

FOOD MINISTERS' MEETING

Food Regulation Standing Committee

Regulation of Infant Formula Products

SCOPE/AIM

Purpose

This Policy Guideline provides guidance on the expectations of the Australia and New Zealand Food Regulation Ministerial Council for the composition, labelling, advertising and promotion¹ of infant formula products.

It is recognised that breastfeeding is the normal and recommended way to feed an infant and that the regulation of breastmilk substitutes, such as infant formula, has implications for health outcomes for all infants, formula-fed and breastfed.

Infants are a vulnerable population group because they have immature immune systems and organs and are dependent on adults for feeding. For some infants, infant formula products may be the sole or principal source of nutrition. For these reasons there is a greater level of risk to be managed compared to other population groups. The regulatory framework for infant formula products should include requirements commensurate with this level of risk for the composition, labelling, advertising and promotion of infant formula products.

Scope

This Policy Guideline is intended to cover infant formula, follow-on formula and infant formula for special dietary uses for infants from 0 to 12 months of age.

The requirements for the composition, labelling, advertising and promotion of Special Purpose Foods, such as infant formula, are governed by specific standards in Part 2.9 of the Australia New Zealand Food Standards Code (the Food Standards Code). Some of the general provisions in the Food Standards Code also apply to standards in Part 2.9.

The Policy Guidelines on the Fortification of Food with Vitamins and Minerals and the Addition of Substances other than Vitamins and Minerals do not apply to infant formula products. The Policy Guideline on the Intent of Part 2.9 is relevant to the regulation of infant formula products. The Policy Guideline on Nutrition, Health and Related Claims covers potential exclusions from the ability to make claims for certain categories of foods, including infant formula products.

¹ Reference to 'advertising and promotion' in this Policy Guideline is made with reference to section 16(d) of the Food Standards Australia New Zealand Act 1991 (Cth), which provides that information about food used in labelling, promotion and advertising may be subject to regulation by standards and variations of standards made under the Act.

HIGH ORDER POLICY PRINCIPLES

The Food Standards Australia New Zealand Act 1991 establishes a number of objectives for FSANZ in developing or reviewing of food standards (section 18 of the FSANZ Act).

1. The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:
 - a) the protection of public health and safety; and
 - b) the provision of adequate information relating to food to enable consumers to make informed choices; and
 - c) the prevention of misleading or deceptive conduct.
2. In developing or reviewing food regulatory measures and variations of food regulatory measures, the Authority must also have regard to the following:
 - a) the need for standards to be based on risk analysis using the best available scientific evidence;
 - b) the promotion of consistency between domestic and international food standards;
 - c) the desirability of an efficient and internationally competitive food industry;
 - d) the promotion of fair trading in food;
 - e) any written policy guidelines formulated by the Australian and New Zealand Food Regulation Ministerial Council (that was established by the Food Regulations Agreement in 2000)

These objectives apply to the development of standards regulating Infant Formula Products. A number of other policies are also relevant to the development of food standards including:

- the Council Of Australian Governments document 'Principles and Guidelines for National Standard Setting and Regulatory Action by Australia and New Zealand Food Regulatory Ministerial Council and Standard Setting Bodies' (1995, amended 1997) (Australia only);
- New Zealand Code of Good Regulatory Practice (November 1997);
- the Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System;

SPECIFIC POLICY PRINCIPLES – Overarching Principles

Specific Policy Principles are principles that support and are limited by the High Order Principles.

The specific policy principles applying to all infant formula products are:

- a) The regulation of infant formula products should recognise that breastfeeding is the normal and recommended way to feed an infant.
- b) The regulation of infant formula products should not be inconsistent with the national nutrition policies and guidelines of Australia and New Zealand that are relevant to infant feeding.
- c) The regulation of infant formula products should be based on risk analysis, taking into account the vulnerability of the population for whom they are intended and the importance of these products in the diets of formula fed infants.

SPECIFIC POLICY PRINCIPLES - Composition

- d) The composition of infant formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical and/or functional outcomes) of healthy full term exclusively breastfed infants when infant formula used as the sole source of nutrition up to six months of age.
- e) The composition of follow-on formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical or functional outcomes) of healthy full term breastfed infants at the appropriate age when follow-on formula used as the principal source of liquid nourishment in a progressively diversified diet².
- f) The essential composition of infant formula and follow on formula should be prescribed in regulation and must satisfy the nutritional requirements of infants.
- g) Compositional requirements for infant formula and follow-on formula products should only be mandated in regulation where there is sufficient evidence to demonstrate that they are safe and essential for normal growth and development of infants.
- h) The composition of breastmilk should be used as a primary reference for determining the composition of infant formula and follow-on formula.
- i) Pre-market assessment, relative to principles (d) and (e), should be required for any substance proposed to be used in infant formula and follow-on formula that:
 - i. does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or
 - ii. has a history of safe use in these products in Australia and New Zealand, but which, having regard to source³, has a different form/structure, or is produced using a substantially different technique or technology.
- j) Substances subject to pre-market assessment for use in infant formula and follow-on formula should have a substantiated beneficial role in the normal growth and development of infants or children, or a technological role, taking into account, where relevant, the levels of comparable substances in breastmilk. A substance's role in normal growth and development is substantiated where there is appropriate evidence to link the physiological, biochemical and/or functional effects of the substance to specific health outcomes for infants, in infancy or childhood. Particular caution should be applied by the Authority where such links are less clear.

² This Policy Guideline recognises that if an infant is thriving on regular or standard infant formula and complementary foods, there is generally no advantage in changing to a follow-on formula.

³For the sake of clarity, this principle does not apply to substances with a history of safe use in infant formula products in Australia and New Zealand that are sourced from a different supplier.

SPECIFIC POLICY PRINCIPLES – Labelling and Advertising

The specific policy principles applying to the labelling and advertising of all infant formula products are:

- k) The labelling and advertising of infant formula products should be consistent with the World Health Organization International Code of Marketing of Breast Milk Substitutes⁴ as implemented in Australia and New Zealand.
- l) The labelling and advertising of infant formula products should not represent those products as an equivalent to, or better food than, breastmilk.
- m) The labelling and advertising of infant formula products should provide information on the appropriate and safe use of those products.
- n) The Authority should:
 - i. ensure that the prohibitions and restrictions on nutrient content, health, therapeutic, and prophylactic claims in the Food Standards Code are clear and effective for infant formula products; and
 - ii. consider whether the current labelling regime is leading to consumers being misled about the quality or effectiveness of an infant formula product.

SPECIFIC POLICY PRINCIPLES – Infant Formula Products for Special Dietary Uses

Infant formula products for special dietary uses refers to products specifically formulated to meet the dietary needs of:

- premature or low birth weight infants; or
- infants with metabolic, immunological, renal, hepatic and malabsorptive conditions.

These infants have special dietary or medical needs and are an even more vulnerable population group than infants generally. The diet of these infants is usually managed under the supervision of a medical specialist or paediatric dietitian.

As infant formula products for special dietary uses are formulated for relatively small population groups with varying needs, the specific policy principles relating to the composition for infant formula and follow on formula (principles (d)-(h)) above) do not apply to these products. Policy principles relating to the pre-market assessment of substances without a history of safe use in infant formula (i)-(j) may apply to infant formula products for special dietary uses at the discretion of the Authority.

The specific policy principles for infant formula products for special dietary uses are:

- o) Infant formula products for special dietary uses must be safe, suitable and meet the nutritional requirements to support the growth, development and dietary management of the infants for whom they are intended.
- p) The composition of infant formula products for special dietary uses should be based on appropriate scientific evidence.
- q) The labelling and advertising of infant formula products for special dietary uses should clearly specify the special dietary or medical uses for which the product is intended.

⁴ World Health Organization. *International Code of Marketing Breast-milk Substitutes*. Geneva. 1981.

ADDITIONAL POLICY GUIDANCE

Expert group

FSANZ should consider establishing an independent scientific expert group that may provide advice prior to pre-market assessment, based on scientific criteria established by the Authority, on whether:

- i. a substance proposed to be added to infant formula products has a history of safe use in infant formula or follow-on formula in Australia and New Zealand; and
- ii. there is evidence available that the substance has a substantiated beneficial role in the normal growth and development of infants or children.

Relevant international agreements

The regulation of infant formula products in Australia and New Zealand should be consistent to the greatest extent possible with:

- relevant World Health Organization agreements; and
- relevant World Trade Organization agreements, Codex standards and guidelines.

Definitions

For the purpose of this Policy guideline, the following definitions apply:

follow-on formula means an infant formula product represented as either a breastmilk substitute or replacement for infant formula and which can constitute the principal liquid source of nourishment in a progressively diversified diet for infants aged from six to 12 months of age

infant means a person under the age of 12 months

infant formula means an infant formula product represented as a breastmilk substitute for infants and which satisfies, as the sole source of nourishment, the nutritional requirements of infants up to six months of age

infant formula product means a manufactured product based on milk or other edible food constituents of animal, plant, microbial or isolated human cell origin or that have been designed de novo which is nutritionally adequate to serve as the principal liquid source of nourishment for infants.