

9-04

15 December 2004

INITIAL ASSESSMENT REPORT

PROPOSAL P279

REVIEW OF SCHEDULE 1 AND RELATED CLAUSES - STANDARD 1.3.1 – FOOD ADDITIVES

**DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 9 February 2005
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED**

(See 'Invitation for Public Submissions' for details)

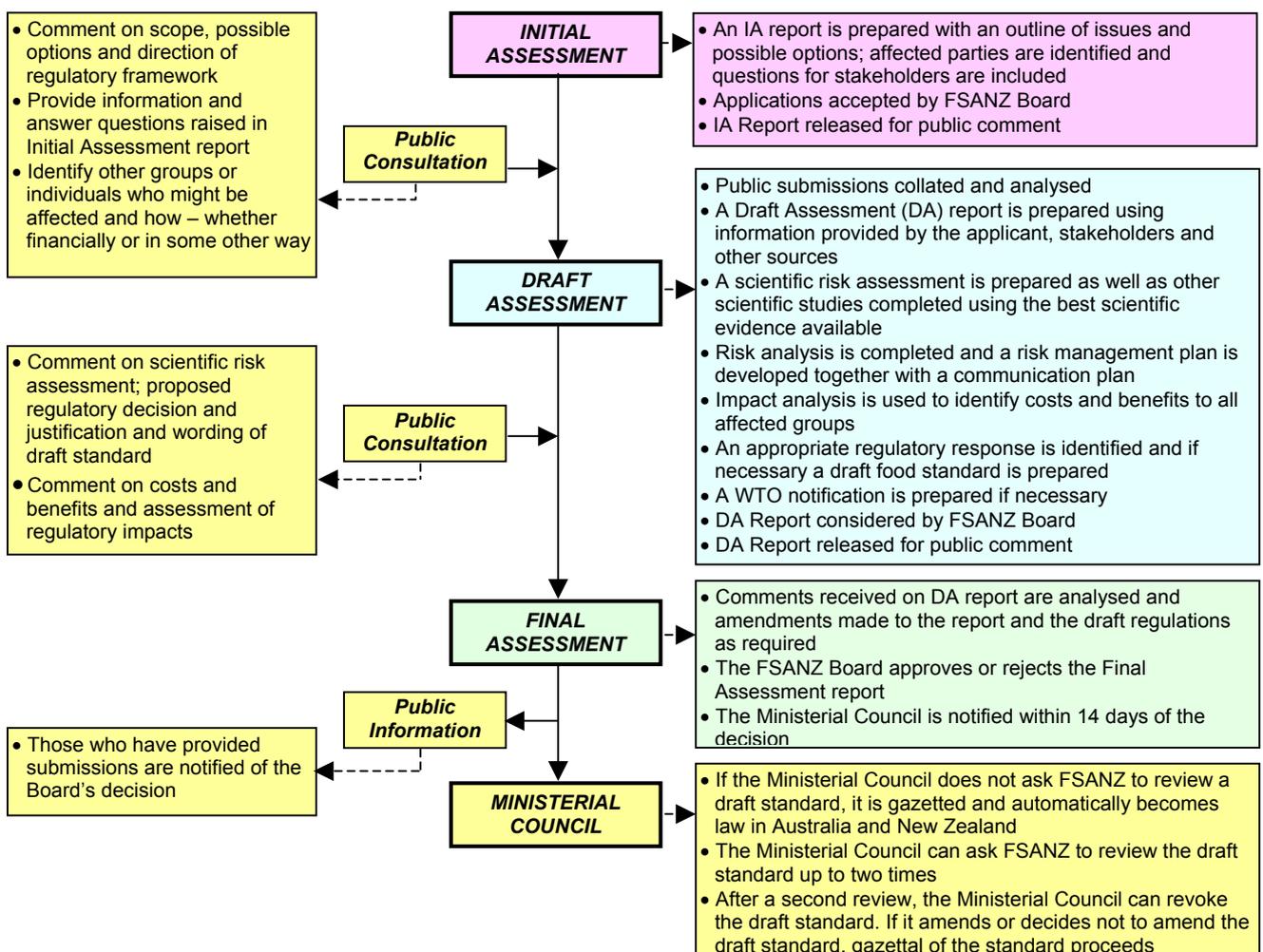
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

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

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

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



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report of Proposal P279, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report 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 preparing the Draft Assessment for this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 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 and provide justification for treating it as commercial-in-confidence. Section 39 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. 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
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions need to be received by FSANZ **by 6pm (Canberra time) 9 February 2005.**

Submissions received after this date will not be considered, unless 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.

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.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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Executive summary

The purpose of this Proposal is to formally review the content and relevant clauses relating to permissions in Schedule 1 of Standard 1.3.1– Food Additives, after practical implementation of the Standard for over 2 years. The review will allow for consideration of complaints and comments received from stakeholders in this period.

This review will not be used as a mechanism to change the substantive content or the structure, of Standard 1.3.1. The review is not an opportunity to seek new permissions for the use of food additives in Schedule 1 of Standard 1.3.1, unless these are considered to be omissions due to anomalies or errors.

In the development of the *Australian New Zealand Food Standards Code* (the Code), Standard 1.3.1 was developed considering food additive provisions from the former *Australian Food Standards Code* and the former *New Zealand Food Regulations, 1984* (NZFR).

The Standard allows for use of a wide range of food additives at levels determined by Good Manufacturing Practice (GMP). The Confederation of Food and Drink Industries of the European Community developed the basic food classification system. Each additive included in Schedule 1 underwent a risk analysis including identification and application of acceptable levels of exposure based upon toxicological and other safety data, examination of the technological function and justification for use.

The principles applied in establishing this Standard were consistent with those set out in the preamble to the draft Codex General Standard for Food Additives (GSFA).

Regulatory Problem

After extensive discussions with the team members of the Advice Line and review of comments from both external stakeholders and internal sources, it has been determined that many users of the Code have difficulty interpreting Schedule 1 and related clauses of Standard 1.3.1.

Schedule 1 provides a hierarchical structure which restricts the use of most additives at the higher category levels, for mainly unprocessed foods, but allows for cascading permissions down through the hierarchies, consistent with the technological processes applied.

Most of the permitted food additives are now listed in Schedule 2 with levels of use determined by GMP. Colours permitted to GMP levels are contained in Schedule 3 and colours generally restricted by numerical levels are listed in Schedule 4. Permissions for uses of additives listed in Schedules 2, 3 and 4 are provided by the categories within Schedule 1.

Matters for Review

Matters that have been identified for review are:

- the removal of the asterisk from Schedule 1;

- the inclusion of an explanation and/or a diagram to explain the permissions allowed through the hierarchies in Schedule 1 categories;
- review of the qualifications column in Schedule 1;
- review of clause 7 and its practical implications;
- review of clause 8 and its practical implications;
- review of the editorial note to Clause 4;
- the review of permissions of sulphur dioxide in formulated spirit drinks; and
- minor anomalies and ambiguities within Schedule 1.

It is recognised that other matters may be identified and considered as part of the review.

Objectives

The objectives of this Proposal are to ensure that the review of Schedule 1 in Standard 1.3.1 – Food Additives is conducted in a manner that is consistent with the section 10 objectives of the FSANZ Act and with the principles of minimal effective regulation, or specifically:

- the 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;
- the need for the general standard for food additives to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards for food additives; and
- the desirability of an efficient and internationally competitive food industry;

Regulatory Options

Possible regulatory options for Proposal P279 are given below.

1. Maintain the *status quo*
2. Amend Schedule 1 and other relevant clauses of Standard 1.3.1 – Food Additives in the Code to assist with the practical use and interpretation of the Standard.

Other regulatory options may also be possible and will be considered if necessary at Draft Assessment.

Impact Analysis

In order to determine the most cost-effective and least prescriptive regulatory option for the review of Schedule 1, FSANZ will consider the potential impact of each of the regulatory options described above, as reflected in the attributable costs and benefits to various stakeholder groups.

In the interest of assessing the impact of each of the above options (or any others that may be raised) FSANZ needs to determine how the stakeholder groups may be affected and what the likely costs and benefits will be.

In seeking public submissions from all stakeholders for use in preparing a Draft Assessment, FSANZ requests information regarding:

- Any safety concerns with currently approved additives in Schedule 1 of 1.3.1.
- The need for provision of guidance for consumers and industry, in Standard 1.3.1.
- Current information, quantitative where possible, that identifies the relevant costs and benefits of any proposed changes to Standard 1.3.1.

Consultation

The purpose of this Initial Assessment Report is to notify stakeholders of the review of Schedule 1 and related clauses of Standard 1.3.1 – Food Additives. The report is intended to raise issues involved in the interpretation and use of Standard 1.3.1, especially for Schedule 1. The report is designed to assist in identifying the affected parties, to provide regulatory options, and to analyse the potential impacts of any regulatory or non-regulatory provisions. The information needed to review this Proposal will include information from public submissions. Public submissions are now invited on this Initial Assessment Report.

Conclusions

This Proposal is prepared in accordance with section 12AA of the FSANZ Act. Written submissions on the Proposal will now be sought.

After public submissions have been received, FSANZ will prepare a Draft Assessment as prescribed in section 15AA of the FSANZ Act.

1. Introduction

The purpose of this Proposal is to formally review the content and relevant clauses relating to permissions in Schedule 1 of Standard 1.3.1 – Food Additives, after practical implementation of the Standard for over 2 years. The review will allow for consideration of complaints and comments received from stakeholders.

This review will not be used as a mechanism to change the substantive content or the structure of Standard 1.3.1. The review is not an opportunity to seek new permissions for the use of food additives in Schedule 1 of Standard 1.3.1, unless these are considered to be omissions due to anomalies or errors.

In the development of the Code, Standard 1.3.1 was developed considering food additive provisions from the former Australian *Food Standards Code* and the former *New Zealand Food Regulations, 1984* (NZFR).

A food additive is described in the purpose clause to Standard 1.3.1 – Food Additives as follows:

*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 to Standard 1.3.1. It or its by-products may remain in the food.*

The Standard allows for use of a wide range of food additives at levels determined by Good Manufacturing Practice (GMP). Many such additives are considered to be safe, even if consumed in excess or are self-limiting. Schedule 1 is based on the same classification system used by the Codex Alimentarius Commission to categorise all foods to ensure the comprehensive regulation of all foods and to allow for better accuracy in dietary exposure estimates. The Confederation of Food and Drink Industries of the European Community developed the basic food classification system. Each additive included in Schedule 1 underwent a risk analysis including identification and application of acceptable levels of exposure based upon toxicological and other safety data, examination of the technological function and justification for use.

The principles applied in establishing this Standard were consistent with those set out in the preamble to the draft Codex General Standard for Food Additives (GSFA).

2. Regulatory Problem

2.1 Current Standard

After extensive discussions with the team members of the advice line and review of comments from both external stakeholders and internal sources, it has been determined that many users of the Code have difficulty interpreting Schedule 1. There are many areas within the Schedule and related clauses where rewording may provide clarity of the original intent and assist with the general use and interpretation of the Schedule.

2.2 Matters for review

Matters that have been identified for review are:

- the removal of the asterisk from Schedule 1;
- the inclusion of an explanation and/or a diagram to explain the permissions allowed through the hierarchies in Schedule 1 categories;
- the removal or review of the qualifications column in Schedule 1;
- the review of clause 7 and its practical implications;
- the review of clause 8 and its practical implications;
- the review of the editorial note to clause 4;
- the review of permissions of sulphur dioxide in formulated spirits drinks; and
- minor anomalies within Schedule 1.

It is recognised that other matters may be identified and considered as part of the review.

This review will not be used as a mechanism for the approval of new food additives in New Zealand and Australia. New additives will need to go through the normal application process.

3. Objective

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

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

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

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

4. Background

4.1 Historical Background

In June of 2003, preliminary information was presented to the FSANZ scoping group regarding issues and/or concerns with Schedule 1 of Standard 1.3.1. It is *not* the intention of this review to change the substantive content or permissions of Schedule 1 or other clauses of Standard 1.3.1.

From the discussions at scoping group Proposal P279 was raised identifying two main tasks requiring action.

1. Check that Schedule 1 food additive permissions are correctly gazetted, reflecting intent of the standard at the time of gazettal in December 2000 and that subsequent amendments have also been correctly gazetted.
2. Clarify the inconsistencies and ambiguities that are recognised with this Schedule, particularly those associated with the use of the asterisk, which indicate permissions to use food additives in Schedules 2, 3 and 4.

5. Relevant Issues

5.1 Removal of the asterisk (*)

The purpose of the asterisk (*) in Schedule 1 is to indicate which additives in Schedules 2, 3 and 4 **are** permitted for use in the particular food type. This is used in conjunction with an explanation in the general provisions of Standard 1.3.1 and editorial notes on the bottom of each page. However, the asterisk does not legally provide permissions, just clarification of the permissions as a quick reference. Removing the asterisk does not affect the functionality of Schedule 1, as permissions are listed and explained under the relevant category headings.

In the following two examples Schedule 2 additives are permitted in two different categories using different styles.

Example 1: 4.1 Unprocessed fruits and vegetables

Additives in Schedules 2, 3 & 4 must not be added to unprocessed fruits and vegetables unless expressly permitted below.

4.3 Processed fruits and vegetables*

220 221 222	sulphur dioxide and sodium and	20	mg/kg	ginger only
223 224 225	potassium sulphites			
228				

* Additives in Schedules 2, 3 and 4 are permitted

The asterisk indicates that additives in Schedules 2, 3 & 4 are permitted in processed fruits and vegetables, however, if the asterisk were removed these additives would still be permitted as indicated in the general provisions.

Example 2:

2.1 Edible oils essentially free of water*

475	Polyglycerol esters of fatty acids	20000	mg/kg	shortening only
476	Polyglycerol esters of interesterified ricinoleic acids	20000	mg/kg	shortening only
900a	Polydimethylsiloxane	10	mg/kg	frying oils only

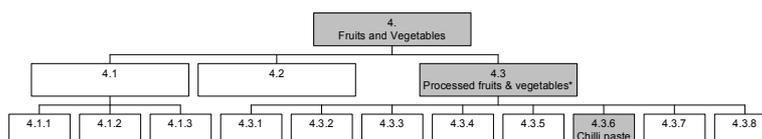
Additives in Schedules 3 & 4 must not be added to olive oil.

In the second example it would be simpler to permit Schedule 2 additives in olive oils, rather than to provide an asterisk and then explain that Schedule 3 and 4 additives are not permitted.

5.2 Explanation and/or diagram to explain the permissions through the hierarchies

The FSANZ Advice Line (help line) has identified issues raised by jurisdictions and consumers regarding the interpretation of some aspects of Schedule 1. In particular, the difficulty understanding the permissions allowed through the hierarchies.

This issue is made somewhat clearer in the relevant user guide, however it has been suggested that a diagram within the schedule perhaps as part of an editorial note may be useful. *For example: to explain which additives are permitted in chilli paste, the relevant hierarchical permissions are represented diagrammatically as follows:*



Chilli paste is a sub group of 4.3.6 and is therefore allowed the additive permissions of those food types directly above it in the hierarchy i.e. additives in 4.3 and 4.

5.3 Removal or review of the qualifications column

The intent of the qualifications column in Schedule 1, is to assist users in the interpretation of the Schedule. The qualifications column at present performs 2 distinct functions:

- (a) to limit permissions; and
- (b) to explain permissions and exemptions from permissions.

Using the qualifications column to limit permissions provides more than a qualification and the dual purpose of the qualifications column is confusing.

Some of the clarifications at present actually limit the application of the Schedule 1 permissions. For example: ginger only. This should not be the purpose of a qualification as it is not legally enforceable. A preferred approach may be to list the food as a separate category within the hierarchy.

The other statements in the qualifications column explain permissions e.g. ‘clause 4 limits do not apply’. This statement is not particularly useful in the interpretation of the Schedule as the restrictions of clause 4 are more fully explained within the clause itself, and there are no obvious clause 4 limits.

5.4 Review of clause 7 - Carry-over of additives

Clause 7 (with the accompanying editorial note) explains how the carry-over principle for food additives works in relation to a food classification other than by direct addition allowed by the permission for a particular food additive. However, it is not clear whether the clause applies to:

- (a) the addition of vitamins and minerals and processing aids as they are not regulated by Standard 1.3.1; and

- (b) the permitted levels of an additive in the preparation of another food with a different level of permission of the same additive.

Example 1:

Benzoic acid is permitted to a maximum level of 1000 mg/kg in preparations of food additives, however benzoic acid is not permitted in flavoured liquid milk in category for 1.1.2 Liquid milk products and flavoured liquid milk.

- The final food i.e. a flavoured milk, has a permitted level of the additive based on the clause 7 permission. Calculating for carry-over at a 10% level of flavour in the drink, the resulting level of permission for benzoic acid in flavoured milk is:

$$\frac{1000 \times 10}{100} + \frac{0 \times 90}{100} = 100 \text{ mg/kg}$$

Example 2:

Benzoic acid is permitted to a maximum level of 1000 mg/kg in preparations of food additives *and* benzoic acid is also permitted in category 14.1.3 water-based flavoured drinks to a maximum level of 400 mg/kg.

- Can the level in the final food i.e. a flavoured drink exceed 400 mg/kg? Calculating for carry-over at a 10% level of flavour in the drink, the resulting permission level is:

$$\frac{1000 \times 10}{100} + \frac{400 \times 90}{100} = 460 \text{ mg/kg}$$

Using the same calculations in example 1, a level higher than the maximum permitted level is permitted. In most practical cases the difference in the final level of permission would not be significant. 10 % is an unusually high level for a flavouring in a drink.

5.5 Review of clause 8 – Food for use in preparation of another food

Foods used in the preparation of another food are permitted to contain any or all of the food additives permitted to be present in the final food.

The maximum permitted levels of additives in premixes are determined by the level permitted in the final food. Clause 8 outlines these permissions as follows;

Any food additive permitted in a food may be added to an ingredient intended for use in the preparation of that food provided that the level in the final food when prepared complies with the maximum permitted level in the Standard.

- is the meaning of Clause 8 clear; and
- how is the principle applied when the premix could be used for the manufacture of several different products e.g. one with the additive permission and one without?

The wording in Clause 8 is complex and may simply need an editorial note.

5.6 Review of the Editorial note to Clause 4

Clause 4 - Requirements for use of intense sweeteners, restricts the use of intense sweeteners to the amount necessary to replace the sweetness normally provided by sugars or as a flavour enhancer.

This review should consider the editorial note in clause 4 and possibly replacing it with a reference to the user guide. The editorial note to clause 4 however, refers to reduced joule and low joule foods and to other sweeteners that are not 'intense sweeteners'.

Note also that in the qualifications column of Schedule 1 for category 5 Confectionery, there is a reference to clause 4 for chewing gum that the Clause 4 limits do not apply. There is also a qualification about clause 4 limits for category 14.1.3.1 – Brewed soft drinks. However there are no obvious limits evident in clause 4.

5.7 Review of permissions for sulphur dioxide

- (a) There are inconsistencies with the entries for the use of sulphur dioxide or the broader group of sulphites as indicated in the following categories of Schedule 1:

13.4.2 Liquid formulated supplementary sports foods*

220	sulphur dioxide	115	mg/kg
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14.2.2 wine, sparkling wine and fortified wine containing greater than 35 g/L residual sugar

220	221	222	sulphur dioxide and sodium and	400	mg/kg
223	224	225	potassium sulphites		
228					

- (b) The current entries under 13.4 Formulated supplementary sports foods* (13.4.1 and 13.4.2) duplicate some of the additive permissions and permit sulphur dioxide and not other sulphites, as follows:

13.4 Formulated supplementary sports foods*

123	Amaranth	300	mg/kg
160b	Annatto extracts	100	mg/kg

13.4.1 Solid formulated supplementary sports foods*

210	211	212	Benzoic acid and sodium,	400	mg/kg
213			potassium, and calcium		
			benzoates		
220			Sulphur dioxide	115	mg/kg
280			Propionic acid	400	mg/kg
281			Sodium propionate	400	mg/kg
282			Calcium propionate	400	mg/kg

13.4.2 Liquid formulated supplementary sports foods*

200	201	202	Sorbic acid and sodium,	400	mg/kg
203			potassium and calcium sorbates		
210	211	212	Benzoic acid and sodium,	400	mg/kg
213			potassium, and calcium		
			benzoates		
220			Sulphur dioxide	115	mg/kg

There are no gaseous formulated supplementary sports foods, only liquid and solid forms are available. As sulphur dioxide is a gas it cannot be incorporated into solid formulated supplementary sports foods.

The category could therefore be simplified as follows:

13.4	Formulated supplementary sports foods*		
123	Amaranth	300	mg/kg
160b	Annatto extracts	100	mg/kg
210 211 212	Benzoic acid and sodium,	400	mg/kg
213	potassium, and calcium benzoates		
220	Sulphur dioxide	115	mg/kg

13.4.1	Solid formulated supplementary sports foods*		
280	Propionic acid	400	mg/kg
281	Sodium propionate	400	mg/kg
282	Calcium propionate	400	mg/kg

13.4.2	Liquid formulated supplementary sports foods*		
200 201 202	Sorbic acid and sodium,	400	mg/kg
203	potassium and calcium sorbates		

5.8 Other minor anomalies within Schedule 1

- (a) There is a consistency issue with the explanation of permissions for additives in Schedules 2, 3 and 4 in some of the categories in Schedule 1.

For example in categories 5.1 and 8.3 permissions to use Schedule 2 additives is provided by different means as follows:

5.1 Chocolate and cocoa products

Additives in Schedules 3 & 4 must not be added to chocolate and cocoa products unless expressly permitted below

476	Polyglycerol esters of interesterified ricinoleic acids	5000	mg/kg
477	Propylene glycol esters of fatty acids	4000	mg/kg

8.3 Processed comminuted meat, poultry and game products*

160b	Annatto extracts	100	mg/kg
220 221 222	Sulphur dioxide and sodium and	500	mg/kg
223 224 225	potassium sulphites		
228			
249 250	Nitrites (potassium and sodium salts)	125	mg/kg

sausage and sausage meat containing raw, unprocessed meat

Additives must not be added to sausage and sausage meat containing raw, unprocessed meat, unless expressly permitted below

Additives in Schedule 2

* Additives in Schedules 2, 3 and 4 are permitted

- (b) Category 4.1.2 contains a typographical error i.e. the entry for walnut and pecan nut kernels doesn't require mg/kg after the GMP permission for 304 Ascorbyl palmitate.
- (c) Category 14.2.1 contains a typographical error as sodium erythorbate is additive 316 not additive 216 as listed.

6. Regulatory Options

Possible regulatory options for P279 – Review Schedule 1 and related clauses of Standard 1.3.1 are given below. Other regulatory options may also be possible.

1. Maintain the *status quo*
2. Amend Schedule 1 and other relevant clauses of Standard 1.3.1 – Food Additives in the Code to assist with the practical use and interpretation of the Standard.

7. Impact Analysis

7.1 Affected parties

- food manufacturers in Australia and New Zealand;
- food additive manufacturers internationally;
- consumers in Australia and New Zealand; and
- Australian, State, Territory and New Zealand Governments involved in the enforcement of the Code.

7.2 Impact of regulatory options

In order to determine the most cost-effective and least prescriptive regulatory option for the on-going management and safe use of food additives, it is necessary to consider the potential impact of each of the regulatory options described above, as reflected in the attributable costs and benefits to various stakeholder groups.

In the interest of assessing the impact of each of the above options (or any others that may be raised) FSANZ needs to determine how the stakeholder groups may be affected and what the likely costs and benefits will be. As part of this process FSANZ seeks input from stakeholders with regard to current information, quantitative where possible, that identifies the relevant costs and benefits.

7.2.1 *Option 1*

Maintaining the status quo would mean that the current permissions may not be up to date in relation to current safety guidelines, and therefore the objectives of section 10 in the FSANZ Act might not be met.

7.2.2 *Option 2:*

To amend Schedule 1 and other relevant clauses of Standard 1.3.1 – Food Additives in the Code would mean that users of the Code would have clearer regulations.

8. Consultation

This Initial Assessment Report has been released for public consultation. The views of submitters will assist in the development of the Draft Assessment and a preferred regulatory approach for the on-going management and safe use of additives. Further public comment will be sought on the Draft Assessment, including any proposed draft variation/s to the Code.

In seeking public submissions from all stakeholders for use in preparing a Draft Assessment, FSANZ requests information regarding:

- the matters raised in this review and any other issues that may require consideration;
- safety concerns with amendments to Schedule 1 and related clauses of Standard 1.3.1 in the Code;
- current information, quantitative where possible, that identifies the relevant costs and benefits of any proposed changes to Standard 1.3.1

8.1 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 not any relevant international standards that directly relate to Schedule 1 of standards 1.3.1. This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

9. Conclusion

This Proposal is prepared according to section 12AA of the FSANZ Act. Written submissions on the Proposal will now be sought.

After public submissions have been received, FSANZ will prepare a Draft Assessment as prescribed in section 15AA of the FSANZ Act.