

18 June 2012
[13-12]

Call for submissions – Proposal P1021

Code Maintenance X

FSANZ has assessed a proposal prepared to update references and correct minor typographical and formatting errors in the *Australia New Zealand Food Standards Code* using the minor assessment procedure, and has prepared a draft food regulatory measure. FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 6 July 2012

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel +64 4 978 5630

Table of Contents

1. EXECUTIVE SUMMARY	2
2. INTRODUCTION.....	3
2.1 THE PROPOSAL.....	3
2.2 REASONS FOR PREPARING THE PROPOSAL.....	3
2.3 PROCEDURE FOR ASSESSMENT	3
3. SUMMARY OF THE ASSESSMENT	3
3.1 RISK ASSESSMENT.....	3
3.1.1 <i>Updating references</i>	3
3.1.2 <i>Updating material from international sources</i>	3
3.1.3 <i>Correcting errors and omissions, and improving clarity</i>	3
3.1.4 <i>Removing material no longer required</i>	4
3.2 RISK MANAGEMENT.....	4
3.2.1 <i>Addressing FSANZ's objectives for standards-setting</i>	4
3.3 RISK COMMUNICATION.....	5
4. DRAFT VARIATIONS.....	5
ATTACHMENT A – DRAFT VARIATIONS TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>	6
ATTACHMENT B – DRAFT EXPLANATORY STATEMENT	13

1. Executive summary

FSANZ prepared Proposal P1021 in order to correct a number of minor grammatical and typographical errors, update references and correct cross references in the *Australia New Zealand Food Standards Code* (the Code).

An example of an issue to be corrected is the expiry date for the maximum level of tutin in honey, which is incorrectly stated as 31 March 2011, instead of 31 March 2013. References to be updated include FAO JECFA Monographs 11 (2011) and Food Chemicals Codex (8th Edition) which are to be inserted into Standard 1.3.4 and the United States Code of Federal Regulations (2012) to be inserted into Standard 1.1.1.

The proposed variations are all minor in nature as defined under section 66 of the Food Standards Australia New Zealand (FSANZ) Act as they do not:

- (a) impose, vary or remove an obligation on any person; or
- (b) create, vary or remove a right of any person; or
- (c) otherwise alter the legal effect of a food regulatory measure.

FSANZ is consulting on the proposed variations with appropriate government agencies and any affected stakeholders.

The proposed variations are at attachment A.

2. Introduction

2.1 The Proposal

The Proposal seeks to correct minor typographical errors or inconsistencies, update references, correct formatting issues and correct cross references.

2.2 Reasons for preparing the Proposal

Minor typographical and grammatical errors are identified in the Code from time to time. Some references in the Code also become superseded as the documents they refer to are updated. This Proposal was prepared to resolve such issues.

2.3 Procedure for assessment

The Proposal is being assessed under the Minor Procedure. Section 66 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) applies as FSANZ is only proposing variations to the Code that do not:

- (a) impose, vary or remove an obligation on any person; or
- (b) create, vary or remove a right of any person; or
- (c) otherwise alter the legal effect of a food regulatory measure.

3. Summary of the assessment

3.1 Risk assessment

All of the issues considered are minor in nature, and fall into the following broad categories:

3.1.1 Updating references

References in the Code will be updated so that the Code cites the latest versions of Australian and international publications such as the Drinking Water Guidelines, FAO JECFA Monographs, the Food Chemicals Codex and the United States Code of Federal Regulations.

3.1.2 Updating material from international sources

The Code relies on nomenclature developed by international bodies and as such, when this nomenclature is changed, the changes need to be reflected in the Code. Examples of these changes include:

- the INS number for mixed tocopherol concentrate in the Code needs to be updated from 306 to 307b to match changes made by JECFA
- the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology has deleted Bromelain EC 3.4.22.4 and replaced it with stem bromelain EC 3.4.22.32 and fruit bromelain EC 3.4.22.33.

3.1.3 Correcting errors and omissions, and improving clarity

Omissions, grammatical, typographical and other similar errors or lack of clarity have been identified in the Code.

For example, there were grammatical and typographical mistakes in subclause 5(3) of Standard 1.3.1, including errors in the examples following the subclause. Another example of a typographical error identified is the expiry date for the maximum level for tutin in Standard 1.4.1 clause 5. The expiry date is given as 31 March 2011, instead of 31 March 2013 as approved under P1009 Maximum Limits for Tutin in Honey.

3.1.4 Removing material no longer required

There are provisions in the Code that have either ceased to have effect, or are no longer required for various reasons and these will be removed. For example, the disodium salts of the nucleotides guanosine – 5' monophosphate and inosine – 5' monophosphate have now been evaluated by JECFA and specifications published in a monograph. Therefore these no longer need specifications in the Code.

3.2 Risk management

When assessing this Proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Proposal outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure
- whether other measures (whether available to FSANZ or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the Proposal
- any relevant New Zealand standards
- any other relevant matters.

As all the proposed variations are minor as defined in section 66 of the FSANZ Act, there are no cost benefit issues.

3.2.1. Addressing FSANZ's objectives for standards-setting

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment and has concluded that the proposed variations do not:

- (a) impose, vary or remove an obligation on any person; or
- (b) create, vary or remove a right of any person; or
- (c) otherwise alter the legal effect of a food regulatory measure.

Therefore they do not have any impact on measures in place for:

- protection of public health and safety
- the provision of adequate information relating to food to enable consumers to make informed choices
- the prevention of misleading or deceptive conduct

3.2.1.1 Subsection 18(2) considerations

FSANZ has also had regard to the matters listed in subsection 18(2) in developing the proposed variations:

- 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
- any written policy guidelines formulated by the Ministerial Council¹.

3.3. Risk communication

Pursuant to section 68 of the FSANZ Act, FSANZ is consulting with appropriate government agencies on the proposed amendments. Members of the public are also welcome to provide comments.

4. Draft variations

The draft variations are at Attachment A.

Attachments

- A. Draft variations to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

¹ Now known as the COAG Legislative and Governance Forum on Food Regulation

Attachment A – Draft variations to the *Australia New Zealand Food Standards Code*



Food Standards (Proposal P1021 – Code Maintenance X) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated X

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the Food Standards (Proposal P1021 – Code Maintenance X) Variation.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

The Editorial notes and Examples in this instrument have been provided for completeness only. They are not part of the approval of the amendments to the Standards.

Editorial notes and Examples are not, by virtue of the definition of “standard” in the *Food Standards Australia New Zealand Act 1991*, part of the a draft standard and therefore not subject to the standards development process under Part 3 of that Act.

3 Commencement

These variations commence on **the date of gazettal**.

SCHEDULE

[1] **Standard 1.1.1** is varied by omitting from subclause 16(1) “2010” and substituting “2012”

[2] **Standard 1.2.1** is varied by omitting from paragraph 2(2)(k) “clause 3” and substituting “clause 2”

[3] **Standard 1.2.4** is varied by

[3.1] omitting from Part 1 of Schedule 2

“Tocopherols concentrate, mixed	306”
---------------------------------	------

and substituting

“Tocopherols concentrate, mixed	307b”
---------------------------------	-------

[3.2] omitting from Part 2 of Schedule 2

“Tocopherols concentrate, mixed	306”
---------------------------------	------

[3.3] inserting in Part 2 of Schedule 2 in numerical order

“Tocopherols concentrate, mixed	307b”
---------------------------------	-------

[4] **Standard 1.2.5** is varied by omitting from the Examples to subclause 5(4) “paragraph” (wherever occurring) and substituting “subclause”

[5] **Standard 1.2.8** is varied by

[5.1] inserting in paragraph 3(l) “, ice” after “water”

[5.2] omitting from subclause 5(7)

“Dietary fibre, total	g	g
– **	g	g”

and substituting

“Dietary fibre, total	g	g
– *	g	g”

[6] **Standard 1.3.1** is varied by

[6.1] omitting from the Table of Provisions “11 Permitted synthetic flavourings” and substituting “11 Permitted flavouring substances”

[6.2] omitting subclause 5(3) and substituting

“(3) To calculate the steviol equivalent levels for a steviol glycoside, the following equation is used –

$$[SE] = \sum ([SG] \times CF)$$

where –

[SE] = concentration as steviol equivalents

[SG] = concentration of individual steviol glycoside

CF = Conversion Factor as listed in the Table for the corresponding steviol glycoside

Table to subclause 5(3)

Column 1	Column 2
Steviol glycoside	Conversion factor
Dulcoside A	0.40
Rebaudioside A	0.33
Rebaudioside B	0.40
Rebaudioside C	0.33
Rebaudioside D	0.28
Rebaudioside F	0.34
Rubusoside	0.50
Steviol	1.00
Steviolbioside	0.50
Stevioside	0.40

Examples:

Example 1 – Calculating steviol equivalents for a single glycoside

A preparation of 100 mg/kg of Rebaudioside B contains $100 \times 0.40 = 40$ mg/kg steviol equivalents.

Example 2 – Calculating steviol equivalents for a mixture of glycosides

For a preparation containing 100 mg/kg of a mixture of 90% Stevioside, 5% Rebaudioside B and 5% Rebaudioside A, the steviol equivalent is

$$= ([Stevioside] \times 0.4) + ([Rebaudioside B] \times 0.4) + ([Rebaudioside A] \times 0.33)$$

$$= (90\% \times 100 \text{ mg/kg} \times 0.4) + (5\% \times 100 \text{ mg/kg} \times 0.4) + (5\% \times 100 \text{ mg/kg} \times 0.33)$$

$$= (0.9 \times 0.4 + 0.05 \times 0.40 + 0.05 \times 0.33) \times 100 \text{ mg/kg}$$

$$= \mathbf{39.7 \text{ mg/kg}}$$

Example 3 – Calculating the maximum permitted level (MPL) of a steviol glycoside preparation

To calculate the MPL of a steviol glycoside preparation which contains 90% Stevioside, 5% Rebaudioside B and 5% Rebaudioside A, in a food where the permission is 160 mg/kg (steviol equivalents).

$$[SE] = 160 \text{ mg/kg} \quad [Stevioside] = 0.9 \times \text{MPL} \quad [\text{Rebaudioside B}] = 0.05 \times \text{MPL}$$

$$[\text{Rebaudioside A}] = 0.05 \times \text{MPL}$$

Substituting into the equation

$$[SE] = \sum ([SG] \times CF)$$

We get:

$$160 \text{ mg/kg} = (0.9 \times \text{MPL} \times 0.4) + (0.05 \times \text{MPL} \times 0.4) + (0.05 \times \text{MPL} \times 0.33)$$

Therefore,

$$\text{MPL} = \frac{160}{0.9 \times 0.4 + 0.05 \times 0.4 + 0.05 \times 0.33} \text{ mg/kg}$$

MPL = 403.5 mg/kg

[6.3] omitting from Schedule 1 Category 0.1 Preparations of food additives

“ 306 Tocopherols concentrate mixed GMP ”

[6.4] inserting in Schedule 1 Category 0.1 Preparations of food additives in numerical order

“ 307b Tocopherols concentrate mixed GMP ”

[6.5] omitting from Schedule 1 Category 2 EDIBLE OILS AND OIL EMULSIONS

“ 306 Tocopherols concentrate mixed GMP ”

[6.6] inserting in Schedule 1 Category 2 EDIBLE OILS AND OIL EMULSIONS in numerical order

“ 307b Tocopherols concentrate mixed GMP ”

[6.7] omitting from Schedule 1 Category 13.1 Infant formula products

“ 306 Tocopherols concentrate mixed 10 mg/L ”

and substituting

“ 307b Tocopherols concentrate mixed 10 mg/L ”

[6.8] omitting from Schedule 1 Category 13.2 Foods for infants

“	306	Tocopherols, concentrate mixed	300	mg/kg	□	of fat in total. Clause 6(1) applies”
	307	Tocopherols, d-alpha-, concentrate	300	mg/kg		

and substituting

“	307	Tocopherols, d-alpha-, concentrate	300	mg/kg	□	of fat in total. clause 6(1) applies”
	307b	Tocopherols, concentrate mixed	300	mg/kg		

[6.9] omitting from Schedule 1 Category 20.2 Food other than beverages “**blanc mange**” and substituting “**blancmange**”

[6.10] omitting from Schedule 2 Numeric Listing “961-” and substituting “961”

[6.11] omitting from Schedule 2

“470 Aluminium, calcium, sodium magnesium
potassium and ammonium salts of
fatty acids”

(twice occurring) and substituting

“470 Fatty acid salts of aluminium, ammonia,
calcium, magnesium, potassium and
sodium”

[6.12] omitting from the headings to Schedules 2, 3 and 4 “**Numeric Listing**” and substituting
“**Numerical Listing**”

[7] **Standard 1.3.3** is varied by

[7.1] omitting from the Table to clause 8 “dimethylaminopro-pylamine” (twice occurring) and
substituting “dimethylaminopropylamine”

[7.2] omitting the Editorial note to clause 9 and substituting

Editorial note:

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is currently reviewing mineral oils, including white mineral oil. To ensure consistency with the outcomes of this review, FSANZ will review the permission and nomenclature for white mineral oil once the JECFA review is completed.

[7.3] omitting from the Table to clause 13

“Dimethyl ether	All foods except dairy ingredients and dairy products	2
Dimethyl ether	Dairy ingredients and dairy products	2”

and substituting

“Dimethyl ether	All foods	2”
-----------------	-----------	----

[7.4] omitting from the Table to clause 16

“Bromelain EC 3.4.22.4	Pineapple stem (Ananas comosus)”
---------------------------	----------------------------------

and substituting

“Stem bromelain EC 3.4.22.32	Pineapple stem (Ananas comosus)
Fruit bromelain EC 3.4.22.32	Pineapple fruit (Ananas comosus)”

[7.5] omitting from the Table to clause 17 “*Lactocococcus*” and substituting “*Lactococcus*”

[7.6] omitting from the Table to clause 17 “*Micrococcus*” and substituting “*Micrococcus*”

[7.7] omitting from the Table to clause 17 “*Rhizopus*” (twice occurring) and substituting
“*Rhizopus*”

[7.8] omitting in the Table to clause 17 "*amyloliquifaciens*" and substituting "*amyloliquefaciens*"

[7.9] omitting from the second Editorial note to clause 17 "*Micrococcus luteus*" and substituting "*Micrococcus luteus*"

[8] Standard 1.3.4 is varied by

[8.1] inserting in paragraph 2(b) "and FAO JECFA Monographs 11 (2011)" after "and FAO JECFA Monographs 10 (2010)"

[8.2] omitting from paragraph 2(c) "*Food Chemicals Codex* (7th Edition) published by United States Pharmacopoeia (2010)" and substituting "*Food Chemicals Codex* (8th Edition) published by United States Pharmacopoeia (2012)"

[8.3] omitting from the **Specifications for nucleotides** in the Schedule

"Inosine – 5' monophosphate disodium salt (IMP)

1. Empirical chemical formula: $C_{10}H_{11}N_4Na_2O_8P \cdot 7.5H_2O$

In addition the compound must be of the 5 species, ie the disodium monophosphate structure is attached to the fifth carbon in the central structure.

2. Molecular weight: 527.25

3. Structure/ Physical character: Occurs as a colourless or white crystal or as a white crystalline powder. It is odourless and has a characteristic taste.

4. Solubility: 24 g is soluble in 100 g of water at 20°C; is stable in acid liquids under the identical conditions"

[8.4] omitting from the **Specifications for nucleotides** in the Schedule

"Guanosine – 5' monophosphate disodium salt (GMP)

1. Empirical chemical formula: $C_{10}H_{12}N_5Na_2O_8P \cdot 7.5OH_2O$

In addition the compound must be of the 5 species, ie the disodium monophosphate structure is attached to the fifth carbon in the central structure.

2. Molecular weight: 533.26

3. Structure/ Physical character: Occurs as a colourless or white crystal or as a white crystalline powder. It is odourless and has a characteristic taste.

4. Solubility: 20 g is soluble in 100 g of water at 20°C; becomes gelatinous in acid liquids under the identical conditions"

[9] Standard 1.4.1 is varied by

[9.1] omitting from the Purpose "a ML" and substituting "an ML"

[9.2] omitting from the Purpose "A ML" and substituting "An ML"

[9.3] omitting from the Table to clause 5 "The ML for Tutin to cease on 31 March 2011"

[10] Standard 1.5.2 is varied by inserting in Item 1.2 of the Schedule "lines" after "Food derived from herbicide-tolerant canola"

[11] **Standard 2.5.4** is varied by omitting from paragraph (a) of the definition of cheese in clause 1 “coagulating wholly or partly milk” and substituting “wholly or partially coagulating milk”

[12] **Standard 3.2.2** is varied by

[12.1] omitting from clauses 1, 14 and 16 “food-borne” (wherever occurring) and substituting “foodborne”

[12.2] omitting from paragraph 5(2)(b) “an appropriate designation” and substituting “a name or a description of the food sufficient to indicate the true nature of the food”

[13] **Standard 3.2.3** is varied by omitting from the Editorial note to clause 1 “2004”

[14] **Standard 4.1.1** is varied by

[14.1] omitting the Table of Provisions and substituting

“Table of Provisions

Division 1 – Preliminary

- 1 Interpretation
- 2 Application
- 3 When an animal or food is unacceptable

Division 2 – General food safety management requirements

- 4 The general food safety management requirements
- 5 Food safety management statements”

[14.2] inserting before clause 1

“Division 1 – Preliminary”

[15] **Standard 4.2.1** is varied by omitting from paragraph 16(2)(b) “Commonwealth Export Control (Processed Food) Orders” and substituting “Fish and Fish Products Orders (2005)”

[16] **Standard 4.5.1** is varied by –

[16.1] omitting from the Table to clause 3 “Dimethyl dicarbonate”

[16.2] inserting in the Table to clause 4 “Dimethyl dicarbonate” in alphabetical order

Attachment B – Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P1021 to amend Standards in the Code to correct minor typographical errors and inconsistencies, update references, correct formatting issues, and correct cross references. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved draft variations to Standards in the Code.

2. Purpose and operation

The Authority has prepared draft variations. The draft variations are minor in nature as defined under section 66 of the FSANZ Act, i.e., they do not:

- (a) impose, vary or remove an obligation on any person; or
- (b) create, vary or remove a right of any person; or
- (c) otherwise alter the legal effect of a food regulatory measure.

Therefore, the affected Standards will continue to have the same legal effect as before the variations.

3. Documents incorporated by reference

Some of the variations to food regulatory measures update documents incorporated by reference.

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1021 includes one round of consultation with relevant government agencies. Submissions were called for on 18 June 2012 for three weeks.

A Regulation Impact Statement was not required because the proposed variations are minor in nature as described in 2 above.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation to Standards in the *Australia New Zealand Food Standards Code*

6.1 Updating references

Items [1], [8] and [15] update references in the Code.

6.2 Updating material from international sources

Items [3], [6], [7] and [8] update material referenced from other sources.

6.3 Correcting minor errors and omissions, and improving clarity

Items [2], [5], [6], [7], [9], [10], [11], [12], [14], [15] and [16] correct minor errors and omissions in the Code.

6.4 Removing material that is no longer required

Items [8.3] and [8.4] remove material that is no longer required in the Code.

*6.5 Variation to Editorial Notes and Examples in the *Australia New Zealand Food Standards Code**

The amendments to the Code include changes to Editorial notes and Examples. Editorial notes and Examples are not, by virtue of the definition of 'standard', part of a draft standard and are therefore not subject to the standards development process under part 3 of the FSANZ Act. The Editorial notes and Examples have only been provided for completeness.

Items [4], [7.2], [7.9] and [13] correct and update various examples and editorial notes in the Code.