

7 July 2023

FSANZ

Email standards.management@foodstandards.gov.au.

Dear Standards Management

Application A1265 – 2'-FL DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt for use as nutritive substances in infant formula products

The Australian Food and Grocery Council (AFGC) is the leading national organisation representing Australia's food, beverage, and grocery manufacturing sector, which together forms Australia's largest manufacturing sector, representing over 32 per cent of total manufacturing turnover in Australia. The industry makes a large contribution to rural and regional Australia economies, with almost 40 per cent of its 272,000 employees being in rural and regional Australia.

The AFGC appreciates the opportunity to provide comments on [Application A1265 – 2'-FL DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt for use as nutritive substances in infant formula products](#).

As the AFGC understands, application A1265 by Glycom A/S seeks permission to amend the Australia New Zealand Food Standards Code (Code) to permit the voluntary addition of four human-identical milk oligosaccharide (HiMO) products for use as nutritive substances in infant formula products (IFP).

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's 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. The AFGC notes that other countries (the US and UK, Singapore, and Brazil) and the EU permit the addition of 2'-FL/DFL, LNT, 6'-SL and 3'-SL.

The AFGC **supports** harmonisation with international foods standards to enable an efficient and internationally competitive food industry.



SPECIFIC COMMENTS

Risk assessment (Section 2.1)

Application A1265 seeks permission for voluntary addition of four HiMO products for use as nutritive substances in infant formula products (IFP) in proposed maximum permitted amounts as follows:

- A mixture of 2'-fucosyllactose (2'-FL) and difucosyllactose (DFL) (2'-FL/DFL) (96 mg/100 kJ);
- lacto-N-tetraose (LNT) (32 mg/100 kJ);
- 6'-sialyllactose sodium salt (6'-SL) (16 mg/100 kJ); and
- 3'-sialyllactose sodium salt (3'-SL) (8 mg/100 kJ).

The AFGC notes that the safety, technical, nutrition and health effects assessment (SD1) concluded that there are no public health and safety concerns associated with the addition of the applicant's 2'-FL/DFL, LNT, 6'-SL and 3'-SL in IFP at the levels proposed, which are comparable to that of human milk. This includes estimated dietary intakes and naturally occurring levels in human milk, potential beneficial health effects and alignment with international regulations.

The AFGC **supports** fully FSANZ's assessments and resulting decision to permit the voluntary addition of the requested substances alone or in combination at the levels requested to infant formula products..

Use as a nutritive substance in IFP (Section 2.2.2)

The AFGC **supports** FSANZ's assessment that the use of 2'-FL/DFL, LNT, 6'-SL and 3'-SL, individually or in combination in IFP would have a beneficial outcome for infants and align with the equivalent role of these substances in human milk.

The AFGC is very **supportive** of the ongoing endeavours of FSANZ in reviewing new evidence on the beneficial role of a range of HiMOs in the normal growth and development of infants.

Risk management and labelling (Section 2.2.8)

The AFGC **supports** FSANZ's decision that no additional labelling requirement are needed.

The AFGC advocates for amending the **prohibition** on the use of the term, 'human identical milk oligosaccharides' or HiMO and permitting 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 FSANZ Code and the ACCC Australian Consumer Laws regarding truthfulness of the description of ingredients and the provision of adequate information relating to foods to enable consumers to make informed choices and the prevention of misleading or deceptive conduct.

Exclusivity (Section 2.2.9)

The AFGC notes that the applicant has requested an exclusive use permission for a period of 15 months for their combination of the above four HiMO branded substances.

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. The AFGC has previously raised and continues to seek clarity regarding the application of exclusivity and its implications on the food industry to ensure a level playing field.

In summary, the AFGC **supports** this application proceeding.

Yours faithfully

