

5-06 9 August 2006

FINAL ASSESSMENT REPORT

PROPOSAL P302

MINOR AMENDMENTS OMNIBUS VI

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to http://www.foodstandards.gov.au/standardsdevelopment/

EXECUTIVE SUMMARY

Purpose

Food Standards Australia New Zealand (FSANZ) has previously prepared five minor omnibus Proposals (P245, P254, P262, P266 and P284) to correct errors that raised issues of minor significance or complexity in the *Australia New Zealand Food Standards Code* (the Code). Proposal P302 is the sixth minor amendments omnibus. The proposed amendments are intended to correct minor errors such as inconsistencies and ambiguities, omissions, misspellings and grammatical errors.

Decision

The proposed draft variations contained in this Proposal have been prepared to correct errors that raise issues of minor significance or complexity only, identified since the adoption of the Code and previous omnibus corrections.

Reasons for Decision

• This will ensure that the Code is as clear, correct and precise as possible.

Consultation

Under section 36 of the FSANZ Act, FSANZ decided to omit one round of public consultation as it is satisfied that the Proposal raises issues of minor significance and complexity only. Public comment on the Initial/Draft Assessment Report for this Proposal was sought from 4 July 2006 till 17 July 2006. Four public submissions were received.

CONTENTS

| INTRODUCTION3 | | | | |
|---------------|---|--|--|--|
| 1. | BACKGROUND3 | | | |
| 2. | THE PROBLEM | | | |
| 3. | DBJECTIVES | | | |
| 4. | XEY ASSESSMENT ISSUES4 | | | |
| RISK | SSESSMENT4 | | | |
| 5. | RISK ASSESSMENT SUMMARY4 | | | |
| RISK | IANAGEMENT5 | | | |
| 6. | SSUES | | | |
| 6. | Ancillary Documents5 | | | |
| | 5.1.1 Commentary5 | | | |
| 6. | Chapter 1 – General Food Standards5 | | | |
| | Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and | | | |
| | General Prohibition | | | |
| | Standard 1.1A.1 – Transitional Standard for Infant Formula Products7 | | | |
| | Standard 1.1A.3 – Transitional Standard for Country of Origin Labelling | | | |
| | Requirements | | | |
| | 5.2.4 Standard 1.1A.4 – Transitional Standard for the Labelling of Pollen and | | | |
| | Royal Jelly | | | |
| | 5.2.5 Standard 1.1A.5 – Transitional Standard for the Warning Statement for | | | |
| | Condensed Milk, Modified Milk and Skim Milk | | | |
| | Drinks 7 | | | |
| | 5.2.7 Standard 1.2.4 – Labelling of Ingredients | | | |
| | 5.2.8 Standard 1.2.8 – Nutrition Information Requirements | | | |
| | 5.2.9 Standard 1.2.11 – Country of Origin Requirements | | | |
| | 5.2.10 Standard 1.3.1 – Country of Origin Requirements | | | |
| | 5.2.11 Standard 1.3.3 – Processing Aids | | | |
| | 5.2.12 Standard 1.3.4 – Identity and Purity | | | |
| | 5.2.13 Standard 1.4.2 – Maximum Residue Limits | | | |
| | 5.2.14 Standard 1.5.2 – Food Produced using Gene Technology | | | |
| | 5.2.15 Standard 1.5.2 Food Froduced using Gene Technology | | | |
| | 5.2.16 Standard 1.6.2 – Processing Requirements 10 | | | |
| 6. | Chapter 2 – Food Product Standards | | | |
| ٥. | 5.3.1 Standard 2.1.1 – Cereals and Cereal Products | | | |
| | 3.3.2 Standard 2.2.3 – Fish and Fish Products | | | |
| | Standard 2.4.2 – Edible Oil Spreads | | | |
| | 5.3.4 Standard 2.6.3 – Kava | | | |
| | Standard 2.9.1 – Infant Formula Products | | | |
| 6. | Chapter 3 – Food Safety Standards12 | | | |
| | Standard 3.1.1 – Interpretation And Application | | | |
| | Standard 3.2.2 – Food Safety Practices and General Requirements12 | | | |
| 6. | Chapter 4 – Primary Production Standards12 | | | |
| | Standard 4.2.1 – Primary Production And Processing Standard For Seafood 12 | | | |

| 7. Options | 12 |
|---|--|
| 8. IMPACT ANALYSIS | |
| 8.1 Affected Parties | 12 |
| 8.2 Benefit Cost Analysis | |
| COMMUNICATION | 13 |
| 9. COMMUNICATION AND CONSULTATION STRATEGY | 13 |
| 10. Consultation | 13 |
| 10.1 Public Consultation | 13 |
| 10.2 World Trade Organization (WTO) | LYSIS 12 Parties 12 Cost Analysis 13 DN 13 TION AND CONSULTATION STRATEGY 13 ATION 13 Consultation 13 Trade Organization (WTO) 14 ON AND PREFERRED OPTION 14 TATION 14 1 - DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS 15 |
| CONCLUSION | 14 |
| 11. CONCLUSION AND PREFERRED OPTION | 14 |
| 12. Implementation | 14 |
| ATTACHMENT 1 - DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND FOOD S | STANDARDS |
| CODE | 15 |
| ATTACHMENT 2 - SUMMARY OF SUBMISSIONS AND FSANZ RESOLUTION | |

INTRODUCTION

1. Background

In December 2002, the Code became the sole repository of food product standards in Australia and New Zealand. It is therefore important that the Code be as accurate, unambiguous and as correct as possible.

2. The Problem

Since the gazettal of the Code in December 2000, a number of matters that raise issues of minor significance or complexity have been identified as needing amendment. These include inconsistencies, misspellings, grammatical errors, omissions and items requiring updating or clarification. These amendments are required to ensure that the requirements contained in the Code are correctly expressed; thereby furthering FSANZ's section 10 objectives. A number of these matters have been corrected already by amendments agreed in the completed Proposals P245, P254, P262, P266, and P284.

3. Objectives

This new Proposal includes a number of minor amendments to the Code which have been identified since the previous Omnibus. It is expected that there will be regular Omnibus papers to address minor amendments and corrections to the Code as they are identified.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;
- 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.

4. Key Assessment Issues

In seeking to make minor amendments to the Code, FSANZ seeks to maintain the integrity of the Code so protecting public health and safety, ensuring consumers have adequate information and preventing false and misleading conduct.

RISK ASSESSMENT

5. Risk Assessment Summary

The proposed amendments are in this Proposal have been provided to FSANZ from internal staff, jurisdictions and other stakeholders. The issues relate only to:

- the correction of typographical and editorial errors;
- the update of information which is no longer relevant;
- removal of inconsistencies and ambiguities in the Code; and
- clarification of the intent of a number of clauses.

In addition to the Commentary, the following Standards are affected by these proposed amendments:

Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions;

Standard 1.1A.1 – Transitional Standard for Infant Formula Products

Standard 1.1A.3 – Transitional Standard for Country of Origin Labelling Requirements

Standard 1.1A.4 – Transitional Standard for The Labelling Of Pollen And Royal Jelly

Standard 1.1A.5 – Transitional Standard for The Warning Statement For Condensed Milk,

Modified Milk And Skim Milk

Standard 1.1A.7 – Transitional Standard for Caffeine In Artificial Drinks

Standard 1.2.4 – Labelling of Ingredients

Standard 1.2.8 – Nutrition Information Requirements

Standard 1.2.11 – Country of Origin Requirements

Standard 1.3.1 – Food Additives

Standard 1.3.3 – Processing Aids

Standard 1.3.4 – Identity and Purity

Standard 1.4.2 – Maximum Residue Limits (Australia Only)

Standard 1.5.2 – Food Produced Using Gene Technology

Standard 1.5.3 – Irradiation of Food

Standard 1.6.2 – Processing Requirements

Standard 2.1.1 – Cereals and Cereal Products

Standard 2.2.3 – Fish and Fish Products

Standard 2.4.2 – Edible Oil Spreads

Standard 2.6.3 – Kava

Standard 2.9.1 – Infant Formula Products

Standard 3.1.1 – Interpretation and Application

Standard 3.2.2 – Food Safety Practices and General Requirements

Standard 4.2.1 – Primary Production and Processing Standard for Seafood

RISK MANAGEMENT

The draft amendments listed below in Section 6 are intended to address minor inconsistencies, misspellings, grammatical errors and omissions, and to correct items requiring updating or clarification.

The amendments are required to ensure that the information contained in the Code is correct thereby ensuring FSANZ's section 10 objectives are met. Each of these minor amendments has been assessed by scientific and legal staff to ensure that the recommended solutions are consistent with the intent of the Standards within the Code.

The following details are provided with regard to each proposed amendment arranged under the relevant Standards:

Location: the relevant clause, subclause, paragraph, sub-paragraph or Table where the

problems arise or, where relevant, additional details such as section heading

or column;

Issue: the nature of the minor inconsistency/error and rationale for the suggested

amendment; and

Solution: proposed amendment

6. Issues

6.1 Ancillary Documents

6.1.1 Commentary

Location: Commentary

Issue: The composition of the Australia and New Zealand Food Regulation

Ministerial Council has been expanded to include Ministers that may be

nominated by their jurisdictions from portfolios other than the Health portfolio.

Solution: Amend the tenth paragraph of the commentary to include a reference to

other Ministers from related portfolios where these have been nominated by

their jurisdictions.

6.2 Chapter 1 – General Food Standards

6.2.1 Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibition

Location: The Editorial note to the Purpose

Issue: There are some outdated references to the relevant Food Acts of States and

Territories.

Solution: Updating and amending the references to the Food Acts in the Australian

Capital Territory, Queensland, the Northern Territory, Tasmania and South

Australia.

Location: Subclauses 1(3), (4) and (7)

Issue: These subclauses are concerned with the application of the Standard to food

products manufactured or produced prior to 20 December 2003. The relevant time period has passed and these clauses are no longer applicable.

Solution: Subclauses 1(3), (4) and (7) will be deleted from the Standard.

Location: Clause 2

Issue: The definition of AOAC in clause 2 incorrectly refers to Virginia USA

instead of Maryland USA in the publishing details of the AOAC reference

material.

Solution: The definition of AOAC will be amended to refer to Maryland USA.

Location: Clause 2

Issue: The definition of Australian Approved Names List refers to TGA Approved

Terminology for Medicines dated July 1999. The most recent edition of the

publication is 6 March 2001.

Solution: The definition will be updated to refer to the most recent date of

publication, 6 March 2001.

Location: Editorial note immediately following the definition of RDI

Issue: The Editorial note refers to *The National Health and Medical Research*

Council (NHMRC) of Australia 1991. This document has been rescinded.

Solution: The Editorial note will be deleted from the Standard.

Location: Clause 2

Issue: The Code includes a number of definitions in the interpretation clauses

within Standards that purport to establish compositional parameters for the food being defined. An example of this is the definition of 'meat pie' in Standard 2.2.1 which defines the product as a pie containing no less than

25% meat.

Some jurisdictions have expressed a concern that these compositional parameters, contained in an interpretive part of the Standard are unenforceable. The reasoning cited is that interpretive provisions in legislative instruments are not taken by courts to be substantive provisions

and therefore a definition that includes a component such as a

compositional parameter would be unenforceable in legal proceedings.

Accordingly, some jurisdictions have not commenced enforcement

proceedings for breaches of these compositional requirements.

Solution: To ensure the original intention of these provisions is not compromised due

to an issue with enforcement, a general deeming provision in Standard 1.1.1 is proposed. The deeming provision will afford definitions which contain

compositional components, a substantive status. This approach is

supported by New South Wales.

6.2.2 Standard 1.1A.1 – Transitional Standard for Infant Formula Products

Location: Standard

Issue: This transitional Standard ceased to have effect in 2002. However it has

not been formerly deleted from the Code. In order to delete a Standard (whether or not the Standard ceases to have effect), requires FSANZ to progress the matter in accordance with the formal processes under the

FSANZ Act.

Solution: The Standard will be deleted.

6.2.3 Standard 1.1A.3 – Transitional Standard for Country of Origin Labelling Requirements

Location: Subclause 1(1)

Issue: This amendment adds the words 'unless the contrary intention appears' for

the transitional operation of standards 1.1A.3 and 1.2.11. This is necessary

to qualify the specific transitional operation of these standards.

Solution: Amend subclause 1(1) to include the words 'unless the contrary intention

appears'.

6.2.4 Standard 1.1A.4 – Transitional Standard for the Labelling of Pollen and Royal Jelly

Location: Standard

Issue: This transitional Standard ceased to have effect two years from the

commencement of the alternative requirements in the Table to clause 3 of Standard 1.2.3, which deals with Mandatory warning statements and advisory statements and declarations. The two year period has passed and

this transitional Standard ceases to have effect.

Solution: The transitional Standard will be deleted.

6.2.5 Standard 1.1A.5 – Transitional Standard for the Warning Statement for Condensed Milk, Modified Milk and Skim Milk

Location: Standard

Issue: The transitional Standard ceased to have effect on 17 September 2004.

Solution: The transitional Standard will be deleted.

6.2.6 Standard 1.1A.7 – Transitional Standard for the Caffeine in Artificial Drinks

Location: Standard

Issue: The transitional Standard ceased to have effect on 20 December 2003.

Solution: The transitional Standard will be deleted.

6.2.7 Standard 1.2.4 – Labelling of Ingredients

Location: Editorial notes following subclause 6(1) and clause 7.

Issue: The Editorial notes refer to flour instead of wheat flour, which is the

relevant ingredient in the example provided. Amending the Editorial notes will also ensure compliance with clause 4 of Standard 1.2.3 – Mandatory

warning statements and advisory statements and declarations.

Solution: The Editorial notes after subclause 6(1) and clause 7 will be amended to

refer to 'wheat flour' instead of 'flour'.

6.2.8 Standard 1.2.8 – Nutrition Information Requirements

Location: Subclause 6(4)

Issue: There is a typographical error in the phrase 'of the food, the'. The correct

statement should be 'of the food, or'.

Solution: Correct the wording of the subclause.

6.2.9 Standard 1.2.11 – Country of Origin Requirements

Location: Subclause 1(1)

Issue: This amendment adds the words 'unless the contrary intention appears' for

the transitional operation of Standards 1.1A.3 and 1.2.11. This is necessary

to qualify the specific transitional operation of these Standards.

Solution: Amend subclause 1(1) to include the words 'unless the contrary intention

appears'.

Location: Subclause 1(1)

Issue: This amendment is required to remove any doubt that the 12-month lead-in

provisions in Standard 1.1.1 do not apply to the new labelling requirements for unpackaged food in standard 1.2.11. This intended affect was expressed

in the Editorial note following subclause 1(1) of standard 1.2.11.

Solution: Insert subclause 1(1A) following subclause 1(1).

Location: Subclause 1(4)

Issue: Subclause 1(4) will be deleted and new subclauses 1(4) and (5) will be

inserted. This amendment is required to remove any doubt that the 12-month lead-in provisions in Standard 1.1.1 do not apply to the new labelling requirements for unpackaged food in Standard 1.2.11. New subclause 1(4) will specify fish, fruit and vegetables and new subclause 1(5) will specify

fresh pork and preserved pork.

Solution: Deleted the current subclause 1(4) and insert new subclauses 1(4) and (5).

Location: Editorial note following clause 2

Issue: The third paragraph in the Editorial note following clause 2 needs to be

amended in a minor way to better reflect the operation of the country of origin safe harbour defences available under the *Trade Practices Act 1974*.

Solution: Amend the third paragraph of the Editorial note following clause 2.

6.2.10 Standard 1.3.1 – Food Additives

Location: Subparagraph 11(a)(i)

Issue: Subparagraph 11(a)(i) lists a reference publication *Food technology*, A

Publication of the Institute of Food Technologist, Generally Recognised as Safe (GRAS) lists of flavouring substances published by the Flavour and Extract Manufacturers' Association of the United States from 1960 to May 2003. The list has been updated to include GRAS flavourings up to August

2005, which is GRAS 22. Therefore the publication needs updating.

Solution: The reference to May 2003 will be updated to August 2005.

Location: Subparagraph 11(a)(ii)

Issue: Subparagraph 11(a)(ii) lists as a reference publication *Flavouring*

Substances and Natural Sources of Flavourings, 4th Edition, Volume 1, Chemically-defined flavouring substances, Council of Europe, 1992. The

reference is outdated and should refer to a more recent edition of

Chemically-defined flavouring substances.

Solution: The subparagraph will be amended to cite the most recent edition of the

publication i.e. 2003.

6.2.11 Standard 1.3.3 – Processing Aids

Location: Clause 1

Issue: The definition of 'maximum permitted level' in clause 1 refers to a

Schedule in the Standard. However there is no referable Schedule in the Standard. The definition should instead refer to the Tables to clauses 3 to

18 inclusively.

Solution: The definition of maximum permitted level will be amended to refer to the

Tables.

Location: Table to clause 14

Issue: The permission in relation to the use of ethylene oxide ceased to have effect

on 30 September 2003. The reference to ethylene oxide under the

substance, function and maximum permitted level (mg/kg) of the Table to

clause 14 should be removed.

Solution: The reference to ethylene oxide will be removed.

6.2.12 Standard 1.3.4 – Identity and Purity

Location: Schedule

Issue: Under the Specifications for nucleotides, there are references to the full

name of compounds and for ease of reference, their abbreviated form, for example Uridine – 5' monophosphate disodium salt (UMP) and Adenosine-

5' monophosphate (AMP). Abbreviated forms of the compounds 'Cytidine-5' monophosphate' and 'Guanosine – 5' monophosphate

disodium salt' have not been similarly referenced.

Solution: Cytidine-5' monophosphate will include reference to the abbreviated form

CMP and Guanosine – 5' monophosphate disodium salt' will include

reference to the abbreviated form GMP.

6.2.13 Standard 1.4.2 – Maximum Residue Limits

Location: Clause 2

Issue: Clause 2 currently lists subclauses (1), (2) and 2(3). The latter subclause

should read (3).

Solution: The typographical error in clause 2 will be corrected.

Location: Schedule 1

Issue: Schedule 1 currently lists Parsley under the heading Diazinon and refers to

a permissible MRL of T.07. This is an incorrect MRL reference and should read T0.7. This has occurred due to a typographical error and was gazetted

as part of A486 in Amendment 69 in December 2003.

Solution: The MRL typographical error under the heading of Diazinon in Schedule 1

will be corrected.

6.2.14 Standard 1.5.2 – Food Produced using Gene Technology

Location: Subclauses 4(5) and (6) and the Editorial note following clause 4.

Issue: Subclauses 4(5) and (6) and the Editorial note following clause 4 ceased to

have effect on 7 December 2002 and should be removed from the Standard.

Solution: Subclauses 4(5) and (6) and the Editorial note following clause 4 will be

removed from the Standard.

Location: Editorial note following clause 7

Issue: The Editorial note following clause 7 includes reference to the three year

review period for Division 2 of the Standard, which commenced from the date of gazettal. The review date is now obsolete as the review has been

completed.

Solution: This particular reference in the Editorial note will be omitted.

6.2.15 Standard 1.5.3 – Irradiation of Food

Location: Subclause 6(1)

Issue: There has been a minor drafting error in subclause 6(1) which refers to food

which has been processed by ionising radiation rather than irradiated food. This is an inconsistent use of terminology, as the remaining subclauses, that is 6(2), (3) and (4) refer to irradiated food. If the inconsistency remains there may be unintentional consequences, for example, it may provide a basis for a view that subclause 6(1) would require labelling of x-rayed

cargo, as it does not use the defined term 'irradiated'.

Solution: Subclause 6(1) will be amended to refer to 'irradiated food' rather than

'food which has been processed by ionising radiation.

6.2.16 Standard 1.6.2 – Processing Requirements

Location: Clause 9(1)

Issue: Under Proposal P289, clause 9 of Standard 1.6.2 was to be deleted 12

months from gazettal of the amendment (24 November 2006). Under Proposal P289, clause 9 of Standard 1.6.2 was transferred into new

Standard 4.2.3.

Standard 4.2.3 was also gazetted to commence 12 months from gazettal (24 November 2006). However, because of the operation of subclause 1(2) of Standard 1.1.1, the requirements in Standard 4.2.3 are not mandatory for a further year, that is 24 November 2007. This would create a 12-month gap in the legal requirements covered in clause 9 of Standard 1.6.2. This current amendment removes the gap by aligning the cease date for clause 9 of Standard 1.6.2 with the effective commencement date for Standard 4.2.3.

Solution: Insert subclause 9(1A) clarifying that clause 9 ceases to have effect on

24 November 2007.

6.3 Chapter 2 – Food Product Standards

6.3.1 Standard 2.1.1 – Cereals and Cereal Products

Location: Editorial note to clause 4

Issue: The Editorial note refers to reviewing the Standard prior to the

commencement of the Code. The Code has commenced and this Editorial

note has become obsolete.

Solution: The Editorial note to clause 4 will be removed

6.3.2 Standard 2.2.3 – Fish and Fish Products

Location: Editorial note to clause 1

Issue: The reference in (1) in the Editorial note is an incorrect reference. It refers

to a notice issued in 2000 concerning certain specifications regarding animal products intended for human consumption. The reference needs to be corrected to accurately refer to the most recent notice issued in 2004

concerning the scientific names of fish.

Solution: The reference in (1) in the Editorial note to clause 1 will be amended to

refer to the correct reference.

6.3.3 Standard 2.4.2 – Edible Oil Spreads

Location: Editorial note after clause 3

Issue: The Editorial note after clause 3, refers to clause 2 and to reviewing

subclauses (2) and (3) in this Standard prior to the commencement of the Code. The Code has commenced and this Editorial note has become

obsolete.

Solution: The Editorial note to clause 2 will be removed from the Standard.

6.3.4 Standard 2.6.3 – Kaya

Location: Paragraph 3(1)(b)

Issue: There is a typographical error in the drafting of paragraph 3(1)(b). The

paragraph inadvertently ends in 'and'.

Solution: The 'and' needs to be removed from the end of the paragraph.

6.3.5 Standard 2.9.1 – Infant Formula Products

Location: Schedule 1

Issue: In Schedule 1 of the Standard the permitted form for molybdenum is listed

as 'sodium molybdate VI dehydrate'. Many users of the Code have indicated that the term 'dehydrate' is confusing, as some interpret this to mean a form of molybdenum containing two water molecules (i.e. dihydrate – the correct interpretation), while others interpret the absence of water

from the form (i.e. anhydrous).

Furthermore, the reference to a 'hydrated' form is unnecessary in the Code, as this aspect of a chemical form relates to its purity, which is already regulated under Standard 1.3.4 – Identity and Purity. All other permitted chemical forms throughout the Code do not make reference to a hydrated version.

Solution: The r

The reference to 'dehydrate' will be removed from the permitted form for

molybdenum in Schedule 1 of the Standard.

6.4 Chapter 3 – Food Safety Standards

6.4.1 Standard 3.1.1 – Interpretation And Application

Location: Paragraph 1(o)

Issue: There is a typographical error in paragraph 1(o) under the definition of

'sell'. The paragraph should end with a semicolon and not a comma.

Solution: The error will be corrected.

6.4.2 Standard 3.2.2 – Food Safety Practices and General Requirements

Location: Subclause 21(1)

Issue: During other amendments to subclause 21(1) the term 'food premises' was

inadvertently deleted. Prior to the former Omnibus Proposal P284 the expression 'food premises' was covered in subclause 21(1). This

amendment simply reinstates the term.

Solution: Amend subclause 21(1) to refer to the term 'food premises'.

6.5 Chapter 4 – Primary Production Standards

6.5.1 Standard 4.2.1 – Primary Production And Processing Standard For Seafood

Location: Titles of Divisions 2 and 3

Issue: The titles of Divisions 2 and 3 in the Table of Provisions and in the

corresponding parts of the Standard do not match. The correct title for each

division is as in the Table of Provisions.

Solution: The titles of Division 2 and Division 3 in the body of the Standard will be

amended to match the tiles as they appear in the Table of Provisions.

7. Options

The two options for the amendments are outlined in this Proposal are:

- 1. adopt the proposed draft variations contained in this Proposal; or
- 2. reject the proposed draft variations contained in this Proposal.

8. Impact Analysis

8.1 Affected Parties

The parties affected by this Proposal are:

- Consumers in Australia and New Zealand.
- Food industry, including Australian and New Zealand manufacturers, exporters to Australia and New Zealand including multi-national manufacturers, and Australia and New Zealand importers.
- Government agencies in Australia and New Zealand who enforce the Code.

8.2 Benefit Cost Analysis

Assessment of this Proposal was undertaken to examine primarily whether there were any significant public health and safety risks. There are no identifiable public health and safety risks associated with the proposed amendments to the Code.

By correcting minor errors this Proposal also ensures the provision of adequate information to consumers and prevents misleading or deceptive conduct. The assessment also has regard to using the best available scientific risk assessment and ensuring consistency between domestic and international food standards.

Overall there are no significant costs related to this Proposal and there are some benefits to be gained by consumers, industry and governments. There are no perceived benefits associated with remaining with the *status quo*. Finally, this Proposal will not adversely affect international trade.

COMMUNICATION

9. Communication and Consultation Strategy

FSANZ 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 is satisfied that this step will not have an adverse effect on anyone's interests and that the Proposal raises issues of minor complexity only.

Section 63 of the FSANZ Act provides that, subject to the *Administrative Appeals Tribunal Act 1975*, an application for review of FSANZ's decision to omit to invite public submissions prior to making a Draft Assessment, may be made to the Administrative Appeals Tribunal.

The proposed amendments in this Proposal have been discussed internally within the Authority by relevant scientific and legal staff to ensure they are accurate and consistent with the Code.

10. Consultation

10.1 Public Consultation

Public comment on the Initial/Draft Assessment Report for this Proposal was sought from 4 July 2006 till 17 July 2006. Four submissions were received, of which one supported the Proposal, one had no comment, and two raised issues. These issues are addressed in the Attachment 2 which summarises the submissions received during the round of public comment and provides the FSANZ resolution.

10.2 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 to the Code to correct errors and clarify the intent of certain provisions are unlikely to have a significant effect on international trade as the issues are minor and without serious implication. The issues were therefore not notified to the agencies responsible for Australia and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements.

CONCLUSION

11. Conclusion and Preferred Option

The proposed draft variations in this Proposal have been prepared to correct errors of minor significance and complexity (including inconsistencies, misspellings, grammatical errors and omissions) identified in the Code. FSANZ's section 10 objectives will be maintained by ensuring minor errors are amended and there is consistency in the Code.

12. Implementation

It is proposed that the variations in this Proposal should take effect on 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] The Australia New Zealand Food Standards Code is varied by –
- [1.1] *omitting from the* Commentary –

Standards or variations to standards developed and approved by the Authority are subject to review by a council of Health Ministers known as the Australia and New Zealand Food Regulation Ministerial Council. The Council meets approximately twice a year, with some business conducted out-of-session through correspondence.

substituting –

Standards or variations to standards developed and approved by the Authority are subject to review by a council known as the Australia and New Zealand Food Regulation Ministerial Council. The Council comprises Health Ministers from all Australian States and Territories, the Australian Government and New Zealand, as well as other Ministers from related portfolios where these have been nominated by their jurisdictions. The Council meets approximately twice a year, with some business conducted out-of-session through correspondence.

- [2] Standard 1.1.1 of the Australia New Zealand Food Standards Code is varied by –
- [2.1] omitting the Editorial note to the Purpose, substituting –

Editorial note:

This Code is adopted as the required standards for food produced in New Zealand and the States, Territories and Commonwealth of Australia in relation to food sold and/or imported into both countries under the following Acts –

Food Act 1981 (New Zealand)

Health Act 1911 (Western Australia)

Food Act 2001 (Australian Capital Territory)

Food Act 2006 (Queensland)

Food Act 2003 (New South Wales)

Food Act 2003 (Tasmania)

Food Act (Northern Territory)

Food Act 1984 (Victoria)

Food Act 2001 (South Australia)

Imported Food Control Act 1992 (Commonwealth)

- [2.2] *omitting subclause 1(3), substituting*
- (3) Deleted

- [2.3] *omitting subclause 1(4), substituting*
- (4) Deleted
- [2.4] *omitting subclause 1(7), substituting*
- (7) Deleted
- [2.5] omitting from clause 2, the definition of AOAC substituting
 - **AOAC** means the publication entitled *Official methods of Analysis of AOAC International* published by AOAC International, Maryland USA and includes earlier editions of this publication under its previous name.
- [2.6] *omitting from clause 2, the definition of* Australian Approved Names List *substituting*
 - **Australian Approved Names List** means the list of names or terms included in the document entitled *Australian Approved Names for Pharmaceutical Substances* published by the Therapeutic Goods Administration in its edition *TGA Approved Terminology for Medicines* dated 6 March 2001.
- [2.7] omitting the Editorial note from clause 2, that follows the definition of RDI –

Editorial note:

The RDIs used in this Code are based on those published by the National Health and Medical Research Council (NHMRC) of Australia in 1991.

[2.8] inserting after clause 13 –

14 Interpretation of definitions

Where a definition for a food in this Code contains a reference to the composition of the food, the definition is to be taken as a –

- (a) substantive requirement for the composition of the food; and
- (b) standard for the composition of the food.
- [3] Standard 1.1A.1 of the Australia New Zealand Food Standards Code is varied by omitting the Standard
- [4] Standard 1.1A.3 of the Australia New Zealand Food Standards Code is varied by omitting subclause 1(1), substituting –
- (1) Unless the contrary intention appears, for the matters regulated in this Standard, food must comply with this Standard or Standard 1.2.11, but not a combination of, or parts of both.
- [5] Standard 1.1A.4 of the Australia New Zealand Food Standards Code is varied by omitting the Standard

- [6] Standard 1.1A.5 of the Australia New Zealand Food Standards Code is varied by omitting the Standard
- [7] Standard 1.1A.7 of the Australia New Zealand Food Standards Code is varied by omitting the Standard
- [8] Standard 1.2.4 of the Australia New Zealand Food Standards Code is varied by –
- [8.1] *omitting from the* Editorial note *following subclause 6(1),* flour *substituting* wheat flour
- [8.2] *omitting from the* Editorial note *following clause* 7, flour *substituting* wheat flour
- [9] Standard 1.2.8 of the Australia New Zealand Food Standards Code is varied by omitting from subclause 6(4), of the food, the substituting –

of the food, or

- [10] Standard 1.2.11 of the Australia New Zealand Food Standards Code is varied by –
- [10.1] *omitting subclause 1(1), substituting*
- (1) Unless the contrary intention appears, for the matters regulated in this Standard, food must comply with this Standard or Standard 1.1A.3, but not a combination of, or parts of both.
- [10.2] Inserting after subclause 1(1) –
- (1A) Subclause 1(2) of Standard 1.1.1 does not apply to subclause 2(2) and the Table to subclause 2(2) of this Standard.
- [10.3] omitting subclause 1(4), substituting –
- (4) The requirements in the Table to subclause 2(2) for fish, fruit and vegetables
 - (a) commence on 8 June 2006; and
 - (b) apply exclusively.
- (5) The requirements in the Table to subclause 2(2) for fresh pork and preserved pork commence and apply exclusively from 8 December 2006.
- [10.4] omitting the third paragraph in the Editorial Note following clause 2, substituting –

In complying with this Standard, manufacturers and retailers should be consistent with trade practices law. For Australia, the provisions of sections 65AA-AN of the *Trade Practices Act* 1974 apply to statements as to the country of origin of goods.

There are conditions for the safe use of 'product of' representations and other statements as to country of origin, such as 'made in' or 'manufactured in' or other like statements. These statements may be used safely in the following circumstances –

- [11] Standard 1.3.1 of the Australia New Zealand Food Standards Code is varied by –
- [11.1] omitting from subparagraph 11(a)(i), May 2003; or substituting –

August 2005; or

- [11.2] omitting subparagraph 11(a)(ii), substituting
 - (ii) Chemically-defined flavouring substances, Council of Europe, 2003; or
- [12] Standard 1.3.3 of the Australia New Zealand Food Standards Code is varied by –
- [12.1] omitting from clause 1, the definition of maximum permitted level, substituting –

maximum permitted level means the maximum amount of the processing aid which may be present in the food as specified in the tables to clauses 3 to 18.

[12.2] *omitting from the* Table to clause 14 –

| Ethylene Oxide | Sterilisation of herbs, spices, and | 20 |
|--|-------------------------------------|----|
| | dried vegetables used as | |
| This permission ceases to have effect on | seasonings – herbs, spices, and | |
| 30 September 2003. | dried vegetables used as | |
| This permission is an Australia Only | seasonings sterilised by the | |
| Standard. | application of ethylene oxide | |
| Subclauses 1(2), 1(3) and 1(4) of | may only be sold or imported | |
| Standard 1.1.1 do not apply to this | into Australia 21 days after such | |
| permission | sterilisation | |

- [13] Standard 1.3.4 of the Australia New Zealand Food Standards Code is varied by –
- [13.1] *omitting from the* Schedule, Cytidine 5' monophosphate *substituting* –

Cytidine – 5' monophosphate (CMP)

[13.2] *omitting from the* Schedule, Guanosine - 5' monophosphate disodium salt *substituting* –

Guanosine – 5' monophosphate disodium salt (GMP)

- [14] Standard 1.4.2 of the Australia New Zealand Food Standards Code is varied by –
- [14.1] *omitting subclause 2(3), substituting*
- (3) If a chemical is not listed in this Standard there must be no detectable residue of –

- (a) that chemical in food (whether or not the food is listed in Schedules 1, 2 or 4); and
- (b) metabolites of that chemical in food (whether or not the food is listed in Schedules 1, 2 or 4).
- [14.2] omitting from Schedule 1, under the entry for the following chemical, the maximum residue limit for the food, substituting –

| - | DIAZINON DIAZINON | |
|---------|--------------------------|------|
| PARSLEY | | T0.7 |

- [15] Standard 1.5.2 of the Australia New Zealand Food Standards Code is varied by –
- [15.1] *omitting subclause 4(5), substituting*
- (5) Deleted
- [15.2] *omitting subclause 4(6), substituting*
- (6) Deleted
- [15.3] *omitting the* Editorial note *following clause 4*
- [15.4] *omitting from the* Editorial note *following clause* 7 –

Division 2 of this Standard is to be reviewed 3 years from its date of gazettal.

- [16] Standard 1.5.3 of the Australia New Zealand Food Standards Code is varied by omitting subclause 6(1), substituting –
- (1) The label on a package of irradiated food must include a statement to the effect that the irradiated food has been treated with ionising radiation.
- [17] Standard 1.6.2 of the Australia New Zealand Food Standards Code is varied by inserting immediately before subclause 9(1),—
- (1A) This clause ceases to have effect on 24 November 2007, and subclause 1(2) of Standard 1.1.1 does not apply.
- [18] Standard 2.1.1 of the Australia New Zealand Food Standards Code is varied by omitting the Editorial note to clause 4
- [19] Standard 2.2.3 of the Australia New Zealand Food Standards Code is varied by omitting from the Editorial note following clause 1 –
- (1) clause 32 of the Animal Products (Specifications for Products Intended for Human Consumption) Notice 2000; and

substituting –

- (1) Scientific names of fish, approved under clause 32 of the Animal Products (Specifications for Products Intended for Human Consumption) Notice 2004; and
- [20] Standard 2.4.2 of the Australia New Zealand Food Standards Code is varied by omitting the Editorial note to clause 2
- [21] Standard 2.6.3 of the Australia New Zealand Food Standards Code is varied by omitting from subclause 3(1) 'May cause drowsiness'; and substituting –

[22] Standard 2.9.1 of the Australia New Zealand Food Standards Code is varied by omitting from Schedule 1 –

| Molybdenum | sodium molybdate VI dehydrate | | |
|----------------|-------------------------------|--|--|
| | | | |
| substituting – | | | |
| | | | |
| Molybdenum | sodium molybdate VI | | |

[23] Standard 3.1.1 of the Australia New Zealand Food Standards Code is varied by omitting from paragraph 1(0) under the definition of sell, defined, or substituting –

defined; or

- **Standard 3.2.2** of the Australia New Zealand Food Standards Code is varied by omitting subclause 21(1), substituting –
- (1) A food business must maintain food premises and all fixtures, fittings and equipment, having regard to their use, and those parts of vehicles that are used to transport food, and other items provided by the business to purchasers to transport food, in a good state of repair and working order having regard to their use.
- [25] Standard 4.2.1 of the Australia New Zealand Food Standards Code is varied by –
- [25.1] omitting the heading from Division 2, substituting –

Division 2 – General seafood safety requirements

[25.2] omitting the heading from Division 3, substituting –

Division 3 – Harvesting and other requirements for bivalve molluscs

[26] Standard 4.2.3 of the Australia New Zealand Food Standards Code is varied by inserting –

3A Application

This Division commences and applies exclusively from 24 November 2007 and subclause 1(2) of Standard 1.1.1 does not apply.

^{&#}x27;May cause drowsiness'.

Summary of Submissions and FSANZ resolution

Under section 36 of the FSANZ Act, FSANZ decided to omit one round of public consultation as it is satisfied that the Proposal raises issues of minor significance and complexity only. Public comment on the Initial/Draft Assessment Report for this Proposal was sought from 4 July 2006 till 17 July 2006. Four public submissions were received:

1. New Zealand Food Safety Authority (17.7.06; Carole Inkster)

The New Zealand Food Safety Authority had no comments to make.

2. Food Technology Association of Victoria Inc. (17.7.06; David Gill)

Agreed with Option 1 – to adopt the proposed draft variations contained in this Proposal.

3. NSW Food Authority (17.7.06; Bill Porter)

6.2.9 Standard 1.2.11 – Country of Origin Requirements New subclause 1 (4)

Use of the words 'from 8 June 2006' appear to give this clause retrospective effect. This may invalidate the clause. Would it be better to say –

'The requirements in the Table to subclause 2(2) for fish, fruit and vegetables apply exclusively'

6.2.16 Standard 1.6.2 – Processing Requirements

It is unclear whether clause 1(2) of Standard 1.1.1 applies to the requirements of Standard 4.2.3 or not. On current accepted interpretation of clause 1(2) of Standard 1.1.1 the food product in question would need to be in existence and compliant with the Code at commencement of Standard 4.2.3 (24 November 2006) in order for clause 1(2) of Standard 1.1.1 to have any effect.

Rather than amend Standard 1.6.2, NSW suggests amending Standard 4.2.3 to explicitly state –

Subclause 1(2) of Standard 1.1.1 does not apply to the requirements of this Standard , and The requirements in this Standard commence and apply exclusively from 24 November 2006.

This will maintain the intended commencement date of 24 November 2006 for all food products effected by the new standard.

Resolution

The first issue is concerned that by stating a past commencement date of 8 June 2006, the regulation may be offending the rule against retrospectively.

21

The instruments of original gazettal stated this commencement date. The provision is for 'the removal of any doubt', however as an abundance of caution measure, the subclause is modified the by splitting the commencement component from the exclusivity part. This is a common drafting practice to avoid having valid parts of a clause tainted by potentially invalid parts – 'severability'. Under the subclause as redrafted below, if (4)(a) was held invalid it would not affect the continued validity of (4)(b). The outcome would be exactly the same as suggested by NSW Food Authority submission.

- [10.3] omitting subclause 1(4), substituting –
- (4) The requirements in the Table to subclause 2(2) for fish, fruit and vegetables –
- (a) commence on 8 June 2006; and
- (b) apply exclusively.

The second issue is on clause 9 of Standard 1.6.2 and Standard 4.2.3. The intention has always been that there is to be a two year lead in time for the new requirements in Division 3 of Standard 4.2.3. This was done by stating the insertion of the Division commences one year from gazettal, but relying on subclause 1(2) in Standard 1.1.1 the actual mandatory compliance time is 2 years from gazettal. In more recent drafting in the Code the drafting approach is simply to state - commencement 2 years from gazettal and subclause 1(2) of Standard 1.1.1 does not apply. Consistent with this latter approach, the drafting is amended by inserting an application provision into Standard 4.2.3 as follows -

[26] Standard 4.2.3 of the Australia New Zealand Food Standards Code is varied by inserting –

3A Application

This Division commences and applies exclusively from 24 November 2007 and subclause 1(2) of Standard 1.1.1 does not apply.

However, that would still leave the problem of clause 9 of 1.6.2 ceasing on 24 Nov 2006, leaving a gap. Therefore, the drafting retains the amendment to Standard 1.6.2 (item 17) which says that the clause ceases to have effect on 24 November 2007.

4. Queensland Health Department (17.7.06; James Stephanos)

The Environmental Health Unit of Queensland Health is generally supportive of the proposal. However, one item of concern was identified. This related to: Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibition

It is currently proposed that the Editorial note immediately following the definition of RDI be deleted. This being the result of the National Health and Medical Research Council (NHMRC)document having been rescinded. I request clarification as to why the document has been rescinded. Queensland Health's concern is that the RDIs specified in the document are contained within the schedule and that if the document was rescinded due to incorrect figures or out of date information there may be potential impacts on human health.

Resolution:

Revision of documents is an ongoing process. The editorial note referenced a NHMRC document that had been rescinded. This document was published in 1991.

The definition for RDI in the Code will not be changed by omitting the editorial note. The RDIs specified elsewhere in the Code will not be changed by omitting the editorial note. There is no potential impact on human health resulting from the omission of this editorial note.

The document referenced by the editorial note provided advice on 'Recommended Dietary Intakes' (RDIs) or 'Allowances', which are the amounts of specific nutrients required on average on a daily basis for sustenance or avoidance of deficiency states. Since the time of publication, our scientific knowledge about nutrient needs has expanded greatly and we also have new evidence on a range of nutrients for which it was not possible to estimate needs in the past. In line with current National Health and Medical Research Council (NHMRC) policy, its recommendations will be reviewed five years from their publication. The most recent revision in 2006 was undertaken by the National Health and Medical Research Council in collaboration with the Australian Government Department of Health and Ageing and the New Zealand Ministry of Health.

RDI values in the Code will continue to be based on the current available information from the NH&MRC at the time of standard setting. An editorial note referencing an out of date document would not reflect the use of the most current available scientific information in the standards development process.