20 October 2021

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Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on ***Consultation paper 3: Regulatory framework and definitions – Proposal P1028 – Infant Formula.***

Yours sincerely

[redacted]

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Consultation paper 3: Regulatory framework and definitions – Proposal P1028 – Infant Formula

Submission by the New Zealand Food & Grocery Council

20 October 2021

NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council ("NZFGC") welcomes the opportunity to comment on ***Consultation paper 3: Regulatory framework and definitions – Proposal P1028 – Infant Formula*** (CP3).

2. NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over $40 billion in the New Zealand domestic retail food, beverage and grocery products market, and over $34 billion in export revenue from exports to 195 countries – representing 65% of total good and services exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 45% of total manufacturing income. Our members directly or indirectly employ more than 493,000 people – one in five of the workforce.

COMMENTS

3. NZFGC is fully supportive of the position taken by INC on the many issues canvassed in CP3 particularly in the area of labelling changes. We appreciate the extent of work that has been applied to the issues canvassed in CP3 and we would not want our comments below to diminish that work.

4. As was found by INC, our key concern is the regulatory framework and the consequential impacts that flow from the single category approach proposed by FSANZ. This proposal appears to be a case of the pendulum swinging too far in a decision opposite to the multi-category approach explored in 2017. We are proposing a slightly lesser swing.

5. The proposal for a single category appears to have been intended to emulate as closely as possible the risk management strategy that underpins Standard 2.9.5. This is consistency taken too far.

6. We believe that a single category with no sub-categories approach (there are currently four sub-categories in Standard 2.9.1, Division 4) is an abrogation of the FSANZ risk-based approach that we have consistently supported across the many years of work of FSANZ. Most recently, this has been in relation to the Modernisation activities in the policy area. We say this because a single category in the regulatory structure for all infant formula products (IFP) for special dietary use (IFPSDU) irrespective of risk is what we understand to be proposed.

7. We strongly support the INC alternative of a single category of IFP for special dietary use (IFPSDU) encompassing a single subcategory for those products that are high risk and which might be termed Infant formula products for special dietary use or IFPSMP.

8. The low-risk products are those whose composition mirrors infant formula (IF) closely except in a specified area(s) aimed at addressing a particular disorder, disease or condition. Healthy infants would not be at a safety risk in their growth and development if they consumed these in error. This is not the case with the high-risk products.

9. High-risk products, those that are intended for infants with clinically serious or potentially life-threatening disorders, disease, or medical conditions could have restricted distribution and market access and should have flexible labelling requirements to ensure international alignment. They are typically prescribed by a doctor, frequently PBS or Pharmac listed or are those distributed directly to institutions such as hospitals e.g. for premature or low birth weight infants.

10. The composition of these high-risk is often a globally accepted composition as specified by medical experts for particular diseases or conditions. Without government funding, they are otherwise very expensive products and would not be expected to be purchased except on prescription. These are products that would be most unsuitable for the healthy infant.

11. The impact of a single category IFPSDU is to restrict the sale to consumers from pharmacies only.

12. There is no evidence of market failure, or health risk or safety reason for categorising all IFPSDU at so high a risk as to warrant such limited access. Similarly, there is no justification for products that are safe for otherwise healthy infants to be exempted from a range of labelling requirements.

13. Adopting the same risk management 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. FSANZ states in CP3 that the restrictions under Standard 2.9.5 are part of their overall risk management strategy given their minimal prescribed composition. FSANZ also states 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 be safe and low risk. Including the same risk management strategy as Standard 2.9.5 by restricting sale for all IFPSDU is not appropriate given the composition requirements and low risk for some of the products for transitory conditions. A more risk-based framework with a IFSMP sub-category for which restrictions are justified could be supported (as proposed by INC).

14. NZFGC has concerns about the cost and access burden for consumers that could result from limiting the availability of all IFPSDU and the regulatory burden involved. Typically, the grocery channel is more affordable for shoppers due to economies of scale meaning some parents/carers will be disadvantaged in their access of these products, due to increased cost and time taken to locate within more restricted hours.

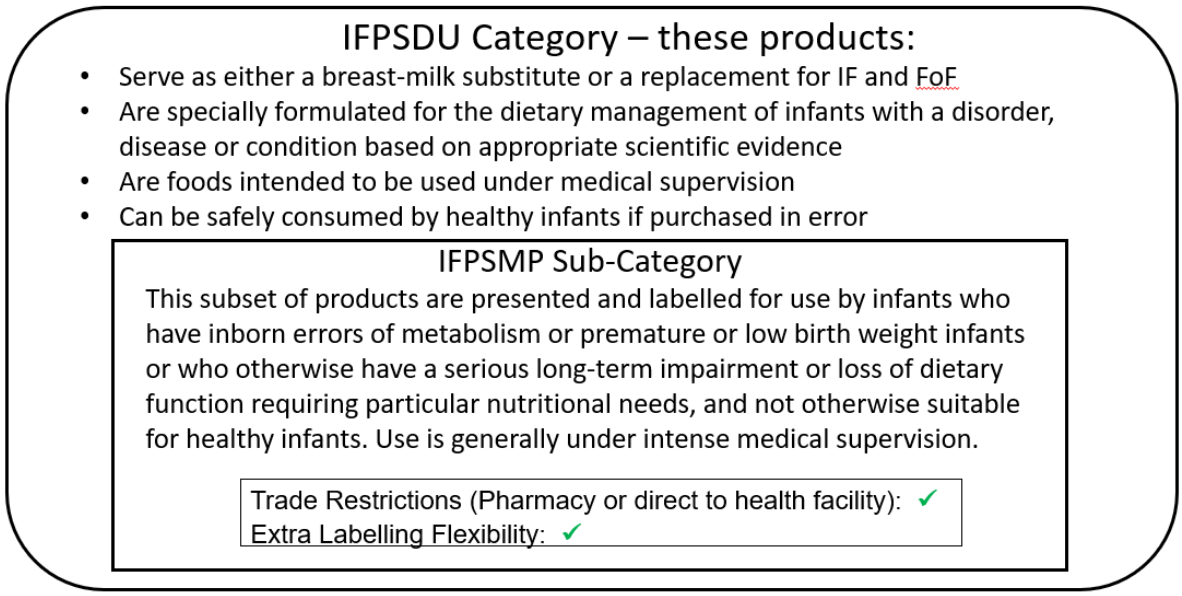
15. It's important for carers and parents of infants experiencing more transitory conditions to be able to purchase products recommended to them by health care professionals from the most convenient retail outlet. This will most commonly be the supermarket with its broad hours of operation and outlets across the community/geographic spread of New Zealand (and Australia).

16. If access is restricted to the pharmacy/healthcare institution channels, the likely retail cost to the parent/carer will also increase due to lower volume sales per outlet and far mor limited shelf space deployed by the pharmacy channel as retail pricing is at the sole discretion of the retailer.

17. Supply of these products could also be jeopardised by requirements in scientific evidence that are additional to those internationally accepted. These products generally enter the market with significantly less volume because of their specialisation but with significant medical scrutiny because of the role they play in supporting the nutritional requirements of infants subject to health care professional/medical oversight and recommendation. This is why a reliance on global composition and international safety assessments ensures that they are available in Australia and New Zealand.

18. We note that to be eligible for Pharmac listing (and PBS listing) the suppliers of these products are required to provide extensive detail about them to for review. We note that Pharmac has over 130 specialists available to review products it lists, that the reviews and scrutiny are intensive. Adding further requirements within the Food Standards Code that deliver no additional benefit to safety and ultimately the consumer could lead to very

reduced supply to this regional market. This could also significantly delay the access to products for serious or life-threatening disorders, diseases or medical conditions. We are aware that these products form an extremely small/minute segment of the IF/FUF market and adding unnecessary barriers to their availability could well see them exit.



19. NZFGC is supportive of not proceeding with a separate review of novel foods and nutritive substances applicable to IFP under P1028. We support modification of composition of IFPSDUs to meet the intended special medical purpose, to ensure supply of IFPSDU and to have flexibility in labelling and composition to harmonise with Codex, EU and USA. We would support other foods for special medical purpose for infants that are not the sole or principal source of nutrition being regulated within Standard 2.9.5 rather than Standard 2.9.1.

20. We support the Division of IFPSDU remaining with that name, removing all sub-categories except that for IFPSMP and special provisions being made for international labelling and composition for these products.

21. NZFGC supports restrictions on the use of novel foods in Schedule 25 from use in products for infants and young children where demonstrated by risk assessment. Retrospectively added conditions do not meet this process and while we consider it likely that this would be the case for infants, this is not necessarily the case for young children. Young children are increasingly sharing family foods and could be exposed to minute amounts of the products in question through such sharing. It is therefore inconsistent and likely to be more difficult to substantiate the conditions proposed.

22. It is also not appropriate to propose conditions of use for these products as part of P1028 since they are not included within the scope of the proposal, and the same applies for infant foods.

23. NZFGC does not support reference to a specific age for IF in the definition of IF. We consider this to be unhelpful and potentially confusing. It does not indicate the infant age range applicable for IF which is from birth to 12 months based in part it being *represented as a breast milk substitute for infants.* Reference instead to “the first months of life up to the introduction of complementary food” is more accurate in relation to being a sole source of nutrition, with the role of the product subsequently moving to the principal liquid source of nutrition.

24. NZFGC considers that principles to apply to IFPSDU a require further examination since some to the principles apply to all IFP not just IFPSDU, some are appropriate such as 'formulated for infants with a specific disease, disorder or medical condition' and some are considered not appropriate.

25. In other areas NZFGC supports the following for IFPSDU:

- IFPSDU having compositional modifications that are based on acceptable scientific data and address the specific condition and its intended purpose
- no definitions for soy-based infant formula and medium chain triglycerides
- stating that IFP may be low lactose and lactose-free and IFPSDU that are formulated for the management of lactose malabsorptive conditions remaining in Division 4
- IFPSDU being used beyond infancy at the discretion of the healthcare professional
- maintaining the current approach for products formulated for premature or low birthweight infants to allow deviation
- removing the sub-category based on a protein substitute as this is not required for composition requirements
- permitting voluntary addition of chromium and molybdenum without any compositional limits for the sub-category of IFPSMP (see the categorisation below)
- aligning IFPSDU labelling provision with FSMP provision in Standard 2.9.5—10(1)(a) to (f) and not mandating the location of certain statements on the label to align with Standard 2.9.5 and Codex
- not mandating statements that are unnecessary for IFPSDU but required under Standard 2.9.5—10(g) (that the food is not for parenteral use)
- maintaining the flexibility in allergen declaration requirements under Standard 1.2.3
- maintenance on the labelling information on safe preparation and use.

26. For the sub-category of IFPSMP, NZFGC supports:
- the statement of ingredients to be made in accordance with Standard 1.2.4 or in compliance with EU or US regulations as per Standard 2.9.5
- not requiring the prescribed name 'infant formula' and also including follow-on formula (this was not proposed by FSANZ)
- the exemption from the 'breast milk is best' warning statement, the statement about offering other foods in addition to IFPs, the requirement for a statement that the IFP may be used from birth, the requirement to state specific source of protein (this was not proposed by FSANZ), the labelling information on safe preparation and use (this was not proposed by FSANZ) and the warning statement for preparation (this was not proposed by FSANZ).
- aligning with the nutrition information in accordance with Standard 2.9.5 (this was not proposed by FSANZ).

27. NZFGC does not support:
- removing the reference to a product that is "based on milk or other edible food constituents" from the definition of IFP
- a maximum age being included for products that can be used beyond infancy particularly for serious conditions which will be managed closely under medical supervision for a wide range of conditions
- the need for definitions of protein substitutes, hypoallergenic formula, partially hydrolysed formula, extensively hydrolysed formula and amino acid-based formula)
- the continuation of the existing labelling requirements in relation to lactose free and low lactose formulas.

28. Finally, NZFGC is strongly opposed to the application of efficacy in the Standard to products that are for dietary management (and any associated guide). It is the nutritional suitability of the products for use in infants that have a disease, disorder or medical condition that is being provided, not a therapeutic product to treat the condition. Such a requirement would set Australia and New Zealand apart from the international community in the requirements associated with IFPSDU to the ultimate detriment of the very population we are purporting to support.

29. We therefore do not support the development of guide for this purpose.