

19 August 2022

FSANZ

Email standards.management@foodstandards.gov.au.

Dear Standards Management

Application A1251- 2'-FL combined with galacto-oligosaccharides and/or inulin-type fructans in infant formula products

The Australian Food and Grocery Council (AFGC) is the leading national organisation representing Australia's food, drink, and grocery manufacturing industry. The membership of AFGC comprises more than 180 companies, subsidiaries, and associates. With an annual turnover in the 2019-20 financial year of \$132 billion, Australia's food and grocery manufacturing sector employs more than 270,800 Australians, representing 32 per cent of total manufacturing employment in Australia. Food, beverage, and grocery manufacturing together forms Australia's largest manufacturing sector, representing 32 per cent of total manufacturing turnover in Australia. This sector makes a substantial contribution to the Australian economy and is vital to the nation's future prosperity.

The AFGC appreciates the opportunity to provide comments on [Application A1251 - 2'-FL combined with galacto-oligosaccharides and/or inulin-type fructans in infant formula products](#) to permit 2'-fucosyllactose (2'-FL) in combination with galacto-oligosaccharides (GOS) and/or inulin-type fructans (ITF) in infant formula products (IFP).

The AFGC understands that the Australia New Zealand Food Standards Code (the Code) currently permits 2'-FL, GOS and ITF to be added separately to IFP but prohibits the addition of 2'-FL to IFP in combination with GOS and/or ITF.

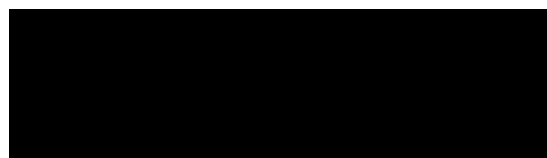
The consultation documents have been reviewed and the comments below relate to these specific documents.

In response to the Consultation, the AFGC has had the opportunity to review the submission to this consultation by the Infant Nutrition Council of Australia and New Zealand (INC). The AFGC strongly supports the INC positions as stated in its submission and shares the concerns that the INC has described in detail.

GENERAL COMMENTS

The AFGC supports government policies for the protection and promotion of breastfeeding and recognises the role of scientifically developed infant formula product as the only suitable and safe alternative when breast milk is unavailable for an infant.

When breastfeeding is not possible, however, a safe and nutritious substitute for human milk is needed. Given that current permissions for the addition exist in the Code from previous applications for 2'-FL (Applications A1155 and A1190) and GOS and/or ITF (Proposal P306 and Application A1055), the AFGC supports this application proceeding. The AFGC notes that other countries (the US and Brazil) and the EU permit the combination of 2'-FL with GOS and/or ITF .



The AFGC supports FSANZ's harmonisation approach with international foods standards:

"FSANZ considers the removal of the prohibition would harmonise the Code with international regulations and result in consistency between domestic and international food standards and support an efficient and internationally competitive food industry." (page 8 CFS)

SPECIFIC COMMENTS

The AFGC wishes to make a few specific comments in relation to this application.

Exclusivity (Section 2.2.4)

The AFGC

- supports in principle the concept of exclusivity as it recognises the investment made in developing the food or ingredient and the need to achieve return on this investment, thereby **supporting innovation**.
- however, has general **concerns regarding FSANZ's approach** towards **exclusivity** and its implications on the food industry.

Implications on the food industry

The comments made below do not relate to the exclusivity of this particular application. Having said that, the AFGC intends to seek **clarity and consideration** on the **current and future scope of exclusivity** applications.

The AFGC notes and strongly agrees with the INC's position that

- exclusivity of use for novel foods has been in place since 2007 and was, at that time, subject to a specific proposal and consultation in *Proposal P305: Permission for exclusivity of use of novel foods*. As a result of this proposal, FSANZ considered the capacity for including a specific provision for exclusivity of use for novel foods in Standard 1.5.1 – Novel Foods of the Code. A note is now included in Standard 1.5.1 Novel Foods that states:

"Novel foods are added to the table to section S25—2 by variations to the Code. When added for the first time, the conditions may include some that apply to the novel food only during the first 15 months after gazettal of the variation."

- such an inclusion provides **clarity for users** of the Code about the implementation of the **capacity for exclusive permissions** for novel food products and prospective 15-month time limits on exclusive permissions.
- the **exclusivity of use for nutritive substances** was only **introduced in 2020** with the finalisation of Application [A1155 – 2'-FL and LNT in infant formula and other products](#). As this application concerned the infant formula industry, the **potential implications** for the broader food industry were not considered and remain uncertain. The AFGC will seek clarification with regard to this issue.
- the scope of "Exclusive Capturable Commercial Benefit" being expanded by applications on a case-by-case basis rather than in a more transparent and regularised way so that the entire food industry is aware of, and has opportunity to comment on, various implementation pathways of the concept of exclusivity. For example, future combinations of foods (not necessarily novel foods or nutritive substances) could be subject to exclusivity through an application.

The AFGC therefore urges FSANZ to introduce and implement a clear and consistent approach towards exclusivity, thus levelling the playing field for the broader food industry.

Risk Management and Labelling (Section 2.2.7)

The AFGC

- continues to have concerns regarding the **prohibition** on the use of the term, 'human identical milk oligosaccharides' or **HiMO**.
- recommends an approach that permits flexibility through the use of common terms, acronyms/abbreviations and additional information.
- recommends an approach that permits the use of common terms, acronyms/abbreviations, and additional information. This current restriction does not permit manufacturers to **provide information to caregivers** in accordance with the subsection 18(1) of the **FSANZ Act** to allow for **provision of adequate information** relating to foods to enable consumers to make **informed choices** and the **prevention of misleading or deceptive conduct**.
- is of the view that only the very informed caregiver can make an informed decision based on the prescribed names and format. The typical **caregiver** is **not familiar** with **scientific names**, and therefore providing additional information can **provide more context**. Thus, the use of consumer-friendly language and **commonly understood terminology** (permitted in other food categories) seems logical.

In summary, the AFGC supports this application proceeding but shares the concerns that the INC has described in their submission and highlights the need for **clarity and consideration** on the **current and future scope of exclusivity** applications.

Yours sincerely

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