AUSTRALIAN FOOD & GROCERY COUNCIL

AFGC SUBMISSION

CALL FOR SUBMISSIONS – APPLICATION A1233

2′-FL FROM NEW GM SOURCE FOR INFANT FORMULA

31 January 2022

Sustaining Australia

PREFACE

The Australian Food and Grocery Council (AFGC) is the leading national organisation representing Australia's food, beverage and grocery manufacturing sector. The membership of AFGC comprises more than 180 companies, subsidiaries, and associates.

Food, beverage, and grocery manufacturing together forms Australia's largest manufacturing sector, representing 32 per cent of total manufacturing turnover in Australia. This $132 billion sector significantly contributes to the Australian economy and directly employs 270,800 Australians, with many more employed across an expansive supply chain.

The diverse and sustainable industry is made up of 16,000 businesses and accounts for $81 billion of the nation's international trade. These businesses range from some of the largest globally significant multinational companies to small and medium enterprises. Industry made $2.8 billion in capital investment in 2018-19.

Many food manufacturing plants are located outside the metropolitan regions. The industry makes a large contribution to rural and regional Australia economies, with almost 40 per cent of the total persons employed 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.

In Australia, the food and beverage (grocery was not included in the Government's strategy but is recognised as a vital industry) manufacturing sector has been confirmed as an essential service and a National Strategic Priority.

The Australian Government through its recently announced Manufacturing Strategy has challenged the sector to develop an industry roadmap describing how it will contribute to the post-COVID-19 recovery through expanding manufacturing, growing jobs, boosting exports, and enhancing sovereign capability across the sector.

Food and beverage manufacturing plays an integral role in Australia's economic and social fabric. It is the lifeblood of many regional and rural communities. As such it is well placed to do the heavy lifting in the Manufacturing Strategy through its size, its know-how in adding value to the commodities of the agricultural sector, and to leverage the reputation for safety and quality among consumers in overseas markets.

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 – A1233 – 2'-FL from new GM source for infant formula.*

The AFGC understands that FSANZ has assessed an application made by Friesland Campina Ingredients to amend the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of 2'-O-fucosyllactose (2'-FL)[3] derived from a genetically modified *Escherichia coli (E. coli*) strain as a nutritive substance in Infant Formula Products (IFP) i.e., infant formula, follow-on formula and infant formula products for special dietary use.

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 Friesland Campina Ingredients to amend the Code, FSANZ has prepared a draft variation to permit the voluntary addition of 2'-O-fucosyllactose (2'-FL) produced via a new GM *E. coli* strain 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.

COMMENTS

The AFGC welcomes the opportunity to comment on the *Call for submissions – A1233 – 2'-FL from new GM source for infant formula.*

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 also supports FSANZ's decision to approve the voluntary addition of new substances that have been shown to be safe and suitable for addition to IFP.

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 as stated in its submission and shares the concerns that the INC has described in detail.

SUPPORT OF 2′-FL USAGE

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

It notes an exclusive permission period of 15 months would apply, linked to the applicant's brand name 'Aequival® 2'FL', commencing on the date of gazettal of the variation. The AFGC notes that

"FSANZ has previously determined that there are no safety concerns associated with the addition of 2'-FL to IFP at concentrations up to 2.4 g/L, which is within the range of naturally occurring levels in human milk from the majority of women (0.6 – 7.8 g/L). Newly available information relating to previously assessed studies of 2'-FL produced by the applicant and another manufacturer did not indicate a reason to change this conclusion."

The AFGC further notes that previous food technology and safety assessments conducted by FSANZ found no safety concerns associated with the addition of 2′-FL to IFP. New information provided did not change this conclusion.

The AFGC notes FSANZ's

- ***biochemical assessment*** determined the 2′-FL sourced from the microbial fermentation was shown to be chemically and structurally identical to the naturally occurring 2′-FL in human milk.
- ***microbiological assessment*** concluded that the host strain had a recognised safe history of use.
- ***biotechnology assessment*** found the production strains were safe.
- ***nutritional assessment*** concluded the addition of 2′-FL to infant formula was not expected to affect the growth profiles of infants, and there was no evidence to indicate concern at concentrations that were typically observed in human milk.
- ***benefit assessment*** that there was evidence to support a role for 2′-FL in promoting a bifidogenic effect in infants and limiting infection by pathogenic strains of *Campylobacter jejuni* in infants and young children. Although the evidence base for these effects in young children was found to be limited, there was evidence for an effect in young children.

Additionally, FSANZ has previously assessed 2′-FL (separately and in combination with LNnT per *A1155 – 2'-FL and LNnT in infant formula and other products* as well as *A1190 - 2'-FL in infant formula and other products*) and confirmed its safety.

It must be duly noted that while assessing *A1155 – 2'-FL and LNnT in infant formula and other products*, FSANZ undertook an exhaustive review of the safety, technical and health effects assessment only to re-confirm/re-affirm the conclusions about safety and benefit. FSANZ spent an immense amount of time to conduct this review, in addition to the number of financial and workforce resources that were utilised.

Protection of public health and safety is the underlying objective that guides all the decisions made by FSANZ. Having considered all aspects of the assessment against the statutory requirements, including relevant Ministerial Policy Guidelines, FSANZ has repeatedly provided substantial evidence to permit the voluntary addition of 2′-FL to IFP, with that evidence accepted by the Food Ministers' Meeting. Consequently, this demonstrates that FSANZ's indisputable technical evaluation expertise and their recommendation with regard to this application should be supported.

Thus, the AFGC supports fully FSANZ's safety assessment and resulting decision to permit the voluntary addition of 2'-FL at the levels proposed of up to a maximum of 2.4 g/L to IFP.

SUPPORT TO USE TERMS 'HUMAN MILK IDENTICAL OLIGOSACCHARIDE', 'HMO' OR 'HIMO'

The AFGC, as raised previously in submissions to A1155 and A1190, has concerns regarding the decision to prohibit the use of the terms such as 'human milk identical oligosaccharide' or 'HiMO' (or similar words or abbreviations) on IFP (and formulated supplementary foods for young children (FSFYC)) with permissions otherwise available in the Code *Standard 1.2.7. Nutrition, Health and Related Claims.*

FSANZ is proposing a regulatory measure that allows the addition of a nutrient, which has demonstrated health benefits into a food, but is prohibiting food companies from simply informing consumers of its presence.

The proposed prohibition of terms such as 'human milk identical oligosaccharide' or 'HiMO' (or similar words or abbreviations) on the labels of IFP (and FSFYC) is counteractive to informing care givers and health professionals for the following reasons:

- It conflicts with the decision to apply generic ingredient labelling requirements (the Code *Standard 1.2.4—4 Information requirements – statement of ingredients*)
- These terms have been used in scientific literature for over 20 years
- The terms are more easily understood by consumers
- The use of these terms on the labelling of IFP is limited to the ingredient list and nutrition information panel only, which are not for promotional purposes and do not claim the product is "humanised" or equivalent to human breast milk
- The process resulting in the regulatory prohibition is based on limited consumer sample populations (in limited research) which does not comply with good regulatory practice, and
- It has the potential to constrain innovation and create trade barriers. A requirement for unique ANZ labelling restricts imports (and hence availability of products to consumers) and increases export costs.

Additionally, FSANZ, in assessing A1155 and A1190, has repeatedly failed to provide any substantial evidence to support its decision to prohibit the use of words 'human milk identical oligosaccharide' or 'human milk oligosaccharide', and abbreviations 'HMO', 'HiMO' or any word or words or abbreviations having the same or similar effect. The AFGC wishes to seek conclusive evidence regarding the link between the use of these words or abbreviations and consumer views on breastfeeding. The AFGC contends that the opinions of the anti-breast feeding factions are placing pressure upon FSANZ, and health ministers to prohibit the use of these oligosaccharides and their generic descriptors with no sound evidence.

The AFGC would welcome and support 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*.

RECOMMENDATION FOR SCHEDULE 3 AND SCHEDULE 26 AMENDMENTS

The AFGC notes draft variations proposed in the drafting of the Code *Schedule 3* - *Identity and purity*, and makes recommendations to improve consistency:

- Microbiological criteria are included in some specifications and not others.

  The AFGC recommends that microbiological criteria and limits for heavy metals are not included within specifications unless there is a significant reason for inclusion for specific substances. Further, the AFGC preference is that the onus is upon manufacturers to assess microbiological suitability for their particular application.

- Multiple entries for 2'-FL.

  The AFGC recommends that there be one entry for 2'-FL from microbial sources with one definition. Please note, this is the case in the EU novel food list in which 2'-FL from microbial sources has one definition, followed by information relating to the two permitted sources (this follows immediately after definition for 2'Fucosyllactose (synthetic).

In addition, the AFGC supports the FSANZ approach to the amendment to Schedule 26 to permit the genetically modified source organism E. coli K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* but without specifying the strain E997 to provide flexibility in strain improvement and therefore avoid the need for new applications to be lodged for new strains.

SUPPORT OF HARMONISATION AND INTERNATIONAL CONSISTENCY

The approval of this application provides harmonisation with international standards, and allows domestic manufacturers access to the latest technologies, and encourages the creation of innovative products with approval safeguards that will drive domestic and export markets.

The 2'-FL compound when added to IFP will result in an enhanced, safe product better able to support infant nutrition and health, and better able to compete in international markets, and international manufacturers competing directly with Australian infant formula companies.

SUPPORT OF ADDING 2'-FL TO FSFYC

The AFGC, as previously raised in submission to A1155 and A1190, has concerns regarding the prohibition of adding 2'-FL to FSFYC. FSFYC are intended to supplement young children's diets when energy and nutrient intakes may be inadequate. The addition of 2'-FL as a voluntary ingredient does not change this intended purpose, in keeping with *Food Regulation - Policy guideline on intent of Part 2.9 of*

the food standards code - special purpose foods, since the overall food vehicle meets the intended purpose. These ingredients are intended to facilitate product differentiation and consumer choice and offer an alternative to the already approved inulin-type fructans and galacto-oligosaccharides.

CONCLUSION

In summary, the AFGC supports FSANZ's decision to permit the voluntary addition of '2' Fucosyllactose' (2'-FL) to IFP at the levels proposed in A1233.

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.

The AFGC also recommends review of the draft variation of Schedule 3 such that microbiological criteria and limits for heavy metals are not included within specifications for specific substances, and there be one entry for 2'-FL from microbial sources with one definition.

It also requests FSANZ consider other drafting options for the associated amendments of the Code given the concerns with the proposed Code amendment outlined in the comments above.

Finally, the AFGC recommends that addition of 2'-FL to FSFYC be permitted.

The AFGC would welcome consideration of alternative options by FSANZ and is ready to engage with FSANZ further if indicated.

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:**

[redacted]