



AUSTRALIAN  
**FOOD &  
GROCERY**  
COUNCIL



AFGC SUBMISSION

**Application A1277**  
**2'-FL from new GM *Escherichia coli* K-12**  
**(gene donor: *Helicobacter enhydrae*) in**  
**infant formula products**

21 November 2023

## PREFACE

The Australian Food and Grocery Council (AFGC) is the leading national organisation representing Australia's food, beverage and grocery manufacturing sector.

With an annual turnover in the 2020-21 financial year of \$133 billion, Australia's food and grocery manufacturing sector makes a substantial contribution to the Australian economy and is vital to the nation's future prosperity.

The diverse and sustainable industry is made up of over 16,000 businesses ranging from some of the largest globally significant multinational companies to small and medium enterprises. Each of these businesses contributed to an industry-wide \$3.2 billion capital investment in 2020-21.

Food, beverage, and grocery manufacturing 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.

It is essential to the economic and social development of Australia, and particularly rural and regional Australia, that the magnitude, significance, and contribution of this industry is recognised and factored into the Government's economic, industrial and trade policies.

Throughout the COVID19 pandemic, the food and grocery manufacturing sector proved its essential contribution to Australian life. Over this time, while our supply chains were tested, they remain resilient but fragile.

The industry has a clear view, outlined in *Sustaining Australia: Food and Grocery Manufacturing 2030*, of its role in the post-COVID19 recovery through an expansion of domestic manufacturing, jobs growth, higher exports and enhancing the sovereign capability of the entire sector.

*This submission has been prepared by the AFGC and reflects the collective views of the membership.*

## OVERVIEW

The Australian Food and Grocery Council (AFGC) welcomes this opportunity to comment on Food Standards Australia New Zealand's (FSANZ) *Call for submissions – A1277 – 2'-FL from GM Escherichia coli K-12 (gene donor: Helicobacter enhydrae) in infant formula products*.

The AFGC understands that FSANZ has assessed an application made by Inbiose N.V. to amend the Australia New Zealand Food Standards Code (**the Code**) to permit a new genetically modified strain of *Escherichia coli* K-12 for the production of 2'-fucosyllactose (**2'-FL**) as a nutritive substance in Infant Formula Products (**IFP**).

The AFGC has reviewed FSANZ's assessment with three options and supports **permitting the use of the applicant's 2'-FL in IFP**.

## INTRODUCTION

Following an application made by Inbiose N.V. to amend the Code, FSANZ has prepared a draft variation to permit the voluntary addition of 2'-FL derived from *E. coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *H. enhydrae* as a nutritive substance and food produced using gene technology to IFP. The AFGC membership includes food manufacturers, importers and marketers that will be directly impacted by FSANZ's proposal to change the Code.

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

- Call for submissions
- Supporting document 1 – Safety assessment

In response to the Consultation, this submission will expand upon the AFGC's views in the Comments section.

## GENERAL COMMENTS

The AFGC welcomes the opportunity to comment on the *Call for submissions – A1277 – 2'-FL from GM Escherichia coli K-12 (gene donor: Helicobacter enhydrae) in infant formula products*.

2'-FL is permitted for use in over 37 countries. Harmonisation with international standards that are based on relevant science and scientific expert opinion is essential to allow the manufacture and availability of these types of products for consumers in Australia and New Zealand and for export.

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.

The AFGC supports FSANZ's position to approve the use of new substances that have been shown to be safe and suitable for addition to IFP in line with Ministerial Policy Guidelines.

## SUPPORT OF INFANT NUTRITION COUNCIL POSITION

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 and concerns as stated in detail in their submission.

## SUPPORT OF 2'-FL USAGE

The AFGC supports permitting the use of the applicant's 2'-FL in IFP.

## SPECIFIC COMMENTS

The AFGC wishes to make the following specific comments in relation to this application.

### Risk assessment

The AFGC notes that the Code already permits 2'-FL from different source organisms for addition to IFP. The AFGC also notes FSANZ's assessment that:

*“Based on previous FSANZ assessments of 2'-FL and the toxicological assessment in the present application, it was concluded that there are no public health and safety concerns associated with 2'-FL produced from the new GM source organism that is the subject of this application.”*

The AFGC further 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 (from the new source organism) to infant formula products at the proposed use levels.

FSANZ's **nutritional assessment** concluded that 2'-FL Inbiose added to infant formula products was unlikely to pose a risk to the normal growth of infants. Since Inbiose did not request any change to the level of 2'-FL that might be added to infant formula products, the benefits to infants remains the same as in previous assessments:

- (1) an anti-pathogenic effect;
- (2) immunomodulation; and
- (3) development of the gut microbiome through supporting growth of *Bifidobacteria* spp.

### Risk management and labelling

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

The AFGC supports FSANZ's decision to apply generic ingredient labelling requirements, rather than prescribed ingredient names previously proposed, consistent with the general approach in the Code.

[Standard 1.2.4—4](#) requires ingredients to be identified using a name by which they are commonly known, or a name that describes its true nature, or a generic ingredient name if one is specified in the Code [Schedule 10 – Generic names of ingredients and conditions for their use](#).

Thus, the AFGC continues to advocate 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 to support informed choices.

This current restriction does not permit manufacturers to provide information to caregivers in accordance with the Code (similar to other foods) and Australian and New Zealand Consumer Laws regarding truthfulness of the description of ingredients, the provision of adequate information relating to foods to enable consumers to make informed choices and the prevention of misleading or deceptive conduct.

### **Exclusivity**

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, it has general concerns regarding FSANZ’s approach towards exclusivity and its implications on the food industry. 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.

### **The five year review for 2’-FL and LNnT in infant formula products**

The AFGC notes that FSANZ is committed to reviewing any new evidence on the beneficial role of HiMOs in the normal growth and development of infants.

The AFGC is supportive of seminal references provided by the INC in their submission which may be helpful as evidence of a substantiated beneficial role of 2’-FL and Lacto-N-neotetraose (LNnT) in the normal growth and development of infants.

## **CONCLUSION**

The AFGC supports FSANZ’s decision to permit the voluntary addition of ‘2’ Fucosyllactose’ (2’-FL) to IFP at the levels proposed in A1277.

However, it is opposed to prohibition of the use of terms such as ‘human milk identical oligosaccharide’ or ‘HiMO’ (or similar words or abbreviations) on the labels of IFP.

In summary, the AFGC supports this application proceeding but shares the concerns that the INC raised in their submission.

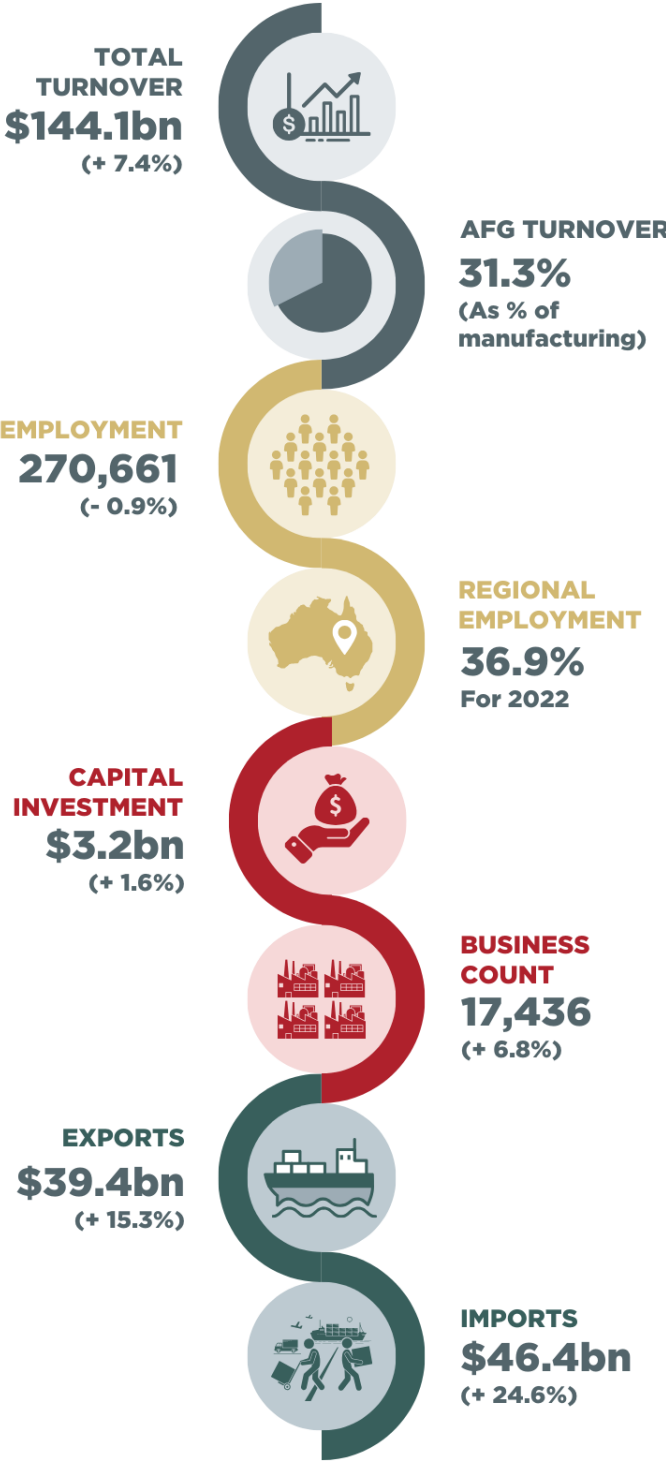
## **RECOMMENDATION:**

**The AFGC supports permitting the use of the applicant’s 2’-FL in IFP.**

- **For further information about the contents of this submission contact:**
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# State of Industry 2021-22

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The figures on this page exclude the fresh food sector and are based on 2021-22 ABS data.  
 1: This is total number of employees, head count basis and does not include seasonal employees.  
 2: Gross fixed capital formation for food, beverage and tobacco manufacturing subsector is taken as indicator of capital investment.