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

10 July 2014
[13–14]

2nd call for submissions – Proposal P1025

Code Revision

FSANZ has assessed a Proposal to reform the *Australia New Zealand Food Standards Code* and has prepared a draft food regulatory measure. Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at information for submitters.

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*.

Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.
Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

Submissions should be made in writing, be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on documents for public comment. You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 12 September 2014

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

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

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

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Attachments (published separately due to their size)

The attachments to this document are available on the FSANZ website at
http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx

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

Supporting documents

The following documents which informed the assessment of this Proposal are available on the FSANZ website at http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx:

SD1 Legislative audit report provided by the Office of Legislative Drafting and Publishing
SD2 Table of matters identified in the legislative audit report and responses
SD3 FSANZ response to 1st call for submissions
SD4 Table of provisions—current Code to draft food regulatory measure
SD5 Table of provisions—draft food regulatory measure to current Code
SD6 Legal advice on application of interpretation laws

1. Executive summary

The *Australia New Zealand Food Standards Code* was first published on 20 December 2000 and has been amended approximately 80 times since.

In 2009 the Supreme Court of New South Wales delivered a judgment in a criminal prosecution under the Food Act (NSW), during which the court commented critically on the legal efficacy of the Code. This Proposal is a response to the court's comments and subsequent consultation with New Zealand, state and territory enforcement agencies and relevant departments of state. This second call for submissions also responds to the submissions received from industry, enforcement agencies and consumers in response to the first call for submissions in 2013.

The Proposal seeks to modernise how the Code is presented to create an instrument that better meets the needs of a very broad range of stakeholders in industry, commerce and enforcement and provide a sounder base for future variations. It does this by:

- more clearly presenting requirements that impose an obligation relating to the conduct of a food business or the sale of food, or relating to the composition of food or labelling
- greater reliance on definitions already present in the food acts of New Zealand, the states and the territories; and
- presenting the Code as a unified instrument.

The major effect of the proposed changes is to clarify and give priority to the primary role of the food laws of the states, territories and New Zealand (the application Acts) and to strengthen the relationship between the Code and the application Acts. In doing this some change has been necessary to ensure that the Code does not inappropriately impinge on the criminal law function of the application Acts. The revised Code provides explicit requirements that can be enforced by enforcement agencies to replace implicit restrictions in the current Code, which might not be effectively enforced.

It is FSANZ's intention that this Proposal should not alter the effect of provisions that impose requirements or obligations. While the Proposal is lengthy (because it involves every Standard in Chapters 1 and 2) it is not complex. Nonetheless, many issues have been raised in the review process because the revision has identified areas of uncertainty.

Less significant changes modify or add definitions and alter the structure of the Code to help navigation or address problems of expression.

It has not been possible to address all the matters raised by the Court's decision or the submissions made in the earlier consultations. Significantly, the Court's comments about the provisions of the Code that regulate novel foods and nutritive substances have not been addressed in this Proposal. Those matters are being considered in a separate proposal that is unlikely to be finalised in the timeframe for this Proposal. Nonetheless, the revision will establish a firmer legal basis for the consistent application of the Code by industry and enforcement agencies and for future development of the Code.

2. Introduction

2.1 The Proposal

The *Australia New Zealand Food Standards Code* (the Code) is a collection of food regulatory measures[1] [2].

Many of the standards were last reviewed more than a decade ago when a joint Australia-New Zealand review was conducted to facilitate the development of joint food standards for Australia and New Zealand.

A legal review of the Code was conducted after the decision of the Supreme Court of New South Wales in *Christine Tumney (NSW Food Authority) v Nutricia Australia Ltd* [13660/08] (the *Nutricia* Case or *Nutricia*). The review identified a wide range of issues about the enforceability or interpretation of the Code and the consistency of application of the Code across jurisdictions[3]. It identified 14 legal issues arising from the court's decision and 176 additional matters were identified by food regulators following consultation. This Proposal addresses most of the issues identified in the review. However, it has not been practical to address all matters raised as some require consideration of complex food safety, labelling or composition issues that cannot be completed in the time allocated for this Proposal or are more appropriately considered in stand-alone proposals.

In the draft food regulatory measure proposed after assessing this Proposal the existing provisions of the relevant standards are, for the greater part, repeated or restated with only minor editorial change to address legal drafting issues identified in the review. More significant change has been made in limited areas, and is discussed in this paper.
Finally, FSANZ has identified a small group of issues that, for technical legal reasons, could not be dealt with earlier, because there was no appropriate proposal or application for consideration of those issues. The issues are identified in paragraph 3.2.25 and are dealt with in this Proposal, which is under the major procedure and not subject to limitation as to subject matter.

Some matters identified in the review have already been addressed in P1013 – Code Maintenance Proposal IX.

2.2 The current Standards

The *Code* is published at www.comlaw.gov.au. Individual standards can be accessed through the FSANZ website at http://www.foodstandards.gov.au/foodstandards/foodstandardscode.cfm.

2.3 Procedure for assessment

The Proposal is being assessed under the major procedure.

[1] Food regulatory measures are standards or codes of practice: section 4 FSANZ Act
[2] The Code is defined in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) as the Code that had been published as the Australian *Food Standards Code* on 27 August 1987, together with any amendments of the standards in that Code since that time, including any insertion, revocation or substitution of a standard in that Code.
[3] The legal review was conducted for FSANZ by the Office of Legislative Drafting and Publication in the Commonwealth Attorney-General's Department. That office is now a division within the Commonwealth Office of Parliamentary Counsel.

3. Summary of the assessment

3.1 Risk assessment

An audit report prepared by the Office of Legislative Drafting and Publishing in the Australian Government's Attorney-General's Department identified the following issues:

- the application of rules of statutory interpretation such as the relevant Acts Interpretation Acts
- the inconsistent interpretation of words that are used in relevant legislation and in the Code
- the integration of provisions of the Code that impose obligations and the relevant offence provisions in model offence legislation
- the accessibility of definitions in the Code
- the construction of food composition provisions
- the relationship between permissions and general prohibitions within the Code
- incorporation of documents by reference
- the structure of the Code, including the placement in Schedules
- the use of purpose and outline statements.

The FSANZ response to the OLDP recommendations is set out in **SD1**. Consultation with jurisdictions identified a further range of issues.

The full range of issues identified in the audit report and subsequent consultation is in **SD1**.

A first call for submissions on the proposal and a draft food regulatory measure were consulted on in 2013. A summary of the submissions received and the Authority's response to those submissions is at **SD3**.

3.2 Risk management

The food regulatory measure developed during assessment of this Proposal has no direct effect on public health and safety, the provision of adequate information to consumers or the prevention of misleading or deceptive conduct. The revised food regulatory measure primarily addresses legal matters to improve the efficacy of the legislation. For a similar reason it is not necessary to consider specifically the matters that are listed in subsection 18(2) of the FSANZ Act.

The Office of Best Practice Regulation has previously advised (reference ID: 14493) that, based on the information provided by FSANZ, a Regulation Impact Statement is not required as the Proposal has only a minor regulatory impact on businesses and the non-profit sector since the Proposal does not alter the intention of the Code but, instead, ensures that the intention is better communicated.

Submissions received from industry and food regulators in response to the first call for submissions indicated a possibility of a financial impact associated with introduction of a revised Code notwithstanding the primary intention not to substantially alter the effect of the Code. FSANZ recognises that, as with any Code variation, there will be some transitional costs associated with the implementation of the variation. However, FSANZ has, with minor exceptions, avoided variation that will result in a change in the regulatory requirements and impose additional cost on consumers or industry.

In particular, FSANZ has responded to industry suggestions that the numbering systems used in the present Code should not be changed in order to maintain continuity of industry's compliance systems and to maintain a level of consistency with the practice of international trading partners. The possibility of changes in the numbering systems appeared, in the submissions, to be the major potential cause of any cost impact.

3.2.1 The *Australia New Zealand Food Standards Code*

The Code is a Commonwealth legislative instrument that establishes food standards. It is a requirement of the Commonwealth Imported Food Control Act, in relation to food that is imported, and the Food Acts of the states and territories, in relation to food that is for sale, that food complies with relevant standards or that persons who are required to do something by a Code provision comply with that requirement. In New Zealand, the Code is replicated in standards made under the Food Act and enforced by provisions of that Act.

The presentation of the Code involves a compromise of the needs of quite different audiences in both Australia and New Zealand including audiences that use the Code as a technical tool and those that use it as a regulatory tool supporting criminal sanctions in 10 separate jurisdictions.

Two examples of the unique character of the Code as an Australian legislative instrument are:

- the presence of a standard that has no application in Australia
- provisions that purport to establish a defence for non-compliance that is unintentional—a matter that is more appropriately dealt with in the application Acts.

3.2.2 Application of rules of statutory interpretation

The Code is a Commonwealth legislative instrument and has no operative effect by itself. The implementation of the Code and enforcement of the standards is achieved through other Commonwealth, New Zealand, state and territory food laws (the application Acts).

A Commonwealth law, the *Imported Food Control Act 1992*, creates an offence of importing food if the importer knows, among other matters, that the food does not meet applicable standards. The concept of applicable standards involves, in relation to a food, a national standard that applies to the food, other than a labelling standard. The Code is the source of national standards.

The way the Code is implemented in New Zealand, state and territory law differs from jurisdiction to jurisdiction.

In New Zealand, standards are issued by the New Zealand Minister[4]. As New Zealand law, the standards made in New Zealand will be interpreted under that country's interpretation law. No issue arises in New Zealand about the choice of an interpretation law.

The COAG Food Regulation Agreement provides for standards to be adopted or incorporated into the laws of the Australian states and territories. The state and territory application Acts generally implement the Code by establishing offences of not complying with a requirement of the Code or of selling food that does not comply with a Code requirement. A false description offence can be proved by evidence of non-compliance with a Code requirement.

[4] Under Part 2A of the *Food Act 1981*. It is likely that the New Zealand legislation will be repealed and substituted by new legislation while this Proposal is being assessed.

While the application Acts are interpreted according to the provisions of local interpretation laws, the interpretation laws do not apply consistently to the Code, if they apply at all; creating a potential for inconsistent enforcement.

FSANZ has received legal advice that, in the absence of a provision to the contrary in the Code or state or territory law, the default position is that the Commonwealth interpretation law will apply to the Code. FSANZ considers that advice to be correct, notwithstanding the different conclusion expressed by the New South Wales Supreme Court in *Nutricia*. This is a matter that should not be left in doubt. Any doubt can be resolved by an explicit statement in the Code.

Three options were considered by FSANZ in the first call for submissions in order to achieve the objectives of having a common approach to the application of interpretation laws in all jurisdictions and to reduce any doubt about the application of the Commonwealth Acts Interpretation Act. They are:

(a) to amend the Code to provide that, in Australia the Commonwealth *Acts Interpretation Act 1901* and, in New Zealand, *The Interpretation Act 1999* shall apply to the Code
(b) to amend the application Acts to provide that the Commonwealth interpretation law shall apply to the Code
(c) to include relevant provision of the Commonwealth Interpretation Act in the Code.

Option 1 remains preferred by FSANZ as this is the simplest mechanism to achieve consistency of interpretation and maintains the current law.

We were initially attracted to the suggestion by some regulators that local interpretation laws should apply. However, the legal advice makes it clear that the problems inherent in that approach are not limited to simple inconsistency of interpretation. The legal advice also clarifies and removes any question that the proposed provision might be beyond power. The variation of the Code that is required to achieve the application of state or territory interpretation laws is, in our view, unnecessarily complex[5]. Accordingly, we have prepared the draft food regulatory measure on the basis that the Commonwealth interpretation law should apply to the Code. The legal advice is at **Attachment H**.

Option 2 would require amendment of state and territory legislation in at least 4 jurisdictions and may require amending legislation in others.

Option 3 provides a level of inconsistency with the overarching Commonwealth Interpretation Act, without significant offsetting advantage.

This matter is addressed in section 1.1.1—4 of the draft food regulatory measure. While it is not strictly necessary for the Code to set out the position in relation to New Zealand we have included this provision for information.

[5] The required provision would be along the lines of:
Application of jurisdictional interpretation rules:
(1) In applying this Code under an application Act, general rules of interpretation of the jurisdiction apply to this Code unless the contrary intention appears.
(2) In subsection (1):
general rule of interpretation of a jurisdiction means a rule of interpretation that appears in an Act of the jurisdiction and is expressed to have general application in the interpretation of other Acts or of instruments (for example rules set out in an interpretation Act, an Act dealing with the making and interpretation of instruments or an Act dealing generally with the criminal law).

3.2.2 Consistent interpretation of words in state and territory legislation and the Code

The application Acts define some terms that are also used in the Code. However, New Zealand and state and territory legislation does not consistently adopt the definitions in the model food provisions.

Three options to address that inconsistency have been considered. They are:

(a) Option 1: to provide in the Code that the words have the meaning given in the application Acts.
(b) Option 2: to provide in the application Acts that words in the Code have the same meaning as in the FSANZ Act.
(c) Option 3: to provide definitions in the Code.

Option 1 is preferred as this option ensures that jurisdictionally-based courts and law enforcement agencies are not faced with inconsistency between the Code, which is not state or territory law, and the relevant state or territory law[6].

Options 2 and 3 are not preferred because they carry a higher risk of inconsistency between the Commonwealth legislation and the application Acts.

3.2.1.1 What is a food?

Food regulation in Australia is based on a very broad definition of food. In New Zealand a narrower definition is used in the New Zealand Food Act 1981[7].

The definition in the state and territory application Acts is an inclusive definition, which does not purport to describe comprehensively all of the things that might be foods. The inclusive statements provide that the concept of food includes any substance or thing used, or represented as being for use, for human consumption or as an ingredient or additive; any substance used in the preparation of a substance or thing used for human consumption, such as a processing aid; and chewing gum or a substance or thing declared to be a food.

In New Zealand, the definition is exclusive. That is, it defines the scope of the concept as things that are used or represented for use as food or drink, and then provides inclusive examples. The examples include ingredients and nutrients or other constituents of any food or drink. The definition has an unfortunate circularity in that food is defined as a thing used as a food.

Both definitions introduce the concept of ingredient, but neither defines that concept. The Australian definitions also introduce the concepts of additive and processing aid, again without definition.

The use of the very broad definition of food derived from the application Acts in the Code is problematic as provisions of the Code are not always intended to apply to the very wide range of things that might be food. More often a more limited subset of 'food' is intended to be the subject of Code provisions. For example, for provisions about food additives and processing aids to be effective they must rely on a more limited concept of food than in the broad definition.

[6] This is a uniquely Australian problem as the Code does become subordinate legislation of the enforcing jurisdiction through the operation of the New Zealand Food Act.
[7] Legislation to repeal and replace the *Food Act 1981* was passed by the New Zealand Parliament on 29 May 2014. That legislation will commence in 2016.

Some terminology is needed in the Code to differentiate those levels in order to avoid circularity or unintended outcomes if the Code is given a strict interpretation. Alternatively, many uses of the term would require qualification, which would add to the complexity and length of the Code and, possibly, add uncertainty.

The current Code introduces concepts such as final food and food product without definition. It also introduces the concept of component—with a definition. Some substances will be food products when sold alone; ingredients when sold as an element of another food; a food additive when used for some technological purposes; a processing aid when used for another technological purpose and a nutritive substance when used for a nutritional purpose. The Code needs to distinguish between these uses and characterisations without leaving regulatory gaps.

The approach taken in the draft food regulatory measure is to apply the very broad definition of food when a broad interpretation is intended to be used. Where it is intended that a requirement relates to a more limited range of food either the term 'food for sale' is used or the context makes it clear that the provision relates to food that is for sale.

3.2.3 Integration of obligation and offence provisions

The food legislation in each state or territory and New Zealand and the *Imported Food Control Act 1992* (the IFC Act)—the application Acts—establish a regulatory regime for the supply of food that is 'safe and suitable'. The IFC Act applies similar principles to determine whether an imported food is a 'failing food'.

In the food regulatory system the Code performs a supportive function. It is not the primary legislation for food regulation. The purpose of the Code is to provide greater detail about safety and suitability, in order to achieve the statutory objective of a high degree of confidence in the quality and safety of food produced, processed, sold or exported from Australia or New Zealand[8].

The Code does not, and cannot, contain offence provisions. Offence provisions are in the application Acts. Most of the offence provisions in the application Acts do not rely on the Code. However, the application Acts rely on the Code to establish requirements against which some offences can be based.

The basic offences under the application Acts are for selling food that is unsafe or unsuitable. Food will be unsafe or unsuitable if it is likely to cause physical harm (*unsafe*), or is damaged or perished, is from a diseased animal or contains biological or chemical agents that are foreign to the nature of the food (*unsuitable*). In some cases a food that would otherwise be unsafe or unsuitable will not be if a relevant provision of the Code is complied with.

Other offence provisions apply if:

- food for sale does not comply with a requirement of the Code relating to the food, or the packaging or labelling of the food (a packaging or labelling offence);
- a person fails to comply with a requirement imposed on that person in relation to the conduct of a food business or food intended for sale or for sale (a food business conduct offence), or
- food for sale is packaged or labelled in a way that falsely describes the food (a false description offence).

[8] See paragraph 3(a) FSANZ Act.

If the provisions of the Code that impose requirements are to be enforced, they must have certainty of interpretation and must establish clear requirements. Any uncertainty will be applied in favour of the defendant in a prosecution under the application Acts. Standard 1.3.1, 1.3.3 and Standard 1.4.2 are examples of standards that do not establish intended requirements clearly. Standard 1.3.1 prohibits the addition of food additives without making it clear what a food additive is. Standard 1.3.3 purports to prohibit the use of processing aids without permission. But, because the definition is self-limiting, the prohibition applies only to those aids that are permitted and does not achieve the intended effect. Standard 1.4.2 is intended to establish a requirement that residue limits should not be exceeded but does no more than state permissions. Any prohibition is implicit, at best.

Provisions of the Code that impose obligations or set out requirements to be complied with are to be amended to ensure that it is clear who is required to comply with the obligation or requirement (if it is intended that a person be responsible) and to ensure a higher level of certainty of meaning and operation about the actual requirement.

The provisions in Part 1 and 2 of the draft food regulatory measure establish requirements for composition, packaging, labelling and the provision of information. It is intended that offences relating to these provisions would be prosecuted under the provisions of the application Acts that relate to selling a food product that does not comply with a requirement relating to the food, or the packaging or labelling of the food. That is, it is anticipated that a failure to comply with a requirement in Part 1 or Part 2 would usually be prosecuted under the local equivalent of section 17(2) of the model food provisions.

The provisions of Parts 3 and 4 create obligations that are to be complied with by identified persons, whether legal persons or natural persons, in relation to the conduct of food businesses. They are intended to be prosecuted under the provisions of the application Acts that relate to failure to comply with a requirement imposed on a person in relation to the conduct of a food business or food intended for sale or for sale. That is, it is anticipated that a failure to comply with a requirement in Part 3 or Part 4 would, generally, be prosecuted under the local equivalents of subsection 17(1) of the model food provisions.

The false description offences in the application Acts[9] are referenced in the draft food regulatory measure by provisions that establish requirements, usually compositional requirements, that apply if a food is sold as a particular food. For example, if a food is sold as butter it must comply with the compositional requirements for butter. Conversely, a food that is not butter cannot be sold as butter, but may be sold as another food.

Non-compliant foods may be subject to any of a range of offences under the application Acts. The Code does not include provisions that have the function of directing, or suggesting, the manner in which offences should be prosecuted. That is a function of the application Acts and the exercise of prosecutorial discretion. It is not the function of the Code to determine how food regulation will be enforced. However, it is an appropriate function of the Code to ensure that relevant application Act offences are supported by clear requirements. Accordingly, for example, the Code does not impose requirements about who can institute proceedings or take other action under an application Act.

One issue that has been necessary to consider in the drafting is the interaction of the intention element of many provisions of the Code and the strict liability nature of offences under the application Acts. Intention is a basic element in substantial parts of international and domestic food regulation. For example, food additives and processing aids are generally described as substances that have been added *intentionally* to achieve a purpose. In this revision we have sought to make a distinction between objective and subjective intention.

[9] These are the equivalent of section 14 of the model food provisions.

It is reasonable for the Code to rely on objective intention but inappropriate for the Code to express requirements in a manner that relies on the subjective intention of a manufacturer or supplier. Accordingly, we have not sought to deal with the unintentional addition of prohibited plants or fungi as an operative provision in this draft. However, we have left a reference to unintentional presence of a food produced using gene technology in Standard 1.5.2. While it would be possible to remove the element of intention, leaving the exception as a maximum presence of 1%, it is considered to be beyond the scope of this Proposal to make that change.

Another issue that was raised by a submitter was that the Code does not identify a person as having an obligation to comply with a requirement in cases where there might be an intention that, say, a manufacturer rather than a wholesaler or retailer is responsible for compliance. This is a matter to be resolved by prosecutorial discretion rather than the Code. The revised Code provisions, consistently with the application Acts, relate to complying with Code requirements when selling a food. That requirement can apply equally to a sale from a manufacturer to a wholesaler or retailer, or to a sale by a retailer to a retail customer. So, for example, the requirement to fortify wheat flour sold for bread making can be applied to any sale, although there may be an expectation that fortification will be done by the flour miller.

3.2.4 Accessibility of definition provisions

In the current Code, definitions are spread throughout various standards. In some cases words have been given a different meaning in different standards[10]. To avoid inconsistency of interpretation of words used throughout the Code a compendium definition section is to be included at the beginning of the Code, with appropriate signposts to words defined in a part of the Code that is more relevant. For example, compositional definitions (which are to be separated from compositional requirements) will remain in Chapter 2, and be signposted from the compendium definitions provision.

In some cases different definitions for the same term remain. This happens because the term has a different meaning when used in a specific context. In each of these cases a decision has been made that the definitions would be more appropriately reconsidered in a different proposal. It is beyond the scope of this proposal, for example, to consider whether one or other of the definitions of sugars that are in the current Code should be varied. The different definitions exist because the provisions have a different regulating purpose.

Submitters responding to the first call for submissions paper gave strong support to the establishment of a ‘glossary’ or ‘dictionary’ for the Code. However, a number of issues were raised about the presentation of that material.

Submitters were concerned that some definitions that were in recently commenced standards had not been included in draft section 1.06. This was substantially a timing issue. That omission has now been rectified.

Other submitters expressed a view that all definitions should be in the primary definitions section rather than being signposted. This is a matter for judgement and there is clearly a very broad range of views about how that judgement should be exercised. Our conclusion is that definitions that have an application in only one division of the Code should be signposted and definitions that are used in more than one Division should be in the primary definitions section. We suspect this approach has a stronger basis and will have greater acceptance if the Code is presented as separate standards, as it is now, and as proposed by many submitters.

[10] e.g. *one day quantity* and *sugars*

Finally, it was suggested that some definitions, such as the definitions for wholemeal and wheatmeal, should be amended to reflect changes in industry use. Although such changes might appear innocuous we have not included those changes in this Proposal as the changes could introduce a requirement to change labelling. The impact of that change has not been assessed. Such variations should be the subject of an application by the proponent.

3.2.4.1 For this Code/In this Code

A number of submitters commented on what was seen as an inappropriate use of the terms 'For this Code…' and 'In this Code' in what were identified as definition provisions. This usage is in accord with Commonwealth legislative drafting protocols.

'For this [legislative instrument]' is used to introduce a provision that describes how a term, whether a word or a phrase, is used in the instrument.

'In this [legislative instrument]' is used to introduce a provision that contains definitions for terms used in the instrument.

3.2.4.2 Placement of definitions in the Code, Divisions and sections

Submitters also commented on the placement of definitions in Divisions. It was noted that sometimes definitions appear at the beginning of a division and on other occasions a definition is at the end of a section. Again, this is an example of Australian legislative drafting practice.

Definitions and interpretative statements of terms that have an application only within a section are, in Australian legislative drafting practice, placed at the end of the section unless the section would be meaningless unless the term was defined earlier. Definitions of terms that apply throughout a division are placed in the introduction to the division.

Definitions that have an application in more than one division are in the general definition provisions—sections 1.1.2—2 and 1.1.2—3. Definitions that only have an application in one division are signposted from those sections. Definitions that operate in one section only are in the relevant section.

3.4.2.3 Definition, meaning of or interpretation?

Some submitters were concerned about the different terms used in the draft food regulatory measure to introduce different interpretive provision types. Although there is a technical distinction between the various types of provision, and it might be appropriate to make that distinction in a document that has a higher legal function, we have decided that the interests of simplicity are served by describing all such provisions as definitions. The trade-off for simplicity is a loss of precision, because some interpretation aids are not definitional. Submitter comments indicate that precision, at least in this respect, is not valued. Accordingly, the term 'definition' is used throughout the revised draft food regulatory measure.

3.2.5 Food definition and composition provisions

Many of the food definitions in the Code currently contain both a definition and a substantive provision. It is not always clear whether an element of a definition is characterising or compositional.

It is a general drafting rule that definitions should not include substantive material, i.e. the definition should not impose an obligation or state a requirement.

Compositional standards should only establish compositional requirements and not attempt to define foods or food products. All food definitions have been reviewed to, where appropriate, remove substantive requirements and to restate the compositional requirements independently of the definition.

The definitions have been revised, where appropriate, to include only the identifying characteristics of the food and to state compositional requirements separately. Some definitions have been added, in response to comments received, in order to provide a definition where it is considered that one is necessary to avoid doubt. In a few limited cases it has been decided to keep characterising and compositional elements in the same provision, primarily because to separate them would lead to unnecessarily complex drafting with uncertain benefits.

3.2.5.1 Food, food product, ingredient and component

A clear understanding about what constitutes food is essential for effective food safety regulation. The decision of the Supreme Court of New South Wales in the *Nutricia* case demonstrated that the Code does not, at present, provide that clear understanding. The court declined to apply the definitions of food that appear in the FSANZ Act or the New South Wales application Act. Instead, the court applied what was described as 'a common understanding' about what constitutes food.

The current food regulation system is based on the premise that all food can be sold if it is safe and suitable. Food standards are established to provide certainty as to safety and suitability in order to facilitate the production and sale of food and enforcement. While it is clear from the record of enforcement of food law by enforcement agencies that the food laws, including the Code, are functional; it is also clear, from the Nutricia decision, that the Code could be more effective.

Food is defined in very broad terms in a definition of food that is similar, although not identical, in the FSANZ Act and the application Acts. The breadth of the definition is designed to include everything that might be considered to be a food, but is itself a source of uncertainty because some elements of the regulatory system are aimed at food in its broadest sense and others have a narrower application. For example, some of the labelling provisions are directed at foods that are yet to be used in processing and are not in a state suitable for sale for immediate consumption. Other labelling provisions are clearly directed to retail sale, where the intention is that the food will be consumed, although not necessarily by the purchaser, without further processing. Similarly, the additive provisions are intended to regulate how foodstuffs will be processed and the extent to which additives will be in the food at the end of processing. However, the offence provisions apply only at a point of sale.

Foods at the end of processing are described in the Code in terms such as final food or as products, e.g. meat or milk products. Sometimes final food and product mean the same thing: sometimes they do not. The level of an additive in a food might exceed the maximum limit at the end of production, but be below the maximum limit when made available for sale. For these reasons the legislation should distinguish between the various stages of production and sale in order that it is clear when a requirement is intended to be implemented. The application Acts do not do this, although the offence provisions of the application Acts have a practical application, in relation to Chapters 1 and 2, only in relation to the sale or advertising of food.

The matter is complicated by provisions such as clause 7 of Standard 1.1.1, which provides that compositional requirements apply to the 'composition of the final food'. While the term 'final food' might be understood in the food industry it is not a term with legal certainty.

To resolve the uncertainty the first call for submissions proposed use of the term 'food item' to describe a food that is for sale on the basis that it is ready for consumption without further processing. In consultation with stakeholders it was made clear that this term was not acceptable because the notion of food item involved elements beyond the sale itself. While we do not accept that this was a source of legal uncertainty we have modified the language to refer, where appropriate, to food for sale.

FSANZ has not considered in P1025 the question whether any of the general requirements set out in current Chapters 1 and 2 should be re-expressed as personal requirements. Any change would impose new legal obligations—a matter that is considered to be out of scope and more appropriately the subject of a separate proposal or application.

3.2.5.2 Definition and compositional elements

Some submitters expressed concern that the draft food regulatory measure in the first call for submissions paper had not consistently separated the composition and definitional elements of current definitions. The prime example cited was the definition of chocolate. Submitters considered that the requirements that chocolate be prepared from a minimum of 200 g/kg cocoa bean and contain no more than 50 g/kg edible oils are compositional requirements. On its face, this appears a simple and compelling argument.

However the simplicity of the argument is not supported by the history of development of the definition or the plain words of the Code. That history makes it clear that the current definition describes the characteristics of the product known as chocolate and none of it is a formal compositional requirement. The plain words of Standard 1.1.2 are that the Standard sets out definitions for foods that have no specific compositional requirement. Chocolate is defined in that standard. The effect is that only a food prepared from a minimum of 200 g/kg cocoa bean and containing no more than 50 g/kg edible oils can be described as chocolate. The only compositional requirement for chocolate is that it be chocolate, as described, although this requirement is an inference, rather than an explicit statement, in the current Code. It is clear that the definition was included in the Code to ensure that consumers are not misled about the true nature of a cocoa-based product.

Concern was also expressed about the range of ways in which food definitions and compositional requirements were presented in the draft food regulatory measure. That range of presentations reflected the range of options for food definitions and compositional requirements in the current Code and the obscuring of that range, in the current Code, by including some definitions and compositional requirements in the same provision. The matter is complicated by the fact that some foods have requirements that interact with the false description provisions of the application Acts while others do not.

The combinations are:

- foods that have a definition and a compositional requirement and both are provided in Chapter 2 e.g. butter
    - In relation to this group a decision was made to retain both the definition and the compositional requirement in a revised provision in Chapter 2. The alternative is to separate the definition and the compositional requirement.
- foods that have a definition only, where the definition is provided in a Chapter 2 standard e.g. game meat or fruit and vegetables.
    - In relation to this group a decision was made to leave the definition where it has a context in Chapter 2. The alternative is to separate the definition and the context.

The signpost for these provisions is for example' 'see section 1.169'. There is no need to refer to the food as 'a food that may be sold as…' because there is no compositional requirement to link to.

- The general purpose of these provisions is to establish a link to the food additive permissions.

- foods that have a definition only, where the definition is provided in a Chapter 1 standard, such as the list of foods currently in Standard 1.1.2, including chocolate. While these foods do not have a specific compositional requirement there is, nonetheless, a requirement that they be the defined food. This is made clear by the history of the provisions, which establishes that the current Standard 1.1.2 was developed solely to ensure that the named foods would have a requirement that linked to the false description provisions of an application Act. Accordingly, a person cannot sell as chocolate a substance that does not meet the definition of chocolate, but cannot be prosecuted for failing to comply with a non-existent compositional requirement.

    - For this group, the definitions have been set out in section 1.1.2—3

3.2.5.3 Use of food names in quotation marks

Some submitters questioned the use of food names in quotation marks. This was, and is, done to address the reality that the food names used in the Code are not always used when selling food. The use of quotation marks addresses the gap between what a food is sold as and what it actually is. If this was not done a food product that is non-compliant, e.g. because it does not comply with a compositional requirement, could be out of the reach of regulators for some purposes. Alternatively, foods that are not intended to be regulated could be within the scope of a permission. The approach taken to this issue is that requirements will generally apply to a food if it is represented in a manner that suggests that the requirement is applicable. However, for some foods a requirement will only apply if the representation is more specific—the name of the food is used to identify the food for sale.[11]

3.2.5.4 Specific food issues

Cider and perry

Some submitters made representations that Standard 2.7.3 – Fruit Wine and Vegetable Wine, should be varied so as to restrict a practice of adding other fruit or vegetable juices or alcohol derived from other sources to products that are sold as cider or perry. We consider that the issue should be raised in an application, as it is inappropriate for consideration in P1025.

Cider and perry are alcoholic beverages that are defined in the Code as fruit wines that are made from apples and pears. Cider is made essentially from apples, but no more than 25% vol/vol pears can be included. Perry is made essentially from pears, but no more than 25% vol/vol apples can be included. Fruit wines may also include other fruit or vegetable juices or fruit or vegetable juice products, but a fruit wine that is made from fruits other than apples or pears is not cider or perry.

Cider or perry to which another juice or juice product has been added should be named in a manner that indicates the true nature of the food. That is, the words cider or perry, if used, should be qualified in a manner that indicates that the food is not cider or perry as defined or characterised in the standard. The context in which a name is used can make it clear that a food is not a food for which there is a standard.

[11] Notes to section 1.1.1—13 provide an indication of the division of defined foods into these two categories.

Other laws may apply to foods that are named in a manner that is misleading.

Salt substitute

Salt substitute is currently defined as being a food made as a substitute for salt consisting of permitted food additives. This definition is incomplete, as a salt substitute will usually include other foods and can only contain the food additives that are specifically permitted for salt substitutes. The provision is revised to clarify which additives may be used.

3.2.5.5 Specific definition issue

RDI and ESADDI

The current definitions of RDI and ESADDI rely on footnotes to a schedule to explain how some values are to be determined. The footnotes provide no legal certainty as their implementation relies entirely on an understanding of the practice of nutritionists. In the revision, the provisions have been incorporated into operative provisions to provide greater certainty.

A separate provision, section 1.1.2—14, sets out how the amount of vitamins and minerals is to be calculated and expressed for the purposes of nutrition content statements or percentage daily intake statements.

3.2.6 Relationship between permissions and general prohibitions

General prohibitions in the current Code act to prohibit an action, such as the addition of some substances to food, unless that action is expressly permitted elsewhere in the Code. Separate prohibitions exist for substances used as food additives or used as processing aids, for example. While the permissions are generally stated close to the prohibition in the current Code, some permissions are provided in unrelated standards. This makes interpreting the Code difficult because the links between the prohibition and the permission are not transparent or coordinated. General prohibitions and permissions have been reviewed to provide a single, complete statement of the prohibition and all permissions in the one provision, or proximate provisions.

3.2.6.1 Substances added to foods

The major change in this regard is the proposed statement in new section 1.1.1—10 of prohibitions on the presence of some substances in food for sale, together with signposts to the provisions that qualify the prohibition and provide further detail about the permissions.

As a general proposition, substances can be added to food provided the food remains safe and suitable, subject to a restriction (in the application Acts, not the Code) on the addition of biological or chemical agents that are foreign to the nature of the food. As the Nutricia decision demonstrated, there can be difficulty in determining whether a substance is foreign to the nature of a food. Accordingly, the Code should provide both a clear prohibition and clear permissions.

The Legislative and Governance Forum on Food Regulation[12] (Forum) has established policy principles to guide the development of standards about the addition of substances to food.

The overarching policy principle established by food ministers is that it should be permissible to add substances to foods where:

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

(a) the purpose for adding the substance can be articulated clearly by the manufacturer (ie, the 'stated purpose'); and
(b) the addition of the substance to food is safe for human consumption; and
(c) the substance is added in a quantity and a form that is consistent with delivering the stated purpose; and
(d) the addition of the substance is not likely to create a significant negative public health impact to the general population or sub population; and
(e) the presence of the substance does not mislead the consumer as to the nutritional quality of the food.[13]

More detailed policy principles apply to the addition of substances to achieve a technological purpose[14], the addition of vitamins and minerals[15] and caffeine[16].

The detailed policy principles are implemented in the current Code through standards that regulate the addition or use of food additives[17], vitamins and minerals[18], processing aids[19], and certain plants and fungi[20] by imposing a series of general prohibitions on the addition of those substances and then specifying permissions for their addition. However, the overarching policy principle is implemented on a case-by-case basis through the consideration of applications for the addition of nutritive substances[21] and the sale or use of novel foods[22].

Food additives

Substances used as food additives are regulated by the current Code only if the substance is listed in the schedule to Standard 1.3.1, which purports to provide a standard for food additives.

Clause 2 of Standard 1.3.1 is a general prohibition on the addition of food additives. However, there is no definition of food additive. So, it is not clear what is prohibited. The only effective requirement in the current Code is that a substance that is listed in the Schedules, that is, a permitted substance, can only be added in accordance with the limits provided in the Schedule.

It can be inferred from all editorial notes that it is only the listed substances that are permitted and, by inference, that other substances are not permitted. A purpose statement suggests that the substances that are intended to be prohibited are substances that are,

> *not normally consumed as a food in itself or 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*. [23]

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[13] *Addition to food of substances other than vitamins and minerals, Specific Order Policy Principles–any other purpose*, Food Regulation Ministerial Council, 2008
[14] *Addition to food of substances other than vitamins and minerals, Specific Order Policy Principles–Technological Function*, Food Regulation Ministerial Council, 2008
[15] *Policy Guideline on the fortification of food with vitamins and minerals,* Food Regulation Ministerial Council, 2009.
[16] *Policy Guideline on the addition of caffeine to food*, Food Regulation Ministerial Council, 2003
[17] Standard 1.3.1
[18] Standard 1.3.2
[19] Standard 1.3.3
[20] Standard 1.4.4
[21] clause 9 of Standard 1.1.1
[22] clause 2 of Standard 1.5.1
[23] The definition can be compared to the current Codex definition:
Food additive means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment,

This is, potentially, a broader category of substances than are in the lists in the schedules. However, the purpose statement has no legal effect and is of no value in determining what is or is not a food additive.

The proposed revision of the additive standard operates by prohibiting, in a general prohibition, the addition of any substance that is a listed substance or a substance that has been selectively refined or extracted, or synthesised, and is not normally consumed as a food product or used as an ingredient by consumers, if the purpose of the addition is to achieve one or more of the technological purposes that are performed by food additives. This gives greater clarity to the identification of substances 'foreign to the nature of the food' that are intended to be regulated by the food additive provisions.

Some stakeholders have suggested that the test should be whether the addition has a technological purpose rather than whether that purpose is intended. We consider that it would be inconsistent with the policy principles[24] to take that approach.

The revised definition refers to a technological purpose, rather than a technological function, in accord with the current Codex terminology. A number of submitters were concerned about this change because the change of terminology was inconsistent with Codex. It is our opinion that the revised terminology reflects the evolution of Codex standards and terminology embodied in the current definition. FSANZ has regard to Codex standards, in order to promote consistency with international standards, but where clarity is achieved by a different use, will adopt different terminology or outcomes. For example, adoption of the current Codex definition of food additive would result in a different treatment of enzymes.

The first arm of this provision (a listed substance) achieves the primary objective of establishing a prohibition on the addition of those substances that are recognised as food additives, subject to any permission for their addition. Listed substances may be added for any of the listed technological purposes subject to conditions of use, such as good manufacturing practice.

The second qualification (a substance selectively refined or extracted) is necessary to ensure that the provision actually regulates the addition of substances as food additives and does not operate only as a list of permissions for a limited range of substances. It also ensures that it is the use as a food additive that is being regulated rather the substance. The revised words make it clear that it is not simple refining or extraction that is relevant. There must be a level of selective concentration to produce a substance suitable to perform the required technological function.

The scope of this provision is narrower than the implicit scope of the description of food additive in the current purpose statement as it applies only to substances that have been selectively refined, extracted or synthesised to perform a technological purpose. The reduced scope has an effect of reducing regulatory burden, without reducing the protection of public health and safety, while providing greater certainty. It is recognised that this arm of the prohibition suffers from the use of the phrase 'not normally consumed'. Submitter comments are sought as to whether the second arm could rely solely on the concept of selective refining or extraction to achieve a technological purpose. Additionally, a possibility remains that some substances will continue to be regulated by the wider operation of the application Acts. The Code provisions do not limit the operation of the application Acts, but simply set out the limits of regulation by a standard.

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packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by- products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities.

[24] The addition must have a 'stated purpose…articulated clearly by the manufacturer'.

Some submitters expressed disquiet about the use of the terms ‘additive approved at GMP’, ‘colouring approved at GMP’ and ‘colouring approved at a maximum level’. In the revised draft food regulatory measure those terms are replaced by ‘additive approved in processed foods’, ‘colouring approved in processed foods’ and ‘colouring approved in processed foods at a maximum level’. That terminology draws on the condition of the current description of the schedules of food additives permitted at GMP or at maximum limits—that the permissions are for the addition of the additives to processed foods. We consider that any initial confusion that might arise from the decision not to refer to these lists by reference to the section number will pass quickly.

Processing Aids

Processing aids are regulated in the current Code by a provision that prohibits the addition of the substances listed in Standard 1.3.3 to perform any technological purpose unless the addition is specifically permitted, either generally or for a specified purpose and a food additive technological purpose is not performed by the substance in the final food. The current provision does not regulate any use as a processing aid of substances that are not permitted in Standard 1.3.3 as processing aids—although there appears to be a common belief (and, perhaps, an intention) that it does. This, potentially, creates a gap as the application Acts apply only to substances that are in the food that is sold. Processing aids are often not present in the food that is sold.

The approach adopted in the draft food regulatory measure restates the definition of processing aid in terms of the use that is intended when adding or using the substance in processing. In other words, rather than regulating substances the proposed provisions regulates use. This ensures that all substances used as processing aids that are of regulatory interest because the use might pose a risk to human health or safety are actually regulated and subject to a safety assessment before being permitted.

Nutritive substances

A further general prohibition in the current Code is the prohibition on the addition of nutritive substances.

The overarching prohibition in the application acts is a prohibition on the presence of a ‘biological or chemical agent, or other matter or substance that is foreign to the nature of the food. It is arguable that this provision operates to prohibit the addition of vitamins and minerals and other biologically active substances.

The Code provisions operate to define a more limited prohibition and associated permissions. The prohibition operates by prohibiting the addition of a substance that is ‘not normally consumed as a food in itself or used as an ingredient of food, but which, after extraction, refinement or synthesis, is intentionally added to a food to achieve a nutritional purpose’. The uncertainty of this definition of nutritive substance, particularly the use of the phrase ‘not normally consumed as a food’, was criticised in the *Nutricia* judgment.

The proposed revision of the definition of nutritive substance does not address that uncertainty fully, although the revised definition does attempt to provide greater clarity. We have not been able, in this proposal, to identify a phrase that better conveys the sense of the words ‘not normally consumed as a food’. However, the issue will be considered in Proposal P1024 – Revision of the Regulation of Nutritive Substances & Novel Foods. We note that the phrase is used in most relevant international standards and the legislation of other countries. The phrase appears to be well understood by the food industry and food regulators, although it is a phrase that has considerable legal uncertainty. When developing food standards FSANZ is required to promote consistency between international and domestic standards.

The regulation of novel foods and nutritive substances is being considered in Proposal P1024. That Proposal will consider matters including the scope of the regulation of substances that are added to foods for purposes that are not technological purposes.

In the draft food regulatory measure, the approach that has been taken is, consistent with the current provision, to prohibit the addition of some substances to food to achieve a nutritional purpose. Those substances are vitamins and minerals; substances identified as being nutritive substances; and a catch-all category of extracted, refined or synthesised substances that are not ordinarily understood to be food products or food ingredients used by consumers. Where the addition of such substances is permitted, there is a specific permission. This approach repeats substantially the provisions in the current Code and does not seek to pre-empt the outcome of P1024. The purpose of the prohibition is to ensure that only substances that have had a safety assessment can be added to food for a nutritional purpose.

Novel foods

The Code also regulates the retail sale, or sale for use as a food ingredient, of foods or substances that do not have a history of human consumption and have a potential for harmful effects in humans. Those foods or substances cannot be sold to the public or sold for use as a food ingredient unless specifically permitted. This element of the Code is also under review in P1024.

In the draft food regulatory measure the current provisions of the Code are substantially replicated. Provisions of the current Code that purport to provide a period of exclusivity for approved novel foods are now expressed as a requirement to comply with conditions imposed as an element of the approval. It is considered that the current provision is unnecessarily cumbersome and may be beyond power. A requirement that any conditions about sale of the novel food be complied with achieves the same outcome without raising questions about legislative authority.

Some submitters questioned the application of the novel food provisions to retail sales only. It is beyond the scope of P1025 to review that issue.

3.2.7 Incorporation of documents by reference

Concern has been expressed about the practice in the Code of incorporating external references to materials such as other standards or methods of food analysis. FSANZ has concluded that this concern can only be addressed through regular review of such provisions, for example, in a Code maintenance proposal. It is not feasible, under current Australian legislation, to provide in the Code that external documents shall be incorporated by reference to their most recent version as that would involve an unlawful delegation of legislative authority and be inconsistent with the Commonwealth Acts Interpretation Act[25]. The issue is resolved in New Zealand, for New Zealand standards, through a provision in New Zealand legislation.

Most submitter comments acknowledged the legal issues and supported the proposed approach.

3.2.8 Structure of the Code

The first draft food regulatory measure was prepared on the assumption that the Code should now be presented as a single legislative instrument.

[25] The Commonwealth legislation only permits incorporation by reference of a document that is a Commonwealth disallowable instrument.

That is consistent with the general approach to the presentation of legislative instruments in the Federal Register of Legislative Instruments (FRLI)[26] and the recommendation of the Office of legislative Drafting and Publication.

Submitter comments in response to the first call for submissions revealed significant levels of concern about the proposal to alter the structure and numbering of the Code. In particular, concern was expressed about the costs that might be involved in amending internal compliance systems and a possible impact on international trading systems, which are accustomed to the current Code structure.

Additionally, in the period following release of the first call for submissions the Commonwealth Office of Parliamentary Counsel, which administers FRLI announced changes to the cost recovery arrangements for the conduct of the FRLI. The new arrangements, as originally established, could impose a cost of approximately $100,000 each year on presentation of the Code as a single instrument[27]. Revised arrangements introduced for 2014–15 are not compatible with the existing cost recovery arrangements. A small part of the cost could be passed on to applicants that pay a fee under section 146 of the FSANZ Act and the remainder would be borne by FSANZ. FSANZ has not received supplementation of its budget to compensate for the cost of user-pays arrangements introduced by the Office of Parliamentary Counsel.

In response to these issues, FSANZ has decided not to proceed with presenting the Code as a single instrument. In the draft food regulatory measure attached to this call for submissions the Code is presented as a collection of stand-alone standards—substantially as in the current Code. This approach has the disadvantage of requiring some repetition of editorial notes and introductory sections.

FSANZ is proposing to present the Code as a series of text standards (the numerical series) and a related set of schedules standards (the S series). Users of the Code will be able to access the Code as they wish. For example, it will be possible to print or read single text standards and their related schedules, or to print the entire Code as a two volume collection of text standards (first volume) and schedule standards (second volume) or a single volume in which each text standard is followed by its related schedule standards. User preferences will be addressed not by the formal presentation of the Code but by the choice of the user.[28]

This presentation adds some minor complexity that would not be necessary in a single document. Each standard will commence with introductory words that name the standard, provide a statutory context for the standard in Australia and New Zealand and provide for commencement. There will also be some additional cost to FSANZ in maintaining the legislative structure requested by stakeholders.

3.2.9 The use of purpose and outline statements and editorial notes

3.2.9.1 Purpose and outline statements

Purpose and outline statements have been used in the Code to provide a summary of individual standards. In many cases, they do no more than the provisions themselves and have a potential to be misleading. More problematic is that some purpose statements include operative statements that should properly be substantive provisions of the Code.

[26] The Federal Register of Legislative Instruments is an authoritative record of Australian subordinate legislation and legislative instruments, established under the provisions of the *Legislative Instruments Act 2003*. The Code is a legislative instrument.

[27] On the basis of the annual charge notified for 2014-15, the estimated cost of registration of each variation of the entire Code would be approximately $6 000.

[28] In this call for submissions the standards are presented as consecutive parts of a single document.

The draft food regulatory measure implements a policy of reducing the number of purpose or outline statements. In general, outline statements will only be used to provide a guide to a major section of the Code e.g. a Chapter. Where purpose statements are provided, they will be substantive provisions of the Code in order to ensure that the purpose can be given effect.

3.2.9.2 Editorial notes

FSANZ has sought to reduce the number of editorial notes in the Code. Editorial notes are not legally binding and should not contain substantive provisions. However, a number of new notes have been provided and the scope of some notes expanded in order to improve navigation.

3.2.10 Microbiological limits for food—Standard 1.6.1

Standard 1.6.1, the microbiological limits standard, establishes limits for pathogens that are recognised as being a risk for food safety. Limits are not established for all pathogens, but the overarching requirement that food be safe and suitable remains.

In the first call for submissions a range of variations were suggested; consistent with the reorganisation of the Code to state prohibitions in one place and permissions separately. Submitter comment indicated that this emphasis was not considered appropriate for microbiological limits.

In the current call for submissions the prohibition is that a food for sale should not have an unacceptable microbiological load. Draft Standard 1.6.1 describes what an unacceptable level of microorganisms is. This establishes a clearer requirement than the current Code provisions, which require that a food must 'comply with the microbiological limits set in relation to that food'[29] and that 'a lot of food fails to comply'[30] if certain conditions exist.

The draft food regulatory measure reflects that Code as at Amendment No. 148 (including the limits set at that time) and, accordingly, does not include amendments made by Proposal P1017 (such as those relating to ready-to-eat foods). It is intended that those amendments will be incorporated in a minor proposal early in 2015.

P1017 reviewed criteria for listeria. FSANZ will commence work to review microbiological limits for other pathogens during the next year.

Submitter comments on the first call for submissions argued that scientific notation used in the current Standard should be retained, although the notation is not essential for an understanding of the Standard and adds complexity. In response to the submissions the scientific notation has been incorporated into the text.

The revision does not address a known problem in the schedule, which fails to identify that the limits for coliforms are based on the results of a testing methodology (most probable number) rather than being a level of a specific microorganism.[31]

3.2.13 Packaging standards

FSANZ is considering whether there is a demonstrated need to establish specific regulatory requirements for food contact and other packaging materials.

[29] clause 2(1)
[30] clause 5
[31] For example, see AFGC comment at p 30 of the AFGC submission, in relation to Schedule S27.01.

At present, the matter is dealt with through a combination of the packaging contaminants standard, Standard 1.4.3, and the food and consumer safety legislation requirements that food products, including packaging and similar materials be safe and suitable.

There is no change to current regulation proposed in this Proposal. However, the current packaging requirement, in Standard 1.4.3, has been moved to Standard 1.1.1[32], where it appears with other general requirements.

Some submitters suggested that the existing requirement should be removed from the Code. Our view is that this is beyond the scope of P1025. The issue will be considered further by FSANZ during 2014–15.

3.2.14 Issues concerning infant formula products

The compositional requirements of infant formula products do not always align with international or major overseas standards and this can cause difficulty for industry involved in importing or exporting infant formula products to or from Australia and New Zealand. The labelling of infant formula products may need updating to manage risks to public health and safety. The regulation of infant formula products for special dietary use needs clarification, particularly the extent to which the composition of these products could lawfully deviate from the regulatory requirements of regular infant formula and follow-on formula in achieving their specific purpose.

FSANZ has prepared Proposal P1028 to review, and potentially to revise Standard 2.9.1 which regulates infant formula. These and other issues related to infant formula will be considered in that Proposal. FSANZ may review the regulation of special infant formula and follow-on formula at a later stage.

3.2.15 Issues concerning infant foods

FSANZ is yet to finalise a proposal to consider the labelling of the minimum age of introduction of infant food (Proposal P274). This work, which commenced in 2003 and was suspended in 2007, resumed after the publication of infant feeding guidelines by the National Health and Medical Research Council. The draft food regulatory measure for P1025 reflects the current provisions in the Code.

3.2.16 Issues concerning formulated meal replacements and supplementary foods

Formulated meal replacements can have vitamin K added in the permitted form. However, no permitted forms were listed. This has been addressed by including reference to permitted forms of vitamin K for these foods. The forms are already permitted for infant formula products.

3.2.17 Issues concerning formulated supplementary sports foods

Standard 2.9.4 is to be reviewed. It is, however, unlikely that the proposed review will commence in 2014–15.

3.2.18 Issues concerning contaminants and natural toxicants

Standard 1.4.1 sets out the maximum levels (MLs) of specified metal and non-metal contaminants and natural toxicants in nominated foods. The requirements in the Standard and MLs are unchanged by the draft food regulatory measure. However two significant changes have occurred to the presentation of the requirements.

[32] As subsection 1.1.1-18(10)

First, the requirements for mercury in fish, crustacea and molluscs have been separated from those for other metal contaminants since the requirements for mercury relate to the sampling of fish to comply with a specified level, based on mean values, rather than a single maximum level as used for other metal contaminants. These levels and the outcomes of sampling to ensure compliance are now set out in a separate schedule (Schedule 19). We have combined the specification of levels with the sampling plan and simplified the expression of the sampling required to be performed, for clarity.

Secondly, we have combined the tables specifying the maximum levels of natural toxicants from the addition of flavouring substances (currently the table to clause 4) with the table for the maximum levels of other natural toxicants in food (currently the table to clause 5). This is because the distinction between the presence of these toxicants due to flavouring or because they are naturally present is not always clear, or relevant to the managing the risk of their presence. For example the presence of hydrocyanic acid in stone fruit juices does not arise from its addition to these products as a flavouring, but is due to its natural presence, yet currently permitted maximum levels are prescribed in the table to clause 4 which is applicable to flavouring substances. In making this change we have also clarified that the levels pertaining to hydrocyanic acid in all foods, including cassava chips refers to all hydrocyanic acid including hydrocyanic acid evolved from cyanogenic glycosides and cyanohydrins during or following enzyme hydrolysis or acid hydrolysis. Previously the definition was specific for hydrocyanic acid released from cassava.

These proposed changes do not alter the policy or intent of the contaminant provisions in the standard.

3.2.19 Issues concerning maximum residue limits

Standard 1.4.2, which is referred to as the Maximum Residue Limits (MRLs) Standard, is varied regularly by FSANZ and, pursuant to Division 2A of Part 3 of the FSANZ Act, by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

In the draft food regulatory measure, Standard 1.4.2 has been revised to establish a clear requirement that maximum residue limits should not be exceeded. The current Code does not establish such a requirement. In addition, the Division is renamed to make it clear that it provides for the regulation of residues of agricultural and veterinary chemicals.

The current Standard provides, circularly, in clause 2(1) that the permitted MRL is the amount specified for a chemical in Schedule 1. The provision is circular as ‘MRL’ is defined as being the maximum level of a residue of a chemical that is permitted. ‘Chemical’ is defined to mean an agricultural or veterinary chemical. The term agricultural and veterinary chemical is undefined. The common meaning of the term might lead to a conclusion that it means the same as agricultural chemical product or veterinary chemical product in the Agvet Code. The actual intention is that it should have the same meaning as the term active constituent has in the Agvet Code.

The provisions of the Code relating to residues of agricultural and veterinary chemicals operate in the context of application Act provisions that prohibit the presence in a food of a chemical agent that is foreign to the nature of the food unless the Code permits that chemical when the food is sold. The presence of these chemicals in a food before sale does not render a food unsuitable. The offence relates to a food that contains a residue that ‘contravenes the Code’. It is not clear what ‘contravenes the Code’ means. Presumably, it is intended that the Code would establish a limit that should not be exceeded in food for sale. Accordingly, it is necessary that the Code be expressed in terms that can be ‘contravened’.

The current Code provides permissions for residues of agricultural and veterinary chemicals in designated foods.

While it is stated that the maximum residue limits are the maximum level that is permitted, there is no clear statement prohibiting a higher presence. It must be inferred that a higher presence 'contravenes the Code'. There is such a statement in relation to unlisted chemicals or when an MRL has not been established for a chemical in a particular food—'there must be no detectable residue'. However, in relation to unlisted chemicals it would be necessary to prove that the substance was an 'agricultural or veterinary chemical'.

The provision has been revised to ensure that maximum and extraneous residue limits are established as requirements that can be addressed by the application Act offences in the manner intended. In addition, the revised provisions strengthen the link to the Agvet Code, which provides the basis for determining the greater part of the MRL schedule by establishing MRLs for the domestic use of a agricultural or veterinary chemicals.

The provisions make it clear that it is active constituents and their metabolites that are prohibited in food. This approach is consistent with the Agvet Code and the related control of use legislation of the states and territories, which permit the use of chemical products and rely on the analysis of permitted residues as an indication of appropriate or inappropriate use. We have considered whether the prohibition should be applied to agricultural or veterinary chemical products, as they are defined in the Agvet Code, or to active constituents. On balance, we have adopted what we understand to be the intent of the current standard, that is, that the chemical referred to in the current standard is the active constituent of an agricultural or veterinary chemical product. We understand that there is a counter-argument that a lesser precision would avoid the need to prove that a chemical is an active constituent in relation to an agricultural or veterinary chemical product that is not listed in Schedule 20. We consider that the same issues arise for that class of chemical regardless of the terminology used in the general prohibition. There is no permission for a chemical that is not listed in Schedule 20 to be present in food for sale. If that chemical is foreign to the nature of the food it is a state or territory offence to sell the food. If an enforcement agency sought to rely on contravention of the Code it would be necessary in either case to prove that the chemical is an agricultural or veterinary chemical. Proving that the chemical is an active constituent would be a component of that proof as a chemical cannot be an agricultural or veterinary chemical if there is no active constituent. An active constituent is essential to achieve the purpose of an agricultural or veterinary chemical. Residues are defined in the Agvet Code by reference to active constituents rather than chemicals.

3.2.20 Issues concerning prohibited and restricted plants and fungi

Standard 1.4.4 currently provides that a prohibited plant, or a derivative, must not be intentionally added to food or offered for sale as food. The general prohibition on the addition of prohibited or restricted plants in food for sale is now in section 1.1.1-10. New section 1.1.1-3 provides permission for the use of restricted plants and fungi and section 1.4.1-4 sets out the current conditions for the use of coca bush.

3.2.21 Issues concerning labelling

As part of the National Seamless Economic Reform Agenda, the Council of Australian Governments engaged Dr Neal Blewett AC and a panel of experts to examine food labelling law and policy.

In January 2011, the Panel released its Report (*Labelling Logic*)[33] including 61 recommendations to improve food labelling law and policy, the panel's intent being to address the current ad hoc approach to food labelling, acknowledge the concerns of the Australian and New Zealand communities, and provide a clear path forward.

Australian and New Zealand Governments provided a response to the recommendations of *Labelling Logic*[34] in December 2011. FSANZ has been asked to take responsibility for action in response to a number of the recommendations arising from *Labelling Logic*.

This work will potentially affect a number of labelling areas including the nutrition information panel (NIP)and a review of irradiation labelling requirements. The approach taken to revision of the labelling provision of the current Code in this Proposal has had regard to the work that FSANZ is to undertake in response to Labelling Logic. In the draft food regulatory measure we have avoided drafting that changes the labelling requirements. That is a matter that will be considered by FSANZ in another proposal, which is unlikely to be finalised within the timeframe of this Proposal.

In the draft food regulatory measure the most significant change in the expression of labelling requirements is to express those requirements in active terms and to simplify, to the extent possible given the complex matrix of requirements that is in the Code, the presentation of the labelling requirements that are to be satisfied.

The labelling requirements are expressed in the draft food regulatory measure in two distinct ways. The first, in Division 1 of Part 4 of Chapter 1, sets out all of the basic requirements for labels on food products or for the provision of information with a food product. Secondly, detail about how the basic labelling requirement is to be satisfied is set out in the following provisions of the Code. The fact that a labelling requirement exists is signposted by the introductory words, 'For the labelling provisions …'

The revision places all basic labelling requirements in the one place, in contrast with the current Code in which basic labelling provisions are found throughout the Code and exceptions to those provisions sometimes in a separate part of the Code.

3.2.22 Issues concerning labelling of genetically modified food

Standard 1.5.2 provides requirements relating to the sale and use of foods produced using gene technology and for labelling of such foods. The requirements are unchanged by the draft food regulatory measure.

The definitions of novel DNA and novel protein have been varied to provide greater clarity where they apply to substances added for technological purposes (food additives and processing aids). Currently in Standard 1.5.2, the definition for 'novel DNA and/or novel protein' refers to:

> *DNA or protein which, as a result of gene technology, is different in chemical sequence or structure from DNA or protein present in a counterpart food which has not been produced using gene technology*.

The term 'counterpart food' is not appropriate where a novel protein is used as a food additive or processing aid.

[33] http://www.foodlabellingreview.gov.au/internet/foodlabelling/publishing.nsf/Content/labelling-logic
[34] http://www.foodlabellingreview.gov.au/internet/foodlabelling/publishing.nsf/content/home

The revised definition more precisely reflects the original intent of the Standard which was to capture novel proteins used as food additives or processing aids, produced using gene technology, in which the protein sequence is not identical to that found in nature.

The proposed changes do not alter the policy or intent of the GM labelling provisions. The re-drafted GM provisions continue to require GM foods and ingredients to be labelled as 'genetically modified' where novel DNA or novel protein remain present in the final food product. The requirement to label food additives (whether GM or non-GM) in the ingredient list on packaged food will also continue to be required in the Code.

The concept of 'altered characteristics' has not been used in the revised drafting as that concept is not essential to achieving the same regulatory outcome. FSANZ will continue to determine during our assessment process whether a new GM food has altered characteristics which requires the food to be labelled as 'genetically modified' regardless of the presence of novel DNA or novel protein, and whether additional labelling about the nature of any altered characteristics should be applied. The outcome of this assessment will be described in our assessment reports. Where FSANZ determines that labelling for altered characteristics is warranted, the labelling requirements will be clearly specified in Schedule 26 of the revised drafting—through the statement of conditions in subsections S26—3 (2) or (3). It is therefore not necessary to include the factors that FSANZ considers in the assessment process for altered characteristics in the Standard as they do not impose obligations for food businesses to comply with the Code.

In the first Call for Submissions, it was proposed to vary the wording of a provision that provided an exception from the basic definition of 'genetically modified' food for highly refined food where the effect of the refining process is to remove novel DNA or novel protein. It was proposed that this exception would be revised to provide greater clarity to food that has been highly refined so that the novel DNA or novel protein has been removed. There was substantial industry opposition to the proposed revision because it was perceived as imposing a higher standard in relation to the removal of novel DNA or novel protein from highly refined food, compared with the existing provision (e.g. complete removal compared to having 'the effect of removing'). While FSANZ does not agree with this interpretation, we have decided to retain the existing words of the Code in the draft food regulatory measure. However, industry should refer to the *Compliance Guide to Australia New Zealand Food Standards Code Standard 1.5.2: Food Produced Using Gene Technology*[35] for guidance on the matter of highly refined food.

3.2.23 Recommended Dietary Intakes

In the current Code, clause 2 provides definitions for Recommended Dietary Intake (RDI) and Estimated Safe and Adequate Daily Dietary Intake (ESADDI). The definitions each refer incorrectly to Column 2 of the Schedule to the Standard as the location of information about the form in which a vitamin or mineral should be expressed. It is inferred, although not stated, that the same form should be considered when determining a percentage daily intake figure for labelling purposes. The information required to calculate percentage RDIs and ESADDIs is to be inferred from footnotes to the Schedule.

In the first call for submissions it was proposed to remove most of the references to isomers in Column 3, because the permitted isomers have equivalent bioavailability. The references to the use of retinol equivalents and alpha-tocopherol equivalents were to be retained. Submitters were concerned that this reduced the regulatory certainty of the provision.

[35] Available from enforcement agency websites, for example, New South Wales Food Authority at: http://www.foodauthority.nsw.gov.au/_Documents/industry_pdf/Complaince_Guide_Standard_1_5_2.pdf

Our review of the provisions has revealed considerable uncertainty about its intended operation. Accordingly, the draft food regulatory measure proposes a method of calculating and expressing bioavailability that has greater detail. We consider that the method of calculation and expression proposed is aligned with the method intended to be used and the method most likely to be being used by industry. Industry that is not applying this method will have 12 months after commencement to realign calculation and expression of the relevant vitamins.

3.2.24 Substantive changes of the Code

The following substantive changes to the Code are to be effected by the draft food regulatory measure:

- Recognition of phylloquinone as a permitted form of vitamin K for meal replacements
  - This corrects an omission in the current Code

- Statement of the intake amount for biotin and pantothenic acid in Standard 2.9.4 is corrected to achieve consistency with the ESADDI specified in Standard 1.1.1.
  - This corrects an error in the current Code.

- Reinstatement of the permission to use adjusted cow's milk in the production of evaporated milk
  - This corrects the inadvertent removal of the permission in Amendment No. 124.

- Reference to 'reducing sugars' rather than 'reducing sugar' in the list of food additive permissions
  - This avoid confusion of defined terms.

3.2.25 Comparison of current Code and draft food regulatory measure

SDs 4 and **5** provide a provision-to-provision guide from the current code to the draft food regulatory measure (4) and to the draft food regulatory measure that was in the first consultation draft (5).

3.2.26 Transition and Commencement

The draft food regulatory measure that is circulated with this paper contains all amendments to Amendment 148 and is up to date to 31 May 2014. Chapter 5 provides details of amendments with delayed commencement dates, as at 31 May 2014.

Any variation of the Code made after 1 June 2014 will necessitate amendment of the current Code and the revised Code. Drafting for both amendments will be included in the approval reports for A1039 (review report), P1014 and P1017, P274, A1088, A1091, A1094, P1029, P1030, M1010, P1022 and P1027. Arrangements for drafting of necessary transitional provisions that are a consequence of applications and proposals that are in the FSANZ Work Plan and due to be determined in 2015 can be advised after a decision is made on this proposal.

It is proposed that the food regulatory measure will commence on the first day of the sixth month after the month in which the food regulatory measure is notified in the Commonwealth *Gazette* under section 92 of the FSANZ Act.

3.3. Risk communication

FSANZ has developed and applied a basic communication strategy for this Proposal. The strategy involves notifying subscribers and any interested parties about the availability of reports for public comment and placing these reports on the FSANZ website. Media releases will be developed for all consultation and these will be promoted on the FSANZ website; through social media and in Food Standards News.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the Proposal and the effects of regulatory options. Draft variations are considered for approval by the FSANZ Board after taking into account comments received from calls for submissions.

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

3.3.1 Consultation

This is the second of two rounds of consultation on this Proposal. The consultation period for the first round was 16 weeks. The consultation period for this round will be 8 weeks.

In addition to public consultation there has been targetted consultation with enforcement agencies, and peak industry groups.

3.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged 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.

We consider that none of the provisions of the proposed revised Code create new requirements that might be inconsistent with international standards or are likely to have a significant effect on international trade.

However, in the interests of openness and transparency, notifications to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade and Sanitary and Phytosanitary Measures Agreement have been made to enable other WTO member countries to comment on the proposed amendments.

4. Draft Food Regulatory Measure

The draft food regulatory measure is at **Attachment A**. The draft includes variations of the Code to Amendment 148 notified on 15 May 2014.

5. Implementation

The variation is intended to have effect from a date 6 months after gazettal.

Attachments

A Draft variation to the *Australia New Zealand Food Standards Code*
B. Draft combined Explanatory Statement.

Note: Some submitters have requested that FSANZ provide a marked up version of the current Code, so as to make the extent of variations easier to identify. This has not been possible as the draft food regulation measure was not prepared as a variation of existing text, but as a new document. The task of preparing a marked up record of all variations would require a disproportionate allocation of resources.
A mark-up indicating changes made after the consultation in 2013 is available on the FSANZ website.