AUSTRALIAN FOOD & GROCERY COUNCIL

AFGC SUBMISSION

P1028 - INFANT FORMULA CONSULTATION PAPER 3 - REGULATORY FRAMEWORK AND DEFINITIONS

19 October 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. The membership of the AFGC comprises more than 180 companies, subsidiaries, and associates.

Food, beverage, and grocery manufacturing together forms Australia's largest manufacturing sector, representing 31.4 per cent of total manufacturing turnover in Australia. This $127 billion sector significantly contributes to the Australian economy and directly employs over 276,000 people with 108,000 of these jobs in rural and regional Australia.

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.

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.

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 Consultation Paper 3 - Regulatory framework and definitions: 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. alternative.

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.

COMMENTS

The AFGC wishes to make key specific comments in relation the regulatory framework and restriction on sale, Schedule 25, some definitional changes, and some other product treatments.

2 Novel Foods and Nutritive substances
2.1 Pre-market assessment requirement

The AFGC

- supports FSANZ not proceeding with a separate review of novel foods and nutritive substances applicable to IFPs under P1028 but rather address Standard 2.9.1 - Infant formula in the scope of Proposal P1024 – Revision of the Regulation of Nutritive Substances & Novel Foods. Issues that are identified in P1024 that apply to the general food supply should be addressed in a similar and consistent regulatory manner to those in Standard 2.9.1.

2.2 Novel foods – Schedule 25

The AFGC notes that Schedule 25 - Permitted novel foods indicates the conditions of use for novel foods added recently in relation to IFP, infant foods and formulated supplementary food for young children (FSFYC) aged 1 to <4years. For other substances listed, the Schedule is silent, which may be interpreted as being permitted in IFP, infant foods and FSFYC.

The AFGC

does not support the inclusion of conditions of use to the substances identified in Table 5 as proposed by FSANZ. However, in the case that FSANZ does include the conditions, they should be restricted to the most vulnerable group of infants consuming infant formula (IF) or follow-up formula (FoF).

3 Specialised Infant Formula Products
3.1 Approach to the regulation of IFPSDU

The AFGC notes that FSANZ proposes to retain the regulation of IFPSDU in Standard 2.9.1. Regulating IFPSDU in Standard 2.9.1 means it would be an IFP as defined.

The AFGC

- supports the approach to regulate products that are the sole or principal source of nutrition for infants with special dietary needs who are under medical supervision for their condition within Standard 2.9.1.

3.2 Human milk fortifier and pre-term supplementary products

The AFGC notes that FSANZ proposes to regulate IFPSDU that are sole or principal sources of nutrition as IFP, whereas other infant products for special medical purposes that serve a supplementary role are proposed to be regulated by Standard 2.9.5.

The AFGC

- supports the approach that other foods for special medical purpose for infants that are not the sole or principal source of nutrition should be regulated within Standard 2.9.5 rather than Standard 2.9.1.

- variable modular products for conditions, sometimes serious/severe or life threatening, produced in small quantities and with often special distribution arrangements, are better addressed under the regulatory framework of Standard 2.9.5.

4 Definitions
4.1 Definition of infant formula product

The AFGC notes that FSANZ is proposing a change to the definition of IFP to remove reference to a product that is "based on milk or other edible food constituents. The definition proposed is:

> *An infant formula product means a product that 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 AFGC

- recommends that the phrase "based on milk or other edible food constituents" be modified.
- recommends (in line with the INC's position) the following phrase "*and/or other ingredients" be adopted in lieu* which aligns more closely to wording used by Codex for consideration as it covers the full scope of ingredients used in infant formula production (and is suitable for IFPSDU as well as IF and FoF).

  An 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 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.

5 Regulatory Framework for IFPSDU

The AFGC notes that Division 4 of Standard 2.9.1 does not currently include a definition of IFPSDU but consists of three subcategories of IFPSDU, and that there is regulatory uncertainty and overlap related to the broad nature of the current subcategories, the range of products in each subcategory and related definitions.

The AFGC

- recommends, in support of INC's position, a risk management approach for high versus low-risk IFPSDU through the creation of a sub-category of Division 4 called "*IFPSDUs not available at the retail level and exempted from labelling requirements"* which may also be named Infant Formula Products for Special Medical Purposes (IFPSMP) while retaining the broader term 'IFPSDU' for the Division.

IFPSMP, as proposed by INC, are intended for those infants with clinically serious or potentially life-threatening disorders, disease, or medical conditions. products should continue to be made available in supermarkets.

IFPSDU available in supermarkets are formulated based on compositional requirements of IF for the healthy infant and are labelled as for IF for healthy infants. Unlike the sub-category IFPSMP, they can be safely consumed by healthy infants if purchased in error. The AFGC, aligned with INC, considers that these low-risk products should continue to be made available in supermarkets.

5.3.3 (2) Restriction on sale

The AFGC notes that FSANZ considered arrangements for highly specialised products and less specialised products, and reached the view that, to be consistent with the risk management strategy established for Standard 2.9.5, a restriction on sale should be imposed on the entire range of IFPSDU. On this basis, FSANZ proposed that IFPSDU should be subject to a restriction on sale.

The AFGC

- recommends that current risk management approach should be retained as there is no substantial evidence to adopt the risk management strategy of Standard 2.9.5 for the entire range of IFPSDU for all low and high-risk products within IFPSDU.

- supports adopting the risk management strategy of Standard 2.9.5 for a separate sub-category for high-risk infant formula for special medical purposes (IFPSMP).

- contends that there is no 'market failure' in respect of IFPSDU and that only those products for less serious/transient conditions are sold in supermarkets. It notes that products not required under prescription are safe and low risk as stated by FSANZ under CP3 section 5.6.4:

  "that IFPSDU not required under prescription or used in the hospital setting would be based on compositional requirements for IF for healthy infants and therefore safe and low risk".

- does not support the idea that the availability of IFPs is a factor in the cessation of breastfeeding or inappropriate use of IFPSDU. The evidence provided (in table 16) is based on overseas describing a negative impact that advertising these products could have on breastfeeding rates. Please note that advertising and promotion to the general public for IFP 0-12 months is not permitted under both the Marketing in Australia of Infant Formula (MAIF) Agreement and the New Zealand INC Code of Practice of Marketing of Infant Formula, which are government supported in both countries to restrict advertising and promotion of IFP in accordance with the WHO Code. Thus, the relevance of this overseas evidence is not directly applicable in Australia/New Zealand context.

- shares INC's concern that a general restriction on sale of IFPSDU will have a crucial impact on three major areas:
  - a negative effect on some health outcomes for infants who require these products
  - less accessibility and availability to, and of, these products for parents and carers
  - supply chain logistics

5.6 Provisions for IFPSMP – Purpose, use and sale
5.6.1 Scientific evidence of purpose

The AFGC notes that FSANZ proposes to regulate the principle that IFPSMP are formulated in accordance with scientific evidence that demonstrates the efficacy of the product in accordance with its intended purpose.

The AFGC

- supports the INC stance that ALL IFPSDU (including IFPSMP) must have compositional modifications that are based on acceptable scientific data and address the specific condition demonstrating the product and its intended purpose. Note: Currently manufacturers are required to hold scientific evidence that substantiates the nutritional suitability for the disease, disorder, or medical condition in line with its represented purpose. This is required as part of the overarching jurisdictional food act requirements.

- does not support the inclusion of scientific evidence as proposed as this is not aligned with Standard 2.9.5 for FSMP products.

- would support, if a statement were to be included in Division 4, the continuation of this arrangement allowing for a simple statement of requirement similar to the Ministerial policy guidelines .

  "the composition of infant formula products for special dietary uses should be based on appropriate scientific evidence".

- does not support the use of the term "efficacy" in the Code for IFPSDU. These products are not therapeutic but rather are for the dietary management of a specific disease, disorder, or medical condition. Note: the composition of IFPSDU is formulated based on sound medical and nutritional principles that have demonstrated through scientifically acceptable evidence (specific to the product and its indication) to support growth and development in the infants for whom it is intended.

- does not support the introduction of a guidance document to be produced either in the Food Standards Code (FSC), similar to Schedule 6 for health claims, or elsewhere such as a code of practice, on how the efficacy requirement should be met. This would lead to the following unwanted impacts:

    - additional requirements to those already applicable internationally and would create unnecessary misalignment internationally as guides are not available under any other jurisdiction
    - products not being made available or a significant delay in launching products in Australia or New Zealand for serious or life-threatening disorders, diseases, and conditions

- supports INC in emphasising that IFPSMP for serious conditions are generally listed on the Australian Pharmaceutical Benefits Scheme (PBS) and New Zealand's Pharmac.

    Note: in order for IFPSMP to be considered on these schemes, companies are required to provide adequate scientific evidence for their use in the management of a particular medical condition, disease or disorder which is then assessed by their respective clinical experts. Hence, IFPSMP for serious or life-threatening disorders, diseases or conditions already currently have the science reviewed independently by experts in both countries before the products are accepted for reimbursement intended.

- recommends that neither FSANZ nor jurisdictional food regulators should be expected to, or need to, replicate the level of expertise necessary to review this information and it would be best for the relevant agencies to recognise that PBS and Pharmac review the science provided and anything further by FSANZ or jurisdictions would be duplicative.

5.6.4 Distribution and access

The AFGC

- has concern regarding the proposed approach to restrict the sales channels.

- does not support that IFPSDU should be restricted in sale where these products are for low-risk conditions. Adopting the same approach for all IFPSDU in accordance with Standard 2.9.5 for the sake of consistency with Standard 2.9.5, is not supported by evidence of risk. This principle is also not included in the Ministerial policy guidelines.

- is unaware of any evidence to support concerns regarding inappropriate access to any IFPSDU. IFPSMP for more serious disorders, diseases and conditions are normally provided under prescription and are therefore not generally available currently despite the FSC not restricting sale under Division 4. Nonetheless, the AFGC supports the INC in saying that the trade and distribution restrictions be made consistent to that of Standard 2.9.5 for the sub-category of IFPSMP within a broader IFPSDU category (as previously described above).

- shares INC's concern that a general restriction on sale means reduced accessibility to a range of products when they might be most needed and will create stress and heightened concern for carers when dealing with distressed or unwell infants. Due to the COVID-19 pandemic, food shortages including infant formula, have occurred and has been challenging for carers in accessing necessary product. Restricted sale could potentially force carers to feed their babies alternatives that may be unsuitable.

- supports INC's evidence regarding the level of common, global occurrence of functional gastrointestinal disorders (FGIDs). This covers a wide range of disorders related to the gastrointestinal tract that is unexplained by physical or biochemical abnormalities. With such common levels of occurrence, the products for these conditions require greater access then can be provided in the pharmacy setting due to the limited shelf space provided for IFP, and less access to the competitive pricing provided by the supermarket setting. In addition, pharmacies do not usually offer the same access to products due to their limited opening hours or at home delivery.

- investigated the potential impact on supply chain and notes that the sales of the following eight products stocked nationally at **Coles supermarket** would be impacted by this proposal, thus restricting easy availability for vulnerable infants:

    - Aptamil Gold+ Colic & Constipation Baby Infant Formula from Birth to 12 Months
    - Aptamil Gold+ Reflux Baby Infant Formula Regurgitation or Mild Reflux from Birth to 12 Months
    - Aptamil Prosyneo Sensitive Baby Infant Formula Formulated for Tolerance from Birth to 12 Months
    - S26 Gold Alula Delicateeze Formula
    - S-26 Gold Lactose Intolerance Formula
    - S-26 Gold Anti Reflux Formula
    - Nan A.R Formula
    - Aptamil Gold+ Lactose Intolerance Baby Infant Formula from Birth to 12 Months

Transition period

The AFGC

- recommends a **transition period** of 5-years from manufacture date which also allows for stock in trade. This would enable labelling, composition, and additive changes to be made whilst minimising costs to industry

In summary, the AFGC supports the submission to this consultation by the Infant Nutrition Council of Australia and New Zealand (INC) and shares the concerns that the INC has described.

[redacted]