23 May 2013
[08-13]

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) 15 August 2013

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

The following Attachments are available on the FSANZ website at http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx:

A1. Draft variation to the *Australia New Zealand Food Standards Code* (Volume 1, Chapters 1 to 5)
A2. Draft variation to the *Australia New Zealand Food Standards Code* (Volume 2, Schedules S1 to S30)
B. Draft Explanatory Statement
C. Legislative audit report provided by the Office of Legislative Drafting and Publishing
D. Table of matters identified in the review and responses
E. Table of provisions–current Code to draft food regulatory measure
F. Table of provisions-draft food regulatory measure to current Code
G. Diagram of relationship of current Code provisions and draft food regulatory measure provisions

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 then.

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 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.

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. It does this by:

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

The task of modernisation has been approached with the intention that this Proposal should not change the effect of provisions that impose requirements or obligations. Accordingly, although the Proposal is lengthy, because it involves every Standard in Chapters 1 and 2, it is not complex.

The major effect of the proposed changes to the Code is to clarify the primary role of the food laws of the states, territories and New Zealand in enforcement (the application Acts) and the relationship between the Code and the application Acts.

Less significant changes modify or add definitions and alter the structure of the Code to facilitate navigation or to address problems of expression. In particular, compositional requirements that combined definitional and requirement elements have been revised to separate the elements.

It has not been possible to address all the matters raised by the Court's decision. 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 within the timeframe established for this Proposal.

There will be two rounds of public consultation for this Proposal. Unusually, because it involves the text of the Code, drafting will be provided in each round. Comment is sought primarily on the effectiveness of the draft as a regulatory instrument. Although submissions offering alternative drafts of the Code can be helpful, it will be more valuable if submissions address issues of broad principle rather than offering a draft that lacks a policy context.

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 in the Code were last reviewed more than a decade ago when a joint Australia-New Zealand review was conducted to facilitate the development of joint 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 of the issues 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.

FSANZ is undertaking other activities that are likely to lead to variations of the Code during the time this Proposal will be completed. As with matters identified in the review, the approach to these matters has been to repeat existing provisions in the Code with only minor editorial change to address drafting issues. If decisions are made to amend the requirements of the Code, new drafting will be prepared in separate proposals. Care will be taken to ensure that any new drafting is consistent with the legal principles that have guided this Proposal. The issues to be considered include:

- sports foods
- very low energy diets
- nutrient reference values
- cyanogenic glycosides
- the use of certain processing aids or food additives, such as carbon monoxide packaging
- enzymes
- health claims
- infant formula products
- labelling—as part of the Response to the Recommendations of *Labelling Logic: Review of Food Labelling Law and Policy (2011)*
- microbiological limits for food—Standard 1.6.1

[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.

- minimum age labelling of infant foods—Standard 2.9.2.
- novel foods
- nutritive substances.

Finally, FSANZ has identified a small group of issues that, for technical legal reasons, could not be dealt with earlier under the minor procedure. These matters are identified in **Attachment D** and are dealt with in this Proposal.

Some matters identified in the review have already been addressed in a variation of the Code—in P1013 Code Maintenance Proposal IX. These are identified in **Attachment C**.

2.2 The current Standard

The current *Australia New Zealand Food Standards Code* is published at www.comlaw.gov.au. Individual standards can be easily 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.

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.

Consultation with jurisdictions identified a further range of issues.

The full range of issues identified in the audit report and subsequent consultation and an indication of the proposed response is in **Attachment C**.

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 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 advised that, based on the information provided by FSANZ, a Regulation Impact Statement is not required as the Proposal appears to have 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.

The OBPR's reference is 14493.

3.2.1 Application of rules of statutory interpretation

The Code is a Commonwealth legislative instrument that is implemented through New Zealand, state and territory food laws (the application Acts). The Code has no operative effect by itself.

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 Australia New Zealand Food Standards Code is the source of national standards.

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

The COAG Food Regulation Agreement provides for standards to be adopted or incorporated into the laws of the Australian states and territories. However, the 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. The application Acts are interpreted according to the provisions of local interpretation laws. State and territory interpretation laws do not apply to the Code consistently, creating a potential for inconsistent enforcement.

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.
Three options have been considered. They are:

(a) to amend the Code to provide 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 is preferred as this is the simplest mechanism to achieve consistency of interpretation. The Code will have a single source of interpretation law where it is adopted. If the Code is incorporated the relevant state or territory law will apply to the incorporated provisions. It has been suggested that this creates a tension between the interpretation of the Code under one law and the interpretation of the application Acts under other law. The tension is acknowledged but is not irreconcilable.

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

[4] Under Part 2A of the Food Act 1981.

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

A further option, to apply local interpretation laws to the Code in each of the states and territories has not been considered as that option would not lead to consistent interpretation of the Code.

This matter is addressed in clause 1.04 of the draft food regulatory measure.

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

The model food provisions define some terms that are also used in the Code. New Zealand and state and territory legislation does not consistently adopt the model food provisions. Three options have been considered. They are:

(a) Option 1 is to provide in the Code that the words have the meaning given in the application Acts.
(b) Option 2 is to provide in the application Acts that words in the Code have the same meaning as in the FSANZ Act.
(c) Option 3 is 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[5].

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

3.2.3 Integration of obligation and offence provisions

The regulation of food in Australia and New Zealand is achieved, primarily, through the food legislation of each state or territory and New Zealand[6].

The application Acts establish a regulatory regime for the supply of food that is safe and suitable. The application Acts interact with therapeutic goods legislation to provide a system that recognises that some goods can have both a nutritional and a therapeutic purpose. Goods that have a therapeutic purpose will be regulated by therapeutic goods legislation unless there has been an overt decision to regulate the goods under food laws, by the making of a food standard in relation to that good; or the good is a traditional food.

Within the food regulatory system the Code performs a supportive function. It is not the primary legislation for food regulation. The function of the Code is to provide greater detail about safety and suitability, in order to achieve a high degree of confidence in the quality and safety of food produced, processed, sold or exported from Australia or New Zealand[7].

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

[5] 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.
[6] The Code is given effect in relation to food imported into Australia by the Commonwealth *Imported Food Control Act 1992*.
[7] See paragraph 3(a) FSANZ Act.

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. With the exception of the last criterion these questions do not generally require a consideration of the Code.

Other offence provisions apply if food does not comply with the Code or a person fails to comply with a requirement imposed by the Code. 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.

Provisions of the Code that impose obligations or set out requirements that must be complied with are to be amended to ensure that it is clear who is required to comply with the obligation or requirement 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. The provisions of Parts 3 and 4 create obligations that are to be complied with by identified persons, whether legal persons or natural persons, and 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.

A note on enforcement of the Code has been included at the beginning of Part 2 of the draft food regulatory measure. The note is explanatory and is not a legally binding part of the Code.

The Code does not include provisions that have the function of directing the manner in which offences should be prosecuted. That is a function of the application Acts. Accordingly, for example, the Code does not impose requirements about who can institute proceedings or take other action under an application Act.

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[8]. 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 case a decision has been made that the definitions would be more appropriately reconsidered in a different proposal.

The current Code contains multiple definitions for some terms. Where possible, a single definition has been adopted.

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.

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

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 remove substantive requirements and to restate the compositional requirements independently of the definition.

The definitions have been revised 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.

Compositional provisions provide that if a good is represented as being for sale as a food or a type of food for which there is a standard, ie a food for which there is a definition, the food must comply with the compositional requirements.

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 processing aids, for example. While the permissions are often stated in the current Code close to the prohibition, 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.

The major change in this regard is the proposed statement in new section 1.21 of the restriction on the addition of substances to foods for some purposes and the restriction on the presence of some substances in food products together with an express statement of the permissions and signposts to the provisions that provide further detail about those permissions. This provision makes it clear that adding substances to food is regulated by the Code only in a limited range of circumstances. As a general proposition, substances can be added to food provided the food remains safe and suitable, subject to the restriction (in the application Acts) on the addition of biological or chemical agents that are foreign to the nature of the food.

The Code operates to regulate the addition of substances for some purposes and to regulate the presence in food of some substances where the presence is not the result of intentional addition to achieve a purpose. The Code also regulates the supply or use of some foods.

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

(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.[9]

[9] *Addition to food of substances other than vitamins and minerals, Specific Order Policy Principles–any other purpose*, Food Regulation Ministerial Council, 2008

More detailed policy principles apply to the addition of substances to achieve a technological purpose[10], the addition of vitamins and minerals[11] and caffeine[12].

The detailed policy principles are implemented in the current Code through standards that regulate the addition or use of food additives[13], vitamins and minerals[14], processing aids[15], and certain plants and fungi[16] 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 only on a case-by-case basis through the general prohibitions on the addition of nutritive substances[17] and the sale or use of novel foods or ingredients[18].

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. 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 has been prohibited, although it can be inferred that it is only the listed substances that are permitted. An editorial note suggests that the substances that are 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'. This is, potentially, a broader category of substances than are in the lists in the schedules. The editorial note, however, has no legal effect.

The proposed revision of the additive standard operates by prohibiting, in a general prohibition, the addition of any substance that has been refined, 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. Listed substances may be added for those purposes, subject to conditions of use, such as good manufacturing practice.

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 and a food additive technological purpose is not performed by the substance in the final food. The current provision does not purport to regulate any use as a processing aid of substances that are not permitted in Standard 1.3.3 as processing aids. 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 the substance. In other words, rather than regulating substances the proposed provisions regulates use.

A further general prohibition in the current Code is the prohibition on the addition of nutritive substances. 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. The regulation of novel foods and nutritive substances will be considered further in a Proposal that has been prepared and will run concurrently with this Proposal.

[10] i.e. food additives and processing aids.
[11] *Policy Guideline on the fortification of food with vitamins and minerals,* Food Regulation Ministerial Council, 2009.
[12] *Policy Guideline on the addition of caffeine to food*, Food Regulation Ministerial Council, 2003
[13] Standard 1.3.1
[14] Standard 1.3.2
[15] Standard 1.3.3
[16] Standard 1.4.4
[17] clause 9 of Standard 1.1.1
[18] clause 2 of Standard 1.5.1

In the draft food regulatory measure, the approach that has been taken is, consistent with the current provision, to prohibit the addition to food, to achieve a nutritional purpose, of extracted, refined or synthesised substances that are not ordinarily understood to be food products or food ingredients that are used by consumers. Where the addition of such substances is permitted, there is a specific permission.

The Code also regulates the retail sale or the use as ingredients 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 added or used as an ingredient unless specifically permitted. This element of the regulatory scheme is under review in the Proposal mentioned above.

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[19]. The issue is resolved in New Zealand, for New Zealand standards, through a provision in the New Zealand Food Act.

3.2.8 Structure of the Code

The draft food regulatory measure has been prepared on the assumption that the Code should now be presented as a single legislative instrument. That is consistent with the general approach to the presentation of legislative instruments in the Federal Register of Legislative Instruments (FRLI)[20].

The current practice, of publishing each standard as a separate legislative instrument, was implemented when FRLI was established in response to capacity limitations in FRLI that have, substantially, been resolved. Development of a single document provides an opportunity to rationalise the presentation of some complex schedules and tables and to avoid unnecessary repetition. In addition, the provisions of the Code are presented in the draft food regulatory measure with sequential numbering.

The establishment of a single instrument will simplify the administration of the Code and assist in ensuring consistency when the Code is amended. As necessary, new provisions of the Code will be numbered in sequence in accordance with standard Australian drafting practice.

A diagram indicating the translation of the current structure to the proposed Code is at **Attachment G**.

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

[20] 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.

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 the fact that some purpose statements include operative statements that should properly be substantive provisions of the Code. 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

The number of editorial notes and their purpose is to be reduced in the draft food regulatory measure. Editorial notes are not legally binding for the Code and should not contain substantive provisions.

3.2.10 Microbiological limits for food—Standard 1.6.1

In Proposal P1017, which is examining criteria for listeria, a review of microbiological limits has been commenced. The outcome of that Proposal, and other work relevant to Standard 1.6.1, will be incorporated in the variation of the Code that is developed in this Proposal.

In the draft food regulatory measure Standard 1.6.1 is restated in its current form, with minor editorial changes only.

3.2.11 Nutritive substances

There is currently a definition of nutritive substance in standard 1.1.1. In the *Nutricia* case that definition was found to be uncertain. FSANZ is reviewing its approach to the treatment of nutritive substances and has commenced a Proposal, P1024, to review the regulatory approach to nutritive substances and novel foods.

Specific permissions for the addition of nutritive substances, as nutritive substances, are those currently in Part 2.9. The addition of vitamins and minerals is dealt with by specific provisions in Standard 1.3.2 and various other provisions of the Code, including in part 2.9. Another provision of the Code, in Standard 2.6.4, permits the addition of named substances that are classed as nutritive substances when they are referred to, in a different permission, in Part 2.9. However, this permission in Standard 2.6.4 does not rely on the definition of nutritive substance. Clause 9 of Standard 1.1.1 prohibits the addition of a nutritive substance to a food, unless the addition is permitted by another provision of the Code.

In the draft food regulatory measure, substances that are listed in section 1.21 and are not specifically permitted as ingredients are excluded from constituting foods or being used as ingredients in foods. Substances that are used as nutritive substances i.e. substances that are not normally consumed as a food product or used as an ingredient by consumers and have been refined, extracted or synthesised and added to a food product to achieve a nutritional purpose are in the group of substances that may not be a food or added to a food as an ingredient unless expressly permitted. The only permissions for addition of substances that would satisfy that definition are in Parts 6 and 9 of Chapter 2 and the provisions concerning the addition of vitamins and minerals to foods.

The revised definition in the draft food regulatory measure addresses two concerns identified in the *Nutricia* decision. The first relates to the use of the phrase 'not normally consumed as a food'. In the draft food regulatory measure the application of the prohibition is limited by excluding the operation of the provision in relation to a nutritive substance that is naturally occurring in the food.

Secondly, the requirement to demonstrate that the addition of the substance was intentional has been removed.

3.2.12 Novel foods

Novel foods and novel food ingredients are foods that do not have a history of consumption in Australia or New Zealand and require an assessment of public health and safety considerations. The Code currently provides that novel foods cannot be sold at the retail level or used as an ingredient unless approved. The provisions of the Code in relation to novel foods sit within a food regulatory system in which the application Acts provide serious offences for handling food that is intended for sale in a manner that is known to, or is likely to render the food unsafe or to sell food knowing the food to be unsafe.

This provision demands consideration, by suppliers, of the history of consumption of a food in Australia and New Zealand and, if there is no local history of consumption, the need for a safety assessment. The provision has the public policy purpose of providing a mechanism by which the public health and safety risks associated with introducing new foods to the local food supply can be managed.

Although consideration of whether a food is a novel food can be undertaken by a manufacturer or supplier, an administrative procedure has been developed to assist industry. The Advisory Committee on Novel Foods was established by the FSANZ Board in 2007 to provide advice to FSANZ, and indirectly to other regulators and suppliers, about the characterisation of a food as novel or otherwise. The advice is not a binding determination and has no legislative basis, although the administrative Scheme has operated effectively to facilitate the operation of the Standard. The advice is also notified to food enforcement agencies, which participate in the work of the committee, to assist in achieving consistent enforcement across all jurisdictions.

The administrative procedure operates as a filtering mechanism that provides a level of comfort to a seller that a food product might be sold without infringing the prohibition on sale of novel foods. Alternatively, a supplier can make its own determination and either apply directly for approval of a food as a novel food or market a food product on the basis that it does not require approval, with the attendant risk.

The administrative procedure lacks the transparency or finality that is a characteristic of other FSANZ decision-making. Decisions are, arguably, non-reviewable. More important, the decisions of the committee have no legal basis and, accordingly, the level of comfort that they can provide to suppliers is minimal. The existence of the procedure is an acknowledgement of the fact that the definitions of non-traditional foods and novel food rely on uncertain concepts and, accordingly, the Standard fails to deliver the level of certainty and objectivity required for effective operation of the food regulatory system.

The draft food regulatory measure continues the current arrangement pending the outcome of Proposal P1024.

3.2.13 Packaging standards

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

At present, the matter is dealt with through a combination of the 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.

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 the import of infant formula products to Australia 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 is planning to prepare a Proposal to review and potentially revise Standard 2.9.1 and other standards that regulate infant formula products. These and other issues will be considered in that Proposal.

3.2.15 Issues concerning infant foods

FSANZ is yet to finalise the labelling of the age of introduction of infant food (Proposal P274). This work is expected to resume now that infant feeding guidelines have been published by the National Health and Medical Research Council.

3.2.16 Issues concerning formulated meal replacements and supplementary foods

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 the permitted forms of vitamin K.

3.2.17 Issues concerning formulated sports foods

Standard 2.9.4 is to be reviewed.

3.2.18 Issues concerning nutrient reference values

The nutrient reference values in the Code are used in nutrition labelling but they are not consistently aligned with the most recent nutrient intake reference values of the Australian and New Zealand governments. Consultation on a possible review was undertaken in 2010 however the timing of further work is yet to be determined.

3.2.19 Issues concerning maximum residue limits

Standard 1.4.2, which is referred to as the Maximum Residue Limits 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 is restated substantially in its current form. The Division is renamed to make it clear that it provides for the regulation of residues of agricultural and veterinary chemicals.

3.2.20 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*)[21] 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*[22] 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), country of origin labelling 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, the 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.

3.2.21 Basic concepts—definitions of 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 application Acts. Instead, the court applied what was described as 'a common understanding' about what constitutes food.

The current design of the Code is based on the concept that all food can be sold provided the food is not specifically prohibited. The Code excludes, and then provides specific permissions for, some types of food or substances that can be added to foods. This establishes a complex matrix of permissions that is difficult to enforce.

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

The draft food regulatory measure goes some way towards resolving the enforcement problem inherent in the current design of the Code by applying a single prohibition, in proposed section 1.22, rather than the range of prohibitions that are in the current Code.

'Food' is defined in the FSANZ Act, the model food provisions and in the legislation of New Zealand and the states and territories. It is a very broad definition, which includes substances that are additives. There is a need to consider how to provide a definition for use in the Code that facilitates regulation and does not lead to the type of uncertainty that was identified in the *Nutricia* judgment, where the court declined to apply the definitions in either the Commonwealth or state legislation and applied the court's own understanding of the term. The options considered are:

- Option 1: to adopt the definition of food that is in section 5 of the FSANZ Act. That definition is in slightly different form to the provisions in state and territory legislation, which provide the basis for enforcement. The definition in the FSANZ Act has no direct relevance for enforcement action, which is conducted under the application Acts.

- Option 2: to provide, in the Code, that the definition in an application Act should apply. This approach operates to apply the relevant local law to any enforcement action and avoids the possibility of doubt in enforcement action about which definition should apply. This is the option that is preferred by FSANZ. Accordingly, food regulation starts from the broad base of the definitions of food in the application acts and the Code operates in a defined space within the penumbra of the application Acts.

- Option 3: to leave the Code silent on the definition of food, subject to a note that directs readers to the relevant state or territory laws. This option is aimed at ensuring that state and territory laws will be applied in enforcement action and will be considered by those who are required to comply with standards and food laws. There is, however, a possibility that consistency cannot be achieved because there are minor differences in the relevant laws or that courts will not have regard to the editorial note. However, the differences are very minor and it is not considered that the risk of inconsistency is high or likely to have a significant impact on enforcement or compliance behaviour. There is also a possibility that another court might not adopt the reasoning of the court in *Nutricia*.

There are some other concepts that are critical for an understanding of the operation of the proposed Code. These are the concepts of *food product*, *ingredient* and *food component*. The draft food regulatory measure provides definitions for each concept.

The concept of food product is especially relevant to labelling standards, which operate at the point of sale and will often require labelling that is related to the food as it is intended to be sold. It is also relevant in other parts of the Code where the food that is being regulated is intended to be in a form for sale or consumption. Although the term is used there is no definition of *food product* in the current Code. The Code refers to *final food,* again without definition, when food product might be a more appropriate term. The use of the term *food product* makes it clear, for labelling purposes, that enforcement action is relevant at the stage of production when a food is intended for sale, whether at retail, for catering purposes or for other purposes.

The concept of ingredient is essential for an understanding of many standards, including those that concern the labelling of ingredients. *Ingredient* is defined in the current Code in standard 1.2.4, in a definition that is expressed to apply only to that standard. In all other places the term is given its dictionary meaning. In that definition an ingredient is described as any substance used in the preparation, manufacture or handling of a food. In the draft food regulatory measure the term is defined consistently, in a revised form, for all purposes in the Code.

Component is defined in the Code as a substance that is used in the preparation of an ingredient that is present in the final food in a primary or modified form. In the revision, component is redefined as a substance that is a constituent part of a food.

3.2.22 Comparison of current Code and draft food regulatory measure

Attachments E and **F** provide a provision to provision guide to the current and proposed Codes. **Attachment E** works from the current Code and **Attachment F** back from the proposed Code.

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 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 Legislative and Governance Forum on Food Regulation. 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 first of two rounds of consultation on this Proposal. The consultation period for the first round will be 12 weeks and for the second round 8 weeks. In addition to public consultation it is likely there will be targeted consultation with enforcement agencies, and peak industry groups.

3.3.2 World Trade Organization (WTO)

Australia and New Zealand are members of the World Trade Organization (WTO) and are obliged to notify WTO member nations when proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

Amending the Code in the manner proposed in the draft food regulatory measure is unlikely to have a significant effect on international trade as the proposed amendments do not make any significant change to the Code. Therefore, a notification to the WTO to give effect to Australia's or New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreement has not been considered necessary.

4. Draft Food Regulatory Measure

The draft food regulatory measure is at **Attachment A**.

4.1.2 Implementation

The variation is intended to have effect from 1 July 2014.

Attachments

A1. Draft variation to the *Australia New Zealand Food Standards Code* (Volume 1, Chapters 1 to 5)
A2. Draft variation to the *Australia New Zealand Food Standards Code* (Volume 2, Schedules S1 to S30)
B. Draft Explanatory Statement
C. Legislative audit report provided by the Office of Legislative Drafting and Publishing
D. Table of matters identified in the review and responses
E. Table of provisions–current Code to draft food regulatory measure
F. Table of provisions-draft food regulatory measure to current Code
G. Diagram of relationship of current Code provisions and draft food regulatory measure provisions