Australian Government

Department of Health and Ageing

Consultation Paper:
Proposed Legislative Changes to the *Food Standards Australia New Zealand Act 1991*

MAKING A SUBMISSION

This consultation paper has been developed by the Australian Government Department of Health and Ageing to seek the views of interested stakeholders on the impacts of proposed changes to the *Food Standards Australia New Zealand Act 1991 (the Act)*. Submissions and feedback will be used to shape the final legislative amendments for consideration by the Australian Parliament.

Many of the recommendations contained in this document have already been the subject of consultation and have been agreed in principle by the Australia and New Zealand Food Regulation Ministerial Council or the Council of Australian Governments. The Australian Government Department of Health and Ageing (the Department) is now examining the means by which to implement the recommendations that require amendments to the Act.

As part of the preparation of the legislative package for consideration by the Australian Government, the Department of Health and Ageing will be preparing a Regulation Impact Statement detailing the impacts on all stakeholders of any significant changes to the legislation (noting that a number of the changes proposed in this document are minor, technical amendments and will not be subject to a Regulation Impact Statement).

The Department will be utilising information received from stakeholders through previous consultation on the issues but will also be pleased to receive any further input from stakeholders. In particular, the Department of Health and Ageing is interested to receive advice on the likely costs and benefits to various stakeholders of proposed amendments to the Act.

Please note that all submissions are subject to the *Freedom of Information Act 1982* in Australia and the *Official Information Act 1982* in New Zealand. If you consider that all or part of your submission should not be released, please make this clear when making your submission and indicate the grounds for withholding the information. Copyright will continue to reside in the author/s of a submission. Electronic submissions to the e-mail addresses below are preferred.

Deadline for input: No later than close of business 27 April 2006 to:

Australia (Submissions)
C/- Food Regulation Policy
Department of Health and Ageing
MDP15 GPO
Box 9848
CANBERRA ACT 2601
Or email the Food Regulation Secretariat
Or fax to: (02) 6289 5100

New Zealand (Submissions)
C/- Policy and Regulatory Standards Group
New Zealand Food Safety Authority (NZFSA)
PO Box 2835
WELLINGTON
Or email the New Zealand Food Safety Authority
Or fax to: (04) 463 2583

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TERMS AND ACRONYMS

APVMA	Australian Pesticides and Veterinary Medicines Authority
COAG	Council of Australian Governments
FRSC	Food Regulation Standing Committee
FSANZ	Food Standards Australia New Zealand
Ministerial Council	Australia and New Zealand Food Regulation Ministerial Council
MRL	Maximum Residue Limit
The Act	*Food Standards Australia New Zealand Act 1991*
The Blair Report	Food Regulation Review
The Code	the Food Standards Code
The Department	Australian Government Department of Health and Ageing
TPA	*Trade Practices Act 1974*

INTRODUCTION

Since the amended *Food Standards Australia New Zealand Act 1991* (the Act) came into effect in 2001, a need to make further improvements to the food regulatory processes has been identified through four different initiatives. The Department is now examining the means by which to implement the recommendations that require amendments to the Act.

Background

The Council of Australian Governments (COAG) agreed to a new food regulatory system in November 2000. This was in response to the recommendations of the Food Regulation Review (the Blair Report). The reforms have resulted in a nationally focussed food regulatory system for Australia that aims to enhance public health and safety. The package included a new food regulation system, an Inter-Governmental Agreement on food regulation signed by COAG, and a Model Food Act. New Zealand has joined the system by way of a Treaty between the two countries.

In July 2001, amendments to implement these changes were made to the *Australia New Zealand Food Authority Act 1991*, including renaming the Act the *Food Standards* Australia *New Zealand Act 1991.*

The primary objective of the FSANZ Act is to ensure a high standard of public health protection through Food Standards Australia New Zealand (FSANZ) achieving the following goals:

a) a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand;
b) an effective, transparent and accountable regulatory framework within which the food industry can work efficiently;
c) the provision of adequate information relating to food to enable consumers to make informed choices; and
d) the establishment of common rules for both countries and the promotion of consistency between domestic and international food regulatory measures without reducing the safeguards applying to public health and consumer protection.

Initiatives leading to recommendations

Outstanding COAG Amendments

Two amendments recommended in the Blair Report and agreed by COAG remain to be implemented. The recommendations are:

1. streamlining the process for setting Maximum Residue Limits (MRLs) between Australian Pesticides and Veterinary Medicines Authority (APVMA) and Food Standards Australia New Zealand; and
2. the creation of a national, compulsory food recall power to be exercised by the Australian Government Minister for Health.

Further details on these proposed amendments are included in Part A of this document.

Recommendations arising from experience with the new system

Since the amended FSANZ Act came into effect, a need for further improvements to food regulatory processes has become apparent. The Australian Government Department of Health and Ageing, in consultation with FSANZ, identified a number of possible improvements in 2004. Consultation with other Australian Government agencies, State and Territory Governments, the New Zealand Government, and key stakeholders, took place on these improvements in 2004.

Details of these recommendations are included in Part B of this document.

Recommendations arising from Food Standards Australia New Zealand assessment and approval processes review project

In July 2004, the Food Regulation Standing Committee (FRSC) agreed to establish a Working Group to advise on reducing delays in FSANZ's assessment and approval processes and enhancing the protection of confidential commercial information.

After public consultation, FRSC presented its report to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) for consideration at its meeting in October 2005. Ministers agreed to a number of measures that will assist FSANZ to expedite food standards development and protect commercially valuable information, including a number of measures that require amendments to the Act.

Details on the proposed Act amendments which relate to these recommendations are included in Part C of this document.

Recommendations of a technical nature

During the course of reviewing the Act, additional amendments of a purely technical nature have also been identified by FSANZ. Details of these proposed Act amendments are at Attachment A.

PART A: OUTSTANDING COUNCIL OF AUSTRALIAN GOVERNMENTS AMENDMENTS

1. Streamline processes for setting MRLs between the APVMA and FSANZ

Purpose

To streamline the process for setting Maximum Residue Limits (MRLs) by the Australian Pesticides and Veterinary Medicines Authority (APVMA) and FSANZ.

Reason

There are two processes for setting MRLs that affect primary producers. The APVMA determines the MRL and registers the chemicals for use in Australia. The APVMA then makes an application to FSANZ for the inclusion of those MRLs in the Food Standards Code. FSANZ then conducts its normal assessment process, which may, in part, duplicate the APVMA process. Following this process the FSANZ Board recommends the MRLs to the Ministerial Council. After this process, the MRLs are included in the Food Standards Code.

This process of setting MRLs leads to a delay between the approval of a chemical for use by the APVMA and its inclusion in the Food Standards Code. As a result, it is possible that certain chemicals could be permitted for use, but the food produced with the aid of these chemicals could not be legally sold. To overcome this problem the APVMA and FSANZ have worked together closely in the setting of MRLs. However, their ability to expedite the process further is currently constrained by limitations in the legislation.

Proposed implementation

Proposed changes to both the FSANZ and APVMA legislation would allow a concurrent assessment process rather than the existing sequential APVMA, followed by FSANZ, assessment processes.

It is proposed that the following policy be implemented through changes to the FSANZ Act and the APVMA legislation:

- application and data requirements between APVMA and FSANZ would be aligned;
- an application to the APVMA would be deemed to be an application to FSANZ (work between the APVMA and FSANZ has commenced to ensure that APVMA can pass on an application to FSANZ); and
- the work required during the assessment process would be divided but shared as following:
  - APVMA would conduct evaluation for toxicology, environment, occupational health, efficacy/target animal or crop safety, residues and trade.
  - FSANZ would conduct the dietary exposure evaluations and prepare a dietary risk summary and develop the Initial/Draft Assessment report.

- A single joint public consultation that covers both legislative requirements would be conducted.
- Following consultation, both agencies would follow current processes to have the MRL approved and gazetted.

These changes would not apply to MRL applications for antibiotics and emergency permits.

2. National food recall power for the Australian Government Minister for Health and Ageing

Purpose

To implement an outstanding Council of Australian Government decision (stemming from the Blair Report) for the creation of a national compulsory food recall power to be exercised by the Australian Government Minister for Health and Ageing.

Reason

The Blair Report published in 1998 called for consistent and timely food recall arrangements. The Report goes on to refer to *"….initiatives that will go a long way to address these concerns"*. This refers to the Model Food provisions subsequently agreed to by the States and Territories and annexed to the Food Regulation Agreement in 2000.

The Blair Report recommended that:

> *"In situations where food offered for sale is posing an immediate threat to the safety of consumers in more than one State or Territory, ANZFA [now FSANZ] currently needs to ask the Minister for Consumer Affairs to order a recall. Experience has shown that this arrangement can be unsatisfactory. To address this situation the Commonwealth Minister for Health should have access to the mandatory food recall powers of the Trade Practices Act 1974 (TPA) in relation to food".*

This would enable a coordinated nation-wide response to any threats to the food supply including where, for example, there may be the introduction of biological, chemical or radiological contaminants into the food supply chain, either deliberately or otherwise.

Some considerable time has passed since the Blair review. Several options have been investigated. These are however difficult to implement in the context of the existing federal framework and respective Australian Government and States and Territories constitutional powers. The options include:

- adding wording to the FSANZ Act based on the Model Food bill emergency provisions to enable the Australian Government Minister for Health to make a recall order in the case of a national food threat; or
- adding provisions, similar to the emergency provisions in the Trade Practices Act (TPA), to the FSANZ Act; or
- creating a new section in the FSANZ Act to provide for a recall order in a cooperative scheme with States and Territories to give some recall, enforcement and disposal of recalled food products powers to the Australian Government.

Capacity continues to exist under the TPA to order a compulsory nationwide food recall. Section 65F of the TPA describes several steps that must be taken before a compulsory recall order comes into effect. This process could cause delays. However, in addition to this section, there exists an emergency power under the TPA

for the Treasurer or other portfolio ministers to make an emergency order if a certain good creates an imminent risk of death, serious illness or severe injury.

Whilst concern has previously been expressed regarding the efficiency of these mechanisms, neither has been fully tested in relation to a food emergency.

It should be noted that States and Territories also have the power to initiate compulsory food recalls in relation to food businesses that operate within their jurisdictions. Under the home state rule, this is interpreted as the jurisdiction where a product is either manufactured, or through which it is imported. However, a mandatory recall order requires the recall of all products regardless of which State/Territory it has been distributed to by the manufacturer/importer.

Implementation options

Advice is now sought from stakeholders regarding the desirability or otherwise of implementing national recall provisions through the FSANZ legislation. Such provisions would be specific to the recall of foods in the event of a national emergency requiring a national response. The most appropriate legislative model would have to be identified in the context of the existing federal framework and respective Australian Government and States and Territories constitutional powers in relation to food regulation.

An alternative is to continue to rely on existing emergency provisions in the TPA. This would avoid any overlap, duplication or confusion about accountability that could result from new powers being expressly described in national food legislation.

Stakeholder advice on this issue, and the options presented, is sought.

PART B: RECOMMENDATIONS ARISING FROM EXPERIENCE WITH THE NEW SYSTEM

3. Coordination of policy development and FSANZ processes

Purpose

To ensure appropriate oversight of the food regulatory system by the Ministerial Council, through coordination of the policy development processes with the FSANZ processes of assessing applications and proposals to amend the Food Standards Code.

Reason

An important aspect of the food regulatory system is the provision of formal policy guidelines by the Ministerial Council to FSANZ. Policy guidelines provide a mechanism by which the Ministerial Council determines food regulation policy.

Currently there are no time limits on the policy development process, and such policy development may occur over extended periods of time. By contrast, any application received by FSANZ must be dealt with by FSANZ within 12 months of the date on which it is received (subject to any "clock stops'), but with some scope to extend this period for a further six months.

FSANZ cannot readily defer dealing with an application to amend a Standard that relates to a matter on which the Ministerial Council is developing policy guidelines. This can result in FSANZ needing to progress an application in the knowledge that a policy is under development but yet to be finalised.

Proposed implementation

It is proposed that section 35 of the FSANZ Act (requiring FSANZ to make decisions within a certain time) be amended to enable FSANZ to defer consideration of an application, or to 'stop the clock', if the subject of the application is under consideration by the Ministerial Council. FSANZ would not be required to finalise its assessment until relevant policy guidelines are finalised by the Ministerial Council and notified to FSANZ.

In order to provide a level of certainty to applicants, it is proposed that a time limit of up to 18 months be prescribed for the deferral of an application on the grounds that FSANZ is awaiting policy advice.

Where there is policy work underway, applicants would be informed of the possibility of delay. An opportunity to resubmit or revise their application would be considered favourably by FSANZ in these circumstances.

Please note that this Recommendation should be read in conjunction with Recommendation 12, which relates to changed powers for the Ministerial Council in issuing policy guidelines.

4. Partial approval of an application

Purpose

To allow FSANZ to approve parts of a multi-faceted application, rather than having the whole application either approved or rejected.

Reason

After accepting an application, FSANZ conducts an initial assessment. After consultation, FSANZ conducts a draft assessment of the application. At both stages FSANZ must either accept or reject the application in its entirety. There is no provision for the partial approval of the application.

The Act does not define what form an application should take. A single application may be long and cover a range of issues. Currently, where some parts of an application are acceptable but others are not, the entire application must be rejected by FSANZ. In such circumstances, applicants must reapply to pursue the acceptable parts of the application. This wastes time and money for both FSANZ and the applicant.

Proposed implementation

It is proposed that a provision be inserted into the Act to allow FSANZ, following consultation with the applicant, to approve or reject parts of an application, with a statement of reasons. This would be able to occur at the initial, draft or final assessment stages.

Please note that this Recommendation should be read in conjunction with Recommendation 10, which relates to formalising application requirements.

5. Explicit function to provide information on the Food Standards Code

Purpose

To ensure that the FSANZ legislation expressly enables FSANZ to provide information about, and advice on, the Food Standards Code.

Reason

The functions of FSANZ outlined in the Act do not include an explicit function to give information about, and advice on, the Food Standards Code, even though FSANZ is responsible for developing and varying the food standards in the Code. Nonetheless, industry, consumer and government stakeholders expect FSANZ to provide information about and advice on, the Food Standards Code.

FSANZ has established a Standards Information Unit and an Advice Line. Requests for advice have increased, and extend to importers, consumers, scientific and educational institutions, and officers from State, Territory and New Zealand Government agencies.

It is important that FSANZ has the express authority to provide advice on the Food Standards Code.

Proposed implementation

It is proposed that section 7 of the FSANZ Act (which describes the functions of FSANZ) be amended to include an additional function – that FSANZ may provide information about, and advice on, the Food Standards Code generally and on individual food standards.

6. Extend the "Exemption from Suit" provisions in the Act

Purpose

To allow FSANZ to carry out its functions to protect the health and safety of Australians in good faith without the risk of legal action.

Reason

An exemption from suit provision is designed to allow a regulatory body to act in good faith, without risking legal action that may prevent the body from adequately carrying out its role.

Section 68 in its current form is, comparatively, a very limited exemption from suit provision. It only applies to loss/injury sustained because of the consumption of or other dealing with food.

Proposed implementation

It is proposed that section 68 of the FSANZ Act (exemption from suit) be extended to allow FSANZ to carry out all of its functions in good faith and that the amendment be consistent with the exemption from suit provisions applicable to other Australian regulatory agencies.

7. Have regard to similar proposals, as well as applications

Purpose

To ensure that FSANZ has regard to similar applications and proposals when considering a new application for an amendment to the Food Standards Code.

Reason

Under the Act an application for the development of a Standard or a variation to a Standard may be made to FSANZ by any external organisation or individual. FSANZ may also generate a proposal to develop a Standard or a variation.

In considering any application, FSANZ must have regard to whether the application is so similar to a previous application that it ought not to be accepted. However, the Act does not stipulate that FSANZ must have regard to whether the application is similar to a previous proposal. Arguably nothing in the Act prohibits this, and it would already seem to be a relevant matter under section 13(e).

However, given that the opportunity has arisen to consider changes to the Act, it is suggested that regard to both similar proposals and relevant reviews (section 33) be articulated as a further consideration.

Proposed implementation

It is proposed that sections 13(2) (b) and 33 of the Act be amended so that FSANZ has regard to similar 'applications and proposals'. It is also proposed that an amendment be made so that FSANZ also has regard to similar reviews of food regulatory measures (for example at the request of the Ministerial Council).

8. FSANZ must make a final assessment

Purpose

To formalise the current practice and policy intent of the Act that FSANZ must make a final assessment of any draft Standard or variation to a Standard.

Reason

The policy intent of the Act is that, after conducting a draft assessment of the application or proposal, FSANZ must:

a) prepare a draft Standard or variation; or
b) in the case of an application, reject the application with appropriate notice provisions; or
c) in the case of a proposal, abandon the proposal.

If FSANZ prepares a draft Standard or variation, the policy intent is that FSANZ must conduct a final assessment in relation to the draft Standard or variation, and then either:

a) approve the draft and notify the Ministerial Council (sections 20 and 23A); or
b) reject the draft.

However, the Act does not currently state that FSANZ must make a final assessment in relation to a draft of the Standard or variation. This is necessary in order to finalise the process.

Proposed implementation

It is proposed that the Act be amended to specify that FSANZ must make a final assessment in relation to the draft Standard or variation of any application or proposal, so that the draft can be either approved or rejected. This amendment would provide clarity in the interpretation of the Act. Urgency provisions would continue to allow a delay of the final assessment until after the Standard or variation has come into effect.

9. Editorial notes and statements of purpose

Purpose

To clarify the effect of editorial notes and statements of purpose.

Reason

In the past there has been some confusion amongst stakeholders regarding the legal effect of editorial notes and statements of purpose. Further, changes to editorial notes have been subject to the full consultative processes.

This can lead to delays in making minor changes to editorial notes that are not legally binding but can assist in providing an explanation of relevant parts of the Code.

Proposed implementation

It is proposed that:

- a statement be added to the Act to explain that the statements of purpose and editorial notes are intended to provide clarification and guidance with respect to a particular provision and are not legally part of a standard; and
- a provision be included in the Act that would enable FSANZ to add or alter editorial notes (that have no force of law) to the Code with the support of the Ministerial Council, but without needing to undertake the statutory processes for amendments to the Code.

PART C: RECOMMENDATIONS ARISING FROM THE FSANZ ASSESSMENT AND APPROVAL PROCESSES REVIEW PROJECT

10. Application requirements

Purpose

To set minimum application requirements for applicants to provide greater certainty and to increase FSANZ's capacity to process applications expeditiously.

Reason

Currently the Act does not provide any detail about what must be included in an application (the Act merely provides that an application must be in writing).

A lack of minimum specification of what is required within an application has led to unnecessary delays in progressing applications. The proposed legislative changes will provide greater certainty for applicants and FSANZ, and will reduce the number of times additional information needs to be requested from applicants later in the assessment process.

Proposed implementation

It is proposed that the Act be amended:

- to require that an application must be in a prescribed form;
- to require that an applicant must fully support their application in accordance with minimum information requirements detailed in Regulations;
- to enable FSANZ to only accept an application when the minimum application requirements are met; and
- to require that, if FSANZ does not accept an application on the basis that it fails to meet the information requirements, FSANZ provide, in writing, a clear reason for not accepting the application.

It is proposed that, after consulting with stakeholders, FSANZ would publish a set of clear application requirements and a proforma checklist to allow applicants to confirm that they have met all of the requirements before submitting an application.

11. FSANZ assessment and public consultation process

Purpose

To reform the FSANZ assessment and consultation processes such that there are different assessment pathways and levels of public consultation, reflecting the different complexity and nature of applications and proposals, while continuing to ensure that the processes are transparent and that FSANZ retains its focus on public health and safety.

Reason

Currently, all applications and proposals assessed by FSANZ are subject to the same process (involving the preparation of three assessment reports), the same level of consultation (two rounds of public consultation subject to limited exceptions) and the same process for Ministerial Council consideration.

This lack of flexibility has created a major impediment to the effectiveness and efficiency of the food regulatory framework.

Proposed implementation

It is proposed that:

- provision would be made in the Act to set out four different assessment streams corresponding to the complexity and impact of the proposed change to the Code;
- each stream would require a different level of public consultation:
  - if the application or proposal relates to an amendment of minor effect to a Standard (e.g. correction of a typographical error, minor editorial changes or minor changes designed to improve clarity), FSANZ would not undertake public consultation, and the assessment should be completed through consultation with States and Territories within three months;
  - if the application or proposal requires urgent consideration in order to protect public health and safety or in order to address an unintended negative impact on trade (provided that this is not inconsistent with any of FSANZ's objectives as detailed in section 10 of the FSANZ Act), FSANZ may declare the application or proposal to be urgent as is currently outlined in the Act. This would be an extension of the existing urgency power (that may be used only for the protection of public health and safety);
  - if the application or proposal relates to the development of a new Standard or a major revision to an existing Standard, FSANZ would undertake two rounds of public consultation, once each on an initial and draft assessment report; and
  - in all other circumstances, FSANZ should undertake one round of public consultation on an assessment report, and the assessment process should be completed within a maximum timeframe. Examples of these types of applications and proposals include additions to tables in an existing Standard (e.g. food additive or processing aid permissions, MRLs,

addition of vitamins and minerals permissions, genetically modified food approvals and minor labelling changes);

- the types of applications and proposals that would fall into each stream would be clearly defined by FSANZ, in guidelines which would be published following a consultative process;
- the timeframes for assessment of applications in the different streams would be prescribed in Regulations. FSANZ is currently trialling the proposed timeframes for assessment of each of the streams of applications. The timeframes for assessment of Proposals would continue to not be subject to prescribed timeframes;
- provisions relating to initial application assessment and advice to the applicant would be amended to make specific reference to assessment of the application by FSANZ to determine in which stream it would be assessed. Advice would be provided to the applicant regarding the assessment process to be followed. Provision for public notification of the determination regarding the assessment process would also be made;
- the categories of application and associated charges would be amended to reflect the changed assessment processes; and
- the legislation would ensure that review rights are retained for all decisions regardless of the stream of assessment.

12. Ministerial Council policy guidance

Purpose

To enable the Ministerial Council to issue policy principles that must be observed by FSANZ (in addition to the existing policy guidelines that FSANZ must have regard).

Reason

Currently, the legislation enables the Ministerial Council to issue policy guidelines. When FSANZ is developing or varying food regulatory measures, it must have regard to any policy guidelines issued in accordance with section 10 of the Act.

A number of the policy guidelines issued by the Ministerial Council are framed in mandatory terms. This creates uncertainty for applicants and FSANZ regarding whether an application must demonstrate compliance with the relevant policy guideline or whether an alternative perspective may be presented.

Additionally the policy guideline issued by the Ministerial Council is one item in a list of many other matters that FSANZ must have regard to, when developing or varying food regulatory measures. Transparency and clarity are needed as to the priority order that FSANZ should apply to guidance from the Ministerial Council.

Proposed implementation

It is proposed that the Act be amended to empower the Ministerial Council to issue two types of policy guidance to FSANZ:

- Policy Principles – that must be observed by FSANZ; and
- Policy Guidelines – that FSANZ must have regard to when assessing an application or proposal.

The amendment would be modelled on the approach adopted in the gene technology legislation, whereby the Ministerial Council may issue Policy Principles that *must* be observed by the Gene Technology Regulator, and Policy Guidelines that must be taken into account by the Gene Technology Regulator as part of his/her decision- making process.

13. Ministerial Council reviews

Purpose

To expedite the process for finalising a Standard by removing the second round of review by the Ministerial Council.

Reason

Currently, once the FSANZ Board makes a decision on a proposed new or amended Standard, the Ministerial Council is afforded two opportunities to request the FSANZ Board to review its decision. After the second review, the Ministerial Council may accept, reject, or amend the Standard.

A single jurisdiction on the Ministerial Council can trigger a first review of a FSANZ decision if that jurisdiction considers that one or more of the criteria detailed in the Food Regulation Agreement applies to the Standard. In addition, the New Zealand Minister may request a review on additional grounds detailed in Annex C of the Food Standards Setting Treaty.

At the second review stage, the Ministerial Council can only request a review if a majority of jurisdictions consider that such a review should be requested. The original intention behind the "second review" step was to provide a further opportunity for FSANZ to address issues of concern to Ministers before the Ministerial Council is empowered to reject or amend.

However, the fact that only two second reviews have been requested to date suggests that this additional step adds little value to the process. Additionally, the proposed strengthened arrangements for consultation with jurisdictions should minimise the need for a second review.

Proposed implementation

It is proposed that the capacity for the Ministerial Council to request a second review be removed from the legislation. The capacity to request a first review would be retained but following the first review, the Ministerial Council must decide whether to accept, reject or amend the Standard (as currently occurs following second review).

A review would continue to be carried on the basis of a request from one jurisdiction.

Changes would also be made to the Food Regulation Agreement to reflect the proposed new process.

14. Protection of commercially valuable information – health claims

Purpose

To provide a greater incentive for applicants to capture the commercial benefit of innovating in the area of health claims, by reducing the exposure of commercially valuable material during the assessment process.

Reason

The proposed requirement for individual health claims to be assessed and approved, and, in the process, for valuable research and development to be divulged to competitors, has been identified as one of the specific areas where there is the potential for a company to lose a market advantage in which they may have invested heavily.

Proposed implementation

Please note that the following changes are proposed on the basis that the Health Claims Standard would be developed in full consultation with all stakeholders (with two rounds of public consultation), with the new Standard detailing the rules for substantiating a high-level health claim.

In this context, it is proposed that changes be made to the Act to:

- enable FSANZ to assess a pre-market application for high-level claims in accordance with the final Health Claims Standard without first publishing the specific high-level claim application or its supporting data (i.e. it would remain confidential);
- require that FSANZ consult all States and Territories and an expert Committee as part of the assessment (the criteria for selection of committee members and the membership of the expert committee would be made publicly available); and
- ensure that applications assessed in this way are subject to Ministerial Council review.

It is proposed that consequential changes would also be made to provisions relating to charges, and that applicants would have the option of paying to expedite consideration of their health claim.

15. Protection of commercially valuable information – novel foods

Purpose

To provide a greater incentive for applicants to capture the commercial benefit of innovating in the area of novel foods, by allowing applicants to apply to FSANZ for an amendment to the Novel Foods Standard that would apply exclusive rights for a period of 15 months to them and to the specific product(s) for which approval was granted.

Reason

Under the existing assessment process, applications are entered on the FSANZ work plan, which is made publicly available. This potentially provides a signal to competitors about the proposed amendment being sought by an applicant. Information provided to FSANZ in support of an application is also disclosed to the public through assessment reports, unless commercial confidential information (CCI) status is requested and granted. The capacity to grant CCI is limited under the current legislative arrangements.

In addition, although it is currently possible to limit an approval to a brand, there is no ability to prevent applications being made for similar or identical permissions under the Food Standards Code. Consequently, once a competitor is aware that an application has been lodged with FSANZ, they are able to lodge an application for a similar permission. Where the subject of the application is not protected under other mechanisms, such as intellectual property provisions, a free-rider effect is created, resulting in disincentives for industry innovation.

Proposed implementation

It is proposed that the Act be amended to:

- enable applicants to apply to FSANZ for an amendment to the Novel Foods Standard for a product-specific and maker-specific 15 month exclusive period;
- the application would be subject to one round of public consultation (consistent with Recommendation 11);
- enable FSANZ to amend the Standard such that the “approval” applied only to the applicant and the specific product or products for which approval was granted, and for a set period of 15 months from the date of Ministerial approval. After this time the amendment would automatically revert to generic application; and
- require that if applicants choose to seek an approval of this type as opposed to a general amendment to the Standard, applicants would be required to pay for the assessment. Such paid applications would be expedited by FSANZ, as is currently the case.

It is intended that a review of the advantages, disadvantages and impact of this provision would be undertaken within 3 – 5 years of its implementation.

ATTACHMENT A
RECOMMENDATIONS OF A TECHNICAL NATURE

Following are some minor technical changes which are proposed to be made when the legislation is amended. Please note that in many cases, the changes detailed below would be overtaken by more significant changes, as detailed in the body of this Paper.

For example, the numbering and content of a number of sections are likely to alter as a result of the more extensive changes detailed in the body of this Paper. As a result, some of the changes detailed below may be made redundant.

1.	There are currently differing definitions of food in the FSANZ Act and the Model Food Act. It is proposed that the Act be amended to align the definition of food in the FSANZ Act with the Model Food Act. (Section 3(B))
2.	In subsection 10 (4) (objectives of the Authority in developing or reviewing food regulatory measures) a reference is made to 'sanitary or phytosanitary measures', while in the second sentence of the subsection a reference is made to 'sanitary and phytosanitary measures'. It is proposed that the terminology be standardised by amending 'sanitary and phytosanitary measures' to read 'sanitary or phytosanitary measures'. (Subsection 10(4))
3.	There are currently two sections 11A in the Act. It is proposed that the Act be amended to correct the duplicated numbering. (Section 11A)
4.	The wording in the heading of section 17AA is slightly different from the wording in the headings to sections 16 and 17. The headings to sections 16 and 17 refer to 'notice following draft food regulatory measure or variation' whereas the heading to section 17AA omits the word 'food' and refers to 'notice following draft regulatory measure or variation'. It is proposed that the terminology be standardised by inserting the word 'food' after the word 'draft' in the heading to section 17AA. (Heading to section 17AA)
5.	The policy intention of subsections 28A(1); 28B(1) and 28C(1)) was to require the Council to either: • request FSANZ to review a Standard or variation; or • inform FSANZ that the Ministerial Council does not intend to request a review. The subsections currently state that the Ministerial Council may take either of these courses of action, and do not clearly require the Ministerial Council to take one or other course of action. It is proposed that this subsection is amended to make it absolutely clear that the Council must take one or other course of action. It is proposed that this be achieved by replacing the word 'may' with the word 'must'. (Subsection 28A(1), subsection 28B(1) and subsection 28C(1))
6.	The heading to section 35 currently reads 'Authority to decisions under section 18 within a certain time'. It is proposed that the heading be amended to reflect the content of the section, which relates to the Authority making certain decisions. It is proposed that the word 'make' be inserted in the heading before the word 'decisions'. (Heading to section 35).

7.	Amendments to section 43 contained in the ANZFA Amendment Act omitted all references to 'Authority' and substituted 'Board'. The ANZFA Amendment Act also inserted a new subsection 43(4) but inadvertently referred to 'Authority' instead of 'Board'. It is proposed that subsection 43(4) be amended by omitting the word 'Authority' and substituting the word 'Board'. (Subsection 43(4))
8.	The numbering of the subsections 50 commences at section 50(4). It is proposed that the subsections be renumbered to commence at section 50(1).
9.	Section 10(2)(e) refers to policy guidelines formulated for the Ministerial Council 'for the purposes of this paragraph' – paragraph should read 'subsection'. Omit 'paragraph' substitute 'subsection'. (Section 10(2)(e), subsection 10(3) and subsection 10(3A))
10.	In Section 35(7), there is a numerical error in relation to the reference to section 16. Omit the reference to 16(1), substitute 16(2) and (Section 35(7))
11.	The Act refers to the Food Regulation Agreement of 2000. The definition of Food Regulation Agreement should be updated in section 3(1) to reflect subsequent amendments. Further legal advice is required on how to implement this amendment (Subsection 3(1), section 21 (7) section 28A (7))
12.	Subsection 19(1)(e) aims to ensure that interested parties are alerted to any final assessment that the Authority makes in relation to a draft Standard or a draft variation of a standard. A draft Standard can be developed via an application (see Section 12) or a proposal (see Section 12AA). The use of the word 'proposal' in paragraph 19(1)(e) could cause confusion because it may be thought that the paragraph does not apply to a draft Standard or draft variation of a Standard developed via an application. An amendment to the paragraph would be made to make it clear that it applies to draft standards and draft variations of standards developed via both applications and proposals.
13.	There is a small difference in the ordering of words in the description of the Ministerial Council's powers in sections 23 and 28. Under section 23 the Ministerial Council is empowered to 'amend or reject' non-urgent standards. Under section 28C the Council is given similar powers to 'revoke or amend' urgent standards. In the provision relating to non-urgent standards the word 'amend' appears before the word 'reject', whereas in the provision relating to urgent standards the word 'amend' appears after the word 'revoke'. It is proposed that the wording be standardised by omitting the words 'revoke or amend' or 'revoking or amending' wherever occurring in the heading to, and within, section 28C and substituting the words 'amend or revoke' or 'amending or revoking'. (Heading to section 28C and wording within section 28C).
14.	Section 37 is missing from the FSANZ Act. Section 36A should be renumbered as section 37, while ensuring references to section 36A are also updated.

Note - During the review of the *Legislative Instruments Act 2003* some issues in relation to the *FSANZ Act* were identified. For the purposes of consistency it may be necessary to:

- clarify the status of a declaration by the Minister under section 11;
- update section 3B (4) to reflect the repeal of section 46A of the *Legislative Instruments Act 2003;* and
- clarify the commencement date of a declaration by the Minister of what is food under section 3B (3).