AUSTRALIAN FOOD & GROCERY COUNCIL

AFGC SUBMISSION

RESPONSE TO:

CALL FOR SUBMISSIONS – PROPOSAL P1028 INFANT FORMULA

17 June 2022

Sustaining Australia

PREFACE

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.

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.

OVERVIEW

The AFGC appreciates the opportunity to respond to P1028 - Infant Formula to revise and clarify standards relating to **infant formula products** (IFPs) comprising category definitions, composition, labelling and representation of products.

The AFGC supports breastfeeding due to the numerous maternal and infant benefits derived from breast milk. However, for infants that are unable to receive breast milk, then infant formula that is based on the latest evidence-based science is the best alternative.

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

GENERAL COMMENTS

The AFGC acknowledges the immense amount of work **Food Standards Australia New Zealand** (FSANZ) has undertaken on this proposal. Furthermore, the AFGC congratulates FSANZ on the progress which has been made towards revising the parts of the **Food Standards Code** (the Code) covering infant formula products in ways which align with views of all stakeholders.

Notwithstanding this, the AFGC considers that in attempting to meet the concerns of all stakeholders FSANZ has deviated from the fundamental principles of best practice regulation including:

- not clearly defining the problems which are to be solved by some of the changes proposed
- not developing the scientific or fact evidence-base to support specific regulatory interventions
- not adhering to the principle of a proportionate regulatory response informed by appropriate risk assessments, and
- not considering the potential unintended consequences of the interventions.

The AFGC supports FSANZ's stated objective of aligning the Standards with Codex. Harmonisation with international standards reduces regulatory complexity for industry and enables international trade in food products which brings greater choice to consumers, and in some cases of IFP brings specialist products into the market which would not otherwise be available.

Those specialist products, and indeed all IFP currently on the Australian market are testimony to great lengths the infant formula manufacturers go to ensuring their products are of the highest possible quality. The products are not only compliant with current regulatory requirements but are based on the best available science (largely conducted by industry itself) as they must be as the sole source of nutrition for infants.

The AFGC notes that FSANZ has not identified, or provided evidence, that current IFP are not as good as they could be. The FSANZ documentation has not listed any public health and safety issues with current product composition which is undermining the health of infants, or product labelling which is clearly misleading to consumers who are caregivers to those infants.

Thus, the extensive overhaul of the infant formula standard as FSANZ proposes can be summarised as:

- harmonising with Codex requirements,
- clarifying parts of the standard where there is ambiguity, and
- responding to perceived (rather than demonstrated) concerns that some products should be subject to greater restrictions.

In all cases changes are proposed which will result in additional costs on industry and these will be substantial because, as far as the AFGC is aware, changes will need to be made to every single product currently on the market covered by the infant formula standards.

FSANZ should be aware that the net result will be greater regulation on the food industry, with a potential chilling effect on innovation which would lead to new products better able to protect and promote the health of infants.

The AFGC supports the provision of the best possible nutrition for non-breastfed infants. To achieve this, policy and regulatory measures need to balance restrictions on use and formulation to protect public health, while at the same time permit flexibility and incentive for innovation by the food industry. In this way, improvement of infant formulas shall continue in line with scientific developments.

Overall, and as stated above, the AFGC supports FSANZ's efforts to update the infant formula standards to better meet the needs of stakeholders, and particularly the infant formula manufacturing industry and the caregivers to those infants it serves.

Clearly, FSANZ is keen to finalise their recommendations for amendments to the Code recognising that P1028 - Infant Formula changes have been in gestation for 10 years. The corollary is that none of the changes FSANZ is proposing is urgent. Given this, the AFGC would advocate to FSANZ to hasten slowly, and keep faith with their role as an independent Statutory Authority by only progressing in directions supported by the principles of best practice regulation.

SPECIFIC COMMENTS

The AFGC wishes to make key specific comments in relation to the following:

REGULATORY FRAMEWORK

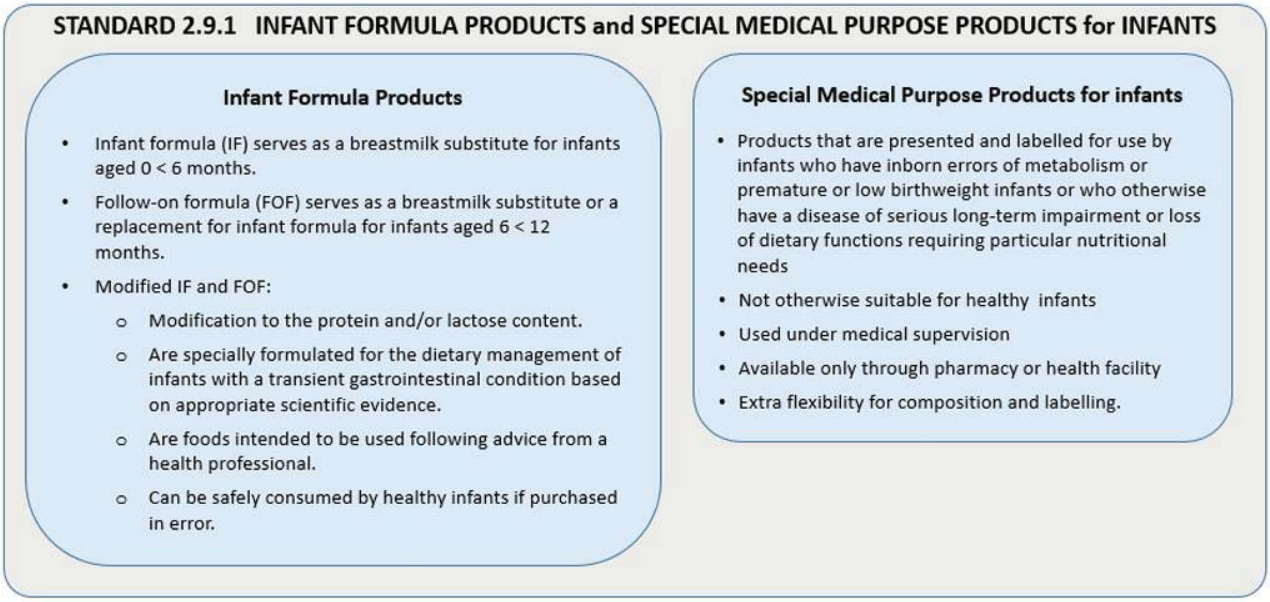
2.4.1 Infant formula products

The AFGC supports FSANZ's proposal to maintain the regulatory framework for IFP intended for healthy infants in Standard 2.9.1 – Infant formula products.

2.4.2 Modified infant formula (MiF) and follow-on formula (FoF) products

The AFGC does **not support** the FSANZ's proposal of a new subcategory that deviates from baseline infant formula or FoF composition by only having modified protein and/or lactose free/low lactose content. See Figure 1.

Figure1: Proposed categories for Standard 2.9.1



The rationale for not supporting the FSANZ's proposed new subcategory is

- It creates confusion between products suitable for healthy infants and products for special conditions that should only be fed to an infant under medical supervision. Infant formula for transient conditions should only be used under medical supervision and must communicate its purpose.
- It does not include all formulas designed for dietary management of infants with functional gastro-intestinal problems.
- It ignores their broader application in IFP and **Special Medical Purpose Products for infants** (SMPPi) by restricting it to partially hydrolysed protein and/or low/no lactose products

- It potentially causes purchase confusion as description of the conditions, such as anti-reflux and colic, are not permitted on the label under the proposed framework. Hence, caregivers may have trouble identifying the correct product for the condition as recommended by health professionals.

2.4.3 Special medical purpose products for infants (SMPPi)

The AFGC **not support** the FSANZ's proposal to remove the category of **Infant Formula Products for Special Dietary Use** (IFPSDU) within Standard 2.9.1, and the current specific subcategories contained within Division 4; and create a new category for SMPPi covering any special medical product formulated for infants under 12 months. This will include all relevant products for infants currently included in Standard 2.9.5 - Food for special medical purposes.

However, the AFGC **proposes** limiting the scope of SMPPi **only** for special medical infant formula products, **not** for other partial/modular products or highly specialised products from Standard 2.9.5 and human milk fortifiers.

Additionally, the AFGC **proposes** removing the proposed modified IFP subcategory and moving all products intended for a special medical purpose to SMPPi, but not applying a trade restriction to products that address transient conditions (i.e. retain status quo for trade provisions).

The AFGC suggests, at a later time, FSANZ to consider raising a separate proposal for consultation of these latter products in Standard 2.9.5.

The rationale for not supporting the FSANZ's approach is

- It presents a new area that has not been considered in previous consultations of incorporating products from Standard d 2.9.5 into Standard 2.9.1.
- It may potentially jeopardise the health and safety of infants with diagnosed diseases, disorders or conditions.
- That only special medical infant formula products that form the sole or principal liquid source of nourishment should be considered under Standard 2.9.1 as they are complete nutrition for infants.
- That special infant products that do not meet the definition of an IFP should remain under Standard 2.9.5.
- No principle of international alignment exists for these specialised SMPPi as the majority of these products are imported which is therefore not aligned to Codex.

Preferred option

The AFGC does **not support** the FSANZ's preferred option in its current form, and instead **proposes** an amendment of removing the proposed 'Modified IF and FOF' subcategory; including any special medical purpose infant formula products under SMPPi; and splitting the trade restriction and requirements of this category.

For those products that are:

- Non-trade restricted SMPPi, they require clear and consistent labelling to address concerns regarding potential misuse e.g. additional labelling statements in a prominent place.

- Trade restricted SMPPi, they be permitted to have flexible labelling since the majority of these products are imported and require continued uninterrupted supply. It is not commercially feasible to create specific labels and formulations for Australia and New Zealand.

3.0 DEFINITIONS

3.1.4 Preferred option

FSANZ proposes to retain definitions, as were proposed in 2021 CP3, for infant formula and include the existing definition in the Code for IFP and FoF.

Infant formula product

The AFGC **proposes** the following definition for IFP by making the changes shown in red below:

> "Infant formula product means a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have proven to be safe for infant feeding that ~~or other edible food constituents of animal or plant origin which~~ is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.

The rationale for an amended definition is that it aligns more closely to wording used by Codex for consideration:

Infant formula

FSANZ proposes to amend the definition for infant formula by making the changes shown in red below:

> "Infant formula means an infant formula product that:
>
> a) Is represented as a breast milk substitute for infants; and
> b) Satisfies by itself the nutritional requirements for infants under the age of ~~4 to~~ 6 months.
>
> Infant means a person under the age of 12 months."

The AFGC **proposes** the following definition by making the changes shown in red below.

> "Infant formula means an infant formula product that:
>
> - Is represented as a breast milk substitute for infants; and
> - Satisfies by itself the nutritional requirements for infants for the first months of life up to the introduction of complementary food. ~~under the age of 4 to 6 months~~."

The rationale for amending the FSANZ's proposed definition is:

- Science is developing rapidly around methods to address allergies from food and currently considers the introduction of allergenic food from as young as 1 month. Thus, setting an age limit ignores this science.
- It does not future proof the standard as evidence is updated

3.2 SMPPi

FSANZ proposes a new definition for SMPPi as follows:

A Special Medical Purpose Product for infants means a food that is

a) specially formulated for the dietary management of infants

i) by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and
ii) whose dietary management cannot be completely achieved without the use of the food; and

b) intended to be used under medical supervision; and
c) represented as being

i) a food for special medical purposes intended for infants; or
ii) for the dietary management of a disease, disorder or medical condition in infants.

The AFGC does **not support** the definition for SMPPi as proposed, rather it **proposes** that only products for infants that are the sole, or principal liquid source of nutrition, are in scope.

The rationale for not supporting the FSANZ's definition is

- It goes beyond the scope of Standard 2.9.1 extending to other special medical infant products that do not meet the current overarching concept of the standard: "*form the sole or principal liquid source of nourishment*" for infants.
- It creates ambiguity around the applicable standard for some products currently regulated under Standard 2.9.5. This In turn may lead to delays at the border due to confusion.
- It does not align with Codex or the EU:

Note :

Codex Stan 72-1981 on formula for special medical purposes intended for infants states the products are substitutes for human milk or infant formula in meeting the special nutritional requirements arising from the disorder disease or medical condition for whose dietary management the product has been formulated.' (Section B: Formula for Special Medical Purposes intended for Infants, p16)

The EU regulated special purpose infant formulas as food for special medical purposes designed for infants (iFSMP). Food for special medical purposes is defined in Regulation (EU) 609/2013. Specific compositional and information requirements are set out in Commission Delegated Regulation 2016/128. This includes a requirement for the nutritional composition of iFSMP to be based on that of infant and follow-on formula, except where necessary for the intended purpose of the product.

4. NOVEL FOODS AND NUTRITIVE SUBSTANCES

The AFGC **supports** and agrees with FSANZ's preferred option to review the regulatory framework for novel foods and nutritive substances in infant formula products with P1024 – Revision of the Regulation of Nutritive Substances & Novel Foods so that requirements for IFP are considered in parallel with other food categories.

5. SAFETY AND FOOD TECHNOLOGY (SD1)

5.4 L(+) lactic acid producing microorganisms

FSANZ's preferred approach is to retain the existing permission, however, stating that L(+) lactic acid producing microorganisms may only be added for acidification purposes. FSANZ also proposes to clarify the permission that only non-pathogenic or nontoxigenic microorganisms may be used.

The AFGC does **not support** FSANZ's preferred approach to retain the existing permission.

The AFGC **strongly proposes** continued permission for L(+) lactic acid producing microorganisms without the proposed clarifications regarding purpose.

The AFCG notes that FSANZ's own risk assessment demonstrated:

> "*no public health and safety concerns, there is no scientific or technical basis to restrict addition of L(+) lactic acid producing microorganisms*" (FSANZ, CP1, 2021).

The rationale for not supporting the FSANZ's approach is

- L(+) lactic acid producing microorganisms are generally considered as safe.
- Does not align with international regulations of Codex, EU and many other overseas regulations.
- Potentially will have severe public health consequences within and external to Australia and New Zealand.
- Creates barriers for trade in an internationally competitive food industry.
- Uses significant resources for FSANZ and all stakeholders to address the potential wave of applications that would be necessary for pre-market assessment to permit addition of L(+) lactic acid producing microorganisms to infant formula within the transition period.
- No indication by guidance or enforcement by authorities to date that the intent was to limit addition of L(+) lactic acid producing microorganisms for acidification purposes only.

6. NUTRIENT COMPOSITION

Macronutrients - Protein source.

FSANZ's preferred approach is that the protein sources in infant formula be specified to be cow's milk protein, goat's milk protein, protein hydrolysates of one or more proteins normally used in infant formula and soy protein isolate. Any protein sources outside of those specified will need to undergo a pre-market assessment through FSANZ.

The AFGC does **not support** a positive list of permitted proteins as sheep-based infant formula made in New Zealand has been available for several years without any issues raised by authorities.

The rationale for not supporting the FSANZ's approach is

- Lack of scientific justification provided by FSANZ to vary from Codex internationally. Codex STAN 72-1981 and Codex draft FUFOI allow milk of other animals.
- Growing use of other mammalian milks (buffalo, goat, sheep) has increased in recent years, noting that most products (including infant formulas) are based on cows' milk which accounts for 83% of global milk production[i]
- Sheep milk, like all mammalian milks, has a high nutritional content and quality protein even before modification in accordance with infant formula standards.

Note:

> *Codex draft FUFOI*
>
> *3.1.1. Follow-up formula for older infants is a product based on **milk of cows or other animals or a mixture thereof** and/or other ingredients which have been proven to be safe and suitable for the feeding of older infants. The nutritional safety and adequacy of follow-up formula for older infants shall be scientifically demonstrated to support growth and development of older infants.*
>
> Codex STAN 72-1981
>
> 3.1.1 *Infant formula is a product based on **milk of cows or other animals or a mixture thereof** and/or other ingredients which have been proven to be suitable for infant feeding. The nutritional safety and adequacy of infant formula shall be scientifically demonstrated to support growth and development of infants. All ingredients and food additives shall be gluten-free.*

7. LABELLING

Declaration of Nutrition Information

FSANZ's preferred option is to prescribe the format of the **nutrition information statement** (NIS) (as per SD3 Figure 1)

The AFCG **supports** some prescribed formatting of the NIS as it aligns with general food and international food standards, however, it does **not support** a **highly prescribed** NIS format.

Research commissioned by FSANZ (SD3 attachment 1 – Consumer research on infant formula labelling) indicates that most caregivers do not understand the purpose of nutrients present in infant formula products.

"*They explained they did not know what the different nutrients were or what benefit they had. So, this information did not tell them which infant formula was better or more appropriate for their infant.*" (FSANZ, SD3, p30)

In addition, the research has shown that healthcare professionals are often unwilling or unable to discuss formula options with caregivers

"While caregivers who use infant formula seek and value information they receive from healthcare professionals, on occasion they report difficulties obtaining information from these sources" (FSANZ, SD3, p28)

Figure 1. Example of the proposed prescribed format of the NIS

NUTRITION INFORMATION	
	Average quantity per 100 mL made up formula
Energy	kJ
Protein	g
Fat	g
Carbohydrate	g
Vitamins	
Vitamin A	µg
Vitamin B_6	µg
Vitamin B_{12}	µg
Vitamin C	mg
Vitamin D	µg
Vitamin E	µg
Vitamin K	µg
Biotin	µg
Niacin	mg
Folate	µg
Pantothenic acid	µg
Riboflavin	µg
Thiamin	µg
Minerals	
Calcium	mg
Copper	µg
Iodine	µg
Iron	mg
Magnesium	mg
Manganese	µg
Phosphorus	mg
Selenium	µg
Zinc	mg
Chloride	mg
Potassium	mg
Sodium	mg
Additional	
(insert any other substance used as a nutritive substance or inulin-type fructans and galacto-oligosaccharides to be declared)	g, mg, µg

Companies only include information in the current NIS that they understand is important and useful for both caregivers and healthcare professionals to be able to make informed choices.

The current FSANZ Code requires that all nutrition information must be accurate and relevant.

Restrictions on use of common terms, acronyms/abbreviations and additional information.

FSANZ currently has restrictions on use of common terms, acronyms/abbreviations and additional information.

The AFCG does **not support** this and recommends an approach that permits flexibility through 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.

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.

> *"Many caregivers reported that they often don't read the ingredient list and expressed a variety of reasons for this. A common reason was that they did not understand the ingredients" (FSANZ,SD3 – attachment 1 p3)*

> *"A few noted longer ingredients lists were problematic for them as they did not know what many of the ingredients were. Some caregivers described long lists as 'scary' or 'off-putting'" (FSANZ,SD3 – attachment 1 p3)*

The use of consumer-friendly language and commonly understood terminology (permitted in other food categories) seems logical. Flexibility also allows for inclusion of common terms or acronyms/abbreviations which healthcare professionals might commonly use with their clients.

In fact, FSANZ states the need for flexibility in the ingredients list:

> *"FSANZ considers any further standardisation of the statement of ingredients beyond the current requirements would reduce labelling flexibility and be a barrier to trade, noting international and overseas regulations contain no such provisions." (FSANZ,SD3 –p7)*

Ingredient claims

The Code currently restricts nutrition and health claims for IFP which should be sufficient to allow enforcement. Additionally, FSANZ proposes to only permit information about ingredients in the statement of ingredients (except for ingredients e.g. nutritive substances) that are required to be declared in the NIS.

The AFGC has concerns regarding the restriction of 'ingredient' claims as it prevents provision of adequate information to caregivers who may not have access to health professional guidance to make an informed choice, as mentioned above. Additionally, the restrictions are not internationally aligned with Codex, the WHO Code, the EU or the US:

Note:

- Codex STAN CXS 72-1981 only restricts nutrition and health claims for foods for infants except where specifically provided for in relevant Codex Standards or national legislation
- WHA58.32 resolutions adopted subsequent to the WHO Code only references restrictions on nutrition and health claims for breastmilk substitutes, unless national/ regional legislation allows.
- ,EU 2016/127 restricts nutrition and health claims on infant formula but allows them on follow-on formula.
- The US FDA allows nutrition and health claims to be displayed on infant formula products that are specifically provided for under the Code of Federal Regulations. Labeling of Infant Formula: Guidance for Industry

It is through innovation and clinical research that IFP continue to be improved. However, the current prohibition is a disincentive for the development of scientifically researched IFP. It also inhibits the ability of companies to describe products accurately, and for their intended use.

Accessibility

Trade restrictions were put in place under Standard 2.9.5 as part of the overall risk management strategy due to the minimal prescribed composition and lack of advertising restrictions. Additionally, there are controls in advertising restrictions in place for IFP due to voluntary government marketing codes which incorporate the principles of the WHO *International Code of Marketing of Breast-milk Substitutes*.

The AFGC has concern regarding the general restriction on sale of SMPPi that are specifically developed for a disease, disorder or condition. Caregivers may be left with less accessibility and availability of products to feed their babies and may in lieu use unsuitable and potentially harmful alternatives.

The level of occurrence of functional gastrointestinal disorders is common worldwide with the most prevalent disorders being infant regurgitation and functional constipation. (1-25.9% and 1-31%, respectively)[ii] .With occurrence at these levels, products for these conditions require greater access than can be provided in the pharmacy setting due to the limited shelf space and hours of operation.

Transition period

The AFGC proposes that 5-years transition period plus 2-years --stock-in-trade (7-years) is required to give effect to the extensive changes.

The rationale is

- Every product will change as FSANZ has observed given the extensive number of composition and labelling changes required.
- Each company will need to develop its change programme.
- Redevelopment will be required of base powder recipes, premixes and individual product recipes.
- Reformulation and label updates of each product will take approximate 36 months, noting that companies cannot start to commence implementation until after gazettal and companies do not have the resources to implemented changes on all products at the same time. Note: 36 months omits consumer studies and full shelf-life studies.

- Label and reformulation changes may require manufacturers to make amendments for other markets. This could include formulation, labels and re-registration.

SUMMARY

The AFGC supports breastfeeding due to the numerous maternal and infant benefits derived from breast milk. However, for infants that are unable to receive breast milk, infant formula that is based on the latest evidence-based science is the best alternative.

Overall, the AFGC supports FSANZ's efforts to update the infant formula standards to better meet the needs of stakeholders, and particularly the infant formula manufacturing industry and the consumers/caregivers of infants it serves.

The AFGC has made a number of proposed changes to the FSANZ's preferred regulatory approach in an effort to balance restrictions on use and formulation to protect public health, while at the same time permit flexibility and incentive for innovation by the food industry. In this way, improvement of infant formulas shall continue in line with scientific developments and ensure that non- breastfed infants are not nutritionally disadvantaged.

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

[i] Verduci E, D'Elios S, Cerrato L, Comberiati P, Calvani M, Palazzo S, Martelli A, Landi M, Trikamjee T, Peroni DG (2019). Cow's Milk Substitutes for Children: Nutritional Aspects of Milk from Different Mammalian Species, Special Formula and Plant-Based Beverages. Nutrients 2019, 11, doi:10.3390/nu11081739.

[ii] Zeevenhooven J, Koppen IJ, Benninga MA. (2017) The Rome IV criteria for functional gastrointestinal disorders in infants and toddlers. Pediatric gastroenterology, hepatology and nutrition. 20(1): 1 13. doi: 10.5223/pghn.2017.20.1.1