3 August 2012
[18-12]

Approval Report – Proposal P1021

Code Maintenance X

Food Standards Australia New Zealand (FSANZ) has assessed a proposal prepared by FSANZ to update references and correct minor typographical and formatting errors in the *Australia New Zealand Food Standards Code*.

On 18 June 2012, FSANZ sought submissions on draft variations and published an associated report. FSANZ received 10 submissions.

FSANZ approved the draft variations on 26 July 2012. The COAG Legislative and Governance Forum on Food Regulation[1] (Forum) was notified of FSANZ's decision on 2 August 2012.

This Report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

[1] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

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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 corrected via P1021 is the expiry date for the maximum level of tutin in honey, which was incorrectly stated as 31 March 2011, instead of 31 March 2013. References that were updated include FAO JECFA Monographs 11 (2011) and Food Chemicals Codex (8th Edition) which were inserted into Standard 1.3.4 and the United States Code of Federal Regulations (2012) which was inserted into Standard 1.1.1.

The variations were 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 consulted on the proposed variations with appropriate government agencies and any affected stakeholders.

The approved variations are at Attachment A.

2. Introduction

2.1 The Proposal

The Proposal sought 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 Some references in the Code also become superseded as the documents they refer to are updated.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 was assessed under the Minor Procedure. Section 66 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) applies as FSANZ was 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.

2.4 Decision

The draft variations as proposed following assessment were approved with amendments.

The draft variations, as varied after submissions were received, are at Attachment A. The draft variations on which submissions were sought are at Attachment C.

3. Summary of the findings

3.1 Risk assessment

All of the issues that were considered were minor in nature, and fell into the following broad categories:

3.1.1 Updating references

References in the Code were 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 was updated to reflect changes in nomenclature developed by international bodies. Examples of these changes include:

- The INS number for mixed tocopherol concentrate in the Code was updated from 306 to 307b to match changes made by JECFA.

- The enzyme bromelain EC 3.4.22.4 was replaced with stem bromelain EC 3.4.22.32 and fruit bromelain EC 3.4.22.33 to reflect changes made by the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology.

3.1.3 Correcting errors and omissions, and improving clarity

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

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 was the expiry date for the maximum level for tutin in Standard 1.4.1 clause 5. The expiry date was 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 were provisions in the Code that had either ceased to have effect, or were no longer required for various reasons and these were removed. For example, specifications for the disodium salts of the nucleotides guanosine – 5′ monophosphate and inosine – 5′ monophosphate were removed as they have now been evaluated by JECFA and specifications published in a monograph which is a primary reference source for the Code.

3.2 Risk management

3.2.1 Summary of submissions

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions.

Every submission on an application or proposal is reviewed by FSANZ staff, who examine the issues identified and prepare a response to those issues. While not all comments can be taken on board during the process, they are valued and all contribute to the rigour of our assessment.

Ten submissions were received, eight from the food industry and two from jurisdictions.

There was general support, or no objection, to the Proposal, except for the proposed name and number change for mixed tocopherol concentrate to reflect the Codex standard.

This issue had been raised because the Code reference had resulted in some exports and imports incurring border action by not using the Codex number. However, there was strong objection to only having the usual stock in trade allowance of one year, given the cost to change labels and the fact that this additive is used in foods and ingredients with, in some cases, long shelf lives.

Table 1: Summary of issues raised in submissions

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Cost to change labelling from INS 306, Tocopherols concentrated, mixed to INS 307b, Tocopherol concentrated, mixed. Longer transition needed.	Food companies, food industry peak bodies, a regulatory authority	Agree with the comments regarding need for a longer transition to change existing labelling, while immediately allowing the use of the Codex description. Increase to transition period proposed.
Error in drafting for revised numbering for fruit bromelain.	Two submitters	Error will be corrected.
The botanical name for pineapple should be in italics	Two submitters	Agreed, drafting will be amended
Other examples noted where the Code number/name do not match Codex	NZMPI	Noted, but would require consultation before changing.
Tocopherol names are abbreviated for labelling in Standard 1.2.4 compared with the names in Standard 1.3.1	NZMPI	Noted, but beyond the scope of this minor proposal.
The revised description for salts of fatty acids proposed for Standard 1.3.1 should also be used in Standard 1.2.4	NZMPI	Agreed, drafting will be amended

3.3 Risk communication

Pursuant to section 68 of the FSANZ Act, FSANZ consulted with appropriate government agencies on the proposed amendments. Food industry and members of the public were also welcome to provide comments.

The call for submissions was announced through a media release and through Food Standards News and social media tools.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

Individuals and organisations that make submissions on this Proposal are notified at each stage of the assessment.

If a draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the COAG Legislative and Governance Forum on Food Regulation Forum. If the draft variations are not subject to a request for a review, stakeholders, including the public, will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

4. Reasons for decision

In assessing the Proposal and developing a food regulatory measure, FSANZ 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 (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 were minor as defined in section 66 of the FSANZ Act, there were no cost benefit issues apart from that described for tocopherols.

4.1 Addressing FSANZ's objectives for standards-setting

4.1.1 Subsection 18(1) considerations

FSANZ also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment and concluded that the proposed variations did 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 variations did 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

4.1.2 Subsection 18(2) considerations

FSANZ had regard to the matters listed in subsection 18(2) in developing the 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 Council[2].

4.2 Transitional Arrangements

With respect to mixed tocopherol concentrate, the drafting allows the Codex name and number to be used immediately, and provides a two year delay in the commencement of the clauses removing the current name and number in the Code.

[2] Now known as the COAG Legislative and Governance Forum on Food Regulation

For all the other variations, commencement is from the day of gazettal.

In all cases, clause 1 (2) of Standard 1.1.1 applies, which allows a further 12 months from commencement for products already manufactured (so-called stock in trade provision).

Attachments

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

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

FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

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.

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.

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*.

3 Commencement

These variations commence on **the date of gazettal**, except for Items [3.1], [3.3], [6.3], [6.5], [6.7], and [6.10] which commence **two years after 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"

[3.2] inserting in Part 1 of Schedule 2 in alphabetical order

"Tocopherols concentrate, mixed 307b"

[3.3] inserting at the end of Part 1 of the Schedule 2
"

Editorial note:

The permissions for food additive Tocopherols, concentrate mixed with INS Number 306 will be repealed 2 years after the date of gazettal of the Food Standards (Proposal P1021 – Code Maintenance X) Variation.

"

[3.4] omitting from Part 2 of Schedule 2

"Tocopherols concentrate, mixed 306"

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

"Tocopherols concentrate, mixed 307b"

[3.6] 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"

[3.7] inserting at the end of Part 1 of the Schedule 1
"

Editorial note:

The permissions for food additive Tocopherols, concentrate mixed with INS Number 306 will be repealed 2 years after the date of gazettal of the Food Standards (Proposal P1021 – Code Maintenance X) Variation.

"

[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" (first occurring)

[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 "Permitted synthetic flavourings" and substituting "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 x 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

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

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

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

= $39.7\ \mathrm{mg/kg}$

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 mg/kg [Stevioside] = 0.9 x MPL [Rebaudioside B] = 0.05 x MPL
[Rebaudioside A] = 0.05 x MPL

Substituting into the equation

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

We get:

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

Therefore,

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

$\mathrm{MPL} = 403.5\ \mathrm{mg/kg}$

”

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

“	306	Tocopherols concentrate mixed	GMP	”

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

“	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 numerical order in Schedule 1 Category 2 EDIBLE OILS AND OIL EMULSIONS

“	307b	Tocopherols concentrate, mixed	GMP	”

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

“	306	Tocopherols concentrate mixed	10	mg/L	”

[6.8] inserting in numerical order in Schedule 1 Category 13.1 Infant formula products

“	307b	Tocopherols concentrate, mixed	10	mg/L	”

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

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

and substituting

“	306	Tocopherols, concentrate mixed	300	mg/kg	of fat
“	307	Tocopherols, d-alpha-, concentrate	300	mg/kg	of fat
	307b	Tocopherols, concentrate mixed	300	mg/kg	of fat”

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

“	306	Tocopherols, concentrate mixed	300	mg/kg	of fat”

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

[6.12] inserting at the end of Schedule 1

“

Editorial note:

The permissions for food additive Tocopherols, concentrate mixed with INS Number 306 will be repealed 2 years after the date of gazettal of the Food Standards (Proposal P1021 – Code Maintenance X) Variation.

”

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

[6.14] 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”

[6.15] 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 3.4.22.33	Pineapple fruit (*Ananas comosus*)"

[7.5] omitting from the Table to clause 17 "*Lactococcoccus*" 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 "*Rhizophus*" (twice occurring) and substituting "*Rhizopus*"

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

[7.9] omitting from the second Editorial note to clause 17 "Microccocus 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 paragraph 2(c) and substituting

"(c) *Food Chemicals Codex* (8th Edition) published by Unites 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 20ºC; 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 disodiummonophosphate 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 20ºC; 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 "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 clause 1 and subclauses 14(1), 16(1) and 16(3) "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

[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 – 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.

Following consideration by COAG Legislative and Governance Forum on Food Regulation[3], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislative Instruments Act 2003*.

2. Purpose and operation

The Authority has approved variations to the Code to correct minor typographical errors and inconsistencies, update references, correct formatting issues, and correct cross references. The 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 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.

[3] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

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. Variations

6.1 Updating references

Items [1], [8.1], [8.2] and [15] update references in the Code.

6.2 Updating material from international sources

Items [3.1] – [3.2], [3.4] – [3.5] and [6.3] – [6.10] update the name and additive number of *tocopherols concentrate, mixed* to match those in Codex Alimentarius. The amendment allows the continuation of the current description for two years followed by the usual one year for stock in trade in order that industry can update product labelling at minimal cost.

Item [7.4] updates the definition of the enzyme bromelain.

6.3 Correcting minor errors and omissions, and improving clarity

Items [2], [5.2], [6.1], [6.11], [6.13], [7.1], [7.5] – [7.8], [9.1] – [9.3], [12.1], [14.1], [14.2], [16.1] and [16.2] correct minor errors and omissions in the Code.

Items [3.6], [5.1], [6.2], [6.14], [6.15], [7.3], [10], [11] and [12.2] improve clarity in the Code.

6.4 Removing material that is no longer required

Items [8.3] and [8.4] remove specifications from the Code that are no longer required because the substances have now been evaluated by JECFA and their specifications published in a monograph which is a primary reference source for the Code.

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

Items [3.3], [3.7], [4], [6.2], [6.12], [7.2], [7.9] and [13] correct and update various examples and editorial notes in the 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.

Attachment C – Draft variations to the *Australia New Zealand Food Standards Code* in the Call for Submissions

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 x 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

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

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

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

= 39.7 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 mg/kg [Stevioside] = 0.9 x MPL [Rebaudioside B] = 0.05 x MPL
[Rebaudioside A] = 0.05 x MPL

Substituting into the equation

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

We get:

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

Therefore,

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

$\mathbf{MPL = 403.5\ mg/kg}$

"

[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.
	307	Tocopherols, d-alpha-, concentrate	300	mg/kg		Clause 6(1) applies"

and substituting

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

[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 "*Lactococcoccus*" 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 "*Rhizophus*" (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 "Microccocus 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 Unites 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 20ºC; 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 disodiummonophosphate 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 20ºC; 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