Consultation Paper P1028 - Regulation of infant formula: infant formula products for special dietary use

Submission to the Food Standards Australia New Zealand

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Prepared by

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About the New Zealand Nurses Organisation

NZNO is the leading professional nursing association and union for nurses in Aotearoa New Zealand. NZNO represents over 47,000 nurses, midwives, students, kaimahi hauora and health workers on professional and employment related matters. NZNO is affiliated to the International Council of Nurses and the New Zealand Council of Trade Unions.

NZNO promotes and advocates for professional excellence in nursing by providing leadership, research and education to inspire and progress the profession of nursing. NZNO represents members on employment and industrial matters and negotiates collective employment agreements.

NZNO embraces te Tiriti o Waitangi and contributes to the improvement of the health status and outcomes of all peoples of Aotearoa New Zealand through influencing health, employment and social policy development enabling quality nursing care provision. NZNO's vision is *Freed to care, Proud to nurse*.

EXECUTIVE SUMMARY

1. The New Zealand Nurses Organisation (NZNO) welcomes the opportunity to comment on Consultation Paper P1028 - regulation of infant formula: infant formula products for special dietary use.
2. NZNO has consulted its members and staff in the preparation of this submission, in particular members of the College of Child & Youth Nurses, Neonatal Nurses College, College of Primary Health Care Nurses, Te Rūnanga and midwives and professional nursing, policy, and research advisers.
3. NZNO supports current regulatory guidelines in Aotearoa new Zealand that special formulas for medical conditions, should be prescribed by a paediatrician, or GP with a vocational scope of practice, in consultation with a dietician and followed up by a GP, though we advocate for nurse practitioners (NPs) with an appropriate scope of practice to also be able

to prescribe special infant formulae, in order to reduce delayed access to suitable nutrition for vulnerable infants.

4. NZNO supports World Health Organization's (WHO) position that manufacturers and distributors of breast-milk substitutes must comply with the *International Code of Marketing Breastmilk Substitutes* ("the Code") with regard to labelling IFPSDUs and is astonished that this is not referenced, as it is pertinent to the industry and the health of both our nations.
5. NZNO supports a prescribed name for the category and some subcategories (eg pre term infant formula) of IFPSDUs both for clarity of purpose and to avoid implied health benefits which companies have taken advantage of before when given a free reign to naming infant formula products.
6. Although no question was asked regarding exemption from the "Breast is Best" statement on labelling NZNO provides reasons why there should be no exemption from this statement, or an adapted version, on preterm infant formula. (For the sake of simplicity, we simply refer to "Breast is Best" throughout this submission, but would be very happy to consider alternative wording.)
7. Despite ostensible high level support for the WHO's recommendations regarding breastfeeding and the Code, the reality is that in Australasia as in other developed countries, the Code is not enforced and there has been an overall decline in breastfeeding and widespread adoption of (nutritionally inferior) substitutes.
8. This has long term implications for population health, so breastmilk substitutes do not only affect 'vulnerable population groups', they affect adult groups and population health outcomes in general.
9. It is essential, therefore, that regulations give effect to the Code and ensure infant formula is used only in the rare instances where it is clinically indicated, and that it need not entirely replace or exclude breastmilk, as breastfeeding itself confers infant and maternal benefits.

Q1: Are any other overseas regulations relevant to IFPSDU?

10. There are various and potential trade agreements which may affect labelling, and specifically the ability to require country of origin labelling, which we submit may be particularly important in dealing with foods for highly vulnerable people – ie infants, those with chronic conditions whose immune system might be compromised)
11. The global event involving melamine poisoning in infant formula from China exported to other countries, including New Zealand and Australia in 2008 (Gossner et.al. 2009) for example, indicates the potential risks of importing infant formula from other countries.
12. NZNO recommends that FSANZ takes into consideration the WHO Code, adopted in 1981 which aims to ensure “the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding, and by ensuring the proper use of breast-milk substitutes, *when these are necessary*, on the basis of *adequate information and through appropriate marketing and distribution*" (Article 1 – emphasis added).
13. In some countries legislation has been weakened by lobbying by the pharmaceutical industry (Sobela et al., 2011) and violations remain common in both developing and developed countries (Brady, 2012). The aggressive marketing of infant formulae that violate the Code undermines breastfeeding and contributes to infant and young child morbidity and mortality. Global sales in 2014 of US$44·8 billion show the industry's large, competitive claim on infant feeding (Rollins et al, 2016).
14. These concerns are reflected in a handful of regulations. In Canada, health claims must not be directed solely at children under two years of age; in Brazil, formula for infants and young children must not bear health claims; and in Israel, health and functional claims are prohibited on foods intended for infant consumption.

Q2 What are the advantages and/or disadvantages of these options, in particular creating an 'infant formula product for special medical purposes' subcategory? If you support creation of a separate category for IFMSP, should products developed for pre-term and low-birthweight infants be included or retained as a separate category?

15. The advantage of regulated subcategories of infant formula is the public health benefit of providing appropriate, scientific and factual information about IFPSDUs. This approach promotes trust and facilitates a focus on education (for both health professionals and consumers) to protect and promote breastfeeding, and safe and adequate infant nutrition when formula is medically indicated.
16. In relation to the specialised care of neonates, pre-term IFPSDUs should be retained as a separate category because it is recognised that preterm infants have higher nutrient requirements than term infants. (European Society for Paediatric Gastroenterology, Hepatology, and Nutrition 2010). There are some indications that a suboptimal intake of protein, energy, and other nutrients may lead to lower cognitive achievements. The major goal of enteral nutrient supply to these infants is to achieve growth similar to foetal growth coupled with satisfactory functional development.
17. Medical advances mean that 'preterm' infants comprise an increasing group, indicating a large and diverse consumer base for these products. It is essential that they are well informed.

Q3 Do you support including a category definition for IFPSDU in the Code? Why or why not? Is the proposed definition of IFPSDU appropriate; if not, what should it say?

18. Yes. NZNO supports including a category definition for IFPSDU in the Code and agrees with stakeholders that the current definition of 'infant formula product' does not capture important elements of many of the formulas used for medical conditions, leading to a lack of clarity and potential enforcement issues.

Q4 If you support including a subcategory definition for IFPSMP in the Code, is the proposed definition of IFPSMP appropriate; if not, what should it say?

19. Yes. NZNO supports FSANZ's proposed definition of IFPSDU.

Q10 Is there a need to prescribe a name for IFPSDU – what are the implications for subcategories?

20. IFPSDUs are highly specialised products for medical conditions. Both professional and consumers need relevant, accurate information to make informed and appropriate choices. It is possible that having a number of subcategories may be confusing and ultimately obstructive if compliance costs are higher than potential profits. However, in the sub category of infant formula for pre term infants, we believe this is necessary.
21. There may be risks if clinicians prescribe IFPSDUs based on subcategories alone. This is important in the context of the diverse demography of NZ, and especially in relation to inequitable health outcomes of Māori. The simple practice of correlating a medical diagnosis with a specifically marketed formula can result in the administration of inappropriate nutrition support and an increased cost of nutrient provision (Fussell, 2004).
22. Some doctors consider specific EN formularies established based on patient population and estimated nutrient needs rather than specific diagnosis (Bankhead et al, 2009). FSANZ could consider monitoring how clinicians use subcategories in prescribing IFPSDUs.

Q11 Is there a need to prescribe names for any the IFPSDU subcategories? If yes, what benefit would this provide?

23. NZNO is not sure about the need to prescribe names for all subcategories, but we are confident that there is a need for a prescribed name for the subcategory of *preterm infant formula IFPSDU.* The benefit would be for infant safety, and to offer clarity for consumers who buy IFPSDUs for infants.

24. Not having, or exempting companies from prescribed names regulation in IFPSDUs may be detrimental to breastfeeding. Naming IFPSDU in any manner that implies it as a substitute for breastmilk will further discourage breastfeeding.

Q19 Could one category of IFPSDU be used for all additional food additives, or should additional or modified subcategories be devised (noting the possible four subcategories in section 2.2).

25. Ideally additional or modified subcategories should be devised for IFPSDU's but it in the case of pre term infant formula it is unquestionably necessary. Studies have shown that because of the increase in available products, "the clinician must rely on nutrition and physical assessment, consideration of metabolic abnormalities, evaluation of GI function, overall medical condition, and expected outcomes for each individual patient to determine product selection (Bankhead et.al, 2009).
26. This systematic comparison of the patient's condition and nutrient needs with the specific properties of the available nutritional formulas can be used to identify the enteral formula that will most closely meet the individual's requirements. Subcategories help clinicians who prescribe IFPSDUs in judging the correct formula for the individual, as each is a case unique in itself.
27. Education is usually offered to health professionals by the industry to inform understanding of the differences of the varied number of formula choices in the market place.

Q25 To what extent is pre-term infant formula used following hospital discharge and how do caregivers access it (for example, by prescription)?

28. Pre term infant formula is prescribed for pre-term and low birth weight (LBW) infants *and* unwell children's nutrition, but we do not have information about the extent of its use.

29. The Canterbury Pathway for "Food Hypersensitivity in Infants" which indicates prescribed access is appended for your information (appendix 1).
30. Access to formula for preterm infants (and special dietary formulae) funded by PHARMAC is via special authority. Ie It is prescribed by a paediatrician or doctor with a GP vocational scope of practice, in consultation with a dietician who authorize a special authority (SA) number for families to access the formula through a pharmacy at a determined rate. Families requesting speciality formulae must seek advice from their health professional.
31. NZNO advocates for Nurse Practitioners (NPs) with an appropriate scope of practice to be able to prescribe IFPSDUs to avoid delayed access to the right nutrition for vulnerable infants. Legislation implementing a proposed new therapeutic products regulatory regime may change means of access, but this has already been considerably delayed so it seems unlikely in the near term.

Q26 Would you support the requirement for a statement that the product must be used under medical supervision, where the wording is not prescribed (an approach which harmonises with the overseas and international requirements)? Please describe your reasons why you do/do not support.

32. Yes. NZNO supports prescription-first IFPSDUs, and front labelling that states consumers should first seek advice from their health profession before consuming IFPSDUs.

33. For most of the uses described, labels provide only a portion of the information needed. Although the compositional labels refer to recommended nutrient levels, this information must be combined with other information to make valid conclusions about dietary adequacy, which is why a statement about the need for medical supervision is required.

Q28 Are there any specific FSMP labelling requirements that should apply to all IFPSDU?

Yes. These should be guided by the Code *and* the General Standard for the Labelling of Pre-packaged Foods, considering they may be available for retail purchase. The Code does not refer to nutrition labelling specifically, but sets down the underlying principles that "pre-packaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect".

Q29 What specific labelling requirements for the safe preparation and use of IFPSDUs are being used that contradict the general requirements set out in subsection 2.9.1—19(3) of Standard 2.9.1?

34. The containers should be labelled as to their focus (special purpose), and include the ingredients, along with the chemical composition, to inform the professionals prescribing.

35. A statement to the effect that it should only be used on the advice of a health professional should be on the front.

36. Instructions on how to make the proper concentration of the formula along with hygiene requirements should be clearly visible. The importance of clear, non-ambiguous language, and rigorous enforcement cannot be overestimated.

Exemption from 'breast is best' warning statement

37. The Code stipulates that labels:
    a) cannot make nutritional and health claims or include images that idealize infant formula;
    b) must include clear instructions on how to use the product; and
    c) must carry messages about the superiority of breastfeeding over formula and the risks of not breastfeeding.

38. It is notable that even though “follow-up” formula is unnecessary and unsuitable as a breastmilk replacement, it is marketed in a way that may cause confusion and have a negative impact on breastfeeding (World Health Organization, 2013).

39. This same risk applies to special preterm infant formulae, indeed is even more pronounced for pre-term infants due to the likelihood that lactation is in the throes of being established (whereas for babies older than 6 months risking being offered ‘follow-on formula’, lactation has already been underway for 6 months, so they are less vulnerable.)

40. Accordingly, FSANZ must ensure that this would not be the case for IFPSDUs, and require labelling that makes it easy for consumers to distinguish differences between infant formula, follow-up formula, IFPSDUs and breastmilk.

41. NZNO is concerned that FSANZ has not put out the issue of “breast is best” warning statement to stakeholders in this consultation. Breastmilk provides the optimal nutrition for infants, including and especially for infants with special dietary needs. There are very special and rare cases where infants are not able to have breastmilk eg death of mother; but for infants with illness such as congenital heart disease, asthmas etc, breastmilk is still considered to be the optimal nutrition and there are benefit to mothers in expressing milk or direct breastfeeding (even with aids to concurrently supply fortified material) in terms of promoting attachment and a more natural sucking action.
42. In Proposal P93 , FSANZ considered the statement was not relevant for infants with these conditions because breast milk is not appropriate for infants with medical conditions. The exemption also recognised that IFPMIRHM are used under the supervision of a health professional. NZNO strongly rejects this rationale.
43. The mother’s milk is the most suitable form of feeding for the pre-term and low birth weight infant because the composition of the milk produced is designed to meet the specific needs of the premature newborn

(Langdon, 2000). Premature milk exhibits increased bioavailability of nutrients, immunologic properties, hormones, enzymes and growth factors (Pereira, 1995) which allow it to provide protection and suitable growth and development for the infant. An extensive review by Kovar et. al. (1984) also attributes lower infant mortality, decreased disease-specific morbidity, and lower rates of allergic disease to feeding hind milk to the pre-term and low birth weight infant.

44. The exemption of the “breast is best” warning statement on any infant formulae goes against the Code.
45. Exempting “Breast is best” warnings will be detrimental to breastfeeding in principle, as this may lead mothers to think that infant formula is the ideal food for *all babies,* regardless of age, or health condition, or may persuade those who have had premature babies that the formula might be better.

Q30 What evidence can you provide to support concerns regarding inappropriate access to any IFPSDU?

46. For most New Zealand families, even if available, IFPSDUs are generally unaffordable without the PHARMAC subsidy.

47. However, because they are designed for specific medical conditions affecting highly vulnerable people, it is important to be vigilant about inappropriate access.

CONCLUSION

In conclusion NZNO, **supports a** prescribed name for the category of IFPSDUs for those with medical conditions, and supports a named subcategory for preterm infant formula, at least. We recommend that these are prescription only and carry a warning label to that effect.

We recommend that you **agree** to regulation labelling and marketing IFPSDUs that is consistent with the substance and intent of the Code. We advise against exempting the ‘Breast is best’ (or amended version)

statement, and recommend requiring a statement to the effect that infant formula should only be used on the advice of a health professional.

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APPENDIX 1

Canterbury Pathway for "Food Hypersensitivity in Infants".

IgE mediated - eliminate food allergen from diet

Strict elimination means careful reading of labels and looking for "hidden" sources of the food allergen.

See also: Allergen Labelling Guide.

Cow's Milk Allergy

Infants who require an alternative form of milk:

The following are **not suitable** as treatment for cow's milk allergy:

- goat's milk and other mammalian milks
- rice and oat milk
- A2 milk
- lactose-free milk
- partially hydrolysed formulae, such as NAN-HA.

Suitable initial formulas that require special authority are:

- Infants aged < 6 months of age - extensively hydrolysed formula e.g., Pepti-Junior
- Infants aged > 6 months of age - soy formula (need to establish infant tolerating soy) - no longer funded by Pharmac
- Anaphylaxis at any age - amino acid formula e.g., Neocate™, Elecare™

To obtain a special authority for an amino acid formula e.g., Neocate™, Elecare™:

- an extensively hydrolysed formula must have been trialled (2 to 4 weeks), or
- the child has had anaphylaxis to cow's milk protein, or
- has eosinophilic oesophagitis.

General practitioners are able to apply for special authority:

- Special Authority form - Extensively hydrolysed formula
- Special Authority form - Amino acid formula