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31 August 2009 **S09.22**

Submission to the Food Regulation Standing Committee (FRSC) Working Group on the Food Regulation Policy – Options Consultation Paper for the Regulation of Infant Formula Products

Introduction

The National Council of Women of New Zealand (NCWNZ) is an umbrella organisation representing 50 nationally organised societies and national members. It has 26 branches throughout the country attended by representatives of those societies and some 150 other societies as well as individual members. The Council's function is to serve women, the family and the community at local, national and international levels through research, study, discussion and action.

This submission has been prepared by the Consumer Affairs Standing Committee following circulation of the questions to NCWNZ members. NCWNZ welcomes the opportunity to consider this consultation paper on Infant Formula Products and comment on the key issues being considered.

NCWNZ has in the past, written submissions on the subject of Infant Formula Products and passed many resolutions on infant health and feeding. Provision of a safe and adequate nutrition for infants as an alternative to breast feeding is necessary and should meet the 3 primary objectives as set out in the FSANZ Act and also update policy guidelines by seeking community comment on issues and options. Consumers and Public Health authorities must have confidence that ingredients added to infant formula products are appropriate to provide health and nutritional benefits to infants as one of the most vulnerable population groups.

Member's responses to questions

Question 1

No

Question 2

International standards of relevance as provided are accepted as adequate.

Question 3

The availability of sufficient labeling information was considered to be important so consumers are not misled, and can make appropriate choices and use products appropriately.

Information provided on packaging, tins or advice leaflets should be clear, easily read and also provide descriptive diagrams showing the measurement per feed as guidelines for correct use. Many parents and caregivers do not understand written English as English is their second language and would find it easier to follow pictures and numbers designating age-appropriate formula product and correct measurement to use.

Affordability of infant formula product was also considered important so all consumers are able to access safe products at reasonable prices. Concern was expressed that manufacturers may attempt to increase profit margins and produce "Premium products" at increased cost to the consumer.

Question 4

In addition to Standard 2.9.1 the infant formula product must replicate breast milk as closely as possible and have an equivalent health outcome as healthy, fully breast fed full term infants. Policy guidelines therefore, need to support appropriate levels of nutrients and ingredients recognized as essential for normal growth and development.

Question 5

Yes, all ingredients and specific ingredients should be subject to pre-market assessment. No manufacturer should add an ingredient to any infant formula without a pre-market assessment. Some responses considered that ingredients, with a history of safe use in the general food supply, should not be added to infant formula products without a full pre-assessment eg pro-biotics. This would be a necessary requirement to meet the primary objective of the joint food setting system and subsequent risk management and risk communication process.

Question 6

Yes, it is the obvious measure when determining the composition of a breast milk substitute. The ultimate desire is for the infant to be healthy and develop as well as a breast fed infant. Health benefit as defined in this paper should equal the health outcome of a breast fed infant. Public health and safety must always be the top priority when considering any health benefit in developing composition of infant formula products.

A few responses considered that it would not be a useful benchmark when determining the composition of infant formula products as there were too many variables.

Question 7

Yes, health benefit should be assessed when regulating infant formula products and would be a useful benchmark. Public Health and safety must always be the top priority when considering any health benefit. However it is acknowledged that with technological advances there is now opportunity for some ingredients that may produce a health benefit and are normally a component of breast milk to be added to infant formula. Some responses asked the question – "When does an infant formula become a pharmaceutical or medicine" with the possible addition of ingredients such as immunoglobulins and cholesterol components?

Question 8

Yes, only ingredients for the purposes of maintaining shelf life, processing aids, additives and nutritive substances. However it is imperative the nutritional composition is not compromised and manufacturers must adhere to the current standard and only include permitted optional ingredients which may be inherently present as a component in breast milk. These should not cause any negative impact on the infant consuming the infant formula product.

Question 9

Responses expressed concern that the addition of optional ingredients by manufacturers was permitted in the Standard 2.9.1 – particularly those over and above the essential nutritional requirements – and would like to see all permitted ingredients mandated.

Appropriate criteria should be developed and optional ingredients become mandatory if there is sufficient evidence that they are necessary for the optimal nutrition of infants and the ingredient is considered to be nutritionally equivalent with components in breast milk and contributes to the positive health outcome of a healthy, full term infant.

Health inequities are certain to result from limited access to the best possible infant formula because of cost and other factors and this must be avoided.

Question 10

Yes – the same policy principles remain, however nutritional composition to meet growing infants will change, but it is acknowledged that infants from 6 months of age are introduced to complementary foods and therefore infant formula is not the sole source of nutrition.

Question 11

It was generally agreed that neonatal dieticians and paediatricians should oversee and guide the dietary management of pre-term neonates or low birth weight infants.

This does not preclude the use of appropriate infant formula products or breast milk with the addition of breast milk fortifiers where required and "prescribed" by the specialists.

Question 12

Yes – pre-market assessment should require the same level of evidence and assessment standards as infant formula products for general use.

Question 13

The same principles apply as for infant formula products for general use to provide healthy growth and development as close as possible to normal breast-fed babies. Rigorous testing must be carried out when providing infant formula product for infants with special conditions eg protein levels and sodium levels may need to be reduced in some cases. This would mean choosing the appropriate infant formula for use on a case by case basis. Some infants are tube fed and others require parenteral nutrition, and very premature babies and some with special conditions are given breast milk. Are there policy principles for infant formula for special health conditions?

Responses agreed generally that special purpose infant formula products should be available only through prescription and subsidized by Government subsidy schemes.

Question 14

Yes – pre-market assess of these products for special health conditions is essential and should be produced with the advice and involvement of specialists working in the area. There should be ongoing surveillance to ensure medically cared for infants are not denied access to these products because of restrictive requirements or increased cost.

Question 15

Yes, it should not be assumed that any proposed ingredient to be added to an infant formula product with the intention of achieving a health benefit – will automatically provide this benefit – without a pre-market assessment. There should be studies looking at efficacy and/or effectiveness to address whether an intervention 'can' work or works in real life setting.

Question 16

Yes – post market surveillance following addition of a new ingredient to an infant formula product to measure the health outcome is necessary.

Cost effectiveness procedures should be applied to prevent the cost of infant formula products escalating and pricing becoming out of reach for the majority of consumers (parents and caregivers). It was considered essential to monitor effects of new ingredients as a health and safety issue with scientific monitoring and research studies.

Question 17

Yes – depending on the ingredient being added to the infant formula product – eg changes in protein composition or addition of immunological compounds would definitely warrant post-market surveillance. Responses expressed concerns that multi-national companies may add ingredients to increase a competitive edge that may compromise health and safety.

Question 18

As outlined in Question 17

In addition concern was expressed that levels of an ingredient added to infant formula product may be vastly different to a similar component in breast milk and subsequently should not be given conditional approval. It would need application of post market surveillance.

Question 19

Yes – provided the 1981 International Code of Marketing of Breast Milk Substitutes is continued and existing standards and measures are dealing effectively with labeling and packaging.

Infant formula product must not be presented as a "better improved liquid food" than breast milk and should be marketed in an appropriate way to enable the purchaser to use the product safely and correctly as an alternative to breast feeding.

Question 20

No other policy options offered for consideration.

Question 21

NCWNZ members considered they did not have the expertise to provide data to support the potential costs or benefits of impacts of the policy options.

Concerns were expressed that infant formula product as a safe and healthy option to breast feeding would become too expensive for many parents and caregivers and less healthy options for infant feeding may be chosen and used as a substitute.

It was acknowledged that costs may increase if the infant formula products continue to meet the objectives as outlined in this paper and address the 3 problem areas associated with the current regulatory framework. It is to be hoped that manufacturers will reduce profit margins and resist seeking a competitive edge in the production and marketing of all infant formula products. Both governments must provide a clear signal to industry on their expectations in respect to these products and the current lack of clarity does not appear to do this.

Question 22

Responses were divided on the preferred option as outlined in the summary.

Option 1 was considered suitable for standard infant formula products to demonstrate health benefit.

Option 2 was considered essential for infant formula product for special health conditions, low birth weight babies and pre-term infants.

Option 2 was considered to provide the optimal evidence of efficacy of health benefit and safety equivalence to breast milk and equivalence of physiological outcomes. Responses supported random controlled studies to provide evidence of effectiveness and efficacy and to address whether an intervention 'can' work or works in a real life setting and confers a health benefit. These are included as trials used in Option 1 and Option 2 to optimally demonstrate effectiveness and safety.

The possibility of increased cost of infant formula products was considered to be an important factor in policy option preference. If Option 2 was the preferred policy option – would this result in a more expensive product? Of paramount importance was the adherence to policy objectives and guidelines.

Post market surveillance was also considered to form an important part of measuring effectiveness particularly in identifying adverse effects and both active and passive surveillance. Evidence based research is of great value and should continue to ensure infant formula products are safe.

NCWNZ thanks the New Zealand Food Safety Authority for the opportunity to comment on this consultation paper on the regulation of Infant Formula Products and looks forward to the outcome and changes to policy that will result from this process.

Elizabeth Bang
National President

Jan Brown
Convener Consumer Affairs Standing Committee