Application 1265 – 2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products

NSW Submission

General Procedure – the 1st call for submissions (CFS)

Summary

NSW appreciates the opportunity to comment on Application 1265 (A1265) – 2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products (IFP). The submission does not represent a NSW Government position, which will be a matter for the NSW Government should notification be made by the FSANZ Board to the Food Ministers' Meeting.

In general NSW supports industry innovation to bring the composition of IFP closer to that of human milk. Breastfeeding is the normal and recommended way to feed an infant. In the situation where breastfeeding is not possible, it is desirable to have IFP with composition closer to human milk available to support normal growth and development of infants.

However, NSW would appreciate further consideration by FSANZ on matters considered in A1265 to ensure the Code protects infant safety and to further investigate beneficial roles played by these substances in infant development. While acknowledging ethical limitations to infant clinical studies, NSW considers the evidence provided in the CFS to substantiate beneficial roles for 2'-FL/DFL, LNT, 6'-SL and 3'-SL and combinations to infants is limited in terms of the number of studies available. These combinations are relatively new to all infant formula product markets, hence a cautious and evidence driven approach should be applied by FSANZ in considering permissions for IFP.

NSW proposes that review of the beneficial effect of these substances is included as part of FSANZ's five-year review of existing human-identical milk oligosaccharide (HiMO) permissions in the Code. NSW would appreciate opportunity to discuss the scope and framework of this review.

NSW supports the notion to set a maximum limit for total added oligosaccharides in IFP and encourages FSANZ to start exploring the option now.

Further comments are provided below.

Safety assessment – EU limits for 2'FL/DFL

Overall NSW notes FSANZ's safety assessment has identified no health and safety concerns for 2'-FL (2'fucosyllactose), LNT (lacto-N-tetraose), 6'SL (6-Siallylactose sodium salt) and 3'SL (3-Siallylactose sodium salt) at the proposed levels. NSW also

notes the proposed limits for these substances are also consistent with the maximum limits approved in the EU.

However, it is unclear to NSW why FSANZ has proposed a higher level of a mixture of 2'-FL/DFL (Difucosyllactose) compared to EFSA proposed levels. EFSA has permitted the combination of these substances at 1.6g/L in infant formula[1] however FSANZ is proposing to permit to a maximum of 2.4g/L. NSW requests further information from FSANZ in the approval report for A1265 for the higher maximum level in the Code than EFSA given it is understood that FSANZ and EFSA assessed similar products from the same applicant.

Five-year review of evidence of beneficial effect

NSW appreciates FSANZ's commitment to the five-year review of the evidence of a substantiated beneficial role of 2′-FL and LNnT in the normal growth and development of infants. However, since gazettal of A1155[2] more combinations of HiMOs with other ingredients have been approved to be added to IFP without clear substantiation of beneficial roles (e.g. Application 1251). If approved, the four HiMOs being considered in A1265 (2'-FL/DFL, LNT, 6'-SL, 3'-SL and combinations) will be another situation where approval is requested on a contestable evidence base for benefit.

Given all HiMOs in IFP are expected to function in cumulative and complementary ways, NSW considers it reasonable and appropriate to include all subsequently permitted HiMOs (individually and in combination) in scope of the five-year review of HiMO's (including 2′-FL and LNnT). This would add significant weight and clarity to the functional and beneficial purpose of these HiMOs when added to IFP. NSW requests clarity from FSANZ as to the process, scope and outcomes of the 5-year review in the approval report for A1265.

NSW notes the four HiMOs being considered in A1265 (2'-FL/DFL, LNT, 6'-SL, 3'-SL and combinations) have only recently become available internationally (i.e. since 2020). It may be prudent for FSANZ to publish pro-active advice to future applicants that permissions sought for new HiMOs could attract the 5-year review requirement.

Use of GOS and/or ITF in combination with HiMOs in IFP

NSW notes in A1155 FSANZ prohibited the combination of 2'-FL (by itself or in combination with LNnT – Lacto-N-neotetraose) with GOS (galactoligosaccharides) and/or ITF (inulin-type fructans) due to a lack of evidence on infant tolerance to this combination.

In considering the removal of the prohibition of the use of GOS and/or ITF with 2'-FL in Application A1251, FSANZ conducted a risk assessment. NSW notes that this risk assessment only considered 2'-FL and no other HiMOs.

ITFs are not present in human milk and GOS is found only in trace amounts. The combination of GOS and/or ITF and HiMOs proposed in A1265 do not occur naturally in breastmilk. Given that synergistical effects played by a combination of these substances is not well established, NSW supports FSANZ applying a cautious and

[1] EUR-Lex - 32019R1979 - EN - EUR-Lex (europa.eu)
[2] A1155 – 2'-FL and LNnT in infant formula and other products (foodstandards.gov.au)

evidence-led approach in considering permission to add new HiMOs to IFP. This is consistent with the Specific Policy Principle j) of MPGI.

Therefore NSW does not support FSANZ's approach in A1265 to propose without specific risk assessment evidence to:

- permit the use of GOS and/or ITF in combination with 2'-FL/DFL, LNT, 6'-SL and/or 3'-SL and
- removing the prohibition of the use of LNnT combined with GOS and/or ITF.

Labelling

Names of substances in the NIS

NSW proposes prescribing names for all substances permitted in the NIS to improve product comparability and informed purchase decisions. Standardising the names of HiMOs that appear in the NIS is particularly important to avoid doubt that the listing HiMOs in the NIS may constitute prohibited representations, or nutrition content or health claims.

Prohibited representations and claims

NSW supports the current labelling prohibitions against:

- *the word 'humanised' or 'maternalised' or any word or words having the same or similar effect;*
- *the words 'human milk oligosaccharide', 'human milk identical oligosaccharide' or any word or words having the same or similar effect;*
- *the abbreviations 'HMO' or HiMO' or any abbreviation having the same or similar effect;*
- *information relating to the nutritional content of human milk*

These prohibitions ensure that IFPs containing HiMOs are not advertised with implication of equivalency to human breastmilk. This is consistent with MPGI as well as national and international policy initiatives to promote breastfeeding such as the Australian National Breastfeeding Strategy[3].

NSW also supports prohibition of nutrition content claims and health claims on IFP. For example the word 'prebiotic', 'prebiotics' or 'postbiotics' in relation to IFP containing HiMOs would constitute a nutrition or health claim.

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.

Dated as 6 July 2023

[3] https://www.health.gov.au/resources/publications/australian-national-breastfeeding-strategy-2019-and-beyond