ATTACHMENT 3

REGULATION IMPACT STATEMENT

PROPOSAL P93 – REVIEW OF INFANT FORMULA

1. INTRODUCTION

The development of food standards by the Australia New Zealand Food Authority (ANZFA) is carried out in accordance with the principles and guidelines adopted by the Council of Australian Governments (COAG)[1] and the draft Code of Good Regulatory Practice (New Zealand).

The review of infant formula (Proposal P93) has been in progress since 1993. Public submissions were received in the preparation of the proposal in 1993, at Full Assessment in 1995 and at the Preliminary Inquiry in 1999. ANZFA completed an Inquiry into the proposed draft standard in November 1999. However, the Inquiry Report and proposed draft standard were not presented to the Australia New Zealand Food Standards Council, due to stakeholder concerns.

Following considerable further consultation with stakeholders since 1999, ANZFA believes it has suitably addressed the concerns of stakeholders. In recognition of the significant time delay and changes that have been made to the draft standard as proposed at Inquiry, the previous regulation impact statement as assessed at Preliminary Inquiry (May 1999) is now revised and updated as part of this Supplementary Final Assessment (Inquiry – s.24). The Office of Regulation Review has assessed this revised regulation impact statement as adequate.

2. BACKGROUND

2.1 History of Proposal P93

Proposal P93 has been in progress since 1993 when the then National Food Authority initiated a review of the existing infant formula standard (R7) of the *Food Standards Code* (Volume 1). Public submissions were received in the preparation of the proposal in 1993 and at Full Assessment in 1995.

On 1 July 1996, an Agreement between Australia and New Zealand (The Treaty) came into force that established a joint Australian New Zealand Food Standards System, which served to underpin the development of the joint *Australia New Zealand Food Standards Code* (Volume 2). Under The Treaty agreement, during the transition period to the joint system, products sold in New Zealand and Australia could comply with either the *New Zealand Food Regulations 1984* (NZFR), (if manufactured or imported into New Zealand) or Volume 1 (existing Australian *Food Standards Code*) until such time as Volume 2 had been developed and became the sole set of regulations for the two countries.

[1] COAG (1997) Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard Setting Bodies.

Volume 2 came into effect in Australia and New Zealand in December 2000. It is expected that most of the existing Australian and New Zealand food regulations (other than Volume 2) will be repealed at the end of 2002.

In 1998, Proposal P93 was included as part of the Review of Food Standards and the development of Volume 2. A round of public consultation in 1999 (Preliminary Inquiry) was included, additional to the usual process, to provide an opportunity for consultation in New Zealand. A draft regulatory impact statement was included in the Preliminary Inquiry Report.

ANZFA completed an Inquiry into the review of infant formula in November 1999. However prior to the date of effect of Volume 2, ANZFA was unable to resolve a number of issues related to the draft standard with industry stakeholders. Consequently, ANZFA proposed a transitional arrangement for infant formula (Proposal P226) that withdrew the draft standard from Volume 2 and maintained the status quo for infant formula, namely Standard R7. This arrangement was to allow ANZFA further time to resolve outstanding issues with stakeholders.

2.2 Regulatory Framework

Under the current transitional arrangements of Volume 2, Standard R7 regulates the composition and labelling of infant formula in Australia. In New Zealand manufacturers currently can choose to comply with either Standard R7 or Regulation 242 of the NZFR. Both Standard R7 and Regulation 242 do not specifically specific provisions for pre-term infant formula or modified formula. The proposed draft standard accommodates all types of infant formula products.

Internationally, Codex standards exist for both for Infant Formula (CODEX STAN 72-1981) and follow-on formula (CODEX STAN 156-1987). The Codex standard for infant formula is currently under review. Completion of this review is not expected within the next two years.

2.3 Current Infant Formula Market

There is strong scientific evidence to show that exclusive breastfeeding to the age of about six months provides the best nutritional start for infants[2]. When compared internationally, initiation rates for breastfeeding in Australia and New Zealand are relatively high (82%[3] and 94%[4] respectively). However the rate of breastfeeding declines significantly with time after birth. In Australia it is estimated that fewer than 20% of infants are achieving the goal of being exclusively breast fed to six months of age[3]. These figures indicate that a substantial number of Australian and New Zealand infants are reliant on the availability of safe alternatives to breast milk for nourishment.

[2] World Health Organisation. The optimal duration of exclusive breastfeeding. Geneva: WHO, 2 April 2001. Note for Press No 7.
[3] National Health and Medical Research Council (2001) Draft Dietary Guidelines for Children and Adolescent, pg 10
[4] Essex C, et al. 1995. Breastfeeding rates in New Zealand in the first six months and the reasons for stopping. NZ Med J 108: 355-7

There is significant international trade in infant formula with 60% of infant formula products being imported from overseas. Five multi-national companies supply the market: two companies manufacture locally (one in Australia and one in New Zealand) whereas three companies import directly into the domestic market. The market for infant formula is static (corresponding to a relatively static birth rate) and is estimated at $118 million in Australia and $18 –20 million in New Zealand.

Products that are imported into Australia and New Zealand are currently formulated and labelled to comply with local food standards. The estimated cost in reformulation or labelling depends on the complexity of changes required. The cost associated with minor re-formulation is estimated at $10 000 per formulation, whereas re-labelling cost for one product line is between $4 300 and $18 000.

Product innovation is strongly linked to advances in scientific research. The existing regulations are outdated and are ambiguous as to whether they permit recent scientific developments to be incorporated into infant formula products. Therefore, currently an inequitable situation exists where product innovation is dependent on manufacturers' interpretation of existing regulations, which may be differ from one manufacturer to another.

2.4 WHO International Code of Marketing of Breast Milk Substitutes

The World Health Organization International Code of Marketing of Breast-milk Substitutes (WHO Code) was adopted at the 34th Session of the World Health Assembly, 20 May 1981. The Code aims, through appropriate marketing and distribution, to contribute to the safe and adequate nutrition of infants by ensuring the proper use of breast milk substitutes. Many countries, including Australia and New Zealand, are signatories to this agreement and have taken action to effect the principles and aims of the WHO Code.

2.5 Implementation of the WHO Code in Australia and New Zealand

The Australian and New Zealand governments have each taken a number of different steps in support of their international commitments to the WHO, either by incorporating the relevant articles of the WHO Code into food standards, or the establishment of voluntary Codes of Practice. The aspects of the WHO Code related to composition and labelling of infant formulas are incorporated into food standards.

The marketing aspects of the WHO Code are implemented in Australia through an authorised agreement under the Trade Practices Act 1974 (the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (1992) (MAIF Agreement). The MAIF Agreement has been adopted by the Infant Formula Manufacturers as their Code of Conduct. The MAIF Agreement is monitored by the Advisory Panel for the Marketing in Australia of Infant Formula (APMAIF).

In Zealand, the marketing aspects of the WHO Code are implemented through an industry Code of Practice (1997) which is monitored by the New Zealand Infant Formula Marketers' Association (NZIFMA).

In both countries the Codes of Practice place certain restrictions on the advertising and promotion of infant formulas. There is general agreement that these Codes of Practice are effective in limiting the advertising of infant formula products to the general public and therefore these restrictions continue, rather than be included in food regulation.

3. PROBLEM

Infants are a very vulnerable group in the community and are at a stage in life where adequate nutrition is essential for their growth and development. Infants that rely either fully or partially on infant formula for their sustenance are at risk if these products do not provide a proper balance of nutrients or contains impurities. Infant formula products are complex and could not be independently verified by consumers; hence it is essential to the health and development of infants that the composition of formula products be assessed as safe under a food standard.

The existing infant formula standards for Australia and New Zealand are out-dated and do not reflect contemporary scientific research. There is confusion for both the infant formula industry and government in the interpretation of the standards, and different judgments are being made on the legality of incorporating scientific developments into the products. There is a need to improve the clarity of the food standards and facilitate the application of recent scientific research to these products.

4. OBJECTIVES

The development and variation of a standard for infant formula must have regard to the following objectives (Section 10, *ANZFA Act* (1991)), which are (in descending priority order):

(a) the protection of public health and safety;

(b) the provision of adequate information relating to food to enable consumers to make informed choices and to prevent fraud and deception;

(c) the promotion of fair trading in food;

(d) the promotion of trade and commerce in the food industry; and

(e) the promotion of consistency between domestic and international food standards where these are at variance.

The specific objectives of Proposal P93 are to:

1. protect the health and safety of formula fed infants;
2. provide carers with enough information about infant formula to enable them to make appropriate choices in feeding their infant and in the safe use of products;
3. develop unambiguous food regulations that reflect contemporary scientific knowledge; and
4. harmonise the food regulations applying to infant formula in Australia and New Zealand.

5. OPTIONS FOR REGULATION

There are two options to this proposal.

Option 1 – Maintain the status quo

This option maintains Standard R7 as regulating infant formula in Australia and allows manufacturers/importers in New Zealand to comply with either Standard R7 or Regulation 242.

Option 2 – Regulation by inclusion of the proposed revised standard in Volume 2.

This option harmonises the regulation of infant formula products in Australia and New Zealand by inclusion of draft Standard 2.9.1 in Volume 2. Draft Standard 2.9.1 prescribes in greater detail the compositional requirements, incorporating recent scientific developments, as well as additional labelling requirements for infant formula products. The standard provides for infant formula products intended for infants with special dietary needs.

5.1. Affected Parties

The parties affected by this proposal are: **consumers** and the general community, particularly formula fed infants and their carers; the **governments** of New Zealand, the States and Territories and the Commonwealth of Australia; and the **infant formula industry** supplying either through the manufacture or importation of products to the Australian and New Zealand markets.

6. IMPACT OF REGULATORY OPTIONS

Option 1 – Maintain the status quo

Benefits

Consumers/Community

- Continued access to the current range of products that are essential to the health and wellbeing of formula fed infants.
- There is sufficient information available to consumers from current product labelling to enable their choices to effectively reflect their preferences.

Government

- The existing standard is effective in ensuring that infant formula products are safe for infants with no negative health impacts.

Industry

- The standard being effective in ensuring product safety, supports the sustainability of the current market and maintains consumer confidence in these products.

Costs

Consumers/Community

- In principle, the current lack of clarity in the regulations can impede product innovation, which in turn has the potential to reduce the future range of products available to consumers. In practise, the market currently provides for considerable diversity.

Government

- Costs of enforcement by government agencies, which are presumed to be small.

Industry

- Increased cost to industry by restriction on ingredients or levels of ingredients that differ from formulas sold overseas or lack of permission for new nutritive substances; necessitating reformulation for the local Australian and New Zealand market.
- Some labelling provisions are different from those required by other countries, which necessitates the relabelling of some formulas.
- Cost to those manufacturers which interpret the current regulations conservatively, and do not supply the market with innovative products.

Option 2 – Regulation by proposed Standard 2.9.1

Benefits

Consumers/Community

- The proposed standard accommodates recent scientific research and product development, allowing formula fed infants to consume products formulated to provide a better nutritional outcome. It allows scope for superior products to be supplied to Australia and New Zealand.
- Greater clarity of the regulation for both composition and labelling of infant formula products provides better information to carers and improves their choices.
- Potential increase in the range of products available

Government

- The greater clarity of regulation, which incorporates the more recent scientific advances in infant formula composition, has the potential to provide for a better nutritional outcome for infants, and reduced enforcement costs.

Industry

- Greater clarity in the regulations leads to less confusion and thereby lowers costs for industry in ensuring compliance with the standard.

- Harmonised Australian and New Zealand regulations with scope for industry innovation, consistent with the latest scientific research and product development that also facilitate international trade.

Costs

Consumers/Community

- There may be products that do not meet the requirements of the new standard and will not be available in the future. This is not expected to be a significant number and it is known that Industry will be making application for assessment of these products during the proposed transition period.

Government

- There are no expected material impacts on the cost of enforcement from this option, and to a certain extent the greater clarity of the regulations may make enforcement easier.

Industry

- Costs to industry associated with any necessary analysis, re-formulation or labelling changes required to comply with the new standard. Industry has indicated that the current costs associated with minor re-formulation is approximately $10 000 per formulation, whereas re-labelling cost for one product line is between $4 300 and $18 000. Two companies have indicated that they will need to re-formulate up to 11 and 8 products, respectively. On this basis, the initial re-formulation costs for one of these companies has been estimated at $1.2 million with on-going costs predicted to be approximately $300 000.

7. CONSULTATION

7.1 Public and Stakeholder Consultation

Three rounds of public consultation have occurred as part of the review of infant formula since 1993. A summary of public submissions from the last consultation is contained at Attachment 7 to the Supplementary Final Assessment Report (Feb 2002).

Additionally, targeted consultations with representatives of industry, health professionals and consumer groups have been conducted. This consultation took place through the establishment of a panel of experts in infant health, an external stakeholder advisory group and the consideration of material provided in submissions.

Following the completion of the Inquiry in November 1999, the infant formula industry requested further consultation on the draft standard claiming some provisions in the standard would affect the affordability and availability of products on the local market. A large number of issues were raised at the time with the key themes being:

- composition particularly where the proposed requirements differed significantly from regulations overseas;

- labelling; and
- special purpose infant formula products.

These issues were considered at a Stakeholders Forum in May 2000, and by the members of the External Advisory Group at a meeting in June 2000. Subsequent meetings between ANZFA staff and industry representatives were also held in August 2000 and in October 2001 to discuss outstanding issues. ANZFA has actively worked with industry stakeholders to resolve all outstanding issues following Inquiry (Nov 1999). ANZFA believes that it has now effectively addressed these issues and has made further recommendations to accommodate the concerns of Industry. Industry has indicated support for these recommendations and the revised draft standard as proposed at Supplementary Final Assessment (Feb 2002). Further details on the assessment of issues and recommendations can be found in Attachment 1 to the Supplementary Final Assessment Report (Feb 2002).

8. RECOMMENDATION

Option 1 satisfies some important objectives of this proposal, namely the basic protection of health and safety of formula fed infants; and provision of information to carers to make appropriate choices in feeding their infant. However, it does not satisfy the other objectives being: development of unambiguous regulations that reflect contemporary scientific knowledge and the harmonisation of regulations in Australia and New Zealand. In contrast, Option 2 satisfies all objectives, and provides for greater clarity of regulation that incorporates the recent scientific advances in infant formula composition, thereby having greater potential to provide for a better nutritional outcome for infants.

Option 2 appears to provide greater net benefits than Option 1. While the transitional costs of Option 2 may be more than minor, ongoing costs of re-formulation and re-labelling are expected to be generally similar. In addition, Option 2 has lower costs in not penalising those manufacturers that interpret the current regulations conservatively and do not market their innovative products. This is an advantage, for Option 2, of greater clarity of the regulations. Option 2 also benefits consumers in allowing scope for superior products to be supplied to the Australia and New Zealand market.

9. IMPLEMENTATION AND REVIEW

9.1 ANZFA Process

It is anticipated that provisions for a 2 year transition period, from the commencement of Standard 2.9.1, will be established involving concurrent operation of the existing regulations (R7) and Standard 2.9.1 to allow manufacturers time to comply with the new regulations.

Monitoring and review of the impact of this regulatory change is likely to occur, in due course, as part of the general evaluation program that ANZFA has in place to evaluate the effectiveness of new standards.

It is also anticipated that ANZFA will closely monitor developments internationally in respect to other agencies' (eg. Codex) review of their respective food standards for infant formula and scientific advances. Any new developments are expected to be considered either through the review of the infant formula standard or by receipt of applications from Industry.

Industry has already indicated that they will be submitting applications to amend the new standard for infant formula products to further update it with the latest scientific developments.

9.2 International and World Trade Organization obligations

Australia and New Zealand are members of the World Trade Organization (WTO) and are bound as parties to WTO agreements. In Australia, an agreement developed by the Council of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the Treaty between the Governments of Australia and New Zealand on joint Food Standards, ANZFA is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

Following Preliminary Inquiry (May 1999), this matter was notified to the WTO as a technical barrier to trade matter as the proposed revisions to the existing infant formula standards are more prescriptive than other standards internationally. One submission from the United States of America was received on this matter.