

**2-04**  
**17 March 2004**

## **FINAL ASSESSMENT REPORT**

### **PROPOSAL P285**

#### **MINOR AMENDMENTS TO STANDARD 2.9.1 - INFANT FORMULA PRODUCTS**

## FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



## **Final Assessment Stage (s.36)**

FSANZ has now completed the assessment of this Proposal and held a single round of public consultation under section 36 of the FSANZ Act. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

If the Ministerial Council does not request FSANZ to review the draft amendments to the Code, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

In New Zealand, the New Zealand Minister of Health gazettes the food standard under the New Zealand Food Act. Following gazettal, the standard takes effect 28 days later.

## **Further Information**

Further information on this Proposal and the assessment process should be addressed to the FSANZ Standards Management Officer at one of the following addresses:

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Assessment reports are available for viewing and downloading from the FSANZ website [www.foodstandards.gov.au](http://www.foodstandards.gov.au) or alternatively paper copies of reports can be requested from FSANZ's Information Officer at [info@foodstandards.gov.au](mailto:info@foodstandards.gov.au) including other general enquiries and requests for information.

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## **Executive Summary and Statement of Reasons**

The purpose of this Proposal is to make minor corrections to Standard 2.9.1 – Infant Formula Products in the *Australia New Zealand Food Standards Code* (the Code). These are to rectify the inadvertent omission of sodium selenate as a permitted form of selenium and to clarify permissions for the L-amino acid ‘cysteine’.

### **Regulatory Problem**

In June 2004, Standard 2.9.1 will become the sole standard for infant formula products. To ensure effective regulation, it is necessary to amend Standard 2.9.1 prior to that date to:

- rectify the inadvertent omission of sodium selenate, as a source of selenium, from the permitted forms of vitamins and minerals for use in infant formula product; and
- clarify ‘cysteine’ as it relates to protein quality to permit the addition of either L-cysteine or L-cystine to infant formula products.

### **Options**

There were two options proposed at Final Assessment:

1. Adopt the proposed draft variations to Standard 2.9.1 of the Code to include sodium selenate as a permitted form of selenium in Schedule 1; and to clarify ‘cysteine’ as it relates to protein quality to permit the addition of either L-cysteine or L-cystine to infant formula products.
2. Reject the proposed draft amendments to Standard 2.9.1 of the Code.

### **Impacts**

The draft variations in this Proposal have been prepared to rectify issues of minor significance and complexity identified in Standard 2.9.1 of the Code. FSANZ has assessed the proposed changes (as per Option 1) as being unlikely to significantly affect costs for any affected parties but more likely to reduce uncertainty for manufacturers of infant formula products, resulting in increased compliance with the Code and greater confidence in the Australian and New Zealand food standards setting system.

### **Consultation**

FSANZ had decided, pursuant to section 36 of the FSANZ Act, to omit to invite public submissions in relation to the Proposal prior to making a Draft Assessment. A total of 9 submissions were received (Attachment 2). All submitters supported the proposed amendments.

### **Conclusion and Statement of Reasons**

Option 1 is the preferred regulatory option because it:

- provides certainty for infant formula manufacturers in complying with Standard 2.9.1 prior to the end of the transition period;
- does not prejudice the section 10 objectives of the FSANZ Act; and
- is consistent with international standards thereby promoting an efficient and internationally competitive food industry.

Therefore it is recommended that the draft variations to Standard 2.9.1 – Infant Formula Products (Attachment 1), incorporating the inclusion of sodium selenate as a permitted form of selenium in Schedule 1 and clarification of ‘cysteine’ so as to permit the addition of either L-cysteine or L-cystine, be adopted in the Code.

## **1. Introduction**

The purpose of this Proposal is to make minor corrections to Standard 2.9.1 – Infant Formula Products in the *Australia New Zealand Food Standards Code* (the Code). These are to rectify the inadvertent omission of sodium selenate as a permitted form of selenium and to clarify permissions for the L-amino acid ‘cysteine’.

The Proposal has been developed according to the simplified procedures under s.36 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) as Food Standards Australia New Zealand (FSANZ) is satisfied that the Proposal raises issues of minor significance and complexity only. Under these simplified procedures FSANZ has omitted to invite public comment in relation to the Proposal prior to making a Draft Assessment.

In December 2003, FSANZ released the Initial / Draft Assessment Report and invited public submissions. A summary of submitter comments is at Attachment 2. This Final Assessment Report explains why the proposed draft variations to the Code (Attachment 1) have been approved.

## **2. Background**

### **2.1 Standard 2.9.1 - Infant Formula Products**

In May 2002, FSANZ finalised Proposal P93 – Review of Infant Formula (Proposal P93) and recommended to the then Australia New Zealand Food Standards Council that proposed draft Standard 2.9.1 – Infant Formula Products be incorporated in the Code. Standard 2.9.1 was subsequently gazetted on 20 June 2002<sup>1</sup>.

Currently a transitional arrangement exists that allows manufacturers to comply with either Standard 2.9.1 or Standard 1.1A.1 - Transitional Standard for Infant Formula Products, which incorporates the previous Australian (Standard R7 of the Australian *Food Standards Code*) and New Zealand (Regulation 242 of the New Zealand *Food Regulations 1984*) infant formula standards. This transitional arrangement will cease in June 2004, when Standard 2.9.1 will become the sole standard for infant formula products in Australia and New Zealand.

### **2.2 Sodium Selenate**

In a letter to FSANZ dated 16 September 2003, Nestlé Australia Ltd drew attention to the inadvertent omission of sodium selenate from the permitted forms of selenium for addition to infant formula products.

Subclause 24(1) of Standard 2.9.1 requires selenium to be present in infant formula in an amount between 0.25 – 1.19 µg / 100 kJ. In meeting this requirement, selenium may be added to infant formula if it is in a permitted form as listed in Schedule 1 – Permitted Forms of Vitamins and Minerals in Infant Formula Products in Standard 2.9.1 [subclause 24(1)(a)].

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<sup>1</sup> Commonwealth of Australia Gazette. Amendment No.60 to the *Food Standards Code*. 20 June 2002.

During Proposal P93, it was recommended<sup>2</sup> that sodium selenate be included in Schedule 1. However, sodium selenate was unintentionally omitted from the Schedule as gazetted in June 2002.

### **2.3 Clarification of ‘cysteine’**

Cysteine is an amino acid that readily oxidises to form cystine, a dimer of two cysteine molecules linked together via a disulphide bond. Both cysteine (monomer) and cystine (dimer) can be present in infant formula products either as naturally occurring constituents of an ingredient or by addition, usually to improve protein quality.

Cysteine is not an essential amino acid as it can be synthesized from methionine, an essential amino acid. However there is evidence that that in young, premature or low birth weight infants this conversion does not occur and therefore, in this instance, cysteine is considered essential.

Standard 2.9.1 requires infant formula products to meet a specified minimum amino acid profile (table to clause 22 and clause 32), which includes cysteine (summed with methionine). As cysteine is essential for some infants, subclauses 22(2) and subclause 32(3) specify a minimum level for cysteine of 6 mg / 100 kJ. In addition, Standard 2.9.1 permits amino acids to be added to infant formula but only to improve the protein quality and they must be in the L-form of the amino acid as listed in the tables to clauses 22 and 32, i.e. as L-cysteine.

Since the commencement of Standard 2.9.1, FSANZ has become aware that the listing of ‘cysteine’ in the specified amino acid profile has created some uncertainty for manufacturers in complying with Standard 2.9.1. In particular, it is unclear whether L-cystine (dimer) can be added to infant formula products to meet the specified protein quality requirements.

## **3. Regulatory Problem**

In June 2004, Standard 2.9.1 will become the sole standard for infant formula products. To ensure effective regulation, it is necessary to amend Standard 2.9.1 prior to that date to:

- rectify the inadvertent omission of sodium selenate, as a source of selenium, from the permitted forms of vitamins and minerals for use in infant formula product; and
- clarify ‘cysteine’ as it relates to protein quality to permit the addition of either L-cysteine or L-cystine to infant formula products.

## **4. Objective**

FSANZ’s three primary objectives in developing or varying a food standard are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;

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<sup>2</sup> Section 6.4.3 4 of the Supplementary Final Assessment Report, Proposal P93 – Review of Infant Formula, pg 67 [http://www.foodstandards.gov.au/srcfiles/P93\\_Attach1.pdf](http://www.foodstandards.gov.au/srcfiles/P93_Attach1.pdf)



- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

## 5. Relevant Issues

### 5.1 Permitted Forms of Selenium

Currently Standard 2.9.1 permits the addition of two forms of selenium, namely sodium selenite and seleno-methionine. At the time of the infant formula review<sup>3</sup>, Codex did not give permission for the use of specific forms of selenium. Consequently FSANZ obtained information which concluded that *fortification of foods with either selenate or selenite would equally be efficient in providing bioavailable selenium*.

Since that time, Codex has commenced a review of the Codex Advisory List(s) of Mineral Salts and Vitamin Compounds for the Use in Foods for Infants and Children (CAC/GL 10-1979). The most recent revised draft list<sup>4</sup> includes sodium selenate as a permitted form of selenium for addition to infant formula. In addition the European Commission (EC) Directive for infant formulae and follow-on formulae (91/321/EEC) permits the addition of both sodium selenite and sodium selenate.

#### 5.1.1 Conclusion

Sodium selenate was originally intended to be included as a permitted form of selenium in Schedule 1 of Standard 2.9.1, and this permission is consistent with international standards.

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<sup>3</sup> Section 6.4.3 4 of the Supplementary Final Assessment Report, Proposal P93 – Review of Infant Formula, pg 67 [http://www.foodstandards.gov.au/srcfiles/P93\\_Attach1.pdf](http://www.foodstandards.gov.au/srcfiles/P93_Attach1.pdf)

<sup>4</sup> Agenda paper CX/NFSDU 03/8 of the 25<sup>th</sup> Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), Bonn, Germany, 3 – 7 November 2003

## 5.2 Cysteine versus Cystine

During Proposal P93 it was proposed that the quality of protein in infant formula be the same as that of human milk. Therefore, the amino acid profile proposed was based on values as recommended by FAO/WHO in 1985 and again in 1991<sup>5</sup>. This FAO/WHO amino acid profile includes a value for cystine (summed with methionine).

Previously the amino acid profile required by Standard R7 referred to cystine. Regulation 242 did not include any specific requirements in relation to cystine/cysteine. There appears to be no apparent reason why the terminology for cystine/cysteine was changed in the course of Proposal P93 and why 'cysteine' was subsequently incorporated into Standard 2.9.1. This unintentional change however has created uncertainty on the permission for the addition of L-cystine to infant formula.

The Supplementary Final Assessment Report (2002) of Proposal P93 noted that the proposed minimum level of cysteine corresponds to the minimum level required by the EC Directive on infant formulae and follow-on formulae (91/321/EEC). However, the EC Directive makes reference to 'cystine' and permits the addition of both L-cysteine and L-cystine.

### 5.2.1 Conclusion

As the amino acid profile contained in Standard 2.9.1 is based on a profile that has reference to 'cystine', for clarity it would seem prudent to preferably reflect this terminology in Standard 2.9.1. This is also consistent with Standard R7 and the EC Directive. However a reference to both cysteine and cystine by adoption of the term 'cyst(e)ine' would assure that both the monomer and dimer forms are explicitly acknowledged in Standard 2.9.1. Additionally, this will also permit the addition of either L-cystine or L-cysteine, which is consistent with EC requirements.

## 5.3 Issues raised in submissions

There were no issues raised in submissions that needed to be addressed.

## 6. Regulatory Options

There are two options proposed at Final Assessment:

### Option 1

Adopt the proposed draft variations to Standard 2.9.1 of the Code to include sodium selenate as a permitted form of selenium in Schedule 1; and to clarify 'cysteine' as it relates to protein quality to permit the addition of either L-cysteine or L-cystine to infant formula products.

### Option2

Reject the proposed draft amendments to Standard 2.9.1 of the Code.

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<sup>5</sup> Protein Quality Evaluation (1991) Report of the Joint FAO/WHO Expert Consultation. FAO Rome

## **7. Impact Analysis**

### **7.1 Affected Parties**

The parties affected by this Proposal are: **consumers**, primarily infants and their carers; **manufacturers** and **importers** of infant formula products; and the **Governments** of New Zealand, the States and Territories and the Commonwealth of Australia.

### **7.2 Impact Analysis**

FSANZ is required, in the course of developing regulations suitable for adoption in Australia and New Zealand, to consider the impact of various options (including non-regulatory options) on all sectors of the community, including consumers, the food industry and governments in both countries. The regulatory impact assessment is conducted so as to identify and evaluate the advantages of regulation.

The proposed changes considered by this Proposal are minor and therefore are not expected to significantly affect costs to the public, government or industry. However, if adopted, they are likely to reduce uncertainty for manufacturers of infant formula products, resulting in increased compliance with the Code and greater confidence in the Australian and New Zealand food standards setting system.

Furthermore, there are no perceived benefits associated with maintaining the *status quo* (Option 2) and the proposed amendments are not expected to adversely affect international trade.

## **8. Consultation**

FSANZ had decided, pursuant to section 36 of the FSANZ Act, to omit to invite public submissions in relation to the Proposal prior to making a Draft Assessment. FSANZ made this decision because it was satisfied that the Proposal raised issues of minor significance or complexity only.

The Initial / Draft Assessment Report for this Proposal was released for a shortened consultation period from 17 December 2003 to 21 January 2004. The length of consultation was shortened due to the urgency in resolving the issues prior to the end of the transition period.

A total of 9 submissions were received. Details of submitters and a summary of their comments are provided at Attachment 2. All submitters supported the proposed amendments.

### **8.2 World Trade Organization (WTO)**

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

The proposed amendments were considered minor and therefore unlikely to raise Sanitary/Phytosanitary (SPS) or Technical Barriers to Trade (TBT) issues; consequently it was not considered necessary to notify the WTO.

## **9. Conclusion and Recommendation**

The proposed draft variations in this Proposal have been prepared to rectify issues of minor significance and complexity identified in Standard 2.9.1 of the Code. FSANZ has assessed that the proposed changes (as per Option 1) are unlikely to significantly affect costs for any affected parties but rather are more likely to reduce uncertainty for manufacturers of infant formula products, resulting in increased compliance with the Code and greater confidence in the Australian and New Zealand food standards setting system.

Therefore Option 1 is the preferred regulatory option because it:

- provides certainty for infant formula manufacturers in complying with Standard 2.9.1;
- does not prejudice the section 10 objectives of the FSANZ Act; and
- is consistent with international standards thereby promoting an efficient and internationally competitive food industry.

The draft amendments to Standard 2.9.1 – Infant Formula Products (Attachment 1), incorporating the inclusion of sodium selenate as a permitted form of selenium in Schedule 1 and clarification of ‘cysteine’ so as to permit the addition of either L-cysteine or L-cystine, are therefore approved.

## **10. Implementation and review**

It is proposed that the draft amendments to the Code come into effect upon gazettal.

### **ATTACHMENTS**

1. Draft variations to the *Australia New Zealand Food Standards Code*.
2. Summary of submissions

**DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE**

**To commence: on gazettal**

[1] *Standard 2.9.1 of the Australia New Zealand Food Standards Code is varied by –*

[1.1] *omitting from clauses 22 and 32, all references to cysteine, substituting –*

*cyst(e)ine*

[1.2] *inserting in clauses 22 and 32, at the end of the clause –*

**Editorial note:**

A reference to cyst(e)ine covers both dimer and monomer forms – that is, cystine and cysteine.

[1.2] *inserting in Schedule 1, Column 2, as a permitted form for Selenium –*

*sodium selenate*

## Summary of Submissions

FSANZ received 8 submissions in response to public consultation on Proposal P285- Minor Amendments to Standard 2.9.1 – Infant Formula Products: sodium selenate as a permitted form of selenium; and clarification of ‘cysteine’ during the public consultation period of 17 December 2003 to 21 January 2004. A summary of submitter comments is provided in the table below.

Two regulatory options were presented in the Initial/Draft Assessment Report. These were:

**Option 1** – Adopt the proposed draft variations to Standard 2.9.1 of the Code to include sodium selenate a permitted form of selenium in Schedule 1; and to clarify ‘cysteine’ s it relates to protein quality to permit the addition of either L-cysteine or L-cystine to infant formula products; and

**Option 2** – Reject the proposed draft amendments to Standard 2.9.1 of the Code.

No.	Submitter	Submission Comments
1	Australian Food and Grocery Council (AFGC)	<b>Supports Option 1</b>  Noted that the proposed recommendations are consistent with the objectives of food standards – namely the protection of public health and safety and the other matters to which FSANZ must have regard; in particular, the promotion of consistency between domestic and international food standards and the desirability of an efficient and internationally competitive food industry.
2	Infant Formula Manufacturers Association (IFMAA)  Orin Chisholm	<b>Supports Option 1</b>  No additional comments.
3	Nestle  Robyn Banks	<b>Supports Option 1</b>  Noted that if proposed changes are not adopted there will be a cost to manufacturers that routinely use sodium selenate and L-cystine in infant formula products as the transitional standard permits.
4	New Zealand Food Safety Authority (NZFSA)  Carole Inkster	<b>Supports Option 1</b>  Noted that sodium selenate, L-cystine and L-cysteine are being considered for inclusion in the Codex Alimentarius Commission: Advisory List(s) of Mineral Salts and Vitamin Compounds for Infants and Young Children by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). Also highlighted that the proposed process involves evaluation for safety, purity and appropriateness for use in infant products.
5	Wyeth  Orin Chisholm	<b>Supports Option 1</b>  No additional comments.

No.	Submitter	Submission Comments
6	Food Technology Association of Victoria Inc (FTAV)	<b>Supports Option 1</b> No additional comments
7	Department of Agriculture, Fisheries and Forestry (DAFF)  Trent Brady	<b>Supports Option 1</b> Expects that the proposed amendment to have no regulatory impact under the <i>Imported Food Control Act 1992</i> .
8	Fonterra Co-operative Group  Joan Wright	<b>Supports Option 1</b> No additional comments.
9	Heinz Watties NZ and Heinz Australia  Julie Dick	<b>Supports Option 1</b> No additional comments.