until further evidence is supplied on the cited health outcomes to remove doubt that they may be consistently and reliably reproduced in the target populations using FSFYC.

A conclusion of 'potential to confer beneficial health outcome' and 'a biological and mechanistic plausibility' would make consideration of any future claims associated with the marketing of FSFYC supplemented with 2'-FL and LNnT problematic for consumers and jurisdictions. NSW does not consider evidence provided to date to be sufficient to provide a substantiated health outcome and requests that FSANZ convene the Independent Expert Scientific Group proposed by the Ministerial Policy Guideline for Infant Formula Products so that a clear decision on this matter may be made. This concerns also extends to nutrient content claims on FSFYC as NSW notes that other nutritive substances in this standard require a minimum quantity of the active ingredient to be present in a serve of the food – e.g. 2.9.3-8(2)(a) requires no less than 10% RDI or ESDADDI to be present for vitamin and mineral presence claim, and 2.9.3-8(6) requires no less than 30µg/serving of lutein to permit a claim concerning the presence of lutein to be made.

NSW further re-iterates its request for FSANZ to consider that the higher risk nature of FSFYC should result in claims only being made once a 'property of a food' or a 'food:health relationship' has been included in Schedule 4 of the Food Standards Code. This will allow claims to be made on FSFYC about substances with clearly established health benefits that may be accessed by all parties supplying FSFYC to the marketplace, assisting consumers in making informed purchase decisions.

NSW also has a concern about the ability for comparative nutrient content claims to be made during the exclusivity period when only one supplier may provide 2'-FL and LNnT supplemented FSFYC into the marketplace. NSW does not consider that its compliance and enforcement resources should be deployed in responding to industry complaints should such a claim emerge during the 15 month exclusivity period.

Doubt could be removed from this matter by FSANZ inserting a clause into the Food Standards Code prohibiting such claims from being made unless a separate application to amend the Code is made.

**Labelling of 2'FL and LNnT in infant formula and FSFYC**

NSW supports FSANZ's proposed prohibition on the use of the terms such as 'human milk identical oligosaccharide', 'human milk oligosaccharide', 'HiMO or 'HMO' on the label of infant formula products and FSFYC. However, NSW has concerns that these prohibitions will be circumvented by mechanisms such as existing or future trademarks. NSW notes that 'Glycare' (the applicants proposed name for 2'-FL and LnNT is already trademarked. NSW suggests that FSANZ alert IP Australia to any further future trademarks that may be lodged to promote 2'-FL and LnNT – e.g. trademarks involving 'oligosaccharide', 'oligo' or words to the same effect.

NSW preferred position on this issue is that FSANZ revert back to its original position at 1st CFS in that 2'-FL and LnNT are named through prescribed names. The prescribed names clearly identify the specific substances and allows consumers (once the health outcome assessment has been adequately completed) to look for these substances on pack in order to make informed purchase decisions. NSW is concerned that use of generic names will invite labelling of the nature 'oligosaccharides' generally where the specific health outcome associated with these specific substances (once clearly established) will not be visible to the consumer.

NSW further notes that 'Glycare' is a registered trademark of the applicant Glycom. As it contains the word 'care' NSW would argue that an implied health claim is being made. As a trademark is exempt from the health claims standard, NSW considers that 'Glycare' could be marketed on infant formula product and FSFYC alike. This makes clear substantiation of the cited health outcomes important to enable consumers to make informed purchase decisions of these products in the marketplace. NSW is suggesting that FSANZ convene the independent scientific expert group proposed in the Ministerial Policy Guideline for Infant Formula Products to provide for adequate substantiation of the claimed health outcomes to enable consumers to purchase products carrying the tradename 'Glycare' with confidence that the claimed health outcome may be consistently and reliably delivered.

**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.**