AUSTRALIAN FOOD & GROCERY COUNCIL

AFGC SUBMISSION

FSANZ 2nd call for submissions – Proposal P1028 Infant Formula

7 July 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.

RECOMMENDATIONS AND SUPPORT STATEMENTS

The AFGC provides the following support and recommendations to the Second Call for Submissions for Proposal P1028 – Infant Formula

OVERALL

- **supports** amendments to Standard 2.9.1 and Schedule 29, Standards 1.12, 1.31, 1.5.1 (parts thereof), Schedules 8,15,19,and 25 (parts relevant to infant formula) as a single set of proposed changes.

REGULATORY FRAMEWORK

- **supports** the amendment to change the regulatory framework for infant formula products (**IFP)** by the separating infant formula and follow-on-formula from specialised products, and thus the creation of a new category "Special medical purpose products for infants" (**SMPPi)** under standard 2.9.1.
- **recommends** flexibility within the category of SMPPi and a splitting of trade restrictions in health care settings, with respect to this new division, with separated requirements for lower and higher risk formulas. These 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 are permitted to have flexible labelling since the majority of these products are imported, and require continued uninterrupted supply.
- **supports** exclusion of human milk fortifiers and supplement products under Standard 2.9.1 as they do not meet the definition of an IFP providing sole or principal source of nourishment, and should remain under Standard 2.9.5.

DEFINITIONS

- **supports** SMPPi as a division within infant formula products with specific descriptive elements.
- **supports** a revised definition of SMPPI in which reference to 'partial feeding' has been removed.
- **supports** removal of the definition for protein substitute as the use of this term is superseded by the categorisation of products as SMPPi.

NOVEL FOODS

- **supports** review of the regulatory framework for novel foods and nutritive substances in IFP with P1024 – Revision of the Regulation of Nutritive Substances & Novel Foods .
- **supports** permission that novel foods must not be added to IFP unless express permission is stated in the table to Schedule 25-2.

LACTIC ACID PRODUCING MICROORGANISMS (LAM)

- **supports** amended approach to retain the current permission for the addition of LAM to IFP.

- **supports** an update of the permissions for IFP to align as best as possible with international regulations especially Codex standards and EU regulations.
- **supports** the view that novel LAM will continue to require FSANZ pre-market approval, as they are captured by horizontal standards in the regulation (E.g. Standard 1.5.1 Novel foods and Standard 1.5.2 Foods produced using gene technology).
- **recommends** permission to label the strain and count (**CFU)** of microorganisms in the nutrition information statement (**NIS**).

FOOD TECHNOLOGY FOR INFANT FORMULA PRODUCTS SD1

- **supports** an update to the permissions for IFP to align as best with international regulations especially Codex standards and EU regulations.
- **supports** the maximum level of aluminium to remain unchanged, therefore does **not support** 0.05mg/100mL maximum level of aluminium for all IFP due to natural varying aluminium levels in soy making the proposed level not realistic for soy-based IFP.

LABELLING FOR INFANT FORMULA PRODUCTS (SD3)

- **supports** prescribed names located on the front of a package of IFP as the prescribed name assists caregivers to choose appropriate products for their infants.
- **recommends** a labelling format of the NIS that allows flexibility in subheadings and consumer friendly terms and acronyms.
- **not supports** restricted use of common terms, acronyms/abbreviations and additional information.
- **not supports** to only permit information about ingredients in the statement of ingredients unless required to be declared in the NIS. The restriction of 'ingredient' statements prevents provision of adequate information.

COST AND BENEFITS (SD4)

- **supports** the analysis that the proposed changes to the Food Standards Code will lead to a net benefit to society. However, the cost for the industry to reformulate and update labels will be significant.
- **supports the** assessment that the Food Standards Code is out of date with current scientific knowledge for some issues, not harmonised with international regulations, and difficult to interpret in some areas.
- **recommends** that the cost benefit analysis be updated to reflect more than one label change during the transition period as these costs may be referenced in other standards development.

TRANSITION PERIOD

- **recommends** a 5-year transition period plus 2-years stock-in-trade but will **agree** to a compromised transition period in which IFP can be sold either compliant the Code as it currently stands, or the Code as amended by the draft variations.
- **recommends** a communication plan by FSANZ and the jurisdictions to proactively inform consumers and heath care professionals.

OVERVIEW

The AFGC appreciates the opportunity to respond to the 2nd Call for Submissions (**CFS2**) P1028 - Infant Formula to revise and clarify standards relating to infant formula products (**IFP**) comprising regulatory framework, 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 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 and stakeholder engagement that the team at Food Standards Australia New Zealand (**FSANZ**) has undertaken on this, and the previous call for submissions 1 (**CFS1**). Furthermore, the AFGC congratulates FSANZ on the progress which has been made towards revising the parts of the Food Standards Code covering IFP in ways which align with the views of all stakeholders.

The AFGC **supports** FSANZ's stated objective of aligning the Food Standards Code Standards with international regulations wherever appropriate such as Codex. Harmonisation with international standards reduces regulatory complexity for industry and enables international trade in food products. This supports greater choice to consumers, and in some cases, a pathway for specialised IFP into the market which would not otherwise be available.

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

However, the proposed changes will result in additional, substantial costs on industry as it will affect almost every product currently on the market covered by the infant formula standards, according to AFGC's member feedback.

The AFGC **strongly 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 permitting flexibility and incentive for innovation by the food industry. In this way, improvement of infant formulas shall continue in line with scientific developments.

Overall, the AFGC **supports** FSANZ's efforts to update the infant formula standard to better meet the needs of stakeholders, and particularly the infant formula manufacturing industry, and the caregivers to those infants it serves through a series of proposed amendments to:

- Standard 2.9.1 and Schedule 29,
- Standards 1.12, 1.31, 1.5.1 (parts thereof)
- Schedules 8,15,19, and 25 (parts relevant to infant formula)

SPECIFIC COMMENTS

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

2 REGULATORY FRAMEWORK

Supplementary products and milk fortifiers

The AFGC **supports** FSANZ's decision to exclude human milk fortifiers and supplement products under Standard 2.9.1 as they do not meet the definition of an IFP providing sole or principal source of nourishment and should remain under Standard 2.9.5.

New category - SMPPi restriction of sale

The AFGC in principle **supports** the amendment to the Food Standards Code to change the regulatory framework for IFP by the separating infant formula and follow-on-formula from specialised products and thus the creation of a new category "Special medical purpose products for infants" (**SMPPi)** under standard 2.9.1.

The AFGC does **not support** proposed trade restrictions on <u>all</u> SMPPi formula.

As background, FSANZ is proposing to restrict the sale of SMPPi to the following health care settings:

- a medical practitioner or dietitian
- a medical practice, pharmacy or responsible institution
- a majority seller of that food for special medical purposes.

The AFGC continues to advocate for flexibility within the category of SMPPi and **recommends** a splitting of trade restrictions and requirements based on level of specialisation and medical need. This could consist of:

Non-trade restricted SMPPi - require clear and consistent labelling to address concerns regarding potential misuse e.g. additional labelling statements in a prominent place. These are: 'lower risk' formula developed for transient gastrointestinal conditions and feeding problems - gastro-oesophageal reflux, colic, constipation.

Trade restricted SMPPi - 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.

These are: highly specialised and high-risk products developed specifically for extremely ill infants, and which may be unsafe for a healthy infant.

Products for metabolic, immunological, renal, hepatic and malabsorptive conditions; products formulated for premature or low birthweight infants; products for specific dietary use based on a protein substitute.

The AFGC **supports** the INC's **recommendation** to exempt **lower-risk** SMPPi products that are used for gastrointestinal conditions and feeding problems (as identified in CFS2 Table 2.3) from the restriction of sale. These are IFP represented as being specially formulated for the dietary management of the gastrointestinal conditions - gastroesophageal reflux/regurgitation, colic, constipation, and lactose intolerance.

The AFGC contends that this restriction may raise **safety issues** related to 'inequity' where limited access in rural and remote communities can place a parent/caregiver in the position of purchasing, in desperation, an adult product at the supermarket and administer it to their infant. Restriction for these products seems unnecessary given they are supported by scientific evidence for the dietary management of these transient gastrointestinal conditions. Please note that the occurrence of gastrointestinal disorders in neonates and toddlers is a common issue[1].

Furthermore, research commissioned by the INC indicates a significant impact of limited access due to the restriction of sales of SMPPI products that would formerly be available from supermarkets.[2].

Recommendation

The AFGC recommends a splitting of trade restrictions and requirements based on level of specialisation and medical need.

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

These are: 'lower risk' formula developed for transient gastrointestinal conditions and feeding problems - gastro-oesophageal reflux, colic, constipation.

Trade restricted SMPPi -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.

[1] Zeehoven J, Koppen IJN, Benninga MA.The New Rome IV Criteria for Functional Gastrointestinal Disorders in Infants and Toddlers. *Journal of Pediatric Gastroenterology Hepatology & Nutrition*, 2017; 20(1):1-13. DOI: 10.5223/pghn.2017.20.1.1.

[2] Personal Communication. 2023. INC commissioned research from IQVIA to examine and analyse channel data relating to SMPPi sales in Australia and New Zealand.

Labelling – prescribed name of food

The AFGC has concerns regarding the restriction of labelling of these SMPPi products and considers the proposed approach is not in the best interest of the carer and infant.

For example, under the proposed approach, hydrolysed protein formula, and "low lactose" and "lactose free" formula must have these words included in the statement of the name of the food (the prescribed name), per CFS2 p15.

The AFGC **supports** the requirements of these above statements as it provides clear information to the carer, and further **supports** this prescribed approach being extended to formula for transient gastrointestinal issues. However, it is proposed that formula for transient gastrointestinal issues are not permitted to reference conditions such as anti-reflux, colic or lactose intolerance as these would be considered health claim, as per IFP for special dietary use 2.9.1—14(2)(d). This is not helpful and hinders carers looking for these products if they are not clearly identifiable. Hence, the AFGC **supports** the INC's position that if terms are prescribed requirements, then they are not claims.

3 DEFINITIONS - DEFINITION FOR SMPPI ; FOR PROTEIN SUBSTITUTE

3.1 Definitions for infant formula products and related terms

The AFGC is generally **supportive** of the definitions proposed.

3.2 Definition for SMPPi

The AFGC **generally supports** the definition of SMPPi but prefers a simpler drafting using plain English.

The AFGC **supports** the approach taken by FSANZ to no longer propose to define SMPPi separately from IFP but will have specific descriptive elements. As stated: (p20)

> *"SMPPi are intended to be positioned in Standard 2.9.1 as a subcategory of infant formula products and no longer includes supplementary products not intended as breast milk substitutes, such as human milk fortifiers."*

The AFGC also **supports** the revised definition of SMPPi in which reference to 'partial feeding' has been removed as supplementary products are no longer intended to be covered in this category.

3.3 Definition for protein substitute

The AFGC **supports** FSANZ's preferred approach to remove the definition for protein substitute as the use of this term is superseded by the categorisation of products as SMPPi.

3.4 Other Definitions

The AFGC **supports** the FSANZ proposal to remove the definitions of 'soy-based formula', 'preterm' and 'medium chain triglycerides' for the reasons set out in CFS1.

4.NOVEL FOODS AND NUTRITIVE SUBSTANCES - PRE-MARKET ASSESSMENT REQUIREMENTS

4.1 Pre-market assessment requirements

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

The AFGC **supports** INC's suggestion that consideration be given to the labelling of novel food and nutritive substances on IFP given the labelling restrictions on the use of certain terms. Applications are very costly; and industry requires some understanding of how the novel food or nutritive substance would be presented prior to application to assess the value.

4.2 Schedule 25 permissions

The AFGC **supports** and agrees with FSANZ's approach that novel foods must not be added to IFP unless express permission is stated in the table to Schedule 25-2.

5 L(+) LACTIC ACID PRODUCING MICROORGANISMS (LAM)

The AFGC **supports** and agrees with FSANZ's amended approach to retain the current permission for the addition of LAM for the reasons as cited in the CFS2 (p30):

1. *No safety concerns*
2. *Long history of use and ubiquitous in products currently on market*
3. *Alignment with Codex*
4. *Removal of permission would cause large reformulation cost to industry, loss of products from market, and potentially a large influx of application to FSANZ seeking permission to add LAM to IFP.*

The AFGC considers that the Food Standards Code provides sufficient clarity on the permission to add LAM to IFP similar to the approach taken in the EU. As with any infant formula ingredient, industry premarket assessment is completed as part of due diligence. This includes an internal safety assessment and review of external sources such as the EU qualified presumption of safety (**QPS**) list.

5.3.4 Labelling of LAM in IFP

The AFGC **recommends FSANZ** consider permitting labelling of the strain and count (CFU) of microorganisms in the NIS in line with best practice labelling guidance to support informed consumer choice.

The AFGC **supports** FSANZ's position that novel LAM will require pre-market approval, as they are captured by horizontal standards in the regulation (e.g. Standard 1.2.1 Novel foods and Standard 1.5.2 Foods produced using gene technology etc).

Recommendation

The AFGC recommends permitting labelling of the strain and colony forming unit (CFU) of microorganisms in the NIS in line with best practice labelling guidance to support informed consumer choice.

6 FOOD TECHNOLOGY FOR INFANT FORMULA PRODUCTS SD1

Carry-over principle for food additives

The AFGC **supports** FSANZ's approach to "*align as best as possible with relevant international regulations, especially Codex standards and EU Regulations*". To ensure the removal does not impact supply of product, it is important that FSANZ aligns with international regulations as stated above.

Additionally, FSANZ may wish to consider the provision of sufficient resources prior to (to allow industry to use the transition period for reformation, if needed) and within the transition period (for approvals) for unintended consequences due to the removal of carry-over provisions.

Contaminants

The AFGC does **not support** 0.05mg/100mL Maximum Level of aluminium for all infant formula. Due to natural varying aluminium content levels in soy, this is not a realistic level for soy- based infant formula. As the proposed level will affect the availability of this product in Australia and New Zealand, it is **recommended** that the current level be maintained, which is supported by the JECFA recommendation (2mg/kg bw/week).

Recommendation

The AFGC recommends that the current maximum level of aluminium for infant formular products is maintained, which is supported by the JECFA recommendation (2mg/kg bw/week).

8 LABELLING FOR INFANT FORMULA PRODUCTS (SD3)

FSANZ has proposed new safety-related labelling requirements in CFS2, Table 8.

Statement that follow-on formula should not be used for infants aged under six months

The AFGC **supports** FSANZ's clarity in CFS2 that "*the wording of the age statements would not be prescribed, and manufacturers would retain flexibility (for example, "0 to 6 months", "from birth")*" (SD3, Section 3.4.2). In particular, this interpretation should be clear for follow-on formula for example "6-12 months" or "from 6 months").

The AFGC **supports** the new requirement for inclusion of the statement on front of pack as this aligns with current approaches by industry in provision of information to consumers.

Statement about age to offer foods in addition to formula

The AFGC **supports** INC's **recommendation** to use the term 'around' to align with NHMRC Infant Feeding Guidelines[3] , Healthy Eating Guidelines for New Zealand Babies and Toddlers (0 – 2 years old)[4] and the ASCIA Guidelines: Infant Feeding and Allergy Prevention[5] (ASCIA, 2020). This change would support the Specific Policy Principle (b)[6] that the regulation of infant formula products should not be inconsistent with national nutrition guidelines.

Recommendation

The AFGC recommends the use of the term 'around' in line with the specific policy principle that the regulation of infant formula products be consistent with national nutrition guidelines.

Nutrition information statement (NIS)

Declaration of nutrition information – format

The AFGC **supports** a NIS format that is standardised to assist caregivers and health professionals in making quicker product, but it recommends a format that allows flexibility in subheadings and consumer friendly terms and acronyms (see section below).

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

While the Food Standards Code requires that all nutrition information must be accurate and relevant, the AFGC strongly advocates for removal of restrictions on 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.

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[3] NHMRC (National Health and Medical Research Council) (2013). Infant Feeding Guidelines: Summary. Canberra: National Health and Medical Research Council. https://www.eatforhealth.gov.au/sites/default/files/files/the_guidelines/n56b_infant_feeding_summary_130808.pdf

[4] Ministry of Health. 2021. Healthy Eating Guidelines for New Zealand Babies and Toddlers (0–2 years old). Wellington: Ministry of Health.https://www.health.govt.nz/publication/healthy-eating-guidelines-new-zealand-babies-and-toddlers-0-2-years-old

[5] ASCIA_Guidelines_Infant_Feeding_and_Allergy_Prevention_2020.pdf

[6] ANZ Food Regulation Ministerial Council Food Regulation Standing Committee Regulation of Infant Formula Products https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/56968B08A431CFE3CA25801B00117E7A/$File/Forum-Policy%20Guideline-Regulation%20of%20Infant%20Formula%20Products.pdf

Thus, the AFGC does **not support** the FSANZ proposed approach to restrict the use of common terms, acronyms/abbreviations and additional information.

Only the very informed caregiver can make an informed decision based on the prescribed scientific names and format. The typical caregiver is not familiar with scientific names (SD3 – attachment 1), and therefore providing additional information can provide more context.

The use of consumer-friendly language and commonly understood terminology seems logical, as permitted in other food categories as per Standard 1.2.4—4 Ingredients to be listed by common, descriptive or generic name and Schedule 10. For example, using terms such as "milk solids" to describe "caseinates". Flexibility also allows for inclusion of these terms 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."* (SD3 –p7)

The AFGC **supports** INC's **recommendation** to permit acronyms in addition to the scientific name:

- Docosahexaenoic acid (**DHA**)
- Eicosapentaenoic acid (**EPA**)
- Linoleic acid (**LA**)
- Alpha linoleic acid (**ALA**)
- Arachidonic acid (**ARA**)

Recommendation

The AFGC recommends a format that allows flexibility in subheadings and consumer friendly terms and acronyms in addition to the scientific name.

Other information requirements - Ingredient statements

Ingredient labelling

The AFGC does **not support** FSANZ's approach to only permit information about ingredients in the statement of ingredients unless required to be declared in the NIS. The restriction of these words elsewhere on the label prevents provision of adequate information to caregivers who may not have access to healthcare 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:

- Codex STAN CXS 72-1981 only restricts nutrition and health claims (not ingredient statements) 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 IFP but allows them on follow-on formula.
- The US FDA allows nutrition and health claims to be displayed on IFP that are specifically provided for under the Code of Federal Regulations. Labelling 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 for their intended use.

This restriction does not allow for provenance statements, such as made with Australian milk or other statements to help carers differentiate between products, such as made with A2 milk (protein). This does not support carers in making informed choices, nor is it internationally aligned.

Stage labelling

FSANZ proposes new provisions to voluntarily permit the use of the number '1' on infant formula and the number '2' on follow-on formula to identify for consumers that the product is infant formula or follow-on formula, respectively. If used, the number must appear on the front of the package of the product and immediately adjacent to the relevant age statements for infant formula and follow-on formula.

The AFGC **supports** the provision of the use of stage numbering to enable caregivers to differentiate between infant formula and follow-on-formula. Research has supported the importance of this information to caregivers (SD3 - attachment 1 p17).

> "*Australian and New Zealand caregivers generally understand that each formula stage has a specific nutrient composition designed to meet the needs of children of a certain age.*"

However, the AFGC does **not support** that this information should only appear on front of pack and supports INC's **recommendation** to also use the relevant stage labelling on other parts of the label including on back of pack. This helps in the provision of information to the consumer on their product choice.

Some companies incorporate numbers within their brand trademarks with the stage number being the main differentiator across different SKUs. In this situation, where companies are unable to declare the number on the back of pack, consumers may be unintentionally misled on the nature of the product and suitability for their infant.

Recommendation

The AFGC recommends the relevant stage labelling be permitted on other parts of the label including on back of pack.

10 FSANZ ACT ASSESSMENT REQUIREMENTS

Consideration of costs and benefits (SD4) and conclusions from cost and benefit analysis

The AFGC **agrees** with FSANZ's assessment that the Food Standards Code is out of date with current scientific knowledge for some issues, not harmonised with international regulations, and difficult to interpret in some areas (SD4, page 5).

The AFGC **mostly supports** FSANZ's analysis that the proposed changes to the Food Standards Code will lead to a net befit to society.

The proposed changes may have significant impacts, the degree of which will not be fully realised until the transition period begins (costs may be higher in the first 5 years) and may possibly flow on after that period has elapsed (and costs may then abate).

Examples of impacts include, but not limited to:

Infants/cares/parents

- mental anxiety.
- costs - due to the changes of labelling, and restricted sales of specialised formula may create issue with limited access to and choice offered by pharmacies depending on their location, range of products within pharmacies, and shelf space.
- potential substitution of formula- for other products that may be unsuitable if that specific formula is not available.

Industry

- time delays and unexpected costs - to reformulate and update labels.
    - The analysis conducted by FSANZ assumes only one label change will occur.
    - While multi-label change will likely not impact on the proposed transition period i.e. extend it, the AFGC **recommends** that it is nevertheless important that this is noted in the costs benefit analysis, and labeling costs adjusted based on this for future labeling cost exercises for future standards development.
- additional costs - associated with development and implementation of manufacturer communications to health care professionals.
- export trade hindrance - due to prohibition of ingredient provenance statements which impacts on ability to compete in a global marketplace via cross border e-commerce (**CBEC**).
- time - seeking exemptions for export labelling from domestic standards. Such requirements also limit product placement into the domestic market should that be necessary in the future.

11 IMPLEMENTATION - TRANSITIONAL ARRANGEMENTS

The AFGC wishes to **acknowledge** the work that FSANZ has undertaken in considering the complexity of the regulatory proposed changes and its impact on the range of IFP. FSANZ is therefore proposing a 5-year transitional arrangement commencing on the gazettal date of the draft variations.

The AFGC **recommended** in the CFS1 a 5-year transition period plus 2-years stock-in-trade for the reasons listed below.

The rationale for an extended transition period 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 program.
- 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.

The AFGC continues to **support** INC's position of a longer period as it will reduce cost of change and smooth the impact for consumers.

Recommendation

The AFGC recommends a 5-year transition period plus 2-years stock-in-trade.

Communication to stakeholders

Finally, given the large number of label and compositional changes required to be made based on proposed approach by FSANZ, the AFGC **recommends** a communication plan by FSANZ and the jurisdictions to proactively inform consumers and heath care professionals. This will assist in abating and addressing concern that parents and cares may have over the transition period.

Recommendation

The AFGC recommends a communication plan by FSANZ and the jurisdictions to proactively inform consumers and heath care professionals.

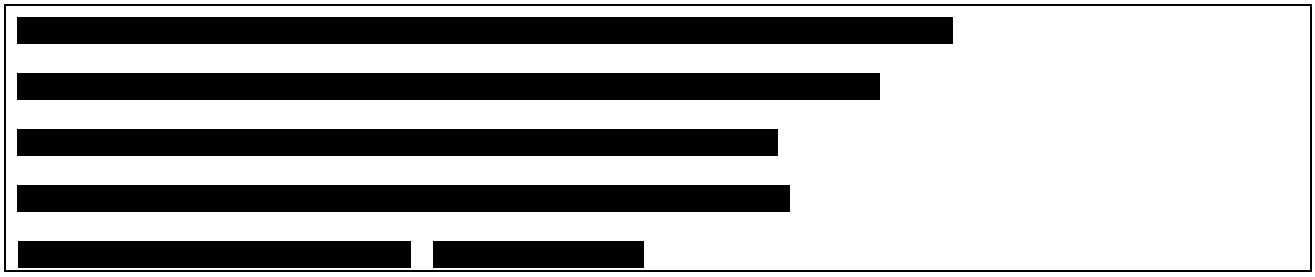
SUMMARY

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

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



State of Industry
2020-21

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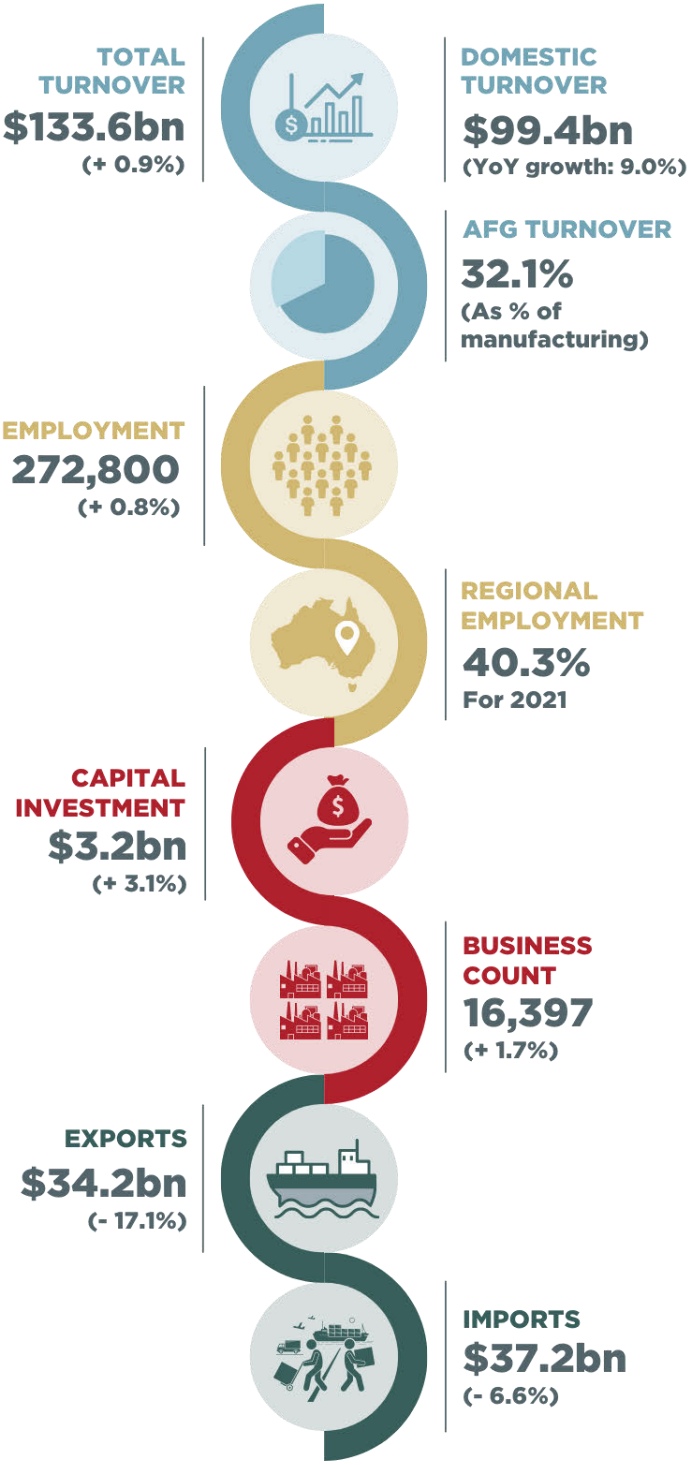

The figures on this page exclude the fresh food sector and are based on 2020-21 ABS data.

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.

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