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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

FOOD STANDARDS AUSTRALIA NEW ZEALAND AMENDMENT BILL 2007

REVISED EXPLANATORY MEMORANDUM

(Circulated by authority of the Parliamentary Secretary to the Minister for Health and Ageing, Senator the Honourable Brett Mason)

THIS MEMORANDUM TAKES ACCOUNT OF AMENDMENTS MADE BY THE SENATE
TO THE BILL AS INTRODUCED

FOOD STANDARDS AUSTRALIA NEW ZEALAND AMENDMENT BILL 2007

OUTLINE

The purpose of this Bill is to amend the *Food Standards Australia New Zealand Act 1991* (the Act) to expedite the development of food regulatory measures (commonly referred to as food standards) by Food Standards Australia New Zealand (the Authority) and improve the framework within which the Authority operates and food standards are made.

The Act establishes a food regulatory system for Australia and New Zealand. The object of the Act is to ensure a high standard of public health protection throughout Australia and New Zealand by means of the establishment and operation of the Authority to achieve the following goals:

- a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand
- an effective, transparent and accountable regulatory framework within which the food industry can work efficiently
- the provision of adequate information relating to food to enable consumers to make informed choices
- 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.

Consistent with this objective, the Act sets out the process for developing and amending of food standards for Australia and New Zealand generally by means of applications received from industry or individuals or proposals raised by the Authority. The process involves scientific assessment by the Authority, stakeholder consultation, and oversight by the Australia and New Zealand Food Regulation Ministerial Council (the Council).

Experience with the system since 2002 (and a review of the standard development and approval process) confirmed the strengths of the current process including the focus on public health and safety. However, the review also highlighted areas for improvement. The main weaknesses of the existing system were found to be the timeframe for decision making, and the "one size fits all" approach fixed in the legislation for developing or amending a food standard. Currently the same process applies to virtually all applications and proposals to amend a food standard regardless of the nature or scope of the application or proposal. This has, at times, led to a significant backlog of applications awaiting assessment by the Authority.

The review also made suggestions for improving the coordination of processes between the Council and the Authority, better management of issues in relation to food innovation, and better engagement of stakeholders in the standards development process.

Consistent with the outcomes of the review and the recommendations agreed to by the Council, this Bill will improve the effectiveness of the regulatory framework within which the food industry can work more efficiently.

In summary, this Bill:

- reforms the assessment and consultation process to:
  - match the process with the nature and scope of the application or proposal under consideration
  - create more meaningful opportunities for consultation with stakeholders
- harmonises as far as possible the processes for the assessment of applications and proposals
- allows for alignment of the policy setting process of the Council and the standard development and approval process of FSANZ
- aligns the processes for setting of Maximum Residue Limits of the Australian Pesticides and Veterinary Medicines Authority and of FSANZ
- recognises the potential need to develop urgent standards due to unforseen negative impacts on trade
- removes the ability for the Council to request a second review while maintaining appropriate oversight of standards by the Council – this amendment is subject to changes to the Food Treaty between Australia and New Zealand
- creates a process for expert scientific assessment of future high level health claims – the later commencement of this provision allows time for finalisation of the Nutrition, Health and Related Claims Standard currently under development.

The Bill also makes a number of minor amendments to the legislation to remove unnecessary red-tape and duplication and to improve clarity.

The issues addressed in the Bill have been subject to extensive consultation with Australian Commonwealth, State and Territory Governments, the New Zealand Government as well as the food industry, consumer and public health groups, and members of the public.

The majority of stakeholders have strongly supported the proposed changes as a means by which to improve the food regulatory system while maintaining the existing open and publicly accountable arrangements that ensure the protection of public health and safety.

FINANCIAL IMPACT STATEMENT

The financial impact of the Bill is cost neutral. Cost savings achieved through efficiencies will be reinvested through improved planning and making consultation more effective. The current resources within the Authority will be refocused accordingly. To assist with the transition to the new system the Australian Government has provided $2.9 million over two years to the Authority and the Department of Health and Ageing (the Department).

	2006-07	2007-08
Department	**0.521**	**0.526**
Authority	**1.149**	**0.721**

Expenses in $m

REGULATION IMPACT STATEMENT - RIS ID: 6118

BACKGROUND

In November 2000, the Council of Australian Governments (COAG) agreed to a new food regulatory system in response to the recommendations of the Food Regulation Review (the Blair Report). The package of reforms included a new food regulatory system, an Inter Governmental Agreement on food regulation, and a Model Food Act for implementation in all Australian jurisdictions. New Zealand also joined the system by way of a Treaty between the two countries. In 2001, amendments were made to the *Food Standards Australia New Zealand Act 1991* (the Act) to reflect the new co-operative bi-national system for food regulation.

Since the amended Act came into effect, a need to further improve the food regulatory processes has become apparent. The Australian Government Department of Health and Ageing, in consultation with Food Standards Australia New Zealand (the Authority), identified a number of possible improvements in 2003. Consultation on these improvements was undertaken with other Australian Government agencies, State and Territory Governments, the New Zealand Government, and key stakeholders. In May 2004 the proposed Act amendments were presented to the Australia and New Zealand Food Regulation Ministerial Council (the Council).

In 2004, the Food Regulation Standing Committee (FRSC) (comprising senior officials from the New Zealand, Australian and all State and Territory Governments) undertook a review of the food regulatory system aimed at identifying opportunities for reducing delays in the Authority's food standards assessment and approval processes and enhancing the protection of confidential commercial information. During 2005, as part of the review, industry and consumers were consulted on any additional concerns with the current standards development process.

The FRSC recommendations that were developed in further consultation with consumers and industry were agreed by the Council in October 2005 and February 2006. The recommendations that required legislative amendment were referred to the Australian Government for further consideration and action alongside the legislative amendments previously considered at the Council meeting of 28 May 2004.

PROBLEM

Since the amended the Act came into effect in 2002, experience with the system has identified a number of legislative impediments to the effective operation of the legislation. In particular these relate to:

- the "one size fits all" approach. In general, the Authority treats all applications and proposals the same. The applications and proposals are subject to the same assessment process (involving the preparation of three assessment reports) and are subject to the same level of consultation (two rounds of public consultation subject to limited exceptions).

- the lack of flexibility in the legislation to provide for different applications and proposals to be subject to different assessment and consultation processes creates a major impediment to the expedited assessment of applications and proposals. This has contributed to the long period for standard development (approximately 16.8 months) and the considerable backlog of applications awaiting assessment by the Authority;

- problems relating to the interaction between the standards development process undertaken by the Authority and the policy development and final checks and balances role of the Council have also contributed to the long delays and uncertainty in the process. For example:

  - currently the Authority cannot readily defer dealing with an application to amend a Standard that relates to a matter on which the Council is developing Policy Guidelines. This has placed the Authority in the difficult position of having to progress an application in a policy vacuum. This situation has also led to uncertainty for applicants and unnecessary time delays;

  - the Council has two opportunities to request review of a proposed Standard or variation to a Standard - second reviews have only been requested on four occasions which suggests that this middle step adds little value to the process. However, the second review process adds a minimum of 5 months to an already lengthy process.

- the "free rider" effect that results from generic standards. Sectors of industry have indicated that health claims will be a large new area of product differentiation and that, subject to the finalisation of the health claims standard, industry will seek approval of certain high level health claims. This would require an amendment to the standard and currently there is no capacity for industry to capture exclusive benefits because all details of the application are made publicly available and because, once amended, the new Standard applies to everyone (resulting in a free rider effect). The absence of protections for commercially valuable information (particularly in relation to health claims) has been seen as a disincentive for innovation. This was also seen as an issue in relation to novel foods.

OBJECTIVES

There are three key objectives:

- to expedite and, where possible, harmonise the process for assessing applications and proposals while continuing to ensure that the processes are transparent and that the Authority retains its focus on public health and safety;

- to better co-ordinate the Authority assessment processes and the Council's role in both setting policy and overseeing all changes to Standards; and

- to provide a greater incentive for applicants to capture the commercial benefit of innovation particularly in the area of health claims.

IMPACTED PARTIES

The groups likely to be affected by any changes to the food regulatory system are: industry, consumers, the Authority and Government (Australian Government, New Zealand Government and State and Territory Governments).

OPTIONS AND IMPACT ANALYSIS

Options

Option 1: Retain the Status quo.

Option 2: This Option involves three elements:

(a) Reforming the Authorities processes such that:

- there would be clearly defined application requirements;
- there would be three different assessment procedures corresponding to the nature and scope of the proposed change to the Code;
- each assessment procedure would have corresponding level of public consultation;
- all applications and proposals would be publicly notified along with an estimated timeframe for their assessment; and
- the timeframes for assessment of applications would also be matched to the different procedures (between 3 months and 12 months).

(b) Better co-ordinating the Authorities processes and the Council processes such that:

- the Authority would be given the power to defer consideration of an application, by up to 18 months, if the subject of the application is under consideration by the Council as a policy guideline; and
- the Council may only request one review of a Standard rather than two.

(c) Enabling an alternative process for health claims such that Authority would undertake a pre-market application assessment of high level claims in accordance with the final Health Claims Standard without first publishing the specific high level claim application or its supporting data. The Authority would consult all States and Territories and an expert Committee as part of the assessment and all applications would be subject to Council review.

Consideration was also given to enabling the Council to issue binding "Policy Statements" (to be distinguished from policy guidelines that are not binding but must be taken into account by the Authority). However, consultations gave rise to very divided

opinions on this issue and it is therefore proposed that the matter be deferred, subject to further consideration and consultation.

Additional, changes to further encourage innovation in the area of novel foods are also proposed. However these are not part of the legislative changes or this RIS. It is proposed that applicants would be able to apply to the Authority for an amendment to the Novel Foods Standard for a product-specific and maker-specific 15 month exclusive period. After this time the amendment would automatically revert to generic application. It is proposed that changes to effect this policy should be made in the Food Standard rather than in the legislation. Any changes to the novel foods standard would be accompanied by a RIS.

Further detail regarding Option 2 is included at Attachment A.

IMPACT ANALYSIS

Impacts of Option 1: Retain the status quo

***Industry*:**
Retention of the status quo would not appear to present any major benefits to industry. A minor benefit is that the current system is known to industry and as such this option avoids any costs associated with transition to a new system. However, this option would not address the problems identified above. For example, simple applications would continue to be subject to lengthy assessment and consultation periods, the backlog of applications would continue to exist, there would continue to be a lack of certainty regarding timeframes (including because of the opportunity for two reviews to be requested) and this would continue to impede industry's ability to properly plan for new products.

In relation to health claims, applicants would be able (once the Standard is finalised) to apply to have a high level health claim included in the Standard but the details would be publicly available (approximately 12 months in advance of an amendment to the Standard). If the Standard is amended, anyone would, in most instances, be able to make the high level health claim (the free-rider effect). Industry believes this inhibits research and innovation because there is no capacity to capture exclusive benefits.

Consumers:
Retention of the status quo would have minimal impact on consumers. All applications and proposals would continue to be subject to the same level of public consultation. While the status quo provides consumer groups with certainty that they will be consulted on all applications and proposals, some consumers have suggested that this also poses challenges given their limited resources and that there is no pre-warning of consultation.

If the regulatory system does inhibit the capacity of industry to innovate then this may have flow on effects to consumers in terms of product range.

The Authority:
Retention of the status quo would leave the Authority with existing problems. For example, this option means that the Authority must spend more resources than is considered necessary on very simple applications and in undertaking second reviews, if

requested. The Authority has indicated that this is one of the factors that has led to the backlog of applications.

***Government*:**
As a predominantly Government-funded body, all governments have an interest in the level and effective use of resources required by the Authority to undertake assessments of applications and proposals.

Impacts of Option 2:

***Industry*:**
Element (a) - This will clearly identify and reduce timeframes for assessment of applications and should also assist in reducing the backlog of applications awaiting consideration. This means that the overall timeframes for assessment of applications will decrease, to the benefit of applicants, the majority of whom are part of the food industry.

Element (b) - This element provides industry with greater certainty and transparency regarding the reasons for any delay and also the maximum delay expected. Industry has expressed concern that if the Council creates policy on numerous matters this could delay many applications, to the detriment of the applicant. Concern has also been expressed that the submission of an application may itself give rise to the Council deciding that new policy is needed and that the application would then be subject to a delay that was not anticipated at the time that the application was made.

In relation to the removal of the opportunity for the Council to request a second review, this reduces the potential time for finalisation of a Standard and, as a result, has benefits for applicants.

Element (c) - This element provides an incentive for both large and small companies to innovate in the area of health claims. Applicants would have the option of paying to have consideration of their health claims expedited by the Authority or not paying and being placed on the waiting list along with other unpaid applications. This is consistent with current practice and is therefore not likely to create any new inequities between smaller and larger companies.

Consumers:
Element (a) - This element has no impact on health and safety and would not appear to have any significant costs to consumers. During consultations, consumer groups noted that early notification of the likely timeframes for consultation would enable them to better plan resources to respond, therefore enabling more meaningful consultation. It was acknowledged that there are some types of applications (for example, involving minor amendments to Standards to fix typographical errors) that do not need to be subject to consultation.

Element (b) - This element has no impact on health and safety and would not appear to have any adverse impact on consumers. As is currently the case, Policy Guidelines will continue to be subject to public consultation.

In relation to co-ordinating applications and policy development, consumer groups have indicated that this provides a safeguard by ensuring that where the Council is developing

policy on an important issue the Authority has the capacity to delay consideration of an application on the matter.

In relation to the removal of the second review, this would not appear to have any adverse impact on consumers. The important role of the Council is retained, as are the existing safeguards which include the capacity for the Council to amend, reject or accept a proposed Standard or variation to a Standard.

Element (c) - This element has no impact on health and safety. In terms of consultation, there would be full public consultation on the health claims standard. However, there would not be public consultation on the data provided by an applicant to substantiate their compliance with the rules detailed in the standard as this assessment would be undertaken by the Authority with advice from an expert committee. Consumer safeguards will continue to exist including through Council oversight.

If this option has the desired effect of encouraging innovation (by providing a commercial advantage to innovators), this could lead to a greater range of health claims which have been demonstrated to provide a public health benefit as required by the Council Policy Guideline.

The Authority:
Element (a) - This element better enables the Authority to align resources with the complexity of applications and proposals. Valuable resources would not be unnecessarily consumed by simple applications.

Element (b) - This element is not expected to have any negative impact on the Authority. One possible benefit is that the Authority is not in the position of having to "pre-empt" advice from the Council or progress an application before policy guidelines have been issued (where such guidelines are needed and are in the process of being developed).

Element (c)- This may lead to an increase in applications for pre-market approval of high level claims.

Government:
Element (a) - This element has been endorsed by all governments through the Council as a means by which to sensibly and appropriately streamline the Authorities assessment processes to ensure that resources are appropriately directed based on the complexity of the individual application or proposal.

Element (b) - This option provides reassurance to Governments that, in circumstances where policy is being developed, there is an opportunity for the Authority to defer consideration of applications and proposals to align the assessment process with the policy process. The capacity for the Authority to defer for up to 18 months only, also provides a degree of discipline for governments in terms of timeframes for developing policy. Under this option, a review will still be able to be requested by one jurisdiction and therefore the influence and sovereignty of each jurisdiction is maintained.

Element (c) - All jurisdictions will be consulted on any applications for approval of a high level health claim and there will continue to be Council review of high level health claims. This provides an important safeguard and is likely to increase consumer

confidence in the process. In the case of health claims, the approach is consistent with the Council Policy Guideline on Health Claims and ensures that there is pre-market approval of high level claims by the Authority.

This option has been endorsed by all governments through the Council.

CONSULTATION

Consultation was undertaken as part of the FRSC review of the Food Standard assessment and approval processes and protection of confidential commercial information. This involved consultations with the Authority, other public health regulators and public consultations in Auckland and capital cities in all States and Territories of Australia except Northern Territory. Targeted consultations with industry and consumer groups were also held in Sydney and Wellington.

Following the Council consideration of the FRSC recommendations, further consultation has also been undertaken on the issues described in this RIS. This involved circulation of a Consultation Paper, a call for written submissions and face to face meetings with stakeholders in Sydney, Melbourne and Wellington in early 2006.

There has also been ongoing consultation between the Australian Government, State and Territory governments and the New Zealand Government.

Following approval from the Prime Minister, the exposure draft of the Bill was released to State and Territory, New Zealand and Australian government Agencies for final consultation on 20 December 2006.

RESULTS OF CONSULTATION

On the whole:

- the majority of stakeholders did not support retaining the status quo (Option 1). It was widely recognised that one of the key problems with the Food Standard assessment and approval process is the "one size fits all approach" and the fact that the Authority is unable to apply different assessment processes for different types of applications and proposals. The interaction between the Authority and the Council was seen as less than optimal and it was also widely recognised that the system has the potential to inhibit innovation;

- the majority of stakeholders supported element (a) of Option 2 and the proposed changes to the Food Standard assessment process such that there are different processes for different types of applications and proposals based on the level of complexity and public interest. Stakeholders noted that it is important to clearly define the types of applications and proposals that would fall in each category;

- the majority of stakeholders supported element (b) of Option 2 – While there was support for enabling the Authority to stop the clock while awaiting Council policy, it was noted that the circumstances in which this power should be exercised should be clear, that it should be acknowledged that Council policy is not necessary in relation

to all Standards and that there should be limits on the time during which assessment is stopped pending finalisation of Council policy;

- while some stakeholders questioned the need for the Council to consider all applications and proposals and also expressed concern that a review could be triggered by only one jurisdiction, it was generally considered that this is an important safeguard given the fact that changes to Standards have the force of law and are not subject to parliamentary scrutiny. In terms of the opportunities to request review, there was general support for the Council only having one opportunity to request review; and

- there were a range of views expressed in relation to element (c) of Option 2. While there was broad agreement on the "problem" (and the negative impacts to which the "free rider" effect can give rise), there was equally broad agreement that there would appear to be no easy option for addressing industry concerns. There also appeared to be agreement that any changes that were made to enable an applicant to capture an exclusive commercial benefit through a product specific approval would necessarily have negative impacts for others.

CONCLUSION AND RECOMMENDATIONS

The major disadvantage of Option 1 (status quo) is that it does not address the problems identified in this RIS.

Option 2 addresses the problems identified and is therefore the preferred option. Specifically:

- Element (a) ensures that the process employed by the Authority is commensurate with the nature and complexity of the application or proposal. The addition of a requirement for the Authority to issue a publicly available, early notification detailing the proposed timeframes for consultation on the application or proposal, will enable more meaningful consultation to occur.

- Element (b):

  - enables the Authority to stop the clock when the Council is in the process of developing policy guidance and is an important adjunct to the other changes. The capacity to stop the clock would only be available where the Council has identified an issue that requires policy guidance. In order to provide certainty for applicants there should be a limit on the time during which the clock may be stopped awaiting Council policy.

  - on the issue of a second review, it is noted that the original intention was to provide a further opportunity for the Authority to address issues of concern to Ministers before the Council is empowered to reject or amend. However, the fact that only four second reviews have been requested to date suggests that this additional step adds little value to the process. On balance, it would be preferable to streamline the process by measures that would impose greater discipline on the first review step and thereafter empower Ministers to finalise the process by accepting, amending, or rejecting the standard.

- Element (c):
  - provides an incentive to innovate for both small and large companies;
  - provides an opportunity for applicants who seek to capture the commercial benefit of a health claim; and
  - minimises adverse impacts and unnecessary costs that would be associated with any other options.

IMPLEMENTATION AND REVIEW

As requested by the Council, it is proposed that the effectiveness of any changes to the legislation will be monitored by the Australian Department of Health and Ageing and the Authority and regularly reported to the Council. More detailed reporting requirements will also be included in the Authority's Annual Report.

FURTHER DETAIL REGARDING FOOD STANDARD ASSESSMENT PROCESSES

Reforming the Food Standard assessment process (element (a) of Option 2) would involve the following:

- there would be clearly defined application requirements including the requirement to provide supporting material with applications;

- During the acceptance process each application would be allocated to one of three assessment procedures corresponding to the nature and scope of the proposed change to the Code;

- each procedure would require a corresponding level of public consultation. In general, the Authority would undertake one round of public consultation and the assessment process should be completed within a maximum of 9 months, this would apply unless:

    - 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), the Authority would not undertake public consultation, and the assessment should be completed through consultation with States and Territories within three months; or

    - the application or proposal relates to the development of a new Standard or a major revision to an existing Standard, the Authority would undertake two rounds of public consultation and the assessment would be completed within a maximum of 12 months (as is currently the case); and

- the public would be provided with early notification of the procedure that an application or proposal falls within and also the proposed nature, and timing, of consultation.

PROPOSED MINOR TECHNICAL AMENDMENTS

In addition to the more significant changes proposed in the body of this RIS, it is also proposed that a number of minor amendments be made to the Act. As these amendments are minor and technical in nature a RIS has not been prepared in relation to these issues.

They were however discussed during consultations with stakeholders and agreed by stakeholders.

1. 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 Authority may amend these non-legally binding parts of the Code without the need to follow statutory processes in the Act.

2. Amendments to enable the Australian Pesticides and Veterinary Medicines Authority (APVMA) to refer applications relating to Maximum Residue Limits (MRLs) to the Authority and for these to be dealt with in a streamlined manner.

3. Amendment to the functions of the Authority to explicitly enable the Authority to give information about the Food Standards Code. This currently occurs, and is implicit in the functions of the Authority, but it has been suggested that an amendment to the Authority's functions would provide greater clarity.

4. Amendment to section 68 (exemption from suit) to align the exemption of suit provision with the functions of the Authority.

5. Correction of minor typographical errors and cross references throughout the Act.

6. Minor amendments to enable the Authority to draft a Standard in a way that differs from that requested by the applicant. This enables the Authority to approve parts of a multi-faceted application rather than having to reject or approve the whole application.

    - An amendment to enable the Authority to develop guidelines detailing minimum application requirements for applications and to refuse applications that do not meet this minimum requirement.

    - Extension of the existing urgency power (that may be used only for the protection of public health and safety) to allow for unforseen negative impact on trade (provided that this is not inconsistent with any of the Authority's objectives in section 18).

On the advice of the Office of Parliamentary Counsel (OPC), the following changes are also being made:

- The inclusion of further definitions to assist readers.

- Re-organisation of the Act to make the structure more logical.

- Renumbering of the entire Act (using numbers only) to improve readability of the Act.

- Minor changes to reflect contemporary drafting practises and address minor legal issues.

- Changes to harmonise the process for handling applications and proposals.

- Other minor consequential changes in line with the reforms.

FOOD STANDARDS AUSTRALIA NEW ZEALAND AMENDMENT BILL 2007

NOTES ON CLAUSES

Clause 1 - Short title
This clause provides that the Bill may be cited as the *Food Standards Australia New Zealand Amendment Act 2007*.

Clause 2 - Commencement
Subclause 2(1) This clause provides that each provision of this Act specified in column 1 (list of provisions) of the table commences, or is taken to have commenced, in accordance with column 2 (commencement details).

Commencement information table
Clause 1 provides that sections 1 to 3 will commence on the day the Bill receives Royal Assent.

Schedule 1 of the Bill has five Parts. Parts 1 and 2 of Schedule 1 will commence on Proclamation, or no longer that 6 months after Royal Assent. They are immediately followed by items 64 to 67. This is immediately followed by items 68 to 70, which is immediately followed item 71. Schedule 1, Parts 4 and 5 will follow immediately after that.

The commencement of Schedule 1 of the Bill is staggered to facilitate the logical restructuring of the different Parts of the Act. In addition, the insertion of new sections through Parts 4 and 5 of Schedule 1 have required the renumbering of the entire Act. Parts 4 and 5 of Schedule 1 contain the most substantive changes, and repeal and replace Divisions 1-5 of Part 3 of the Act. They describe the new assessment process.

Schedule 2 of the Bill will commence on Proclamation, or no longer than 18 months after Royal Assent. Schedule 2 describes a new process for the assessment of high level health claims. The Food Standard under which such claims would be permitted has not yet been finalised. It is expected that 18 months will be sufficient time to enable the proper consideration and finalisation of the standard.

Schedule 3 of the Bill has two Parts. Part 1 of Schedule 3 will commence on the day the Agreement between the Government of Australia and the Government of New Zealand Establishing a System for the Development of Joint Food Standards (the Treaty) is amended. The amendment will need to reduce from two to one the number of occasions on which the Council may request the Authority to review a draft standard, or a draft variation of a standard. Consistent with Australia's obligations under the Treaty, this commencement ensures that the amendments set out in Schedule 3 do not take effect unless, and until, amendments to reflect this new process have been made to the Treaty. However, if no such amendment of the Treaty is made, the provision(s) do not commence at all.

While there is in-principle agreement to amend the Treaty in the manner required, no time limits have been placed on the period within which the Treaty is to be amended because of the extensive requirements of both Australia and New Zealand before such international treaties can be amended.

Part 2 of Schedule 3 commences immediately after Part 1. Part 2 of Schedule 3 will not commence unless Part 1 is implemented before Schedule 2. This part updates affected cross references only and the amendments will no longer be necessary if the amendments made by Schedule 2 have already been made.

Subclause 2(2) provides that Column 3 of the table can contain additional information that is not part of this Act.

Subclause 2(3) requires that the Minister must announce by notice in the Gazette the day on which the amended Treaty between Australia and New Zealand enters into force.

Clause 3 - Schedule(s)
This clause provides that each Act that is specified in a Schedule to this Bill is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item has effect according to its terms.

SCHEDULE 1 - NEW APPLICATION AND PROPOSAL PROCEDURES

PART 1 - AMENDMENTS CONSEQUENTIAL ON NEW APPLICATION AND PROPOSAL PROCEDURES

Food Standards Australia New Zealand Act 1991

Items 1 to 11
These items amend subsection 3(1) of the Act, which sets out the definitions for words used in the Act. The amendments delete terms that are no longer used in the Act and substitute or insert new definitions for terms such as 'general procedure', 'policy guidelines' and 'Maximum Residue Limits Standard'.

Item 13
This item amends the definition of 'standard' in subsection 3(1) of the Act to clarify that 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).

Items 14 to 16
These items make technical amendments to subsections 3B(1), (2) and (4) of the Act to reflect the legislative environment implemented by the *Legislative Instruments Act 2003*.

In the context of the Act, instruments issued by the Authority are generally legislative instruments. Instruments that are developed under a scheme that involves the Commonwealth and 'one or more States' and New Zealand are not subject to disallowance and sunsetting under the *Legislative Instruments Act 2003* (the LIA).

These amendments are technical only and will not affect the continuity of any existing instruments in force under the Act.

Item 17
This item inserts two new sections after section 3B of the Act – sections 3C and 3D.

Section 3C - How is public notice given?
This section establishes the procedures that must be followed by the Authority in order to satisfy the requirements under the Act to give public notice.

This section makes the public notice provision consistent in all circumstances in which public notice must be given, and replaces several repetitive provisions throughout the Act.

Section 3D - When is an exclusive capturable commercial benefit conferred on an applicant?
The definition of 'exclusive, capturable commercial benefit' is currently within section 66A of the Act. The purpose of this amendment is to move this definition to the front of the Act, alongside all other definitions. There is no change to the substance of the definition of exclusive capturable commercial benefit.

Item 18
This item inserts an additional paragraph into subsection 7(1) of the Act, which describes the functions of the Authority. The additional function allows the Authority to provide general information to a member of the public about the Australia New Zealand Food Standards Code.

This amendment formalises a function that is currently performed by the Authority, but not officially recognised in the Act. A member of the public includes industry, members of organisations, and any other person that requests information. The general information to be provided is not of a legal nature and will not include legal advice or interpretation of the Standards Code.

Item 19
This item requires that policy guidelines formulated by the Council be published on the Authority's internet site. Previously, the requirement was for the guidelines to be published on the internet with no specific reference to publication on the Authority's internet site. This clarification has been included throughout the Act.

This amendment to subsection 10(3) ensures that the guidelines are always available from the Authority's internet site, but also does not prevent the guidelines appearing on other internet sites such as that of the Department of Health and Ageing.

Items 20 and 22
These items make technical amendments to several sections and subsections of the Act to reflect the legislative environment implemented by the *Legislative Instruments Act 2003*. The amendments will make clear whether an instrument (such as a declaration) is a legislative instrument, ensuring that each instrument is treated accordingly.

In the context of the Act, instruments issued by the Authority are generally legislative instruments (but are not subject to disallowance or sun setting because of the bi-national nature of the scheme). Instruments issued by the Council are not legislative instruments. These amendments are technical only and will not affect the continuity of any existing instruments in force under the Act.

Item 21
This item amends section 11A of the Act by requiring the Authority to update its work plan at least every 3 months. The work plan is posted on the Authority's website and contains information about the applications and proposals that are under consideration by the Authority, and those that are awaiting consideration.

Item 23
This item repeals subsection 39(3) (Confidential commercial information) and replaces this subsection. During the course of developing the draft Bill, the Attorney-General's Department highlighted potential concerns regarding the operation of subsection 39(3), and noted that the provision should be amended to clarify the intent of the subsection in relation to the judicial power of State courts. The Bill replaces the subsection to do this, and to make it clear that the Authority must apply to the courts for an order to protect any confidential commercial information, if it is within the jurisdiction of the court to make such an order.

Items 24 to 28
These items make minor consequential changes to numbering and cross references only:

Item 24 - Paragraph 39(7)(a): This item omits the reference to paragraph 38(a) and substitutes reference to paragraph 137(a). The existing section 38 is moved to the end of Division 3 of Part 4, under Part 4 of this Schedule, and is numbered as section 137.

Item 25 - Paragraph 39(7)(b): This item omits reference to paragraph 38(b) and substitutes reference to paragraph 137(b).

Item 26 - Paragraph 39(7)(ba): This item omits reference to paragraph 38(ba) and substitutes reference to paragraph 137(c).

Item 27 - Paragraph 39(7)(c): This item omits reference to paragraph 38(c) and substitutes reference to paragraph 137(d).

Item 28 - Subsection 39(8): This item omits reference to section 38 and substitutes reference to section 137.

Items 29 to 31
These items make minor consequential changes to a number of provisions.

Item 29 - This item updates subsection 50(6), replacing 'the Internet' with 'the Authority's Internet site'.

Item 30 - This item replaces subsection 52B(3), and updates the list of sections under which the Chief Executive Officer is not authorised to act on behalf of the Authority.

Item 31 - This item repeals the existing heading of Division 3, Part 4 and replaces it with an expanded heading such that the new heading of Division 3 of Part 4 reads 'Division 3 – Staff, consultants and assistance from other agencies'.

Item 32
This item inserts section 137 within Division 3.

Section 137 - Arrangements with Commonwealth Departments etc.
This item retains section 38 of the Act but repositions it in the restructured Act. It details the agencies and departments, including executives and staff within such departments, with whom the Authority may make arrangements.

Item 33
This item repeals section 61 of the Act. The offence in relation to false or misleading information or evidence in the Act is an unnecessary duplication of Division 137 in the *Criminal Code Act 1995*.

Item 34
This item amends subsection 62(1) of the Act for clarity. It substitutes 'to assist the Authority in the consideration of an application' in place of 'in the course of a final assessment.' The only change is to adjust the language of the provisions to align with the new assessment processes.

Item 35
This item repeals subsection 63(1) of the Act and substitutes a new subsection, expanded to include new types of decisions by the Authority, against which an applicant may apply to the Administrative Appeals Tribunal.

As part of reforming assessment processes, where possible the new process for applications has been mirrored in the new processes for proposals.

Currently, section 63 of the Act provides that administrative appeals are available with respect to applications; however no opportunity for parties who may be affected by a proposal to request administrative appeals is provided.

Item 34 harmonises the process by conferring rights of review in circumstances which involve abandonment of proposals at an equivalent stage to that currently granted in the overall decision-making process for applications.

Items 36 to 38
These items amend section 66 of the Act that describes the circumstances in which fees may be charged. Essentially, the existing circumstances in which fees are charged are maintained, and the Regulation making powers have been clarified.

It is proposed that the *Food Standards Australia New Zealand Regulations 1994* (the Regulations) be amended to reflect these changes.

Item 39
This is a minor technical amendment to subsection 66C(1) of the Act which changes a cross-reference by replacing reference to 'subsection 12B(1)' with 'reference to subsection 24(2)'.

Item 40
This item repeals subsection 67(1) of the Act, which relates to the right of the Board of the Authority ('the Board') to delegate, and replaces it with an updated list of subsections to reflect the Act as amended.

Item 41
This item updates the exemption from suit provisions. It repeals subsection 68(1) of the Act and substitutes updated wording to reflect current Australian Government policy.

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

The Bill updates section 68 of the Act to allow the Authority to carry out all of its functions in good faith without the risk of legal action. The provision covers the Commonwealth, Board members and any person assisting the Authority in the performance of its functions, provided they are acting honestly and reasonably.

This amendment is consistent with the exemption from suit provisions applicable to other Australian regulatory agencies.

Item 42
This item repeals section 69 of the Act, which relates to the Annual Report of the Authority, and updates it to reflect the new division and section numbers within the Act as amended.

Consistent with reforms to the assessment processes, section 69 has been amended to include additional matters on which the Authority must report. The use of charts, diagrams and graphs should be employed to provide the relevant information. This will make the report more meaningful for the reader.

As requested by the Council, it is proposed that the effectiveness of any changes to the legislation will be monitored by the Department and the Authority, and regularly reported to the Council. These more detailed reporting requirements will assist with the monitoring of the standard development process.

PART 2 OF SCHEDULE 1 – ALIGNING CROSS REFERENCES TO PROVISIONS RENUMBERED BY PART 3 OF THIS SCHEDULE

Food Standards Australia New Zealand Act 1991

Items 43 to 63
This Part reorganises, changes cross references and renumbers certain provisions to make the structure of the Act more logical. The amendments in this Part have no substantive impact on the operation of the provisions.

PART 3 OF SCHEDULE 1 - RESTRUCTURING PART 2 AND RENUMBERING OTHER PARTS OF FOOD STANDARDS AUSTRALIA NEW ZEALAND ACT 1991

Item 64
This item repeals the heading of Part 2 of the Act and substitutes it with 'Part 2 - The Authority'.

Item 65
This item moves section 10A of the Act to the end of Part 2 and renumbers it as section 10B.

Item 66
This item moves section 11 of the Act to immediately after section 8 and renumbers it as section 8A.

Item 67
This item renumbers section 11A of the Act to section 10A.

Item 68
This item inserts, before section 6 of the Act a new Division heading 'Division 1 - Establishment, functions and powers of the Authority'.

Item 69
This item inserts after section 8A of the Act a new Division with the heading 'Division 2 - Food regulatory measures'.

Item 70
This item inserts after section 10A of the Act a new Division heading 'Division 3 - Forward planning'.

Item 71
This item renumbers sections of the Act and sets out a table that identifies the existing and new numbering. Sections 1 to 10B are renumbered to become sections 1 to 20 using roman numerals rather than the current alphanumeric combinations. Sections 39 to70 are renumbered to become sections 114 to 153. This creates a gap in numbering from sections 21 to 113 to insert the new Divisions 1 to 5 into Part 3 of the Act.

PART 4 OF SCHEDULE 1 - NEW APPLICATION AND PROPOSAL PROCEDURES

Agricultural and Veterinary Chemicals Code Act 1994

The purpose of the following amendments to the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code) is to enable the better coordination of assessments for maximum residue limits, and to provide for joint consultation by the Authority and the Australia Pesticides and Veterinary Medicines Authority (the APVMA).

Item 72 (Section 3 of the Code set out in the Schedule)
This item inserts a new definition into section 3 of the Agvet Code. The definition states that Maximum Residue Limits Standard means the Maximum Residue Limits Standard, made under the *Food Standards Australia New Zealand Act 1991*, as in force from time to time, or any standard in force in substitution for that standard. This term is used in the proposed amendments to the Agvet Code.

Item 73 (After section 13 of the Code set out in the Schedule)
This item inserts a new section 13A into the Agvet Code.

Section 13A - Notifying Food Standards Australia New Zealand
This section provides that if it is likely that an application for registration of a chemical product being considered by the APVMA would lead (if approved) to the chemical being used and being present in foods (as defined in the *Food Standards Australia New Zealand Act 1991*) at a level that is not already permitted under the Maximum Residue Limits Standard, the APVMA must notify the Authority of the application.

The notice must be in writing and set out the particulars of the product and its active constituents (excluding confidential commercial information) and any other matters that the APVMA thinks appropriate.

The notice must be given to the Authority at least 30 working days before notice of the application is published in the Gazette under section 13. That is, the APVMA must notify the Authority at least 30 working days before the APVMA intends to undertake consultation on the application. This is intended to enable the APVMA and the Authority to align their consultation processes and conduct one joint consultation.

Food Standards Australia New Zealand Act 1991

Part 3 of the Act currently sets out the procedures for amending food regulatory measures and developing new food regulatory measures. Part 4 of Schedule 1 replaces most of Part 3 of the Act with new Divisions that reflect the new assessment pathways.
These changes result from a review of the Food Standard's assessment and approval processes aimed at identifying potential barriers in the legislation that were unnecessarily delaying the assessment and approval process. The most notable finding was that virtually all applications and proposals were being assessed in exactly the same way, regardless of whether the application was for a major or minor amendment to a standard, or for a new standard altogether. These amendments will enable the Authority to assess different applications and proposals according to their scope. Different procedures will replace the current "one size fits all" model, resulting in a targeted assessment process that will improve efficiency and reduce average assessment times.

Item 74
This item repeals Divisions 1 to 5 of Part 3 of the Act, replacing them with new sections and Divisions.

DIVISION 1 - APPLICATIONS FOR THE DEVELOPMENT OR VARIATION OF FOOD REGULATORY MEASURES

This Division deals with applications for the development or variation of food regulatory measures brought by businesses and individual persons, as distinct from proposals initiated by the Authority (which will be covered in Division 2).

SUBDIVISION A - OVERVIEW

Section 21 - Steps in the consideration of an application
This subdivision inserts a simplified outline of the procedure for considering an application for the development or variation of a food regulatory measure.

Step 1	An application is made.
Step 2	The Authority decides whether to accept or reject the application. If the application is accepted, the Authority proceeds to step 3.
Step 3	The Authority notifies the applicant of acceptance.
Step 4	The Authority gives public notice of the application, indicating when the Authority proposes to undertake key steps in considering it.
Step 5	The Authority assesses the application. The Authority may, after assessing the application, either reject it or proceed to the next step. If the application is for a new food regulatory measure or a major variation of a food regulatory measure, the next step is step 6. In any other case, it is step 7.
Step 6	The Authority calls for public submissions.
Step 7	The Authority prepares a draft food regulatory measure or a draft variation of a food regulatory measure, as the case requires. If the Authority has called for submissions under step 6, the Authority must have regard to the submissions in doing so.
Step 8	If the application is for a minor variation, the Authority calls for submissions from the applicant and appropriate government agencies. In any other case, the Authority calls for public submissions.
Step9(a)	If the draft food regulatory measure is a draft standard or a draft variation of a standard, the Authority must decide whether to approve or reject it and prepare a report, having regard to any submissions made. If the draft is approved, the Authority notifies the Council and the public of the approval and proceeds to step 10.

Step 9(b) If the draft measure is a draft code of practice or draft variation of a code of practice, the Authority must revoke or vary any existing code of practice and give public notice of its decision. No further steps are taken in relation to measures of this kind.

Step 10 The standard or variation comes into effect after it has been considered by the Council and published.

Subdivision B - Applications
This subdivision deals with the specific provisions for applications.

Section 22 - Applications
Section 22 replaces section 12 of the Act, and describes who may apply for the development or variation of a standard. It provides that applications must be in writing, must identify the assessment procedure that the applicant believes is applicable, and must comply with any Application guidelines issued under section 23.

Section 23 - Application guidelines
Section 23 empowers the Authority to issue guidelines specifying application requirements.

It is proposed that after consulting with stakeholders, the Authority will publish a set of clear application requirements and a pro-forma checklist to allow applicants to confirm that they have met all of the requirements before submitting an application.

These amendments seek to address shortcomings in the current Act which provides little guidance about application requirements. Applications received by the Authority often do not contain sufficient information to enable them to be properly assessed. This has led to unnecessary delays while the Authority awaits further information from the applicant.

Subsection 23(4) provides that guidelines are not subject to disallowance or sunsetting. In the context of the Act, instruments issued by the Authority are generally legislative instruments. Instruments that are developed under a scheme that involves the Commonwealth and 'one or more States' and New Zealand are not subject to disallowance and sunsetting under the LIA.

Section 24 - Withdrawal of an application
Section 24 replaces sections 12A and 12B of the Act which deal with withdrawal of applications (12A) and refund of charges (12B). It is intended to streamline the current processes.

SUBDIVISION C - PROCEDURES FOR CONSIDERING APPLICATIONS

Section 25 - Which procedure is appropriate?
This section summarises the new procedures for assessment, each of which is set out in a separate subdivision. The Authority will channel applications it receives into the general procedure, contained in Subdivision D, unless it meets the criteria or description for:

- Subdivision E - minor variations; or
- Subdivision F - applications for new or major variations; or
- urgent applications under section 95.

Once Schedule 3 takes effect, the list of procedures will also include Subdivision G, the process for the assessment of high level health claims against the Nutrition, Health and Related Claims Standard. This procedure will come into existence upon Proclamation of Schedule 2, which will occur as soon as possible once the Nutrition, Health and Related Claims Standard has been finalised, but no later than 18 months after Royal Assent.

SUBDIVISION D - GENERAL PROCEDURE

Section 26 - Accepting an application
This section replaces sections 13 and 13A of the Act. It imposes a 15 business day time limit on the Authority to either accept the application and issue notice, or reject the application if it does not meet the criteria detailed in the section.

In determining whether to accept or reject an application, the Authority must have regard to:

- whether the application meets the requirements set out in section 22;
- whether it relates to a matter that may be developed as a food regulatory measure, or warrants a variation of such a measure;
- whether the application is so similar to a previous application or proposal that it ought to be rejected (although this does not apply to applications resubmitted after failing to meet section 22 requirements); and
- any other relevant matter.

The amendment provides more certainty for applicants by creating a legislated time limit to which the Authority should adhere. It also provides the opportunity for the Authority to ensure that the application is fully supported and can be progressed without delay.

Section 27 - Notice of acceptance
This section replaces part of section 13A of the Act, and requires the Authority to notify the applicant once an application has been accepted, and to advise of the procedure to be adopted.

It also retains the requirements in subsection 12(2)(c) of the Act around the charges to be paid where an application relates to an exclusive capturable commercial benefit, or where the applicant can elect to pay a charge in order to expedite the application.

If an applicant is required, or has elected, to make a payment, the payment or first instalment is required within 20 business days from the notice date. If a payment is required to be made (because the application relates to an exclusive capturable commercial benefit) and the payment is not received within the 20 business days, the Authority cannot proceed with the application and will have to reject it.

Section 28 - Public notice of the application
This section introduces a new step in the assessment process, requiring all applications to be the subject of a public notice. The section sets out the notice requirements and the timeframes for notification. The notice will outline the key steps in the process and will give an indicative time line for undertaking these steps. The key steps are described in Subdivision A – Overview.

This will improve transparency and allow interested parties to manage resources in relation to upcoming consultation.

Section 29 - Assessing the application
This section merges sections 13 and 15 of the Act, and sets out the matters the Authority must have regard to in assessing an application, including:

- the costs of a food regulatory measure versus the benefits;
- whether other measures would be more cost-effective;
- any relevant New Zealand standards; and
- any other relevant matters.

This section should be read in the context of section 10, which sets out the overarching objectives of the Authority in developing or varying food regulatory measures.

Section 30 - Preparing a draft variation
This section replaces section 15A of the Act. It provides that after assessing an application under section 29, the Authority must:

- prepare a draft food regulatory measure or a draft variation if it accepts an application; or
- reject the application.

This section also details the manner of notice that must be given in the case where the draft variation differs from that sought by the applicant. This section enables the Authority to draft a Standard in a way that differs from that requested by the applicant. For example the Authority could choose to only draft parts of a multi-faceted application, rather than having to reject or approve the whole application.

Section 31 - Calling for submissions
This section replaces section 16 and 17 of the Act, and requires the Authority to seek public submissions on any draft food regulatory measure or draft variation it prepares under section 30. The section stipulates what the notice must include.

Section 32 - Alternative steps to be followed
This section provides that where an application results in the development or variation of a standard, the steps in sections 33 and 34 (outlined below) must be followed. Alternative steps set out in section 35 apply where an application results in the development or variation of a code of practice.

This section retains the procedure in relation to a code of practice under existing section 17B of the Act.

Section 33 - Approving the draft standard or draft variation
This section sets out the steps for the Authority to approve, amend or reject a draft standard or variation. It details requirements that the Authority must follow (based on existing requirements), including giving consideration to any submissions received, and preparing a report and a Regulatory Impact Statement (where applicable).

This section replaces sections 18 and 19 of the Act, and introduces the requirement to prepare a report which is more comprehensive than the existing ‘notice’ requirements.

Section 34 - Notifying the Council
This section requires the Authority to notify both the Council and the public within 10 business days if it approves a draft standard or draft variation. It also sets out requirements for the form and content of these notifications.

Section 35 - Alternative to steps set out in sections 33 and 34 - approving the draft code of practice or draft variation
This section sets out the steps for the Authority to approve, amend or reject a draft code of practice or draft variation.

The section retains the steps in relation to a code of practice under existing section 17B of the Act.

SUBDIVISION E - MODIFICATION OF GENERAL PROCEDURE FOR MINOR VARIATIONS

Subdivision E sets out the process to be followed for minor variations to food regulatory measures. This is a new assessment procedure, introduced by this Bill. Minor variation applications undergo a simplified process. They omit a number of steps followed in the general procedure, and requirements for public consultation and the preparation of cost-benefit analysis do not have to be followed.

Section 36 - Application of Subdivision
This section describes the kinds of applications to which Subdivision E applies. Minor variations include variations to a food regulatory measure that, if made, would not directly or indirectly:
- impose, vary or remove an obligation on a person;
- create, vary or remove a right of any person; or
- otherwise alter the legal effect of the measure.

Examples of variations that would fall within this class would be variations to:
- correct a typographical error;
- update a reference to another document;
- change a cross-reference within a food regulatory measure; or
- omit provisions of a food regulatory measure that have ceased to have effect.

Section 37 - Adopt the general procedure with the modifications set out in this Subdivision
This section provides that the general procedure applies with the modifications outlined below to make the process simpler and faster.

Section 38 - Modification of steps set out in section 29
This section provides that a cost benefit analysis is not required as part of the assessment process. This is because the variations that are sufficiently minor to warrant use of this procedure should not impose any direct or indirect costs.

Section 39 - Modification of steps set out in section 30
This section omits the provision that allows for the case where the draft variation is different from that sought in the application.

Section 40 - Modification of steps set out in section 31
This section requires written notice of a draft modification or variation to be given to the applicant and appropriate government agencies. This replaces the public notice requirement that is followed under the general procedure.

Section 41 - Modification of steps set out in sections 32, 33, 34 and 35
This section states that sections 32, 33, 34 and 35 do not apply to minor variations. However, it provides for reporting and notification of approvals as appropriate for this modified process.

SUBDIVISION F - MODIFICATION OF GENERAL PROCEDURE FOR DEVELOPING NEW FOOD REGULATORY MEASURES AND MAJOR VARIATIONS

Subdivision F sets out the process for major variations or the development of a new standard. This is a new procedure of assessment introduced by the Bill. The main difference between this process and the general procedure is that there is an extra round of public consultation.

Section 42 - Application of Subdivision
This section describes the kinds of applications to which Subdivision F applies. It creates a separate assessment procedure covering applications for a new food regulatory measure, or for major variations to an existing food regulatory measure.

In particular, this Subdivision applies to applications for the development of a new food regulatory measure, and for the variation of a food regulatory measure that:

- involves such scientific or technical complexity that it is necessary to adopt the more comprehensive procedure; or
- involves such a significant change to the scope of a food regulatory measure that it is necessary to adopt this procedure.

Section 43 - Adopt the general procedure with the modifications set out in this Subdivision
This section provides that the Authority must adopt the general procedure in considering the application, with modifications set out below that reflect the nature of the major changes proposed under Subdivision F applications.

Section 44 - Additional steps after step set out in section 29
This section adds a round of public consultation to that required under the general procedure. After the Authority has assessed the application (but before accepting or rejecting it) public notice must be given of the application, and written submissions sought.

This additional opportunity for comment matches the process with the nature and scope of the applications in this Subdivision.

Section 45 - Matters to which the Authority must have regard in making a decision under section 30
This section provides that the Authority must have regard to any submissions received under section 44 before making a decision to reject the application, or accept the

application and prepare a draft standard. This does not, however, limit the matters to which the Authority must have regard in making a decision under section 30.

DIVISION 2 - PROPOSALS FOR THE DEVELOPMENT OR VARIATION OF FOOD REGULATORY MEASURES

This Division deals with proposals for the development or variation of food regulatory measures initiated by the Authority, as distinct from applications brought by businesses and individual persons that are covered in Division 1.

The processes are wherever possible the same, with modifications reflecting the fact that in the case of proposals there is no applicant. The Bill divides applications and proposals into different divisions for clarity.

SUBDIVISION A - OVERVIEW

Section 54 - Steps in the consideration of a proposal

This section contains a simplified outline of the procedure for considering a proposal for the development or variation of a food regulatory measure.

Step 1 A proposal is prepared.

Step 2 As the Authority prepares the proposal, there is no equivalent to step 2 of the applications procedure whereby the application is accepted or rejected.

Step 3 As the Authority prepares the proposal, there is no equivalent to step 3 of the applications procedure whereby the Authority notifies the applicant of acceptance.

Step 4 The Authority gives public notice of the proposal, indicating when the Authority proposes to undertake key steps in considering the proposal.

Step 5 The Authority assesses the proposal.

The Authority may, after assessing the proposal, either abandon it or proceed to the next step.

If the proposal is for a new food regulatory measure or a major variation of a food regulatory measure, the next step is step 6.

In any other case, the next step is step 7.

Step 6 The Authority calls for public submissions.

Step 7 The Authority prepares a draft food regulatory measure, or a draft variation of a food regulatory measure, as the case requires. If the Authority has called for submissions under step 6, the Authority must have regard to the submissions in doing so.

Step 8 If the proposal is for a minor variation, the Authority calls for submissions from the applicant and appropriate government agencies.

In any other case, the Authority calls for public submissions.

Step 9(a) If the draft food regulatory measure is a draft standard or a draft variation of a standard, the Authority must decide whether to approve or reject it and prepare a report, having regard to any submissions made.

If the draft is approved, the Authority notifies the Council and the public of the approval and proceeds to step 10.

Step 9(b) If the draft measure is a draft code of practice or draft variation of a code of practice, the Authority must revoke or vary any existing code of practice and give public notice of its decision. No further steps are taken in relation to measures of this kind.

Step 10 The standard or variation comes into effect after it has been considered by the Council and published.

SUBDIVISION B - PROPOSALS

Section 55 - Proposals

This section allows the Authority to initiate a written proposal for the development or variation of a food regulatory measure. This reflects the current approach of section 12AA.

Section 56 - Abandonment of proposals

This section allows the Authority to abandon a proposal at any time. The Authority must give notice if the proposal is abandoned after public notice has been given. This reflects the current approach.

SUBDIVISION C - PROCEDURES FOR CONSIDERING PROPOSALS

Section 57 - Which procedure is appropriate?

This section details the criteria by which a proposal will be channelled into a given assessment procedure by the Authority. As with applications, the general procedure, which is described in Subdivision D, is the default procedure for proposals. The possible alternative procedures are:

- the procedure for proposals for minor variations of a food regulatory measure - Subdivision E;
- the procedure for proposals for new or major variations of a food regulatory measure - Subdivision F;
- the procedure for proposals for a variation of the Maximum Residue Limits Standard - Subdivision H. This is the procedure adopted when the Australian Pesticides and Veterinary Medicines Authority (APVMA) refers a matter to the Authority for concurrent consideration along with the APVMA's consideration of the issue; and
- the procedure for urgent proposals under section 95.

Once Schedule 3 takes effect, the list of procedures will also include Subdivision G, the process for the assessment of high level health claims against the Nutrition, Health and Related Claims Standard. This procedure will come into existence on Proclamation of Schedule 2, which will occur once the Nutrition, Health and Related Claims Standard is finalised, but no later than 18 months after Royal Assent

SUBDIVISION D - GENERAL PROCEDURE

Section 58 - Public notice of a proposal

This section introduces a new step in the assessment process, requiring all proposals to be the subject of a public notice. The section sets out the notice requirements and the timeframes for notification. The notice will outline the key steps in the process and will give an indicative time line for undertaking these steps. The key steps of this Division are described in Subdivision A – Overview.

This early notification improves transparency, and allows interested parties to plan resources and prepare for upcoming consultation.

Section 59 - Assessing a proposal
This section affords the Authority an opportunity to consider the viability of a proposal, having regard to such matters as costs and benefits to the community, and relevant New Zealand standards, prior to preparing a draft food regulatory measure or draft variation.

Section 60 - Preparing a draft food regulatory measure or draft variation
This section requires the Authority to prepare a draft food regulatory measure or draft variation after assessing a proposal; or to abandon the proposal. It mirrors the requirements for applications.

Section 61 - Calling for submissions
This section requires the Authority to seek public submissions on any draft food regulatory measure or draft variation it prepares as a result of a proposal. It sets out the requirements of public notice.

Section 62 - Alternative steps to be followed
This section details the steps to be followed in the case where a proposal results in the development or variation of a standard; or alternatively, where an application results in the development or variation of a code of practice.

This section retains the procedure in relation to a code of practice under section 17B of the Act.

Section 63 - Approving the draft standard or draft variation
This section sets out the steps for the Authority to approve, amend or reject a draft standard or variation. It details the requirements the Authority must meet, including giving consideration to any submissions received, and preparing a report and a Regulatory Impact Statement.

Section 64 - Notifying the Council
This section requires the Authority to notify the Council and the public within 10 business days if it approves a draft standard or draft variation. It also sets out requirements for the form and content of these notifications.

Section 65 - Alternative to steps set out in sections 63 and 64 – approving the draft code of practice or draft variation
This section outlines the steps that must be followed after the submission period for a draft code of practice or draft variation. The section retains the procedure in relation to a code of practice under section 17B of the Act.

SUBDIVISION E - MODIFICATION OF GENERAL PROCEDURE FOR MINOR VARIATIONS
Subdivision E sets out the process to be followed for proposals relating to minor variations to food regulatory measures. This is a new procedure of assessment, introduced by this Bill. Proposals to make minor variations to food regulatory measures omit a number of steps followed in the general procedure, including requirements for public consultation and the preparation of cost-benefit analysis.

Section 66 - Application of Subdivision
This section describes the kinds of proposals to which Subdivision E applies. Minor variations include variations to a food regulatory measure that, if made, would not directly or indirectly:

- impose, vary or remove an obligation on a person;
- create, vary or remove a right of any person; or
- otherwise alter the legal effect of the measure.

Examples of variations that would fall within this class would be variations to:

- correct a typographical error;
- update a reference to another document;
- change a cross-reference within a food regulatory measure; or
- omit provisions of a food regulatory measure that have ceased to have effect.

Section 67 - Adopt the general procedure with the modifications set out in this Subdivision
This section provides that, in relation to minor variations, the Authority must adopt the general procedure with the modifications set out in the Subdivision, making the process more streamlined.

Section 68 - Modification of step set out in section 61
This section provides that the section 61 requirements do not apply, and therefore omits the public consultation and submissions steps. Instead, written notice must be given to the appropriate government agencies, inviting them to make submissions.

Section 69 - Modification of steps set out in sections 62, 63, 64 and 65
This section states that sections 62, 63, 64 and 65 do not apply to minor variations. However, it provides for reporting and notification of approvals consistent with the modified process undertaken in this procedure.

SUBDIVISION F - MODIFICATION OF GENERAL PROCEDURE FOR DEVELOPING NEW FOOD REGULATORY MEASURES AND MAJOR VARIATIONS
Subdivision F sets out the process for proposals for new regulatory measures or major variations. The main difference between this process and the general procedure is that there is an extra round of public consultation.

Section 70 - Application of Subdivision
This section describes the kinds of proposals to which Subdivision F applies. These proposals are for new food regulatory measures, or for major variations of food regulatory measures.

In particular, this Subdivision applies to proposals for the development of a new food regulatory measure, and to proposals for the variation of a food regulatory measure that:

- involve such scientific or technical complexity that it is necessary to adopt the more comprehensive procedure; or
- involve such a significant change to the scope of the food regulatory measure that it is necessary to adopt this procedure.

Section 71 - Adopt the general procedure with the modifications set out in this Subdivision
This section provides that the Authority must adopt the general procedure in considering the proposal, with modifications set out below that reflect the nature of the major changes proposed under proposals that fall into this Subdivision.

Section 72 - Additional step after step set out in section 59
This section adds a round of public consultation to that required under the general procedure. After the Authority has assessed the proposal (but before accepting or rejecting it) public notice must be given, and written submissions sought.

This additional opportunity for comment matches the process with the nature and scope of the proposals that fall into this Subdivision.

Section 73 - Matters to which Authority must have regard in making a decision under section 60
This section provides that the Authority must have regard to any submissions received before making a decision to reject the proposal, or accept the proposal and prepare a draft standard. This does not limit any other matter to which the Authority must have regard in making a decision under section 60.

SUBDIVISION H - VARIATIONS OF THE MAXIMUM RESIDUE LIMITS STANDARD

Section 80 - Application of Subdivision
This section provides that Subdivision H applies to applications for variations to the Maximum Residue Limits Standard that have been referred by the APVMA.

The process is that the APVMA notifies the Authority under section 13A of the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code) that the APVMA is considering an application to register a chemical product. Also, it is likely that the chemical product would, if used, be present in foods at a level that is not already permitted under the Maximum Residue Limits Standard.

Amendments to the Agvet Code (refer items 73 and 74) provide that the notification by APVMA must be made at least 30 working days before the APVMA proposes to consult on the application for registration of the chemical. This enables the Authority and the APVMA to undertake joint consultation on the issue.

Section 81 - Authority must prepare a proposal to vary the Maximum Residue Limits Standard and adopt the general procedure to consider it
This section provides that when the APVMA refers such a matter to the Authority for consideration, the Authority must prepare a proposal to vary the Maximum Residue Limits Standard to include or change a permitted maximum residue limit to cover the chemical product. The procedure to be adopted by the Authority is the general procedure, with the modifications set out in this Subdivision.

Section 82 - Section 58 notice to be given within 10 business days
This section provides that the Authority must give notice in compliance with section 58 (the initial public notice) within 10 business days after receiving the notice from the APVMA.

Section 83 - Authority to complete its consideration of the proposal within prescribed period

This section provides that the Authority must complete the general procedure within the prescribed period. Regulations made under the Act will detail the relevant period.

DIVISION 3 - COUNCIL MAY REQUEST A REVIEW OF APPROVED DRAFT STANDARD ETC.

Section 84 - Council may request a first review

This section retains the requirements and processes in Division 3 of the existing Act, but updates the language in line with the new processes.

In summary the section provides that:

- if the Council requests the Authority to review a draft standard or variation, the Council must inform the Authority of the Council's concerns with the draft;
- the Council may give to the Authority such directions as it thinks fit in relation to the conduct of a review;
- in exercising its powers to request a review, the Council must comply with its obligations under the Food Regulation Agreement and the Australia New Zealand Joint Food Standards Agreement;
- subject to any directions given, a review is to be conducted in such manner as the Authority considers appropriate;
- a review must be completed within 3 months after the request was made, or such longer period as allowed by the Council; and
- after completing a review the Authority must: reaffirm its approval; affirm but make such amendments as the Authority considers necessary; or withdraw its approval. In any case, the Authority must give the Council written notification of the decision, and the reasons for the decision.

Section 85 - Council may request a second review

This section replicates existing section 22 of the Act, but amends the language slightly to accord with the new assessment processes implemented through this Bill.

The section provides that the Council can request a second review. The requirements and processes mirror those for a first review.

This retains the current operation of the Act but, subject to amendments to the Food Regulation Agreement and the Australia New Zealand Joint Food Standards Agreement, this second review stage will be removed (refer Schedule 3, Part 1).

Section 86 - Council may amend or reject draft after second review

This section describes the procedure that the Council must adopt following the Authority's notification that it has reaffirmed a standard, or reaffirmed with amendment(s). The Council can inform the Authority that it does not intend to amend or reject the draft; or amend; or reject a draft standard or variation.

This section replicates existing section 23 of the Act but amends the language slightly in accord with the new assessment processes.

Subsection 86(4) provides that an instrument made under this subsection in not a legislative instrument. The decision described in the proposed subsection is made by the Ministerial Council whose powers are independent of Commonwealth legislation. This decision is not made in the exercise of a power delegated by the Parliament and is therefore not a legislative instrument in accordance with the definition of legislative instruments in section 5 of the LIA. The provision is declaratory and is included for the avoidance of doubt.

Section 87 - Publication of standard or variation

This section replicates existing Division 4 of the Act but amends the language slightly in accord with the new assessment processes. This section requires the Authority to comply with publication requirements as soon as practicable when informed by the Council that it does not intend to seek a review or amend or reject a draft standard or variation.

This section also provides that the standard or variation to a standard takes effect on the date as specified in the notice.

Subsection 87(8) provides that standards are legislative instruments, but are not subject to disallowance or sunsetting. In the context of the Act, instruments issued by the Authority are generally legislative instruments. Instruments that are developed under a scheme that involves the Commonwealth and 'one or more States' and New Zealand are not subject to disallowance and sunsetting under the LIA.

DIVISION 4 - URGENT APPLICATIONS AND PROPOSALS

The new Division 4 replaces existing Division 5 of the Act. It describes the process for consideration of urgent applications and proposals. It contains changes to align with the new assessment process and ensure that after an urgent application or proposal is considered, the Authority undertakes the full process in accordance with the general procedure.

The other notable change introduces the category of negative impact on trade that was not envisaged when the standard was made. This is now one of the grounds on which an application or proposal may be considered urgent. Currently, the urgency procedures are only triggered in response to an immediate threat to public health and safety.

The criteria relating to negative impact on trade that was not envisaged when the standard was made should not be used to gain permission to sell a new product, but are intended to protect products that are permitted under the food standard and due to improved technology of testing would have to be withdrawn.

SUBDIVISION A - URGENT CONSIDERATION OF APPLICATIONS AND PROPOSALS

Section 95 - Declaration of urgency

This section differs from existing section 24 of the Act (the section it replaces) by including a negative impact on trade that was not envisaged when the standard was made as one of the grounds on which an application or proposal may be considered urgent.

This is in addition to the well-established ground of 'protection of public health and safety'. Section 95 also prescribes the manner in which a declaration of urgency must be published and distributed.

The provision includes the proviso that the Authority should not make a declaration of this sort if it would be inconsistent with any of the Authority's objectives as listed in section 18(1).

Section 96 - Preparation of draft standard or variation

This section replaces existing section 25 of the Act. It provides that after considering an urgent application or proposal, the Authority must prepare a draft standard or variation, or reject the application or abandon the proposal. Where a draft standard or variation is prepared, public notice must be given and submissions invited (with a 10 business day maximum submission period).

There has been no change to existing policy regarding the processes for dealing with urgent applications – the only change is to adjust the language of the provisions to align with the new assessment processes.

Section 97 - Approval and publication of standard or variation

This section replaces existing section 26 and sets out the steps for the Authority to approve, amend or abandon a draft standard or variation. It provides that the Authority must consider any submissions received. The Authority must provide public notice of any draft standard or variation approved and publish notices in certain newspapers.

Subsection 97(6) provides that standards are legislative instruments, but are not subject to disallowance or sunsetting. In the context of the Act, instruments issued by the Authority are generally legislative instruments. Instruments that are developed under a scheme that involves the Commonwealth and 'one or more States' and New Zealand are not subject to disallowance and sunsetting under the LIA.

SUBDIVISION B - ASSESSING THE RESULTING STANDARD OR VARIATION

Subdivision B outlines the procedures that must be followed after the Authority's approval of an urgent draft standard or variation. Essentially, the Authority needs to complete an assessment under the general procedure within 12 months of the standard or variation taking effect.

These sections replace sections 27 to 28D of the Act. There has been no change to existing policy regarding the processes for dealing with urgent applications – the only change is to adjust the language of the provisions to align with the new assessment processes.

Section 98 - Application

This section provides that Subdivision B applies where the Authority approves a draft standard or variation as an urgent application or proposal.

Section 99 - Assessing the standard or variation

This section sets out matters to which the Authority must have regard in assessing the standard or variation.

Section 100 - Calling for submissions
This section requires the Authority to seek public submissions on the standard or variation, and sets out the process for doing this.

Section 101 - Re-affirm the standard or variation or propose changes
Within 12 months of the standard or variation taking effect, the Authority must reaffirm its approval for the standard or variation, or alternatively, prepare a proposal for the development of a variation or replacement standard. In making its decision, the Authority must have regard to submissions received.

It must notify the Council within 10 business day of making its decision and provide a report, the contents of which are outlined in the section.

Section 102 - Council may request Authority to review
Within 60 days of being notified that the Authority has decided to reaffirm its approval for a standard or variation, the Council must determine whether it will request a review or not. In exercising its powers under this section, the Council must comply with its obligations under the Food Regulation Agreement and the Australia New Zealand Joint Food Standards Agreement.

Section 103 - Review requested
This section provides that the Council must inform the Authority of its concerns where it requests a review of a standard or variation. Further, the Council may give directions to the Authority regarding the conduct of a review.

Subsection 103(3) provides that a direction under this subsection in not a legislative instrument. The decision described in the proposed subsection is made by the Ministerial Council whose powers are independent of Commonwealth legislation. This decision is not made in the exercise of a power delegated by the Parliament and is therefore not a legislative instrument in accordance with the definition of legislative instruments in section 5 of the LIA. The provision is declaratory and is included for the avoidance of doubt.

Section 104 - Authority to respond to request
This section describes the manner in which the Authority must respond to the review request. It imposes a time limit of 3 months on the Authority to conduct the review, unless the Council allows a longer period. After completing the review the Authority must either reaffirm its approval of the standard or variation, or prepare a proposal for the development of a variation or replacement standard. It must notify the Council of its decision and provide reasons.

Section 105 - Council may request second review
This section provides that if the Authority notifies the Council that the Authority reaffirmed its decision to approve the standard or variation, the Council must, within 60 days after the notification, request the Authority to review the standard or variation or inform the Authority that the Council does not intend to request the Authority to review the standard or variation. In exercising its powers under this section the Council must comply with the Food Regulation Agreement and the Australia New Zealand Joint Food Standards Agreement.

This retains the current operation of the Act but, subject to amendments to the Agreement between Australia and New Zealand, this second review stage will be removed (refer Schedule 3, Part 1).

Section 106 - Council may revoke or amend standard or variation
This section, just like section 28C of the Act, describes the procedure that the Council must adopt following the Authority's notification that it has reaffirmed a standard or variation following a second review. Council has 60 days after notification of the Authority's decision to revoke or amend the standard or variation, or alternatively to leave it in place.

There has been no change to existing policy regarding this provision – the only change is to adjust the language of the provisions to align with the new assessment processes.

Subsection 106(6) provides that Instruments of revocation are not subject to disallowance or sunsetting. In the context of the Act, instruments issued by the Authority are generally legislative instruments. Instruments that are developed under a scheme that involves the Commonwealth and 'one or more States' and New Zealand are not subject to disallowance and sunsetting under the LIA.

Item 75
This item replaces the heading of Division 6 of Part 3 of the Act with a new Division 5 heading.

DIVISION 5 - GENERAL RULES IN RELATION TO THE CONSIDERATION OF APPLICATIONS AND PROPOSALS

Item 76
This item repeals Division 6 of Part 3 (other than section 114) and substitutes reordered sections that are currently in Division 6 of the Act, adjusting the language of the provisions to align with the new assessment processes.

Section 107 - General conduct in considering an application or proposal
This section essentially replicates section 30 of the Act, and sets out the general conduct of the Authority in considering an application or proposal. The section gives the Authority discretion and flexibility in the manner it conducts assessments. For example, the Authority is not required to act in a formal manner, is not bound by the rules of evidence, may inform itself on any matter, and may consult with any person as it thinks fit.

The Act describes minimum essential steps the Authority must undertake in the assessment of an application or proposal. The Authority can at any time (within the boundaries described in the Act) undertake additional steps such as additional consultation or assessments.

Section 108 - Authority may require further information
This section essentially replicates the current section 34 of the Act, and sets out the process by which the Authority can obtain further information needed to assess an application, or determine whether a charge is payable by the applicant. Failure to comply

with a request for information without reasonable excuse results in the application being treated as withdrawn.

Section 109 - Period for within which consideration of applications for standards or variations must be complete

Section 109 replaces existing section 35 of the Act, and sets out the timeframes for assessment and the circumstances in which the clock may be stopped.

The maximum period for assessment of applications is 12 months, but Regulations may prescribe a shorter period.

It is proposed that the timeframes for application in each of the processes will be prescribed in the 'the Regulations' as follows:

- a maximum of 9 months for the general procedure;
- a maximum of 3 months for minor variations of a food regulatory measure; and
- a maximum of 9 months for certain variations to the Nutrition, Health and Related Claims Standard.

While in general there are no timeframes for assessment of proposals, a maximum time period will be included in relation to applications referred by the APVMA relating to Maximum Residue Limits (MRLs).

The Authority may extend the assessment period by 6 months (consistent with current practice) in relation to Subdivision E if it is not practicable for the decision to be made within the 12 month period.

The 'consideration period' begins when the Authority begins its assessment or when the applicant pays the relevant fee.

The stop-the-clock provisions that are retained from the Act allow the Authority to stop the clock in a number of circumstances including:

- if the Authority is awaiting further information from an applicant (consistent with current practice);
- while awaiting payment of a fee (consistent with current practice); and
- while an application is being considered by the Administrative Appeals Tribunal.

A new stop-the-clock provision has been added:

- if the Council has notified the Authority that it is developing a policy guideline and an application relates to the subject matter of the policy guideline. In this case, consideration of an application can be suspended by the Authority for up to 18 months. Applicants of paid applications will be given an option to proceed with the assessment process. The Authority will inform applicants about the role of the Ministerial Council in the standards development process and that approval (if granted) of any standard, or amendment to a standard, resulting from assessment of the application may need to be reviewed and could be rescinded or amended, if necessary, following any contrary policy decision by the Ministerial Council.

In the food regulation system, the Authority and Council play important and complementary roles. Allowing the Authority the flexibility to 'stop the clock' on an

assessment provides the structure needed within the standard-setting process to align it with the Council's policy development role.

This also ensures that the standard development process provides regulatory certainty to applicants when policy guidelines are being developed that may affect the outcome of an application. Setting the maximum 'stop the clock' time of 18 months ensures that the Council has enough time to develop a policy guideline, and will avoid the situation in which the Authority must progress an application, even though a new policy guideline may immediately force a review of the resulting standard.

Section 110 - Rejecting an application or abandoning a proposal
Where the Authority rejects an application for the development or variation of a food regulatory measure or a draft measure or variation (resulting from an application), it must provide notice of the rejection to the applicant with reasons. This section further details notice requirements, including public notice and fee refund requirements.

The Authority must give notice to the Council if it abandons a proposal. It must also notify the public where a proposal is abandoned after public notice has been given.

Section 111 - Public hearings
This section describes the discretion of the Authority to conduct a public hearing, and allows this to occur at any point during the consideration of an application or a proposal for a food regulatory measure. It essentially retains and replaces the current section 29 of the Act.

Subsection 111(4) provides that a direction under this subsection is not a legislative instrument. A direction by the Authority prohibiting or restricting the publication of evidence in the course of a public hearing is not legislative in nature and is therefore not a legislative instrument in accordance with the definition of legislative instruments in section 5 of LIA. The provision is declaratory and is included for the avoidance of doubt.

Section 112 - Authority may rely on work or processes of other government agencies
The Authority can rely on work undertaken by other government agencies in place of something it is otherwise required to do in order to avoid duplication of work or processes. The Authority must provide public notice where this occurs.

The section retains the current requirement by replacing the current section 36A of the Act, along with minor amendments to accommodate changes to assessment processes.

The Scrutiny of Bills Committee raised concern that subsection 112(6) involves a delegation of legislative power. Following consultation with FSANZ it appears that the provision has never been utilized and there are no existing regulations to this effect. This provision has therefore been removed from the Bill.

DIVISION 6 - OTHER MATTERS

Section 113 - Review of food regulatory measures
This section retains the current requirements under section 33 of the Act. It provides that the Authority can review a food regulatory measure on its own initiative, or by request.

The Authority must conduct a review if requested to do so by the Council. Such a review must be completed within 3 months (unless a longer period is allowed by the Council) and is subject to any directions from the Council.

The Authority may prepare a proposal for the development of a replacement food regulation measure as a result of a review.

PART 5 OF SCHEDULE 1 - APPLICATION AND TRANSITIONAL ISSUES RELATING TO PARTS 1 AND 4 OF THIS SCHEDULE

Item 77
This item prescribes a 3 month implementation period for amendments made by this Schedule.

Item 78
This item clarifies the transitional arrangements in relation to the Annual report requirements. Applications and proposals should be reported in the Annual report in line with the process that has been used to consider/assess them. As such the report will include separate sections that report on existing work under the current Act, and on new work under the amended Act.

SCHEDULE 2 - AMENDMENTS DEALING WITH HIGH LEVEL HEALTH CLAIMS

Food Standards Australia New Zealand Act 1991

This Schedule sets out the new process for the pre-market assessment of high level health claims that was developed in response to the identified need to encourage industry innovation in the area. The process for pre-market approval protects commercially valuable material during the assessment process, allowing applicants to capture the commercial benefit of their innovation.

Under the new process, each high level health claim will be assessed by the Authority with advice from an expert committee. The assessment will include a scientific, pre-market assessment against substantiation requirements set out in the Nutrition, Health and Related Claims Standard. States, Territories and New Zealand will also be consulted.

During consultation with stakeholders there was some concern expressed that the Bill describes a new process for the assessment of high level health claims, yet the standard under which such claims would be detailed has not yet been finalised. The Bill therefore provides that this Schedule (describing the provisions relating to the assessment of high level health claims) commences on Proclamation or no longer than 18 months after Royal Assent. This should be sufficient time to enable full consideration and finalisation of the Nutrition, Health and Related Claims Standard.

Item 1
This item inserts a definition for High Level Health Claims Committee in subsection 4(1) (the definitions section) of the Act. A High Level Health Claims Committee means a committee established under subsection 118(1A) to give advice on applications or proposals to make a high level health claims variation.

The Authority will consult on the general constitution (skills and knowledge) of the High Level Health Claims Committees. Membership of an Expert Committee (there may be several committees) may be specifically chosen to provide advice on specific applications or proposals.

Item 2
This item inserts a definition for ‘high level health claims variation’ in subsection 4(1) of the Act.

A ‘high level health claims variation’ has the meaning given by subsection 46(2), which is essentially a change to the list of high level health claims, as defined for the purposes of the Nutrition, Health and Related Claims Standard.

Item 3
This item provides that the Nutrition, Health and Related Claims Standard means the Nutrition, Health and Related Claims Standard as in force from time to time, or any standard in force in substitution for that standard. The item inserts this definition in subsection 4(1) of the Act.

Items 4 and 5
These items amend subsections 24(1) of the Act (which relates to withdrawal of applications) and 24(3) to cross reference the addition of the new section 47(1)(a) (which relates to accepting applications for variations to the list of high level health claims) and section 51 (which relates to calling for submissions on high level health claims).

Items 6 to 8
These items insert into section 25 of the Act the new assessment procedure for high level health claims (section 25 describes which procedure should be adopted by the Authority). It also specifies that where an application for a high level health claims variation is included in an application for a variation of another kind, the applications will be treated separately.

This is in order to enable the high level health claim to be considered in accordance with the procedure specifically designed for high level health claims, and the rest of the changes to be dealt with in accordance with whichever other procedure is appropriate depending on whether the variation sought is minor, major or able to be dealt with in accordance with the general procedure.

Item 9
This item inserts a new Subdivision at the end of Division 1 of Part 3 of the Act.

SUBDIVISION G – PROCEDURE FOR CERTAIN VARIATIONS OF THE NUTRITION, HEALTH AND RELATED CLAIMS STANDARD

Section 46 - Application of Subdivision
This section provides that Subdivision G applies to applications to variations to the list of high level health claims that may be made under the Nutrition, Health and Related Claims Standard.

Any other change to the standard cannot utilise this process, and must be considered in accordance with the relevant procedures based on the scope of the change proposed (general, minor or major).

Section 47 - Accepting the application
This section provides that the Authority must accept or reject the application within 15 business days after the application is given to it, having regard to: compliance with section 22(2); any substantially similar application or proposal for a high level health claims variation; and any other matter.

Section 48 - Notice of acceptance
This section requires the Authority to notify the applicant once an application has been accepted. It also sets out requirements around the charges to be paid.

It also retains the requirements in subsection 12(2)(c) of the Act around the charges to be paid where an application relates to an exclusive capturable commercial benefit, or where the applicant can elect to pay a charge in order to expedite the application.

Section 49 - Notice of the application to expert committee and Food Regulation Standing Committee
This section details the manner in which a notice must be given to the High Level Health Claims Committee and the Food Regulation Standing Committee, once the Authority has accepted an application.

If an applicant is required, or has elected, to make a payment, the payment or first instalment is required within 20 business days from the notice date. If a payment is required to be made (because the application relates to an exclusive capturable commercial benefit) and the payment is not received within the 20 business days, the Authority cannot proceed with the application and will have to reject it.

Section 50 - Considering the application
This section details the considerations that the Authority must take into account before approving a draft variation to the list of high level health claims. The Authority must be satisfied about:

- the protection of health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices;
- the prevention of misleading conduct; and
- the set of criteria set out in the Nutrition, Health and Related Claims Standard in to relation to high level health claims.

It must also take account of recommendations by the High Level Health Claims Committee, any submission received from the Food Regulation Standing Committee and any public submissions (if the applicant elects to activate the public process set out in section 51).

This section also requires the Authority to notify the applicant in writing if the draft variation differs from that envisaged in the application.

Section 51 - Calling for submissions
This section allows the applicant to elect whether the Authority should give public notice of the application and call for submissions. It sets out the process for this public consultation to occur.

Section 52 - Approving the draft variation in relation to high level health claims
This section provides that the Authority must approve or reject a draft variation to the list of high level health claims, and prepare a report, the contents of which are specified in this section.

Section 53 - Notifying the Council
This section requires the Authority to notify the Council (and the public, if public submissions were called for) within 10 business days if it approves a draft variation. It also sets out requirements for the form and content of these notifications.

Item 10
This item amends subsection 56(2) (which deals with the abandonment of proposals) by inserting a cross-reference to section 77, which is the section relating to calling for submissions on proposals dealing with high level health claims. The effect of the amendment is that if the Authority abandons a proposal relating to a high level health claim, after public notice has been given under section 58, then the Authority must give another public notice advising that the Authority has abandoned the proposal.

Item 11
This item amends section 57(b) of the Act by adding an additional possible assessment procedure for proposals to which Subdivision G applies (proposals for a high level health claims variation).

Item 12
This item inserts a new Subdivision after Subdivision F of Division 2 of Part 3 of the Act.

SUBDIVISION G - PROCEDURE FOR CERTAIN VARIATIONS OF THE NUTRITION, HEALTH AND RELATED CLAIMS STANDARD

Subdivision G sets out the new process for proposals (as opposed to applications) in relation to high level health claims. It largely mirrors the process for dealing with applications to vary the list of high level health claims set out in Subdivision G of Division 1. However, proposals raised by the Authority require consultation with the public.

Section 74 - Application of Subdivision
This section provides that Subdivision G applies to proposals to vary the list of high level health claims that may be made under the Nutrition, Health and Related Claims Standard.

Section 75 - Notice of the proposal
This section requires the Authority to notify the public, the High Level Health Claims Committee, and the Food Regulation Standing Committee of a proposal. Notice must include a summary of the proposal, the procedure, and the timeline to be followed by the authority in considering the proposal.

Section 76 - Considering the proposal
This section details the considerations that the Authority must take into account before approving a draft variation to the list of high level health claims. The Authority must be satisfied about:

- the protection of health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices;
- the prevention of misleading conduct; and
- the set of criteria set out in the Nutrition, Health and Related Claims Standard in relation to high level health claims.

The Authority must also take account of recommendations by the High Level Health Claims Committee, any submissions received from members of the Food Regulation Standing Committee, and any public submissions.

Section 77 - Calling for submissions
Before approving a variation to the list of high level health claims, this section requires the Authority to notify the public and the Food Regulation Standing Committee, and call for written submissions. This section also sets out the content of the notice.

Section 78 - Approving the draft variation in relation to high level health claims
This section provides that the Authority must approve or abandon a proposal for a draft variation to the list of high level health claims and prepare a report.

Section 79 - Notifying the Council
This section requires the Authority to notify the Council and give public notice within 10 business days if it approves a draft variation. It also sets out requirements for the form and content of these notifications.

Items 13 to 21
These items make consequential changes to sections throughout the Act to cross-reference the new procedure for the consideration of high level health claims when the procedure comes into effect on Proclamation (which is expected to occur once the Nutrition, Health and Related Claims Standard is finalised) but no later than 18 months after Royal Assent.

For example, the changes ensure that the provisions relating to the period within which an application must be completed and the process for rejecting an application, also apply to applications for variations to the list of high level health claims.

Items 22 and 23
This provision provides that the Board may establish such committees as it thinks fit to give advice on high level health claims. However if the Authority considers a high level health claims application or proposal, a committee needs to be established. It is not optional.

Items 24 to 32
These items make consequential changes to sections throughout the Act to cross-reference the new procedure for the consideration of high level health claims when the procedure comes into effect on Proclamation (which is expected to occur once the Nutrition, Health and Related Claims Standard comes into force).

SCHEDULE 3 - AMENDMENTS DEALING WITH COUNCIL REVIEW OF APPROVED DRAFT STANDARDS

PART 1 - AMENDMENTS

Food Standards Australia New Zealand Act 1991

The major effect of this Part is to repeal Division 3 of Part 3 of the Act and replace it with a new Division 3. This Part of the Schedule describes amendments to the Act to expedite the process for finalising a standard by removing the capacity for the Council to be able to request the Authority to undertake a second review.

Consistent with Australia's obligations under the Australia New Zealand Joint Food Standards Agreement with New Zealand, this Schedule does not take effect unless, and until, amendments to reflect this new process have been made to the Agreement with New Zealand.

Items 1 to 4
These items update the notes in the Act in relation to these amendments.

Item 5
This item replaces Division 3 of Part 3 of the Act, and describes the provisions allowing the Council to request a review of a draft standard or variation approved by the Authority. The Council will still be able to request that the Authority undertake a review of its decision as in section 21 in the Act; however the existing opportunity to request a second review will be eliminated.

Following a first review, the Council will precede to the last stage of the process, requiring it to accept, amend or reject the draft standard, retaining requirements under section 23 in the Act.

DIVISION 3 - COUNCIL REVIEW OF DRAFT STANDARDS AND DRAFT VARIATIONS OF STANDARDS

Section 84 - Council may request a review
This section provides that the Council may request a review of a draft standard or variation within 60 days of notification by the Authority. In exercising its powers, the Council must comply with the Food Regulation Agreement and the Australia New Zealand Joint Food Standards Agreement.

Section 85 - Review not requested
This section provides that where the Council does not request a review of a draft standard or variation, the Authority must comply with publication requirements as soon as practicable. The publication requirements are detailed in section 92.

Section 86 - Review requested
This section provides that the Council must inform the Authority of its concerns where it requests a review of a draft standard or variation. Further, the Council may give directions to the Authority regarding the conduct of a review.

Section 87 - Authority to respond to request
This section describes the manner in which the Authority must respond to the review request. It imposes a time limit of 3 months on the Authority to conduct the review, unless the Council allows a longer period. Subsection (2) provides that after completing the review, the Authority must either reaffirm its approval of the draft; reaffirm its approval subject to amendments; or withdraw its approval of the draft. It must notify the Council of its decision, and provide reasons.

Section 88 - Council may amend or reject draft after review
This section describes the procedure that the Council must adopt following the Authority's notification that it has reaffirmed a standard, or reaffirmed with amendment(s). The process for the Council to accept, amend or reject the draft is the same as in section 23 in the Act.

The decision described in the proposed subsection 88(2) is made by the Ministerial Council whose powers are independent of Commonwealth legislation. The decision is not made in the exercise of a power delegated by the Parliament and is therefore not a legislative instrument in accordance with the definition of legislative instruments in section 5 of LIA. The provision is declaratory and is included for the avoidance of doubt.

Section 89 - Council does not intend to amend or reject the draft
This section requires the Authority to comply with publication requirements as soon as practicable when informed by the Council that it does not intend to amend or reject a draft standard or variation. This section retains the publication requirements of section 23A in the Act.

Section 90 - Council amends the draft
This section describes the procedure that the Council must use to amend drafts (retaining the requirements of section 23 of the Act).

Section 91 - Council rejects the draft
This section retains the publication requirements of existing section 23A of the Act, and describes the procedure to be followed in the case that the Council decides to reject the draft.

Section 92 - Publication requirements
This section retains the publication requirements of section 23A in the Act.

Section 93 - When a standard or variation takes effect
This section states that the standard or variation to a standard takes effect on the date specified in the notice given under section 92.

Section 94 – Standards are legislative instruments, but not subject to disallowance or sunsetting

Subsection 94 provides that a standard, or a variation of a standard are legislative instruments, but are not subject to disallowance or sunsetting.

In the context of the Act, instruments issued by the Authority are generally legislative instruments. Instruments that are developed under a scheme that involves the Commonwealth and 'one or more States' and New Zealand are not subject to disallowance and sunsetting under the LIA.

Items 6 to 9
These items make consequential changes to sections 105, 106, 129, and 150 of the Act to reflect the inclusion in the Act of the revised Council processes for accepting, rejecting or amending a standard.

PART 2 - FURTHER AMENDMENT OF SECTION 84

Item 10
This Part updates cross references in section 84(1). Part 2 of Schedule 3 only commences if Part 1 of Schedule 3 is implemented before Schedule 2.