



AUSTRALIAN  
**FOOD &  
GROCERY**  
COUNCIL

## **AFGC SUBMISSION**

**CALL FOR SUBMISSIONS – APPLICATION A1190**

**2'-FL IN INFANT FORMULA AND OTHER PRODUCTS 1190**

19 August 2021

*Sustaining Australia*

## PREFACE

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

There are over 180 member companies, subsidiaries and associates who together comprise 80 per cent of the gross dollar value of the processed food, beverage and grocery products industries.

With an annual turnover in the 2018-19 financial year of \$127.1 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 15,861 businesses and accounts for over \$75.1 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.

Food, beverage and grocery manufacturing together forms Australia's largest manufacturing sector, representing 31.4 per cent of total manufacturing turnover in Australia.

The food and grocery manufacturing sector employs more than 274,800 Australians, representing 32.2 per cent of total manufacturing employment in Australia.

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 – A1190 – 2'-FL in infant formula and other products*.

The AFGC understands that FSANZ has assessed an application made by Chr. Hansen A/S to amend the Australia New Zealand Food Standards Code (the Code) to permit the voluntary addition of '2'-fucosyllactose' (2'-FL) produced via a new genetically modified (GM) *Escherichia coli* (*E. coli*) strain in infant formula products (IFP) and formulated supplementary foods for young children (FSFYC).

The AFGC has reviewed FSANZ's assessment with three options and supports **Option 3 permitting the use of the applicant's 2'-FL in both IFP and FSFYC**.

## INTRODUCTION

Following an application made by Chr. Hansen A/S 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 and FSFYC. The AFGC membership includes food manufacturers, importers and marketers that will be directed 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 – A1190 – 2'-FL in infant formula and other products*.

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 and FSFYC.

## 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 OPTION 3

The AFGC supports **Option 3 permitting the use of the applicant's 2'-FL in both IFP and FSFYC**.

It notes an exclusive permission period of 15 months would apply, linked to the applicant's brand name 'CHR. HANSEN™ 2'-FL', commencing on the date of gazettal of the variation.

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](#)) and confirmed its safety.

Thus, the AFGC

- **fully supports** 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 OF ADDING 2'-FL TO FSFYC

The AFGC **does not support** the FSANZ decision to exclude permission of 2'-FL to FSFYC.

The AFGC, as previously raised in submission to A1155, 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 [Policy Guideline on the intent of Part 2.9 – 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.

There are many formulated supplementary foods on the market that contain ingredients for differentiation rather than to address deficiencies in the diet.

FSFYC can provide ingredients that may contribute a benefit to young children as part of their diet. As stated above, FSANZ found evidence of a beneficial effect in promoting a bifidogenic effect in infants and limiting infection by pathogenic strains of *Campylobacter jejuni* in infants and young children. Further, increases in beneficial *Bifidobacterium* spp have been shown in children and adults with oral supplementation of 2'FL in the diet. Oligosaccharides are permitted for addition to FSFYC in the form of inulin-type fructans and galacto-oligosaccharides and it is inconsistent and restrictive not to permit other sources that have been shown to have prebiotic effects.

The AFGC further notes indication of safety and efficacy in the Therapeutic Goods Administration permission of 2'FL in supplements for young children from age one through to senior adults (ARTG IDs: [362438](#), [320165](#), [320164](#), [320162](#)).

## **SUPPORT TO USE TERMS 'HUMAN MILK IDENTICAL OLIGOSACCHARIDE', 'HMO' OR 'HiMO'**

The AFGC, previously raised in submission to A1155, 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 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 is in conflict 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.

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 AMENDMENT

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)).

## 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, as outlined, when added to IFP and FSFYC 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.

Toddler milk products containing these substances are now allowed in many countries. The inability to introduce novel substances such as 2'-FL into the FSFYC category is likely to place Australian industry at a competitive disadvantage.

## CONCLUSION

In summary, the AFGC is supportive of FSANZ's decision to permit the voluntary addition of '2' Fucosyllactose' (2'-FL) to IFP at the levels proposed in A1190.

However, it is opposed to

- excluding permission of 2'-FL to FSFYC
- prohibition of the use of terms such as 'human milk identical oligosaccharide' or 'HiMO' (or similar words or abbreviations) on the labels of IFP and FSFYC

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.

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

## RECOMMENDATION:

The AFGC supports Option 3 permitting the use of the applicant's 2'-FL in both IFP and FSFYC.

- For further information about the contents of this submission contact:

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