

23 April 2009
[6-09]

PROPOSAL P1008

CODE MAINTENANCE PROPOSAL

ASSESSMENT REPORT

Executive Summary

The purpose of P1008 is a Proposal to assess a range of proposed amendments to the *Australia New Zealand Food Standards Code* (the Code). The proposed amendments are intended to:

- correct minor errors, inconsistencies and ambiguities; and
- amend food regulatory measures in the Code to clarify a number of requirements, including for food additives, and to address some issues with the Code including issues raised in recent Applications.

Purpose

FSANZ regularly seeks to amend the Code to maintain its currency and clarity. FSANZ has prepared this Proposal to amend a number of provisions in the Code to ensure it remains current and to address some issues that have recently arisen. The Proposal is being assessed under the General Procedure.

Assessing the Proposal

In assessing this Proposal and the subsequent development of food regulatory measures, FSANZ has had regard to the following matters as prescribed in section 59 of the *Food Standards Australia New Zealand Act 1991* (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
- there are no other measures that would be more cost-effective that could achieve the same end
- any relevant New Zealand standards
- any other relevant matters.

Preferred Approach

It is proposed to amend the Code in accordance with the draft variations to maintain the effectiveness of the Code.

Reasons for Preferred Approach

- the proposed amendments do not raise any public health and safety concerns;
- the proposed amendments will ensure that the Code remains current and that regulatory measures in the Code are appropriate; and
- FSANZ does not anticipate that these amendments will be of major significance or result in major costs for the community.

Consultation

This Proposal is being assessed under the General Procedure in the FSANZ Act with one round of public consultation.

FSANZ acknowledges that this Proposal includes proposed amendments to a number of food regulatory measures in the Code and will therefore be of interest to a broad range of stakeholders. FSANZ does not anticipate that these amendments will be of major significance and has therefore applied a basic communication strategy to this Proposal. This will involve notifying the availability of the Assessment Report for public comment to an extensive database of interested parties and making the reports available on the FSANZ website for public access. FSANZ will also consult key stakeholders through targeted consultation mechanisms.

In addition, individuals and organisations that make submissions on this Proposal will be notified at each stage of the assessment of the Proposal. If the FSANZ Board approves the draft variation to the Code, FSANZ will notify the Ministerial Council of its decision. Stakeholders, including the public, will be notified of the gazettal of changes to the Code in the national press and on the FSANZ website.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variations to the Code based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection.

If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material.

Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked 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 using the Standards Development tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 20 May 2009

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, 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 (02) 6271 2222**

**Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942**

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INTRODUCTION

The *Australia New Zealand Food Standards Code* (the Code) is regularly amended to reflect the changing nature of the food supply and the associated changes to regulatory requirements. On occasions, minor typographical errors or inconsistencies can occur and FSANZ identifies and corrects these errors and inconsistencies to ensure the Code remains as accurate as possible. This Proposal includes a small number of proposed variations to the Code to address these matters.

In addition to these minor changes, FSANZ also reviews provisions in the Code to identify outdated or unnecessary provisions. This Proposal includes a number of proposed variations to address these matters.

This Proposal includes some proposed amendments to the Code to address specific issues that have been raised with FSANZ, including in Applications. The relevant Applications relate to the specification for bentonite (A1010), classification of ammonium chloride (A1016) and presence of 4-hexylresorcinol in cooked crustacea (A1020).

FSANZ is proposing to address these issues as part of this Proposal because it represents a more timely and efficient means of amending the Code for these issues.

In accordance with the FSANZ Act, this Proposal is being assessed in accordance with the General Procedure with one round of public comment.

1. The Issue / Problem

From time to time, FSANZ identifies and addresses issues with provisions in the Code to ensure that requirements are adequately expressed. These issues include inconsistencies, misspellings, grammatical errors, omissions and items requiring updating or clarification. In addition, there are some issues that arise from time to time (including in Applications) that could more efficiently be considered as part of a Proposal. FSANZ has compiled these issues for consideration as part of this Proposal.

2. Proposed Changes to Food Regulatory Measures

Specific changes proposed in this Proposal include, but are not limited to:

- updating the references to specifications in Standard 1.3.4 – Identity and Purity, including for bentonite
- amending Standard 1.3.1 – Food Additives, including its Purpose and clarifying requirements for certain colourings and the carry-over of food additives
- amending the permissions for additives in reconstituted fruit juices to reflect the use of additives in concentrated juices and more closely align with the Codex standard
- addressing anomalies or duplication in the Code with ammonium chloride, phytosterols/phytosterol esters and silica/silicates
- include a more explicit definition of the derivatives of the *Piper methysticum* plant that may be sold under food legislation and updating the Standard for Kava to reflect the additional regulatory requirements that apply to kava

- amending the definition for 'bread' to clarify its application to mandatory fortification Standards
- aligning the Code with the New Zealand food standard for tutin in honey.

3. Objectives

This Proposal includes a number of amendments to the Code which have been identified by FSANZ and other interested parties. In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety ;and
- 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.

The specific objective for this Proposal is to correct and update food regulatory measures in the Code in relation to errors, outdated provisions or anomalies.

4. Key Assessment Issues

The amendments proposed do not raise any public health and safety concerns. For this reason, an assessment of the risk to public health and safety has not been conducted for any of the proposed food regulatory measures.

5. Risk Assessment Summary

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

- correction of typographical and editorial errors, and addressing anomalies;
- updating of specifications and other references;
- clarification of the intent and application for a number of clauses.

On this basis, the assessment of the issues does not require a risk assessment.

6. Proposed Amendments

The draft amendments are intended to address minor inconsistencies, to amend outdated provisions and to include appropriate food regulatory measures arising from issues currently before FSANZ, including Applications on the workplan. The amendments are required to ensure that the information contained in the Code is correct and current. Each of these amendments has been assessed by scientific and legal staff to ensure that the recommended solutions are consistent with the intent of the food regulatory measures in 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 problem arises or, where relevant, additional details such as the section heading or column
- Issue:** the nature of the inconsistency, error or proposed change and where necessary the rationale for the suggested amendment
- Solution:** the proposed amendment.

There are some specific amendments for which stakeholders may require more detail. For clarity and understanding, FSANZ has provided some additional detail on these issues below.

FSANZ invites comment on the implications of these proposed amendments.

6.1 Standard 1.2.3 – Mandatory Warning and Advisory Statement and Declarations

- Location:** Subclauses 2(2) and 3(2).
- Issue:** The punctuation is inconsistent in the 1st line of each subclause (i.e. a comma after 'clause'). In addition, a comma after the word 'Table' is not required.
- Solution:** In subclause 3(2), remove the comma after the word 'clause'. In subclauses 2(2) and 3(2), remove the comma after the word 'Table'.

- Location:** Table to clause 2.
- Issue:** The entries for foods containing added tall oil phytosterols and foods containing added phytosterol esters could be rationalised into a single table entry of 'Foods containing added tall oil phytosterols or added phytosterol esters'.
- Solution:** Delete the individual entries for foods containing added tall oil phytosterols and foods containing added phytosterol esters and include a specific entry for 'Foods containing added tall oil phytosterols or added phytosterol esters' in Column 1 with the same Column 2 conditions that apply to each of these individual entries.

6.2 Standard 1.2.8 – Nutrition Information Requirements

- Location:** Editorial Note following subclause 5(2), second paragraph.
- Issue:** The reference to 'ml' should be 'mL'.
- Solution:** Amend the Editorial Note following subclause 5(2) to replace the reference to 'ml' with 'mL'.

6.3 Standard 1.2.10 – Characterising Ingredients and Components of Food

Location: Paragraph 2(4)(g).

Issue: Refers to Standard 1.1A.1 which no longer exists in the Code.

Solution: Remove reference to Standard 1.1A.1.

6.4 Standard 1.2.11 – Country of Origin Requirements

Location: Column 2 of the Table to subclause 2(2).

Issue: In Column 2 against 'Pork, whole or cut.....', paragraph (b) should read 'containing a statement indicating that the foods are a mix of local and/or imported foods as the case may be'.

In addition, the two entries that refer to 'pork' should be separated and the table formatted for clarification.

Solution: Add 'be' to the end of the sentence where necessary. Create lines in the Table to clarify the statements.

6.5 Standard 1.3.1 – Food Additives

Location: Purpose.

Issue: FSANZ considers that it is appropriate to provide more context about food additives in the Purpose section of the Standard. The intent of this additional context would be to characterise, in general terms, those substances that would not typically be regarded as food additives. FSANZ considers that this may be appropriate because:

- there are a range of foods and food derivatives that perform technological functions in food (e.g. cornflour, egg white, hops)
- this technological function in food does not of itself make these substances 'food additives'
- the intent of Standard 1.3.1 has never been to capture 'foods' that perform a technological function in food.

The intent of Standard 1.3.1 has been to capture those specific or synthetic substances that are used in food for technological functions but which are not normally consumed as foods or ingredients. The determination as to whether a substance should be regarded as a food additive will depend on the nature of the substance, the circumstances associated with its addition to food and its function in the food. Despite this general approach, there are some foods (e.g. turmeric) which have been determined to be food additives for historical reasons or for international alignment. In a practical sense the determination as to whether a substance is a food additive has been considered on a case-by-case basis and where it is considered appropriate to regard the substance in a food as a food additive then a specific entry in Standard 1.3.1 has been made to reflect this.

The Purpose section of Standard 1.3.1 seeks to provide context to the Standard and the purpose could include more context for those substances that are derived from food and that may perform a food additive technological function in food.

Solution: Amend the purpose of Standard 1.3.1 as indicated in Attachment 1.

Location: Subclause 5(2).

Issue: Following a recent survey on colourings in food, FSANZ proposes to amend Standard 1.3.1 to ensure that the water soluble version of annatto extracts, namely norbixin, is included in any calculated result for annatto extracts. More information about bixin and norbixin is at this link¹. This will involve amending the definition for annatto extracts in subclause 5(2) from ‘**annatto** and annatto extracts shall be calculated as bixin’ to ‘**annatto** and annatto extracts shall include norbixin and bixin, calculated as bixin’.

Solution: Replace existing definition with ‘**annatto** and annatto extracts shall include norbixin and bixin, calculated as bixin’.

Location: Clause 6.

Issue: FSANZ considers that clause 6 of Standard 1.3.1 could be made clearer and more consistent with other provisions in the Code that:

1. allow mixtures of related substances to be present in a food
2. apply restrictions such that the presence of these mixtures is no greater than would be permitted if a single substance were present (e.g. a mixture of preservatives may be present but the mixture should be limited to a level that would be consistent with the level used for a single preservative).

To achieve this FSANZ proposes rewording clause 6 and including an example formula.

Solution: Reword clause 6 as indicated in Attachment 1.

Location: Clause 7.

Issue: Application A1020 is an Application seeking to address a perceived ‘oversight’ in the Code for the substance 4-hexylresorcinol in crustacea. 4-hexylresorcinol is currently a food additive permitted to be used at GMP in uncooked crustacea (Schedule 1 of Standard 1.3.1). It is used to prevent enzyme related spoilage of raw crustacea (blackening). The substance is not applied to cooked crustacea because the cooking process destroys the enzymes and therefore the enzyme related spoilage does not occur in cooked product. 4-hexylresorcinol is likely to be present in cooked crustacea if the original raw crustacea were legitimately treated with products containing 4-hexylresorcinol.

According to the Applicant for A1020, Seafarm Pty Ltd, the provisions in the Code for 4-hexylresorcinol do not apply to crustacea that are subsequently cooked. The Applicant’s view is that as the Code stands, ‘uncooked crustacean treated with 4-hexylresorcinol are permitted, but cannot be cooked prior to consumption in Australia’. The Applicant has applied to amend the Code to ‘allow the presence of 4-hexylresorcinol in cooked crustacean, as carryover from treated raw crustaceans’.

The Application raises potential issues for other single ingredient foods which may contain food additives in their raw form and which are subsequently processed without the addition of other ingredients.

¹ ftp://ftp.fao.org/ag/agn/jecfa/cta_annatto.pdf

It has always been assumed that the 'carry over' provisions in Standard 1.3.1 (clause 7) apply in these circumstances – allowing a food additive to be present in a processed food where the food additive may legally be present or used in a raw material or ingredient of this processed food.

However, the existing clause 7 only refers to 'ingredients' as a potential source of carry over additives in a 'final food'. There is therefore doubt as to whether the existing clause 7 of Standard 1.3.1 allows additives to be present in a cooked or processed single ingredient food, where the presence of these additives is as a result of the use of an additive in uncooked or unprocessed raw material. Given this doubt, it is considered that the Code should be amended to address this anomaly. Consistent with the approach used in the international Codex General Standard for Food Additives², FSANZ proposes to amend clause 7 of Standard 1.3.1 (new proposed text is underlined) to state that:

Other than by direct addition, an additive may be present in any food as a result of carry-over from a raw material or an ingredient, provided that the level of the additive in the final food is no greater than would be introduced by the use of the raw material or ingredient under proper technological conditions and good manufacturing practice.

Given the minor technical nature of this Application and for efficiency, FSANZ has included this issue as part of this Proposal. If the proposed amendment associated with the presence of food additives by carry over is approved and gazetted in this Proposal then the application would need to be withdrawn by the applicant or rejected on the grounds that the issues are resolved by this Proposal.

Solution: Amend clause 7 as indicated in Attachment 1.

Location: Section '0' of Schedule 1.

Issue: Currently refers to 'ANZFA' guide and this should be deleted.

Solution: Delete the word 'ANZFA' and insert in its place the word 'the'.

Location: Section 1.1.3 and 1.1.4 of Schedule 1.

Issue: The categories for liquid milk to which tall oil phytosterols and phytosterol esters have been added could be rationalised into a single entry. This would reflect international practice where these substances are considered collectively.

Solution: Create a single category of '1.1.3 Liquid milk to which phytosterols or phytosterol esters have been added' and group all the currently permitted additives and their limits under it.

Location: Section 2.2.2 of Schedule 1.

Issue: Section 2.2.2 for oil emulsions (<80% oil) has an '**' missing.

Solution: Add an '**' to the heading of 'oil emulsions (<80% oil)'.

Location: Sections 6.4 and 7 of Schedule 1.

Issue: The terms for propionates could be consolidated into a single entry and made more consistent with the expressions used for sorbates and benzoates.

Solution: For sections 6.4 and 7, generalise the entry in the 'Additive Name' column of Schedule 1 to 'Propionic acid and sodium and potassium and calcium propionates' and generalise the associated entry in the 'INS Number' column to '280 281 282 283'. The limits in the 'Maximum Permitted Level' column to be generalised to a single entry that is the same as that which is already in this column.

² <http://www.codexalimentarius.net/gsfaonline/index.html?lang=en>

Location: Section 8.1 of Schedule 1.

Issue: There is an entry for 'fresh poultry' and this is not considered an appropriate descriptor.

Solution: Delete the word 'fresh' in the entry.

Location: Section 13 of Schedule 1.

Issue: This category uses the term 'sulphur dioxide' instead of the more general term 'sulphur dioxide and sodium and potassium sulphites'.

Solution: Replace the term 'sulphur dioxide' with the term 'sulphur dioxide and sodium and potassium sulphites' and the entry for '220' with the entry '220 221 222 223 224 225 228' in sections 13.4.1 and 13.4.2.

Location: Section 14.1.2.1 and Section 14.1.2 of Schedule 1.

Issue: It is proposed to amend category 14.1.2.1 to clarify the food additives that may be present in juices, including reconstituted juices and to remove unnecessary qualifications. The juice industry in Australia and New Zealand has approached FSANZ about problems and concerns it had with the current provisions for additives in fruit and vegetable juices, specifically food additives permitted in juices made from concentrate i.e. reconstituted fruit juices.

Section 14.1.2.1 provides for the food additives permitted in fruit and vegetable juices. These provisions were in part considered in Proposal P182 during the development of the Code. The intent of the existing requirements was that additives in Schedules 2, 3 and 4 be permitted in fruit and vegetable juices where these juices are obtained or produced by techniques that are non-mechanical. The relevant text from Proposal P182 is reproduced below:

Juices manufactured using non-mechanical processes such as heat extraction or concentration will be permitted to contain the additives specifically listed for juices in Standard 1.3.1, as well as those listed in the general schedules of the proposed additives standard, which include flavours and colours. The use of these additives must be consistent with Good Manufacturing Practice and not for disguising inferior ingredients.

The permitted additives for fruit and vegetable juice concentrates are under 'fruit and vegetable juice products' in Schedule 1 (section 14.1.2) and these include additives in Schedules 2, 3 and 4. Where a juice is reconstituted from concentrate or contains concentrate then additives in Schedules 2, 3 and 4 are permitted in the resulting fruit or vegetable juice by virtue of the carry-over of additives permitted in fruit and vegetable juice products (see item on clause 7 of Standard 1.3.1 above). This is acceptable provided that the use of these additives in the concentrate is consistent with Good Manufacturing Practice (GMP). Where obtained by mechanical means only (i.e. not produced from concentrate) then juices are not permitted to contain Schedule 2, 3 and 4 additives (section 14.1.2.1).

FSANZ understands that the concerns with the current provisions are that:

- there are no specific limits for certain food additives that may legitimately be present in juices made from concentrate (e.g. pectins, phosphates) and this creates uncertainty within the industry;
- there is potential for the 'mechanical means only' qualification to be misinterpreted

- there is potential for a broad range of inappropriate additives to be present in juices via concentrates.

FSANZ accepts that these current provisions could be improved and based on suggestions made by the juice industry, proposes the following amendments to Section 14.1.2.1. These amendments would generally align the limits in the Code with the Codex General Standard for Food Additives with the difference being the use of carotenes and flavourings. These ingredients are added to juices in Australia and New Zealand to standardise the colour and flavour of juice products.

FSANZ acknowledges that these proposed amendments, in theory, represent a restriction on the food additives that may be present in juices, although it should be noted that food additives have only ever been permitted in reconstituted juices where this is consistent with Good Manufacturing Practice. In any case, the amendments align the Code more closely with the Codex international standard and the amendments are consistent with requests from industry for more clarity around the additives that may legitimately be present in juices, including reconstituted juices.

In addition to amending Section 14.1.2.1, FSANZ also proposes to delete the qualification in Section 14.1.2 which states 'GMP principle precludes the use of preservatives in juices represented as not preserved by chemical or heat treatment'. This is because this qualification is unnecessary in the Schedule and is therefore unnecessary.

Solution: In Section 14.1.2, delete the qualification, 'GMP principle precludes the use of preservatives in juices represented as not preserved by chemical or heat treatment'

In section 14.1.2.1 make the following changes:

1. Delete the qualification 'applies to fruit and vegetable juices separated by mechanical means only';
2. Amend the heading for Section 14.1.2.1 to 'Fruit and vegetable juices (including juices containing or made from concentrates)';
3. Add specific entries at 'GMP' for the following additives under the Section 14.1.2.1:
 - 'Carotenes' (160a) and 'Carotenal, b-apo-8'-' (160e)
 - 'Phosphoric acid' (338), 'Sodium, potassium and calcium phosphates' (339,340,341), 'Ammonium phosphates' (342), 'Magnesium phosphates' (343)
 - 'Pectin' (440)
 - 'Pyrophosphates' (450), 'Triphosphates' (451), 'Polyphosphates' (452) and 'Bone phosphate' (542)
 - 'Flavourings, except quinine and caffeine'.

Location: Schedule 2 – both the alphabetical and numeric listing.

Issue: Ammonium chloride is currently a generally permitted processing aid listed in the Table to clause 3 of Standard 1.3.3 – Processing Aids. In addition, a number of ammonium and chloride salts are generally permitted food additives in Schedule 2 of Standard 1.3.1.

According to the Applicant for Application A1016, International Flavours & Fragrances (Australia) Pty Ltd, this Application is required because ammonium chloride is generally permitted as a flavouring or food additive internationally and this is not currently the case in Australia and New Zealand.

The Applicant has also noted that until 2002, ammonium chloride was permitted in salt substitutes under the food legislation that existed at that time, but was not included as a permitted additive in salt substitutes in the Code when it was originally gazetted. Given the minor technical nature of this Application and for efficiency, FSANZ has included this issue as part of this Proposal. If the proposed amendment associated with this use of ammonium chloride is approved and gazetted in this Proposal then this would mean that Application A1016 would need to be withdrawn by the applicant or rejected on the grounds that the issues are resolved by this Proposal.

FSANZ has noted that ammonium chloride is:

1. a generally permitted food additive in the Codex General Standard for Food Additives
2. a generally permitted food additive in the USA
3. excluded from the definition of food additive in Europe (including the UK)³.

Application A1016 relates to a minor technical amendment to the Code to allow ammonium chloride as a generally permitted food additive, in addition to its current use as a generally permitted processing aid. Application A1016 seeks to align the Code with the relevant international standard and the regulation of ammonium chloride in other countries. It also serves to address what appears to be an oversight during the development of the Code where the use of ammonium chloride in salt substitutes was not continued into the Code.

Ammonium chloride is already a generally permitted processing aid with no specific limits in food. Given the historical and international status of ammonium chloride, a safety, dietary exposure and food technology report are not considered necessary to amend the Code.

FSANZ proposes to amend the Code to delete the entry for 'ammonium chloride' from the Table to clause 3 of Standard 1.3.3 and include an entry for 'ammonium chloride' in Schedule 2 of Standard 1.3.1. All the substances included in Schedule 2 of Standard 1.3.1 are also generally permitted processing aids for the purposes of Standard 1.3.3. Therefore, the proposed amendment would ensure that the use of ammonium chloride as a generally permitted processing aid is retained but that this is extended to its use as a generally permitted food additive.

Solution: Add 'Ammonium chloride (510)'.

Location: Schedule 4.

Issue: Following a recent survey on colourings in food, FSANZ proposes to amend Standard 1.3.1 to ensure that the limits for Schedule 4 colourings are clarified such that where specified in Schedule 1, the total maximum permitted amount of colourings in Schedule 4 is 290 mg/kg in processed foods and 70 mg/L in beverages. This will involve amending the heading for Schedule 4 to 'Colours permitted to a total maximum level of 290 mg/kg in processed foods and to a total maximum level of 70 mg/L in beverages other than beverages specified in Schedule 1'.

Solution: Amend the heading by replacing it with 'Colours permitted to a total maximum level of 290 mg/kg in processed foods and to a total maximum level of 70 mg/L in beverages other than beverages specified in Schedule 1'.

³ This is because ammonium chloride has traditionally been used as a specific ingredient in certain foods of cultural significance.

6.6 Standard 1.3.2 – Vitamins and Minerals

Location: Clause 1.

Issue: The definition of ‘claimable food’ is unclear and ambiguous due to a formatting error.

Solution: For paragraph (b), ‘a mixture of’ should sit outside subparagraph (i), as in:

- (b) a mixture of –
 - (i) primary foods; and/or
 - (ii) water; and/or
 - (iii) foods listed in the Table to clause 3 excluding butter, cream and cream products, edible oils, edible oil spreads and margarine.

6.7 Standard 1.3.3 – Processing Aids

Location: Clause 1 and the Table to clause 3.

Issue: There are some anomalies with the current entries in the Standard for silica and silicates. These anomalies include:

1. The ‘double-mentioning’ of some silicates as generally permitted processing aids in Standard 1.3.3 when they are already generally permitted food additives in Schedule 2 of Standard 1.3.1.
2. The lack of certainty as to whether the term ‘silicates’ covers silica as distinct from silicon dioxide, the latter which is a generally permitted food additive in Schedule 2 of Standard 1.3.1.

To address this, FSANZ proposes to:

1. Amend the existing entry in clause 1 of Standard 1.3.3. for ‘silicates’ to ‘silica or silicates includes sodium calcium polyphosphate silicate, sodium hexafluorosilicate, sodium metasilicate, sodium silicate, silica and modified silica that complies with a monograph specification in clause 2 or clause 3 of Standard 1.3.4’.
2. Amend the existing entry for ‘silicates’ to ‘silica or silicates’ in the Table to clause 3 of Standard 1.3.3.

This would remove calcium aluminium silicate, calcium silicate, magnesium silicate and sodium aluminosilicate from the list of ‘silicates’ as these are already generally permitted processing aids by virtue of their inclusion in Schedule 2 of 1.3.1. It also includes ‘silica’ and all modified forms of silica provided that there is a specification for this modified silica in one of the primary or secondary specification sources in Standard 1.3.4.

Solution: Amend the existing entry in clause 1 for ‘silicates’ to ‘silica or silicates includes sodium calcium polyphosphate silicate, sodium hexafluorosilicate, sodium metasilicate, sodium silicate, silica and modified silica that complies with a monograph specification in clause 2 or clause 3 of Standard 1.3.4’ and amend the existing entry for ‘silicates’ to ‘silica or silicates’ in the Table to clause 3 of Standard 1.3.3.

Location: Table to clause 3.

Issue: Delete ‘Ammonium chloride’ entry (See item on ammonium chloride above).

Solution: Delete ‘Ammonium chloride’ entry.

Location: Table to clause 17.

Issue: There is a duplication of rows for the entry for asparaginase.

Solution: Merge the two rows into a single entry by deleting:

Asparaginase EC 3.5.1.1	<i>Aspergillus niger</i>
Asparaginase EC 3.5.1.1	<i>Aspergillus oryzae</i>

and adding:

Asparaginase EC 3.5.1.1	<i>Aspergillus niger</i> <i>Aspergillus oryzae</i>
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6.8 Standard 1.3.4 – Identity and Purity

Location: The references in clauses 2 and 3.

Issue: This Standard requires updating to more contemporary editions and publications.

Solution: It is proposed to omit the existing clause 2 and clause 3 as indicated in Attachment 1.

Location: Schedule.

Issue: Bentonite is approved as a generally permitted food additive listed in Schedule 2 of Standard 1.3.1, so it has approval as a generally permitted processing aid (via subclause 3(b) of Standard 1.3.3). Bentonite is permitted as a processing aid in the Table to clause 4 of Standard 4.5.1 – Wine Production Requirements (Australia Only) and can currently be used at a level necessary to achieve a specific function in the processing of food. A specification for bentonite is currently in the sixth edition of the (FCC), one of the primary sources of specifications for substances added to food. The current FCC specification stipulates that the pH range for bentonite dispersions should be in the range of 8.5 to 10.5.

The Applicant for Application A1010, Arumpo Bentonite Pty Ltd, has requested an extension of the pH range for bentonite dispersions from the 8.5 to 10.5 range to a range of 4.5 to 10.5. Given the minor technical nature of this Application and for efficiency, FSANZ has included the pH modification for bentonite in A1010 as part of this Proposal. If the proposed amendment associated with this pH modification is approved and gazetted in this Proposal the application would need to be withdrawn by the applicant or rejected on the grounds that the issues are resolved by this Proposal.

The Applicant for A1010 has requested this change to ensure that the bentonite from a particular deposit in Australia can be used in food, including the use of this bentonite in wine processing. The bentonite dispersion from the particular deposit has a pH of approximately 4.7 and this is outside the current pH range for bentonite in the FCC. The other primary source for specifications (the Food and Agriculture Organization, Combined Compendium of Food Additive Specifications) does not include a specific specification for bentonite.

FSANZ has no safety concerns with the minor modification to the pH range for bentonite, particularly given that the other aspects of the FCC bentonite specification would continue to apply.

The Applicant for A1010 has indicated that the bentonite which is the subject of their Application complies with the other specification requirements for bentonite.

Similarly, and as bentonite is already generally permitted as a processing aid/food additive, FSANZ has no food technology concerns with bentonite of a slightly different pH profile being used in food.

In summary, FSANZ considers that there are no safety or technological reasons why the specification for bentonite should not be modified to extend the pH range for bentonite dispersions, while ensuring that the other aspects of the bentonite specification continue to apply. FSANZ proposes that Standard 1.3.4 be amended to indicate that the pH range for bentonite dispersions should be no less than 4.5 and no more than 10.5.

Solution: Include an entry for Bentonite in the Schedule as indicated in Attachment 1.

6.9 Standard 1.4.1 – Contaminants and Natural Toxicants

Location: Table of provisions.

Issue: The name of clause 6 does not match the name in the body of the Standard.

Solution: Amend the Table of provisions to clause 6 as the 'Sampling plan for mercury in fish, fish products, crustacea and molluscs'.

Location: Subclause 1(6).

Issue: The prescribed formula could be made clearer.

Solution: Amend subclause 1(6) as indicated in Attachment 1.

Location: Editorial Note to clause 1.

Issue: The Editorial note could be simplified in relation to cadmium or lead limits of reporting.

Solution: Amend the Editorial note as indicated in Attachment 1.

Location: Various references throughout the Standard.

Issue: References to 'Column 1' or 'Column 2' in the Standard should be capitalised.

Solution: Capitalise all relevant references to 'Column 1' and 'Column 2'.

Location: Table to clause 5.

Issue: A Food Standard for tutin in honey and comb honey came into force in New Zealand on 25 January 2009⁴. That Standard had been developed to ensure that dangerous levels of tutin do not occur in honey sold in New Zealand or exported from New Zealand. Information about tutin is contained in a consultation document released by the New Zealand Food Safety Authority (NZFSA)⁵. NZFSA has also produced a compliance guide with details about tutin⁶.

FSANZ proposes to align the Code with the Food (Tutin in Honey) Standard 2008 (*New Zealand*) as an interim measure to advance the objectives of the *Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System* (the Treaty).

⁴ <http://www.nzfsa.govt.nz/policy-law/legislation/food-standards/tutin-standard-final.pdf>

⁵ <http://www.nzfsa.govt.nz/animalproducts/subject/bee-products/tutin-discussion/tutin-in-honey-discussion-paper-final-for-web.pdf>

⁶ <http://www.nzfsa.govt.nz/animalproducts/publications/manualsguides/tutin-standard-compliance-guide/index.htm>

Under the Treaty, New Zealand authorities have informed authorities in Australia of this food standard as required under Annex DIII of the Treaty.

The alignment can be readily achieved by including the same limits in the Code as those that are in the New Zealand Food Standard. FSANZ therefore proposes to include a limit of 2 mg/kg for tutin in honey and 0.1 mg/kg for tutin in comb honey in the Table to clause 5. As this is an interim measure, FSANZ also proposes that these limits cease to have effect after 31 March 2011, pending further review.

These limits are proposed as a joint standard because:

- these limits are already in effect in New Zealand;
- the identified plant source of tutin, namely *Coriaria arborea*, is not endemic to Australia and therefore no impacts on honey producers in Australia are expected; and
- the limits are also not expected to impact on importers of honey and in any case, for the protection of public health and safety all honey should comply with these limits.

FSANZ understands that capability for measuring tutin in honey has been developed and details of approved laboratories in New Zealand are available from the NZFSA.

Solution: Include a limit of 2 mg/kg for tutin in honey and 0.1 mg/kg for tutin in comb honey in the Table to clause 5 with these limits to cease to have effect after 31 March 2011.

6.10 Standard 1.4.4 – Prohibited and Restricted Plants and Fungi

Location: Schedule 1.

Issue: The entry for 'Ammi visnaga' was deleted as part of P1001 when the entry for 'Ammi species' should have been deleted.

Solution: Delete the entry for 'Ammi species' and add '*Ammi visnaga*'.

6.11 Standard 1.5.1 – Novel Foods

Location: Table of Provisions.

Issue: The Table does not include clause 3 – Exclusive use of novel foods.

Solution: Add clause 3 to the list in Table of Provisions.

Location: Entry for diacylglycerol oil (DAG-Oil) in the Table to clause 2.

Issue: Column 2 – Conditions of Use states that 'Diacylglycerol oil' is a prescribed name. This is inconsistent with the conditions of use for other novel foods such as α -cyclodextrin, γ -cyclodextrin and phytosterol esters where the name is not prescribed. The rationale for originally prescribing the name 'diacylglycerol oil' was to ensure that consumers could easily identify diacylglycerol oil in the ingredient list and that it was different to other generic oils in the Code. This does not require the use of a prescribed name and can be achieved by one condition of use that requires that the name diacylglycerol oil be used in the ingredient list, in accordance with Standard 1.2.4.

Solution: Amend the entry for DAG-Oil as indicated in Attachment 1.

6.12 Standard 1.5.2 – Food Produced Using Gene Technology

Location: Editorial note after clause 7.

Issue: The reference to the user guide should be deleted as a user guide is no longer available as a FSANZ document.

Solution: Delete the Editorial note.

6.13 Standard 1.6.2 – Processing Requirements

Location: Table of Provisions.

Issue: Clauses 1 and 2 and the Schedule were deleted on 5 October 2008 but the clause list was not updated.

Solution: Amend the Table of Provisions to list clauses 1 and 2 as deleted and to remove reference to the Schedule.

Location: Editorial note following clause 8.

Issue: Clause 9 is referenced, but has been deleted.

Solution: Delete the reference to clause 9 from the Editorial Note.

6.14 Standard 2.1.1 – Cereals and Cereal Products

Location: Clause 1.

Issue: The current definition of ‘bread’ needs to be amended to make it clear that in relation to mandatory fortification of bread does not include pizza bases, bread – crumbs, pastries, cakes (including brioche, panettone and stolen), biscuits or crackers.

Solution: Amend the definition as indicated in Attachment 1. It is proposed that this amended definition commence on 13 September 2009 to reflect the commencement date of other variations to Standard 2.1.1.

Location: Editorial Note after subclause 4(2) of Standard 2.1.1.

Issue: The word ‘Note’ is used instead of ‘Editorial note’.

Solution: Add the word ‘Editorial’.

6.15 Standard 2.5.1 – Milk

Location: Clauses 5 and 6 and the Table of Provisions.

Issue: The two specific clauses for milk containing added tall oil phytosterols and milk containing added phytosterol esters could be rationalised into a single clause for ‘Tall oil phytosterols and added phytosterol esters’.

Solution: Amend the clauses and the Table of Provisions as indicated in Attachment 1.

6.16 Standard 2.6.3 – Kava

Location: Purpose section and clauses 1 and 2.

Issue: The Standard needs to be updated to remove the reference to the National Code of Kava Management, and to refer to the wider regulatory framework for kava (e.g. *Customs (Prohibited Imports) Regulations 1956* and other restrictions on the supply of kava in Australia) and to include a more explicit definition of the derivatives of the *Piper methysticum* plant that may be sold under food legislation.

The requirements for kava were developed as part of Proposal P256⁷ in which the intent of the Standard was to:

- exclude the use in food of kava extracts prepared by organic solvent extraction. Such extracts raise safety concerns with hepatotoxicity; and
- restrict kava to the peeled root and/or peeled rootstock of the plant because these plant parts have a tradition of safe use in the preparation of the kava beverage.

The Standard in its current form could make these exclusions and restrictions more explicit. FSANZ proposes to amend the Standard to more clearly apply this intent and to state that *Piper methysticum* (kava) or any derived substance must not be sold or present in a food unless it is:

- (a) a beverage obtained by cold water extraction; or
- (b) the dried or raw form of the peeled root and/or peeled rootstock of plants of the species *Piper methysticum*.

In relation to additional regulatory requirements, there is other legislation that applies in relation to kava supply, including restrictions under *Customs (Prohibited Imports) Regulations 1956* on the importation of kava into Australia⁸. The existing Standard does not override this legislation but it does complement it. The most effective way of providing this context to the existing Standard is by amendment of the Purpose to reflect recent legislative changes. This approach would place the Standard in the correct context given the other controls that are in place. It would also ensure that the Standard reflects the use of kava in New Zealand (under dietary supplements regulations) and that there are provisions in place should cultivation and commercial supply of kava occur in Australia.

Solution: Amend the Standard to indicate that the Standard only applies where kava is permitted to be supplied i.e. that any other restrictions on supply take precedence over anything in the Standard. To achieve this:

- the Purpose to be amended as indicated in Attachment 1
- clauses 1 and 2 should be amended to delete the definition of 'kava' and exclude the use in food of kava extracts prepared by organic solvent extraction and to restrict kava to the peeled root and/or peeled rootstock of the plant because these plant parts have a tradition of safe use in the preparation of the kava beverage.

6.17 Standard 2.6.4 – Formulated Caffeinated Beverages

Location: Editorial note following subclause 2(3).

Issue: The reference to '*Food Standards Code*' should be to the '*Australia New Zealand Food Standards Code*'.

Solution: Amend the reference.

⁷

<http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp256reviewofkavastandardso10263/index.cfm>

⁸ <http://www.health.gov.au/internet/main/publishing.nsf/Content/importation-of-kava>.

6.18 Standard 2.7.4 – Wine and Wine Products

Location: Table of Provisions.

Issue: There is no longer a clause 3, so reference should be removed from the Table.

Solution: Delete reference to clause 3 – Wine and wine product produced in Australia.

Location: Definition of 'wine product' in clause 1.

Issue: The definition is missing the word 'it'.

Solution: Add the word 'it' such that the definition reads 'mixed with other foods such that it is not wine'.'

6.19 Standard 3.1.1 – Interpretation and Application

Location: Subclause 2(5).

Issue: There are four mentions of '*Food Standards Code*' which should be '*Australia New Zealand Food Standards Code*'.

Solution: Amend all references.

6.20 Standard 3.2.3 – Food Premises and Equipment

Location: Editorial Notes following subclauses 4(1) and 13(1).

Issue: The word 'Clause' in these editorial notes should be 'clause' in lower case.

Solution: Amend all references.

6.21 Standard 4.2.3 – Primary Production and Processing Standard for Meat

Location: Table of Provisions and the Schedule.

Issue: The Table of Provisions does not include any mention of the Schedule to this Standard and the Schedule could be made more specific as to the method.

Solution: Amend the Schedule heading and add it to the Table of Provisions.

6.22 Standard 4.2.4A – Primary Production and Processing Standard for Specific Cheeses

Location: First paragraph of the Editorial Note.

Issue: The word 'paragraph' is repeated.

Solution: Delete the superfluous word 'paragraph'.

7. Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sections of the community, including consumers, food industries and governments. The regulatory options available for this Proposal are:

7.1 Option 1 – To abandon the Proposal

This option maintains the *status quo* by retaining the existing provisions in the Code.

7.2 Option 2 – To prepare draft variations to the Code to incorporate the proposed amendments

This option would require the preparation of amendments to the Code to incorporate the proposed changes.

8. Impact Analysis

8.1 Affected Parties

The parties likely to be affected by this Proposal include:

1. Industry which would need to comply with any amendments to the Code.
2. Consumers who may have concerns about amendments to the Code and the implications of these amendments.
3. Government agencies in Australia and New Zealand which, among other activities, ensure compliance with the Code.

8.2 Benefit Cost Analysis

8.2.1 Option 1

8.2.1.1 Benefits

- there are no perceived or discernable benefits for affected parties if this option is adopted.

8.2.1.2 Costs

- for consumers, there are unlikely to be any discernable costs if this option is adopted
- for industry, there are unlikely to be any discernable costs if this option is adopted
- for New Zealand and Australian Government, State and Territory agencies, adopting this option would be unlikely to result in any specific costs, although the uncertainty associated with some existing regulatory measures may be an inconvenience.

FSANZ invites comment on whether any costs are likely to be discernable by interested parties.

8.2.2 Option 2

8.2.2.1 Benefits

- for consumers, the major benefit would be maintaining existing confidence in the food supply in relation to improving regulatory requirements in the Code
- for some members of industry the proposed amendments will have the benefit of clarifying regulatory measures (e.g. juice industry) and allowing certain substances to be used that are not currently the case (e.g. ammonium chloride, bentonite with a greater pH range)
- for New Zealand and Australian Government, State and Territory agencies, adopting this option would foster community confidence that regulatory authorities are regularly maintaining Standards to ensure clarity and consistency, and will have the benefit of clarifying regulatory measures.

In relation to the proposed amendments for kava and tutin, there is the added benefit of aligning the Code with other national and international legislation.

FSANZ invites comment on whether there are any other benefits associated with this option.

8.2.2.2 Costs

- for consumers, there are unlikely to be any costs associated with the proposed amendments to the Code
- for industry complying with the proposed amendments should not result in any additional costs, because the proposed measures only institute procedures and practices which they already follow
- for New Zealand and Australian Government, State and Territory agencies, adopting this option would be unlikely to result in any specific costs, although there may be a need for these agencies to acquaint themselves with any changes to the Code.

FSANZ invites comment on whether there are any costs for industry or government agencies associated with this option.

8.3 Comparison of Options

In assessing Proposals, FSANZ considers the impact of various regulatory (and non-regulatory) options on all sectors of the community, including consumers, food industries and governments in Australia.

For this Proposal, Option 1 is not regarded as viable or desirable because it would perpetuate errors, inconsistencies and outdated provisions in the Code. While the costs to the community of adopting this option are low, the lack of credibility associated with retaining provisions that are known to be inadequate means that this option is not considered appropriate. Option 2 is a viable and desirable option, as overall it is considered that the benefits to the community of amending the Code will outweigh any costs.

9. Communication

This Proposal includes proposed amendments to a number of food regulatory measures in the Code and will therefore be of interest to a broad range of stakeholders. FSANZ does not anticipate that these amendments will be of major significance and for this reason FSANZ has applied a basic communication strategy to this Proposal. This will involve advertising the availability of the Assessment Report for public comment in the national press and making the reports available on the FSANZ website.

10. Consultation

This Proposal is being assessed under the General Procedure in the FSANZ Act. This means that one round of public consultation is required for the Proposal. FSANZ will also consult key stakeholders through targeted consultation mechanisms.

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

If the FSANZ Board approves the draft variations to the Code, FSANZ will notify the Ministerial Council of its decision. Stakeholders, including the public, will be notified on the gazettal of changes to the Code in the national press and on the FSANZ website.

10.1 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.

There are relevant international standards and the proposed amendments to the Code are unlikely to have a significant effect on international trade as they relate to the correction of errors, clarification of the intent of certain provisions and in some cases amendments to the Code to align with international standards.

On this basis, a notification is not recommended under either the WTO Technical Barriers to Trade (TBT) or Sanitary and Phytosanitary Measures (SPS) Agreement.

CONCLUSION

11. Conclusion and Preferred Option

The proposed draft variations in this Proposal have been prepared to:

- correct minor errors, inconsistencies and ambiguities
- amend food regulatory measures in the Code to clarify a number of requirements
- amend a number of food regulatory measures to address some issues raised with FSANZ, including in recent Applications.

Preferred Approach

It is proposed to amend the Code in accordance with the draft variations to maintain the effectiveness of the Code.

Reasons for Preferred Approach

- the proposed amendments do not raise any public health and safety concerns
- the proposed amendments will ensure that the Code remains current and that regulatory measures in the Code are appropriate
- FSANZ does not anticipate that these amendments will be of major significance or result in major costs for the community.

12. Implementation

It is proposed that the variations in this Proposal should take effect on gazettal except for the definition of bread (item 14.1 in Attachment 1) which is proposed to take effect on 13 September 2009.

ATTACHMENT

1. Draft variations to the *Australia New Zealand Food Standards Code*

Attachment 1

Draft variations to the *Australia New Zealand Food Standards Code*

Section 87(8) of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting

To commence: on gazettal, except for Item [14.1] which commences on 13 September 2009

[1] **Standard 1.2.3** of the *Australia New Zealand Food Standards Code* is varied by –

[1.1] *omitting subclause 2(2), substituting –*

(2) Where a food listed in column 1 of the Table to this clause is not required to bear a label pursuant to clause 2 of Standard 1.2.1, the advisory statement listed in relation to that food in column 2 of the Table must be –

- (a) displayed on or in connection with the display of the food; or
- (b) provided to the purchaser upon request; or
- (c) displayed on or in connection with food dispensed from a vending machine.

[1.2] *omitting from the Table to clause 2 –*

Foods containing added phytosterol esters	Statements to the effect that – <ol style="list-style-type: none">1. when consuming this product, it should be consumed as part of a healthy diet;2. this product may not be suitable for children under the age of five years and pregnant or lactating women; and3. plant sterols do not provide additional benefits when consumed in excess of three grams per day.
Foods containing added tall oil phytosterols	Statements to the effect that – <ol style="list-style-type: none">1. when consuming this product, it should be consumed as part of a healthy diet;2. this product may not be suitable for children under 5 years and pregnant or lactating women; and3. plant sterols do not provide additional benefits when consumed in excess of three grams per day.

substituting –

Foods containing added tall oil phytosterols or added phytosterol esters	<p>Statements to the effect that –</p> <ol style="list-style-type: none"> 1. when consuming this product, it should be consumed as part of a healthy diet; 2. this product may not be suitable for children under the age of five years and pregnant or lactating women; and 3. plant sterols do not provide additional benefits when consumed in excess of three grams per day.
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[1.3] *omitting subclause 3(2), substituting –*

(2) Where a food listed in column 1 of the Table to this clause is not required to bear a label pursuant to clause 2 of Standard 1.2.1, the advisory statement listed in relation to that food in column 2 of the Table must be –

- (a) displayed on or in connection with the display of the food; or
- (b) displayed on or in connection with food dispensed from a vending machine.

[2] **Standard 1.2.8** of the Australia New Zealand Food Standards Code is varied by *omitting the Editorial note to subclause 5(2), substituting –*

Editorial note:

‘Average quantity’ is determined in accordance with the definition set out in clause 2 of Standard 1.1.1. Average quantities may be indicated, for example, by inserting the word ‘Average’ or an abbreviation for average at the beginning of ‘Quantity per Serving’ and the ‘Quantity per 100 g (or 100 mL)’ columns, or including a note at the end of the panel stating that all specified values are averages.

No format is prescribed for the indication of minimum and maximum quantities. They may be indicated, for example, by inserting the bracketed abbreviations ‘(min)’ and ‘(max)’ immediately after the relevant quantities in the Quantity per Serving column and the Quantity per 100 g (or 100 mL) column.

Clause 12 explains when minimum and maximum quantities may be indicated.

[3] **Standard 1.2.10** of the Australia New Zealand Food Standards Code is varied by *omitting paragraph 2(4)(g), substituting –*

- (g) food standardised in Standard 2.9.1; or

[4] **Standard 1.2.11** of the Australia New Zealand Food Standards Code is varied by *omitting the Table to subclause 2(2), substituting –*

Table to subclause 2(2)

Column 1	Column 2
Food	Labelling requirement
<p>Where the food is displayed for retail sale other than in a package</p> <p>Fish, including cut fish, filleted fish, fish that has been mixed with one or more other foods and fish that has undergone any other processing including cooking, smoking, drying, pickling or coating with another food</p>	<p>A label on or in connection with the display of the food –</p> <p>(a) identifying the country or countries of origin of the food; or</p> <p>(b) containing a statement indicating that the foods are a mix of local and/or imported foods as the case may be.</p>
<p>Fresh pork, whole or cut, except where the product has been mixed with food not regulated by this subclause</p>	<p>A label on or in connection with the display of the food –</p> <p>(a) identifying the country or countries of origin of the food; or</p> <p>(b) containing a statement indicating that the foods are a mix of local and/or imported foods as the case may be.</p>
<p>Pork, whole or cut, that has been preserved by curing, drying, smoking or by other means, except where that product has been mixed with food not regulated by this subclause (other than those foods used in the preserving)</p>	<p>A label on or in connection with the display of the food –</p> <p>(a) identifying the country or countries of origin of the food; or</p> <p>(b) containing a statement indicating that the foods are a mix of local and/or imported foods as the case may be.</p>
<p>Fresh whole or cut fruit and vegetables</p>	<p>A label on or in connection with the display of the food –</p> <p>(a) identifying the country or countries of origin of the food; or</p> <p>(b) containing a statement indicating that the foods are a mix of local and/or imported foods as the case may be.</p>
<p>Whole or cut fruit and vegetables where that produce has been preserved, pickled, cooked, frozen or dehydrated except where that produce has been mixed with food not regulated by this subclause (other than with those foods used in the preserving, pickling or cooking as the case may be)</p>	<p>A label on or in connection with the display of the food –</p> <p>(a) identifying the country or countries of origin of the food; or</p> <p>(b) containing a statement indicating that the foods are a mix of local and/or imported foods as the case may be.</p>

<p>Where the food is displayed for retail sale in a package that does not obscure the nature or quality of the food</p> <p>Fresh whole or cut fruit and vegetables</p>	<p>A label on the package or in connection with the display of the food –</p> <p>(a) identifying the country or countries of origin of the food; or</p> <p>(b) containing a statement indicating that the foods are a mix of local and/or imported foods as the case may be.</p>
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[5] **Standard 1.3.1 of the Australia New Zealand Food Standards Code is varied by –**

[5.1] *omitting the Purpose, substituting –*

Purpose

A food additive is any substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which is intentionally added to a food to achieve one or more of the technological functions specified in Schedule 5 of this Standard. Food additives or their by-products may remain in the food to which they have been added. Unless specifically mentioned in this Standard, the following substances are not generally considered food additives:

1. foods in dried or concentrated form
2. aqueous extracts of foods
3. substances derived from foods through physical, enzymatic or mechanical processes (e.g. juicing, cooking) provided that these processes do not result in the selective extraction or selective production of a specific chemical substance that has a technological function in food.

Additives can only be added to food in order to achieve an identified technological function according to Good Manufacturing Practice. This Standard includes limits and requirements for food additives in food. A food additive may only be added to food where expressly permitted in this Standard.

Food additives are distinguishable from processing aids (see Standard 1.3.3) and vitamins and minerals added to food for nutritional purposes (see Standard 1.3.2).

Standard 1.3.4 prescribes standards for the identity and purity of food additives.

Standard 1.4.4 includes requirements for prohibited and restricted plants and fungi.

Standard 1.5.1 includes requirements for novel food and novel food ingredients.

[5.2] *omitting the definition of **annatto** in subclause 5(2), substituting –*

annatto and annatto extracts shall include norbixin and bixin, calculated as bixin.

[5.3] *omitting clause 6, substituting –*

6 Additives performing the same function

- (1) Where a food contains a mixture of food additives that perform the same technological function, the sum of the proportion of these additives in the food must not be more than 1.
- (2) The sum of the proportion of food additives in a food is calculated by:
- (a) dividing the concentration of each food additive in a food by the maximum permitted limit for that additive in that food; and
 - (b) adding the proportions together for each of the food additives performing the same technological function.

Example Formula for Additives Performing the Same Function

$$\text{Sum of the proportion of food additives} = \frac{\text{Conc A}}{\text{MPLA}} + \frac{\text{Conc B}}{\text{MPLB}} + \frac{\text{Conc C}}{\text{MPLC}}$$

In this formula –

MPLA = Maximum permitted limit for food additive A in mg/kg

MPLB = Maximum permitted limit for food additive B in mg/kg

MPLC = Maximum permitted limit for food additive C in mg/kg

Conc A = concentration of food additive A in the food in mg/kg

Conc B = concentration of food additive B in the food in mg/kg

Conc C = concentration of food additive C in the food in mg/kg

[5.4] *omitting clause 7, substituting –*

7 Carry-over of additives

Other than by direct addition, an additive may be present in any food as a result of carry-over from a raw material or an ingredient, provided that the level of the additive in the final food is no greater than would be introduced by the use of the raw material or ingredient under proper technological conditions and good manufacturing practice.

[5.5] *omitting from Schedule 1, under item 0 General Provisions the reference to ANZFA, substituting –*

the

[5.6] *omitting from Schedule 1, the heading and entry for item 1.1.3 Liquid milk to which phytosterol esters have been added, substituting –*

1.1.3 Liquid milk to which phytosterols or phytosterol esters have been added

401	Sodium alginate	2	g/kg
407	Carrageenan	2	g/kg
412	Guar gum	2	g/kg
471	Mono- and diglycerides of fatty acids	2	g/kg
460	Microcrystalline cellulose	5	g/kg

[5.7] *omitting from Schedule 1, the heading and entry for item 1.1.4. Liquid milk to which tall oil phytosterols have been added*

[5.8] *omitting from Schedule 1, the heading for item 2.2.2, substituting –*

2.2.2 Oil emulsions (<80% oil)*

[5.9] *omitting from Schedule 1, the entry for item 6.4 Flour products (including noodles and pasta)*, substituting –*

6.4 Flour products (including noodles and pasta)*

160b	Annatto extracts	25	mg/kg	
200 201 202 203	Sorbic acid and sodium, potassium and calcium sorbates	1000	mg/kg	
220 221 222 223 224 225 228	Sulphur dioxide and sodium and potassium sulphites	300	mg/kg	
234	Nisin	250	mg/kg	Flour products that are cooked on hot plates only e.g. crumpets, pikelets, flapjacks, etc.
280 281 282 283	Propionic acid and sodium and potassium and calcium propionates	2000	mg/kg	
950	Acesulphame potassium	200	mg/kg	
956	Alitame	200	mg/kg	
962	Aspartame-acesulphame salt	450	mg/kg	

[5.10] *omitting from Schedule 1, the entry for item 7, substituting –*

7 BREADS AND BAKERY PRODUCTS*

200 201 202 203	Sorbic acid and sodium, potassium and calcium sorbates	1200	mg/kg
280 281 282 283	Propionic acid and sodium and potassium and calcium propionates	4000	mg/kg

[5.11] *omitting from Schedule 1, the heading fresh poultry for item 8.1, substituting –*

poultry

[5.12] *omitting from Schedule 1, under entry for item 13.4.1 Solid formulated supplementary sports foods*, substituting –*

220	Sulphur dioxide	115	mg/kg
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substituting –

220 221 222 223 224 225 228	Sulphur dioxide and sodium and potassium sulphites	115	mg/kg
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[5.13] *omitting from Schedule 1, the entry for item 13.4.2 Liquid formulated supplementary sports foods*,*

220	Sulphur dioxide	115	mg/kg
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substituting –

220 221 222 223 224 225 228	Sulphur dioxide and sodium and potassium sulphites	115	mg/kg
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[5.14] *omitting from Schedule 1, under item 14.1.2 Fruit and vegetable juices and fruit and vegetable juice products, the entry in the Qualifications column.*

[5.15] *omitting from Schedule 1, the entry for item 14.1.2.1, substituting –*

14.1.2.1 Fruit and vegetable juices (including juices containing or made from concentrates)

***Additives in Schedules 2,3
& 4 must not be added to
fruit and vegetable juices
unless expressly permitted
below***

160a	Carotenes	GMP	
160e	Carotenal, b-apo-8'	GMP	
270	Lactic acid	GMP	
290	Carbon dioxide	GMP	
296	Malic acid	GMP	
330	Citric acid	GMP	
334 335 336 337 353 354	Tartaric acid and sodium, potassium and calcium tartrates	GMP	
338	Phosphoric acid	GMP	
339 340 341	Sodium, potassium and calcium phosphates	GMP	
342	Ammonium phosphates	GMP	
343	Magnesium phosphates	GMP	
339 340 341	Sodium, potassium and calcium phosphates	GMP	
440	Pectin	GMP	
450	Pyrophosphates	GMP	
451	Triphosphates	GMP	
452	Polyphosphates	GMP	
542	Bone phosphate	GMP	
960	Steviol glycosides (calculated as steviol equivalents)	50	mg/kg
	Flavourings, excluding quinine and caffeine	GMP	

[5.16] *inserting in the Alphabetical Listing of Schedule 2 –*

510 Ammonium chloride

[5.17] *inserting in the Numeric Listing of Schedule 2 –*

510 Ammonium chloride

[5.18] *omitting the heading to Schedule 4 wherever appearing, substituting –*

Colours permitted to a total maximum level of 290 mg/kg in processed foods and to a total maximum level of 70 mg/L in beverages other than beverages specified in Schedule 1

[6] **Standard 1.3.2** of the Australia New Zealand Food Standards Code is varied by omitting from clause 1 the definition of **claimable food**, substituting –

claimable food means a food which consists of at least 90% by weight of –

- (a) (i) primary foods; or
- (ii) foods listed in the Table to clause 3; or
- (b) a mixture of –
 - (i) primary foods; and/or
 - (ii) water; and/or;
 - (iii) foods listed in the Table to clause 3 excluding butter, cream and cream products, edible oils, edible oil spreads and margarine.

[7] **Standard 1.3.3** of the Australia New Zealand Food Standards Code is varied by –

[7.1] inserting, following the definition of **processing aid**, in clause 1 –

silica or silicates includes sodium calcium polyphosphate silicate, sodium hexafluorosilicate, sodium metasilicate, sodium silicate, silica and modified silica that complies with a monograph specification in clause 2 or clause 3 of Standard 1.3.4.

[7.2] omitting from the Table to clause 3 –

Ammonium chloride

[7.3] omitting from the Table to clause 3 –

Silicates

substituting –

Silica or silicates

[7.4] omitting from the Table to clause 17 the entries for Asparaginase EC 3.5.1.1, substituting –

Asparaginase EC 3.5.1.1	Aspergillus niger Aspergillus oryzae
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[8] **Standard 1.3.4** of the Australia New Zealand Food Standards Code is varied by –

[8.1] omitting clause 2, substituting –

2 Substances with specifications in primary sources

A substance must comply with a relevant monograph (if any) published in one of the following –

- (a) Combined Compendium of Food Additive Specifications, FAO JECFA Monograph 1 (2005) as superseded by specifications published in FAO JECFA Monographs 3 (2006) and FAO JECFA Monographs 4 (2007) and FAO JECFA Monographs 5 (2008), Food and Agriculture Organisation of the United Nations. Rome; or
- (b) *Food Chemicals Codex* (6th Edition) published by United States Pharmacopoeia (2008); or
- (c) the Schedule to this Standard.

[8.2] *omitting clause 3, substituting –*

3 Substances with specifications in secondary sources

If there is no monograph applying to a substance under clause 2, the substance must comply with a relevant monograph (if any) published in one of the following –

- (a) the *British Pharmacopoeia 2009*, TSO, Norwich (2008); or
- (b) *The United States Pharmacopoeia*, 32nd Revision and *The National Formulary*, 27th Edition; or
- (c) *The Pharmaceutical Codex*, 12th Edition, Council of the Pharmaceutical Society of Great Britain. The Pharmaceutical Press, London (1994); or
- (d) *Martindale; The Complete Drug Reference*. The Pharmaceutical Press London (2007); or
- (e) the *European Pharmacopoeia* 6th Edition, Council of Europe, Strasbourg (2007); or
- (f) the *International Pharmacopoeia* 4th Edition, World Health Organization, Geneva (2006); or
- (g) *The Merck Index*, 14th Edition, (2006); or
- (h) Code of Federal Regulations of the United States of America, 1 April, 2008; or
- (i) the *Specifications and Standards for Food Additives*, 7th edition (2000), Ministry of Health and Welfare (Japan).

[8.3] *inserting in the Schedule an entry for bentonite*

Specification for bentonite

Bentonite must comply with a monograph specification in clause 2 or clause 3 of this Standard, except that the pH determination for a bentonite dispersion must be no less than 4.5 and no more than 10.5.

[9] **Standard 1.4.1** of the Australia New Zealand Food Standards Code is varied by

[9.1] *omitting Clause 6 from the Table of Provisions, substituting –*

6 Sampling plan for mercury in fish, fish products, crustacea and molluscs

[9.2] *omitting subclause 1(6), substituting –*

(6) For a mixed food, the prescribed formula for the purposes of this Standard is –

$$ML1 = \frac{(MLA \times Total A)}{Total} + \frac{(MLB \times Total B)}{Total} + \frac{CF \times (Total - (Total A + Total B))}{Total}$$

[11] **Standard 1.5.1** of the Australia New Zealand Food Standards Code is varied by –

[11.1] *inserting in the Table of Provisions –*

3 Exclusive use of novel foods

[11.2] *omitting from the Table to clause 2 the entry for Diacylglycerol oil (DAG-Oil) substituting –*

Diacylglycerol oil (DAG-Oil)	The name 'Diacylglycerol oil' must be used when declaring the ingredient in the ingredient list, as prescribed in Standard 1.2.4.
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[12] **Standard 1.5.2** of the Australia New Zealand Food Standards Code is varied by *omitting the Editorial Note at the end of clause 7.*

[13] **Standard 1.6.2** of the Australia New Zealand Food Standards Code is varied by –

[13.1] *omitting the Table of Provisions, substituting –*

Table of Provisions

- 1 Reserved
- 2 Reserved
- 3 Processing of egg products
- 4 Eviscerated poultry
- 5 Dried meat
- 6 Crocodile meat
- 7 Game meat
- 8 Fermented comminuted processed meat

[13.2] *omitting the Editorial note at the end of clause 8, substituting –*

Editorial note:

Processed meat in this clause includes processed meat and manufactured meat in accordance with Standard 2.2.1, irrespective of the prescribed names set out in that Standard.

Guidelines for the Safe Manufacture of Smallgoods published by Meat and Livestock Australia, will assist manufacturers and appropriate enforcement agencies to give effect to the provisions in this clause.

[14] **Standard 2.1.1** of the Australia New Zealand Food Standards Code is varied by –

To commence on: 13 September 2009

[14.1] *omitting the definition of bread from clause 1, substituting –*

bread means the product made by baking a yeast – leavened dough prepared from one or more cereal flours or meals and water, but in relation to mandatory fortification of bread, does not include –

- (a) pizza bases;
- (b) breadcrumbs;

- (c) pastries;
- (d) cakes, including but not limited to brioche, panettone and stollen;
- (e) biscuits; or
- (f) crackers.

[14.2] *inserting in the heading to the Note under entry* Wheat flour for making bread, after subclause 4(2) –

Editorial

[15] **Standard 2.5.1** of the Australia New Zealand Food Standards Code is varied by –

[15.1] *omitting from the Table of Provisions, clause 5 and clause 6, substituting –*

5 Tall oil phytosterols and added phytosterol esters

[15.2] *omitting clause 5, Phytosterol esters*

[15.3] *omitting clause 6, Tall oil phytosterols, substituting –*

5 Tall oil phytosterols and added phytosterol esters

Tall oil phytosterols or phytosterol esters may only be added to milk –

- (a) that contains no more than 1.5 g total fat per 100 g; and
- (b) that is supplied in a package, the labelled volume of which is no more than 1 litre; and
- (c) where the total phytosterol ester added is no less than 5.2 g/litre of milk and no more than 6.4 g/litre of milk; and
- (d) where the total tall oil phytosterol added is no less than 3.2 g/litre of milk and no more than 4.0 g/litre of milk.

[16] **Standard 2.6.3** of the Australia New Zealand Food Standards Code is varied by –

[16.1] *omitting the Purpose, substituting –*

Purpose

This Standard regulates the sale and distribution of *Piper methysticum* (kava) in Australia and New Zealand. It also provides for labelling requirements and restrictions on the parts of the *Piper methysticum* (kava) plant which may be sold under food legislation.

In Australia, this Standard should be considered in conjunction with the *Customs (Prohibited Imports) Regulations 1956* and certain State and Territory restrictions on the supply of kava which seek to minimise the detrimental effects associated with kava abuse. Where kava is permitted for supply, the requirements in this Standard complement those restrictions.

[16.2] *omitting the definition of **kava** in clause 1.*

[16.3] *omitting clause 2, substituting –*

2 Prohibition

(1) *Piper methysticum* (kava) or any derived substance must not be sold or present in a food unless it is:

- (a) a beverage obtained by cold water extraction; or
- (b) the dried or raw form;

of the peeled root and/or peeled rootstock of plants of the species *Piper methysticum*.

(2) Kava must not be used as an ingredient in foods other than those products regulated under the *Dietary Supplements Regulations (1985)* in New Zealand as in force on 1 January 2000.

[17] **Standard 2.6.4** of the *Australia New Zealand Food Standards Code* is varied by omitting the words *Food Standards Code* in the Editorial Note at the end of subclause 2(3), substituting –

Australia New Zealand Food Standards Code

[18] **Standard 2.7.4** of the *Australia New Zealand Food Standards Code* is varied by –

[18.1] omitting clause 3 from the Table of Provisions

[18.2] omitting the definition of **wine product** from clause 1, substituting –

wine product means a food containing no less than 700 mL/L of wine as defined in this Standard, which has been formulated, processed, modified or mixed with other foods such that it is not wine.

[19] **Standard 3.1.1** of the *Australia New Zealand Food Standards Code* is varied by omitting the following words wherever appearing in the subclause 2(5) –

Food Standards Code

substituting –

Australia New Zealand Food Standards Code

[20] **Standard 3.2.3** of the *Australia New Zealand Food Standards Code* is varied by –

[20.1] omitting the word *Clause* wherever appearing in the Editorial Note to subclause 4(1), substituting –

clause

[20.2] omitting the word *Clause* wherever appearing in the Editorial Note to subclause 13(1), substituting –

clause

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

[21.1] inserting in the Table of Provisions, after Division 3 – Production of ready-to-eat meat –

Schedule Method for measuring pH

[21.2] *omitting the heading to the Schedule, substituting –*

Method for measuring pH

[22] **Standard 4.2.4A** of the Australia New Zealand Food Standards Code is varied by *omitting the first paragraph from the Editorial Note after the Table to clause 1, substituting –*

Editorial note:

Legislation or documentation will only be listed in the Table to clause 1 if it incorporates or provides for methods which provide a level of safety protection equivalent to that provided by a process that includes treatment of the milk or milk product in accordance with paragraph 2(1)(a) of Standard 1.6.2 before 5 October 2008 and then with paragraphs 16(a) and (b) of Standard 4.2.4 after 5 October 2008, and has adequate hazard identification and process controls.