Food Standards Australia New Zealand Amendment Bill 2007

Susan Dudley
Law and Bills Digest Section

Contents

Purpose ........................................................................................................................................1

Background ..................................................................................................................................1

Main provisions ..........................................................................................................................1

Amendments contained within Schedule 1 – new application and proposal procedures.......1

Applications ...................................................................................................................................2

General procedures ....................................................................................................................2

Modification of general procedure for minor variation ............................................................2

Modification of general procedure for developing new food regulatory measures
and major variations .................................................................................................................3

Proposals ....................................................................................................................................3

General procedure for proposals ...............................................................................................3

Modification of general procedure for minor variations ..........................................................4
Modification of general procedure for developing new food regulatory measures

and major variations ..................................................................................................................4

Variations of the Maximum Residue Limits Standard .................................................................4

Drafting error relating to processing proposals .........................................................................4

Ministerial Council ..................................................................................................................5

Urgent applications and proposals ............................................................................................5

Schedule 3 – Council review of approved draft standards ..........................................................5

Schedule 2 - High level health claims .........................................................................................6

Schedule 1 amendment - Editorial Notes ...................................................................................10

Concluding comments ..............................................................................................................11

Endnotes ....................................................................................................................................12
Food Standards Australia New Zealand Amendment Bill 2007

Date introduced: 28 March 2007
House: Senate
Portfolio: Health and Ageing
Commencement: A range of dates.

Purpose
This Bill changes the arrangements for the development of food standards developed by Food Standards Australia New Zealand. It also puts in place a regime for the variation of the Nutrition, Health and Related Claims Standard. The Bill also makes some other small amendments to the operation of the Food Standards Australia New Zealand Act 1991.

Background
Food Standards Australia New Zealand (FSANZ) is an independent statutory body established by the Food Standards Australia New Zealand Act 1991. FSANZ is responsible for developing food standards and codes of practise covering the content and labelling of food, which are applied in Australia and New Zealand. FSANZ also develops food safety standards that are applied in Australia.

Since its creation in 1991, the nature of FSANZ and its standard setting processes have changed considerably. Further background regarding FSANZ and its standard setting arrangements can be found in Bills Digest No 120. 2000-2001 Australia New Zealand Food Authority Amendment Bill 2007.1

The proposals contained within this Bill have been subject to public comment. The explanatory memorandum to the Bill provides information relating to the consultation processes that the proposed amendments have gone through.2

Main provisions
Amendments contained within Schedule 1 – new application and proposal procedures

The development of food regulatory measures was altered considerably in 2001 following the commencement of the Australia New Zealand Food FSANZ Amendment Act 2001.

Warning:
This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.
This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.
This Bill looks to further change that regulatory development process. The application/proposal method of developing or changing food regulatory measures will remain. The changes are however a move away from the one size fits all assessment process and are designed to increase the efficiency of the current standard setting arrangements. In effect, the Bill suggests three different options for developing and changing food regulatory measures:

- a truncated process for minor variations of a food regulatory measure
- a more extended process for a new food regulatory measure or a major variation to a food regulatory measure, and
- a general procedure for all other changes.

Applications

Where a body or a person other than FSANZ wishes to have a food regulatory measure changed, they must submit an application to FSANZ for the change.³

General procedures

Proposed new sections 26-35 sets out the general procedures to be followed in processing an application. FSANZ must determine whether to accept or reject the application, notify the applicant if the application is accepted (proposed section 27) and also release a public notice of the application (proposed section 28). FSANZ must then assess the application (proposed section 29), which includes performing a cost/benefit analysis (proposed paragraph 29(2)(a)) and either reject it or decide to proceed and prepare a draft of the proposed amendment (proposed section 30). If FSANZ prepares a proposed amendment, it must seek public comment on the draft (proposed section 31). After receiving and considering the public submissions, FSANZ must then decide whether to approve, amend or reject the draft and prepare a report which reflects this decision (proposed section 33). If FSANZ does not reject the draft, it must give the Ministerial Council notification of the approval. Note that changes to codes of practise do not need Ministerial Council approval (proposed section 35).

Modification of general procedure for minor variation

As noted above, the Bill proposes that applications to FSANZ for minor variations of a food regulatory measure should be subject to a shortened assessment process. The Bill proposes that a cost/benefit analysis will not need to be performed for minor variations and FSANZ will not be required to seek public comment on the proposed changes (proposed section 40). FSANZ is however required to provide the applicant and appropriate government agencies with a draft of the standard, and give them an opportunity to provide written submissions. FSANZ is not expressly required to consider submissions received when making a decision whether to approve, vary or reject the draft variation. After the submission period, FSANZ must decide whether to approve, amend or
reject the draft standard and prepare a report which reflects its decision (proposed section 41). If FSANZ does not reject the draft standard, it must give the Ministerial Council notification of the approval (proposed section 41).

Modification of general procedure for developing new food regulatory measures and major variations

An application for the development of a new food regulatory measure or ‘major variations’ to a food regulatory measure will require a more extended assessment process. In relation to a ‘major variation’ the Bill states that it is one which

(i) Involves such scientific or technical complexity that it is necessary to adopt this procedure in considering it; or

(ii) Involves such a significant change to the scope of the food regulatory measure that it is necessary to adopt this procedure in considering it (proposed section 42)

In essence, the extended processes involve an additional round of consultation (proposed section 44) which takes place before the draft variation or new standard is prepared.

Proposals

Where FSANZ wishes to develop or change a food regulatory measure, they must generate a proposal. The Bill proposes to change the processes to be followed where FSANZ generates a proposal.

As with the application process, the proposal processes have been divided into three separate forms depending on whether there is a:

• minor variation of the food regulatory measure
• a proposal for the development of a new food regulatory measure or a major variation of a food regulatory measure, or
• a proposal which doesn’t fall into one of the above categories.

General procedure for proposals

If FSANZ generates a proposal, it must issue a public notice which gives notification of this (proposed section 58). FSANZ is required to assess the proposal (and this includes developing a cost/benefit analysis) and after assessing the proposal it must prepare a draft regulatory measure or abandon the proposal (proposed section 60). FSANZ must then call for public submissions on the proposal (proposed section 61). After receiving and considering the public submissions, FSANZ must then decide whether to approve, amend or reject the draft and prepare a report which reflects this decision (proposed section 63).

Warning:
This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.
This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.
If FSANZ does not reject the draft, it must give the Ministerial Council notification of the approval (proposed section 64).

Modification of general procedure for minor variations

Where FSANZ generates a proposal for minor variations of a food regulatory measure, the proposal is subject to a shortened assessment process. FSANZ is not required to submit the proposal to a round of public comment, although it is required to seek comments from appropriate government agencies (proposed section 68). Unlike the general procedure, there is no express requirement in the legislation for FSANZ to consider the submissions when making a decision regarding the draft standard. After the submission period, FSANZ must decide whether to approve, amend or reject the draft and prepare a report which reflects its decision (proposed subsection 69(1)). If FSANZ does not reject the draft, it must give the Ministerial Council notification of the approval (proposed subsection 69(4)).

Modification of general procedure for developing new food regulatory measures and major variations

A proposal for the development of a new food regulatory measure or ‘major variations’ to a food regulatory measure will require a more extended assessment process. Proposed section 70 sets out the criteria for what is regarded as a major food regulatory measure, namely one which:

(i) involves such scientific or technical complexity that it is necessary to adopt this procedure in considering it; or
(ii) involves such a significant change to the scope of the food regulatory measure that it is necessary to adopt this procedure in considering it.

The extended processes involve an additional round of consultation (proposed section 72) which takes place before the draft variation or new food regulatory measure is prepared.

Variations of the Maximum Residue Limits Standard

Proposed sections 80-83 set out the procedures to be followed for variations to the maximum residue limits standard.

Drafting error relating to processing proposals

There appears to be a minor drafting error in the table set out at proposed section 54. Step 8 states that ‘if the proposal is for a minor variation, FSANZ calls for submissions from the applicant and appropriate government agencies’. This sentence is inconsistent with the legislation which states that FSANZ must only give notice to and call for submissions from appropriate government agencies (proposed paragraph 68(2)(c)). Proposals are
variations to the Code generated within FSANZ and therefore there will be no applicant to seek submissions from in relation to the proposal.

Ministerial Council

The Bill amends the procedures to be followed by the Ministerial Council in relation to approving the standard. **Proposed new section 84** states that the Council can request FSANZ review the draft. FSANZ must then review the draft and decide to re-affirm, re-affirm with amendments or withdraw the draft and notify the Council accordingly. The Council can request FSANZ to review the draft again (**proposed section 85**).

Following the second review, the Council can accept, amend or reject the draft (**proposed section 86**). Once the Council has accepted or modified the draft FSANZ must notify that the food regulatory measures will come into effect on a date specified in the notice through:

- the Australia and New Zealand Gazette and
- generally circulating newspapers in each State and Territory and in New Zealand
- and publishing a copy of the notice on FSANZ’s website.

Urgent applications and proposals

Currently the Food Standards Australia New Zealand Act 1991 contains provisions that deal with progressing urgent applications and proposals. **Proposed sections 95-106** is to an extent a re-write of the current provisions however there are some key changes being:

- In addition to FSANZ being able to amend or vary a standard if there is a public health and safety concern, under **proposed section 95** FSANZ will also be able to vary a standard if the standard has had or will have a negative impact on trade that was not envisaged when the standard was made (**see paragraph 95(2)(b)**).

The Bill also changes the processes to be followed by the Ministerial Council when assessing urgent application and proposals. These changes are needed to ensure consistency with the new processes that are to be followed by the Ministerial Council for all other applications and proposals.

**Schedule 3 – Council review of approved draft standards**

The amendments contained within this schedule will not take effect unless amendments reflecting these changed processes are made to the Australia New Zealand Joint Food Standards Agreement.

In essence, schedule 3 repeals the provisions (as amended by schedule 1 of the Bill) dealing with the operation of the Ministerial Council and inserts new provisions setting out the Ministerial Council’s role in the food standard setting processes.

**Warning:**

*This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.*

*This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.*
The key change made to the Ministerial Council’s role by these provisions is that it removes the second round of review by FSANZ.

Schedule 2 - High level health claims

Food Standards Australia New Zealand is currently finalising a new health claims food standard.

The following draws on documents on FSANZ’s web-site and sets out some background on the current status of the health claims food standard:

In December 2003, the Australia and New Zealand Food Regulation Ministerial Council asked FSANZ to develop a standard and an appropriate management system for the regulation of nutrition, health and related claims. This recognised the increasing complexity of the food supply, especially with the increasing presence of functional foods, and the benefits of regulating nutrition and health claims under a unified and mandatory system.

The Ministerial Council provided FSANZ with policy guidelines to consider in developing the standard. These policy guidelines recommend that manufacturers may make claims if the food is safe, and the claim is socially responsible, does not promote irresponsible consumption patterns, and is scientifically substantiated. They suggest that there must be enough of the specified component in the food to contribute to the claimed benefit. Certain foods are disqualified from health claims, including alcohol and infant formula, and claims must not promote unhealthy food consumption patterns.

We released an initial consultation document in August 2004 seeking views on how these policy guidelines should be translated into food regulations, and options for the way forward. Having considered the comments received, we released a second consultation document in November 2005 describing our preferred regulatory option and containing a draft food standard for inclusion in the Code.

From our second round of consultation we received numerous and detailed comments from 131 submitters. We have now carefully considered these, and in addition have carried out some targeted research to assist our decision making. As a result, we are recommending a number of revisions to our previous recommendations and are now introducing this additional round of consultation.

Currently, FSANZ is proposing the following as the key aspects of the Nutrition, Health and Related Claims Food Standard:

**Claims classification framework**

Nutrition, health and related claims will be classified into three categories:

- Nutrition content claims are statements regarding the amount of a nutrient, energy or a biologically active substance in the food;

Warning:

This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.

This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.
• General level health claims are claims that describe a relationship between the consumption of a food or constituent and particular benefits of the food in relation to health.

• High level health claims also describe a relationship between the consumption of a food or constituent and particular benefits of the food in relation to health, but these claims reference to a serious disease or condition, or a biomarker of a serious disease or condition.

The category of a claim determines how that claim is regulated, including the evidence required for substantiation.

**Nutrition, Health and Related Claims Standard**

The proposed standard will appear as Standard 1.2.7 – Nutrition, Health and Related Claims in the *Australia New Zealand Food Standards Code*. Important provisions include:

• a requirement that all claims be substantiated

• criteria for foods allowed to make claims

• specific qualifying criteria for nutrition content claims (e.g. food described as ‘low salt’ must contain no more than 120mg sodium per 100g for solid food)

• additional labelling for some nutrition content claims (e.g. the level of potassium in the food must be declared if a claim about salt is made)

• specific conditions for some claims (e.g. a weight loss or weight maintenance claim must be made in the context of the importance of regular exercise)

• substantiated and approved claims about diet-disease relationships (e.g. low sodium diet assists in reducing blood pressure)

• recommendations for cause-related marketing and dietary information.

**Substantiation**

All nutrition and health claims on food will have to be scientifically substantiated. FSANZ has developed a Substantiation Framework, which should be used by manufacturers before making a claim on a food product. For nutrition content claims, we require manufacturers to have proof that the nutrient, substance or property that is the subject of the claim is present at levels referred to in the claim.

For general level health claims, manufacturers can make claims based on a list of nutrient function statements considered by FSANZ to have been substantiated, or based on authoritative, generally accepted information sources.

*Warning:*

This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments. This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.
Substantiation of high level health claims will involve a case-by-case assessment by FSANZ. Once a high level health claim is approved and listed in the standard, all manufacturers will be able to use it. We will approve a limited number of high level health claims to go into the standard before the standard becomes law.

Schedule 2 of the Bill amends the Food Standards Australian New Zealand Act 1991 to put in place the necessary legislation framework for variations to the Nutrition, Health and Related Claims Standard which relate to high level health claims. In particular, the Bill requires that FSANZ consult with both the High Level Health Claims Committee and the Food Regulation Standing Committee where there is an application or a proposal to make a high level health claim variation (proposed section 49). The Bill does not contain any requirement that FSANZ seek public comment where an application has been lodged to vary that part of the standard dealing with high level health claims. FSANZ will only be required to seek public comment in the applicant requests that FSANZ does this (see proposed section 51).

Variations to the standard that do not relate to ‘high level’ health claims are to be made following the processes set out in schedule 1.

Health claims are a particularly contentious area of standard development, generating strident comment from both proponents and opponents of the health claims scheme.

Choice have stated the following:

CHOICE does not support the use of health claims on food labels. In our opinion health claims will assist manufacturers to market their products on the basis of nutrient content or a potential health benefit. In particular health claims are most likely to be used on processed foods rather than the fresh foods we should all be eating more of.

Despite our concerns, governments have decided to allow manufacturers to make health claims. Enforceable regulation will be required to ensure they do not mislead consumers.

In countries like the United States, where health claims have been used for a number of years, there is little evidence that health claims have been successful in encouraging healthy eating habits. Instead the incidence of obesity has markedly increased.

In its submission to the recent Senate Community and Public Affairs Committee inquiry into the Bill, Choice made particular criticism of the health claims aspects of the Bill and in particular were critical of the fact that FSANZ will not be required to seek public comment on an application to vary a high level health claim, unless the applicant elects to have public comment. In its submission Choice stated that:

One of the major strengths of the current FSANZ process is its openness and transparency and the consistency of consultation processes for all applications and

Warning:
This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.

This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.
proposals. The proposed changes to the health claims process remove public consultation altogether. In CHOICE’s opinion this threatens the integrity of the FSANZ process and undermines its primary objectives.

CHOICE does not support the proposed changes to the FSANZ assessment and approval processes for health claims. On numerous occasions throughout the consultation process, we have argued that this proposal is not in the best interest of consumers and public health, instead placing industry interests ahead of the three primary objectives of FSANZ. It appears that the views expressed by public health and consumer groups have largely been ignored. Sacrificing openness and transparency and the inhibiting the capacity of public health and consumer organisations to engage in consultation undermines these primary objectives of FSANZ.

CHOICE appreciates that data protection may be of concern to the food industry, because disclosure may prevent any market advantage that may be gained from product innovation. However, the current processes are designed to protect public health and safety and consumer interests, and to do this there must be openness and transparency. CHOICE is also concerned that if information is kept confidential then it will not be subject to peer-review – an important part of the process for establishing the strength of any scientific evidence.

The establishment of an expert panel to advise FSANZ on applications to amend the health claims standard does not go far enough to address CHOICE’s concerns. In order to provide adequate protection of consumer and public health interests, applications to amend the health claims standard must be subject to public consultation to enable all public health and consumer stakeholders to comment on the implications of and strength of evidence supporting the proposed changes. This also places unreasonable onus on State and Territory health departments and food authorities to ensure that public health and consumer issues are adequately addressed. Many departments already struggle to address all the food regulatory issues that they are asked to comment on.

The Food and Grocery Council argue however that the public comment provisions do not go far enough and in its submission to the Community and Public Affairs Committee argued that:

While the new provisions do not compel FSANZ to undertake public consultations, they do not prohibit FSANZ from undertaking such consultations if it sees fit. This is not understood to be the intention of the new procedures, which is that no public consultation occur in relation to such applications.

A specific prohibition against public notification and consultation (except at the request or with the consent of the applicant) needs to be added.

Further information regarding the Health Claims scheme may be found on FSANZ’s website and views of interest groups may be found in submissions to the Senate Community and Public Affairs Committee inquiry into health claims.

Warning:
This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.
This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.
Schedule 1 amendment - Editorial Notes

Item 13 of Schedule 1 amends the definition of ‘standard’ in the Act. The amendment states that:

Neither of the following is taken to be part of a standard

(c) boxed text identified as an editorial note;
(d) boxed text identified as an example.

The explanatory memorandum explains that:

This item amends the definition of ‘standard’ in subsection 3(1) of the Act to clarify that boxed text identified as an editorial note or an example is not part of a standard.

This aims to remove previous confusion regarding the legal effect of editorial notes. Such notes are not legally binding but can assist in providing an explanation of relevant parts of the Australia New Zealand Food Standard Code (the Standards Code).

The Regulation Impact Statement also states that:

Amendment to the definition of a Standard to expressly provide that editorial notes and examples that are identified in a Standard do not form a part of a Standard. As these notes and examples, will not form part of the Standard, the FSANZ may amend these non-legally binding parts of the Code without the need to follow statutory processes in the Act.

The Food Standards Code makes heavy use of examples and editorial notes. Subsection 13(3) of the Commonwealth Acts Interpretation Act 1901 state that ‘no marginal note, footnote or endnote to an Act, and no heading to a section of an Act, shall be taken to be part of the Act.’ All state and territory Interpretation Acts also have words that have the same effect. The proposed amendment set out in item 13 of schedule 1 is for the main part, consistent with the provisions in each jurisdiction’s Acts Interpretation Act, however one glaring point of difference is the reference in the Bill to the notes and examples being contained within a ‘box’.

Some witnesses at the recent Senate Community and Public Affairs Committee Hearing were concerned that the proposed amendment focused only on editorial notes and examples that were inside a text box. The concern being that if an editorial note appeared in the Food Standards Code and not inside a box, that it may be regarded as being part of the standard. It was therefore suggested that the reference to ‘box’ in the Bill, should be removed. Reference to a ‘box’ may also limit FSANZ’s drafting style. If in the future, FSANZ decides that it does not wish to place editorial notes and examples inside a box, it would find that it could not change its drafting style and remove the boxes because the Act makes express reference to the phrase ‘box’.

Warning:

This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.

This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.
Editorial notes are used extensively in the Food Standards Code. This has been the subject of some criticism, especially where it appears that the editorial note may be modifying the law, as set out in the actual food standard. Witnesses at the recent Community and Public Affairs Committee hearing made the following comments in regard to editorial notes.

Mr Chris Preston, Consultant to the Australian Food and Grocery Council gave the following oral evidence at the public hearings that were held by the Community and Public Affairs Committee:

Editorial notes can be a useful thing, in our view. Food regulation is inherently technical; it can get very complicated…..

So I suppose that where we are coming from in that the editorial note is not a bad concept is this sort of regulation where you are dealing with technical concepts. It has a legitimate and good and beneficial use when used appropriately but there has been a tendency-forgive the pun-to editorialise the editorial note and to try and go further than giving examples or explaining terms or cross-referencing terms to actually try and introduce concepts that are not reflected in the law….

One recent example is the editorial note on the country of origin standard, which editorialises and maybe goes beyond what the standard actually says.

Whilst this evidence does not relate directly to amendments contained within the Bill, it is an important issue that FSANZ needs to be mindful of when drafting standards.

Concluding comments

The Bill makes a series of amendments to the Food Standards Australia New Zealand Act 1991. Key elements of the Bill are as follows:

• inserts a provision regarding the use of editorial notes in the Food Standards Code
• seeks to change the processes that FSANZ must go through to develop food standards, and
• puts in arrangements for changes to the food standard dealing with health claims.

The amendments do make considerable changes to Food Standards Australia New Zealand’s current assessment processes. It would appear that they are designed to streamline FSANZ’s assessment processes, however some of the changes, such as those relating to high level health claims, may be criticised for leaving out the vital public consultation element of the assessment processes.

Warning:
This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.
This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.
Endnotes


2. Food Standards Australia New Zealand Amendment Bill 2007 Explanatory Memorandum, p. 4 and 10.


10. ACT section 127(1), NSW section 35(2), NT section 55(3), Qld, section 14(6), SA section 19(3), Tas section 6(4), Vic section 36(6), WA section 32(2).


Warning:

This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.

This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.