SUBMISSION ON

CONSULTATION PAPER ON INFANT FORMULA PRODUCTS FOR SPECIAL DIETARY USES

Submission to: Food Standards Australia New Zealand

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Introduction:

Women's Health Action is a women's health promotion, information and consumer advisory service. We are a non-government organisation that works with health professionals, policy makers and other not for profit organisations to influence and inform health policy and service delivery for women. We are highly regarded as leaders in the provision of quality, evidence-based consumer-focused information and advice to ensure health policy and service delivery meets the needs of diverse women, and has intended and equitable outcomes. We have a special focus on maternal and child health policy and promotion, as well as women's sexual and reproductive human rights (SRHR).

We provide:

- Expertise in the development of high-quality health consumer information resources.
- Consumer representation and women's health perspectives in a range of consultations, working parties and health service reviews.
- Discussion forums, seminars and presentations on women's health, public health and gender issues
- Evidence-based analysis and advice to health providers, NGOs and DHBs, the Ministry of Health, and other public agencies on women's health (including screening), public health, gender and consumer issues including a focus on reducing inequalities particularly for Maori women.
- A range of breastfeeding promotion activities which connects us with young women, their families, and communities.

The following submission presents our perspectives on some of the areas discussed in the consultation paper on infant formula products for special dietary uses

This submission is informed by our extensive background in maternal and child health promotion and policy analysis and through our knowledge and understanding of the spirit and intent of the International Code of Marketing of Breast-milk Substitutes. **Please note** that in addition to the views of Women's Health Action, aspects of this submission represents the views of wider networks with whom we are involved including:

- Formula feeding women
- Health Professionals (including midwives and lactation consultants)

General comments:

We consider that the consultation on infant formula products for special dietary uses is timely and necessary to ensure consumer safety and confidence, and to ensure the activities of the infant formula industry do not undermine activities towards the protection, promotion and support of breastfeeding.

Women's Health Action and our stakeholders involved in this consultation believe that any revisions of the *Regulation of Infant Formula Products in the Australia New Zealand Food Standards Code* should ensure that the three primary objectives (below) of Section 18 of the Food Standards Australia New Zealand Act 1991 (FSANZ Act) lead any revision decisions:

1. The protection of public health and safety;
2. The provision of adequate information relating to food to enable consumers to make informed choices; and
3. The prevention of misleading or deceptive conduct.

1. Introduction

1.6 Current regulatory environment

Q1 *Are any other overseas regulations relevant to IFPSDU?* Nil comments or suggestions made.

2. Regulatory framework

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 IFPSMP, should products developed for pre-term and low birthweight

Women's Health Action supports in principal further development of 'option number 3'. In particular we are keen to see the strengthening of the message that 'all IFPSDU should be used **only** with guidance from a healthcare professional'

We are concerned at the growing body of anecdotal evidence that parents 'self-prescribe' IFPSDU and are therefore not engaging with healthcare professionals to diagnose or manage actual or perceived conditions. Cow's milk allergy (CMA) is a common diagnosis in infants and children. It is clearly over diagnosed in many cases, but it is also underdiagnosed in many others (Lifschitz & Szajewska, 2015; Prescription Foods, 2011). Many health care professionals and consumers confuse CMA with lactose malabsorption, or normal infant gut adjustment when shifting from breastmilk to formula (Lifschitz & Szajewska, 2015). As discussed in (Prescription Foods, 2011) the significant potential for incorrect or over-diagnosis of CMA, exacerbated by misinformation about the significance of milk and food allergies, and the trend for avoidance of cows' milk products make consumers vulnerable to targeted marketing of IFPSDU. In addition to the above, we hold concerns that the over and under diagnosis of CMA and other related conditions are, in part, due to a lack of training among health professionals in understanding *normal* infant feeding behaviour (Lawrence & Lawrence , 2010).

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?*

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

Women's Health Action supports including a category definition for IFPSDU in the Code to increase clarity regarding the specialised nature of IFPSDU. As stated above, we are concerned that these products are being used casually and without consultation with health professionals. We support the introduction of a subcategory for IFPSMP and believe the proposed definition is appropriate.

Q5 – Q11 - Nil comments or suggestions made.

3. Composition

Q12-Q15 - Nil comments or suggestions made.
Q16-Q18 - Nil comments or suggestions made.

4. Food additives

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) - Nil comments or suggestions made.
Q20-23 - Nil comments or suggestions made.

5. Safety

Q24 - Do you support retaining the current maximum PRSL for any IFPSDU? Please provide your rationale. *Nil comments or suggestions made.*

5.2 Contaminant MLs

Comment: Microbiological limits

We are concerned with the lack of awareness among consumers surrounding the non-sterile nature of powdered infant formula and perception amongst many parents that powdered infant formula is sterile product.

Recommendation:

We recommend that a disclosure statement be included in labelling requirements that powdered infant formula is a non-sterile product

6. Labelling

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

Q26 – Q28 *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:*

As above, Women's Health Action strongly supports any efforts to strengthen advice that all IFPSDU should be used **only** with guidance and supervision from an *adequately* trained healthcare professional.

6.5 Labelling information on safe preparation and use

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?

We would like to see (where possible) standardised directions for use and storage of infant formula based on evidence-based best practice. We support the use of World Health Organization 'Guidelines for the safe preparation, storage and handling of powdered infant formula' (World Health Organisation, 2006) as a guiding document for the development of these directions.

6.6 Exemption from 'breast is best' warning statement

We **strongly** disagree, that the 'breast is best warning statement' is not required because 'breast milk is not appropriate for infants with [these] medical conditions'

However, we do not believe that the current requirement to include a 'Breast is best' warning statement provides any meaningful protection of breastfeeding nor does it provide any useful information or support for consumers, we suggest this statement is revised. We believe that to comply with the three primary objectives of Section 18 of the FSANZ Act 1991 consumers do need to be made aware of the potential risks of using IFPSDU without medical guidance. There should also be a statement about the serious health risks of incorrect preparation and storage of infant formula.

7. Distribution and access

We strongly support stakeholder comments made about the concern regarding the availability of IFPSDUs

In particular we agree that readily available IFPSDU may:

- Medicalise' common, normal symptoms in infants
- Encourage self-diagnosis without the accompanying management and review by health professionals
- Lead to the failure to diagnose and manage true conditions
- Lead to the unnecessary replacement of breastfeeding with formulas that are promoted to manage perceived diarrhoea, hunger or unsettled behaviour.

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

There appears to be a dearth of published academic research in this area. However there is strong evidence to support the over-diagnosis of conditions for which IFPSDU products are indicated (Prescription Foods, 2011; Lawrence & Lawrence , 2010). In addition to this, Women's Health Action has a growing body of anecdotal evidence to suggest that IFPSDU products are being used by consumers without seeking medical advice.

We asked a panel of consumers the following question:

Question: 'Those of you who have used: Soy, Goat, (HA) lactose free and low lactose etc, (AR) anti-reflux or colic or constipation formulas - Did you decide to use these through your own research and advice or did you get directed to these formula's by a health professional ?

Answers:

"I used soy for 2/3 of my babies because they couldn't take dairy, i did it on my own and was the best choice for my babies"

"We were on lactose free on my own research. I can't tolerate normal milk so I figured that [child's name] reflux wasn't actually reflux ... It appears I was right 🙂 *doc said just put him on whatever he enjoys and doesn't throw up"*

"[I} used goats milk for a few months. It was my own choice, the doctor told me not [to] because I didn't have a formal diagnose of my baby having any problems with normal formula apart from the fact he was screaming everyday for hours at a time while on it. His fathers side have stomach issues so I guessed he might as well, he's 6months old now and I have switched him back to a regular formula and he's doing fine on it now"

"[low lactose and lactose free] no health professional I talked to was any help. GP said talk to Plunket, Plunket said Breast was best. It was trial and error all by myself. Pretty annoyed really theres not better info/support"

"I ended up resorting to doing my own research as GP was no help and I had no idea what was going on ,was unfamiliar with intolerances but knew my boy's issues weren't normal (as only occurred when we started mix feeding). The Aptamil help line was amazing and helped …. to get samples sent to me of Allerpro"

"Medical professionals weren't super helpful tbh...and we got conflicting info. We spoke to the karicare helpline .. and decided for ourselves. Then stuck to it once we saw what a difference it made. Both HA and de-lac"

"I am allergic to dairy so when my baby became upset and even more gassy on cow's milk formula we tried goat formula and there was an immediate improvement. I suspect she has a dairy intolerance …. So although not directed to do so by my GP after….,we have noticed [huge improvements] after switching to goat.."

Additional comments:

Health claims and representations:

We strongly support the prohibition of nutrition and health claims for infant formula. We believe allowing phrases such as *"Suitable for lactose intolerant babies who are recovering from diarrhoea associated with lactose intolerance"* could be seen by consumers as having therapeutic benefits.

Recommendation:

We would like to see a review of the therapeutic claims made on labels of IFPSDU products.

Conclusion:

We applaud FSANZ for this in depth review of IFPSDU products and its continued acknowledgment of stakeholder perspectives. We thank you for the opportunity to comment on this review and are happy to provide further information or clarification of issues discussed in this submission should that be helpful.