EXPLANATORY STATEMENT

PROPOSAL P305

PERMISSION FOR EXCLUSIVITY OF USE OF NOVEL FOODS

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to http://www.foodstandards.gov.au/standardsdevelopment/

Executive Summary

Food Standards Australia New Zealand (FSANZ) prepared Proposal P305 – Permission for Exclusivity of Use of Novel Foods, having regard to requests from the Food Regulation Standing Committee (FRSC) and the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council). FSANZ was requested to consider the capacity for including a specific provision for exclusivity of use for novel foods in Standard 1.5.1 – Novel Foods of the *Australia New Zealand Food Standards Code* (the Code). FSANZ was also requested to consider that an exclusive permission, if granted, should be limited to a period of 15 months, after which any exclusive approvals revert to generic approvals within the Novel Foods Standard.

Novel foods and novel food ingredients are currently regulated by Standard 1.5.1. Standard 1.5.1 prohibits the sale of novel foods unless listed in the Table to clause 2 in compliance with any special conditions of use in the Table. This means that for any food or food ingredient considered to be novel, an application must be made to FSANZ to amend the Table to clause 2 in the Standard to include the novel food or novel food ingredient before it can be sold in Australia and New Zealand. This Standard does not currently have a specific provision for considering exclusive permissions for novel foods.

Concerns around the current novel food application process have been expressed by industry, particularly in relation to data protection and the potential for competitors to take advantage of FSANZ's transparent processes. That is, a competitor is able to access the information relevant to the application and undertake product development to coincide with the gazettal of an approved novel food, thus removing the benefit for the applicant. Standard 1.5.1 currently provides for novel food permissions to have general application.

The intention of amending the Standard to include specific provision for exclusive permissions would be to make clear that an applicant requesting approval of a novel food is able to apply for a variation to the Standard for a specific brand and class of food. The applicant would need to specify the brand and class of food for which they are seeking exclusivity.

An approval for exclusive permission, if approved, would result in an amendment to Standard 1.5.1 to provide exclusivity for the specified brand and class of food for a period of 15 months and would then revert to a general approval for that specific class of food.

Proposal P305 is being progressed in parallel to Proposal P291 – Review of Novel Food Standard. FSANZ considered that introducing the concept of a specific provision relating to exclusivity of use of novel foods at this late stage in the progress of the Review of Novel Foods may unnecessarily delay the progress of Proposal P291.

The only regulatory options identified were whether or not to amend the Standard, to include the facility for exclusive permissions for the brand and class of food combination for a novel food. An exclusive permission for novel foods provides a clear benefit to industry wanting to capture the commercial benefit of an innovative novel food and promote innovation in the food industry. There was strong support for this option by the majority of submitters to the Initial/Draft Assessment.

Two submitters did not support the inclusion of a specific provision for exclusive permission for novel foods in the Standard. These submitters raised the following issues:

- effect of exclusive permissions on competition in the market for both domestic and international competitors;
- exclusive permissions would limit consumer choices of products containing the novel food ingredient; and
- increased prices of novel food products with exclusive permissions.

In addition, submitters who were in favour of exclusive permissions for novel foods also raised a number of issues, including the following:

- clarification of the process for dealing with similar applications seeking exclusivity and for similar applications requesting exclusive versus general permissions;
- protection of confidential commercial information; and
- the period of exclusivity.

FSANZ has had regard to the above issues, and to a number of other issues raised by submitters in preparing this Report. The issues raised in submissions are addressed in Section 4 of this Report. On balance, the preferred option is to include a specific provision for exclusive permissions to be granted for a specific brand and class of food for a period of 15 months, after which the exclusive permission would revert to a general permission in the Standard.

Purpose

The purpose of this Proposal is to consider the capacity for including a provision for exclusivity of use for novel foods in Standard 1.5.1 – Novel Foods.

Decision

Standard 1.5.1 – Novel Foods be amended to include a specific provision for exclusive permissions to be granted for a specific brand and class of food for a period of 15 months, after which the exclusive permission would revert to a general permission in the Standard.

Reasons for Decision

- This provides a clear mechanism in the Code for the implementation of the capacity for exclusive permissions for novel food products and places a 15-month time limit on exclusive permissions.

- This provides an incentive to industry for innovation and provides a benefit to an applicant that has expended significant resources into the development of a potential novel food.

- It is one of the measures presented in a report to the Ministerial Council in October 2005 in response to the Review of FSANZ assessment and approval processes and treatment of confidential commercial information, and agreed to by Ministers.

Consultation

FSANZ decided, pursuant to section 36 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) to omit to invite public submissions in relation to the Proposal prior to making a Draft Assessment. FSANZ released the Initial/Draft Assessment Report for public consultation in July 2007 and has had regard to submissions received in preparation of the Final Assessment.

The Initial/Draft Assessment Report was advertised for public comment from 13 July 2007 to 10 August 2007. Sixteen submissions were received, 13 from Australia and three from New Zealand. The majority of submissions received were from the industry sector (10), followed by government (5) and an individual (1).

The issues raised in submissions have been addressed in section 4 this Report. A summary of submissions, including a list of submitters, is at Attachment 3.

CONTENTS

INTRODUCTION

1. Background

The Food Regulation Standing Committee (FRSC) has recommended that Food Standards Australia New Zealand (FSANZ) consider the capacity for including a specific provision for exclusivity of use for novel foods in Standard 1.5.1 – Novel Foods of the *Australia New Zealand Food Standards Code* (the Code). The Ministerial Council has subsequently requested that FSANZ consider an amendment to the Standard that would limit the period of exclusive approval as a novel food for a particular brand for a period of 15 months and ensure that any exclusive approvals revert to a generic permission at the expiration of the approved period of exclusivity. FSANZ has prepared Proposal P305 – Permission for Exclusivity of Use of Novel Foods in response to these requests.

In 2004, FRSC established a Working Group to advise on reducing delays in FSANZ's assessment and approval processes and enhancing the protection of confidential commercial information. FRSC presented its report to the Ministerial Council for consideration at its meeting in October 2005. Ministers agreed to measures in relation to novel foods, and suggested that amendments to the FSANZ Act may be required to protect commercially valuable information.

It was initially considered that the FSANZ Act required amending to allow the capacity to include a specific provision for exclusive use of novel foods in the Code. However, it is the view of FSANZ that legislative amendments were not required. FSANZ relies on sections 16(1) and (2) of the FSANZ Act [formerly sections 9(1) and (2)] to progress this Proposal to amend the Code.

1.1 Current Standard

Novel foods and novel food ingredients are currently regulated by Standard 1.5.1. The Standard prohibits the sale of novel foods unless they are listed in the Table to clause 2 and comply with any special conditions of use in the Table. This means that for any food or food ingredient considered to be novel, an application must be made to FSANZ to amend the Table to clause 2 to include the novel food or novel food ingredient before it can be sold in Australia and New Zealand. FSANZ assesses the safety for human consumption of each novel food for which an Application is made prior to its inclusion in the Table. The safety assessment is performed in accordance with FSANZ's safety assessment guidelines.

A number of novel foods have been assessed and approved in accordance with Standard 1.5.1 and permission, with any conditions of use, are provided in the Table to clause 2.

1.2 Review of the Novel Foods Standard

FSANZ received policy guidance on novel foods from the Ministerial Council in December 2003. This Ministerial Policy Guideline recommends that FSANZ review the Standard while giving consideration to the higher order principles and specific principles of that policy guideline.

FSANZ prepared Proposal P291 having regard to this policy guideline, and also established a Standards Development Advisory Committee (SDAC) to assist in the review.

Proposal P291 is at the Final Assessment stage and has already been released for two periods of public consultation. Proposal P291 has centred on improving the definitions of 'non-traditional food' and 'novel food' in the Standard, in addition to examining the process for determining whether a food is novel or not.

Proposal P305 has been progressed in parallel to Proposal P291. FSANZ considered that introducing the concept of a specific provision relating to exclusivity of use of novel foods at this late stage in the progress of Proposal P291 may unnecessarily delay its progress. Therefore, Proposal P305 was prepared in order for FSANZ to consider the capacity for including a specific provision for exclusivity of use for novel foods in the Standard.

2. The Issue / Problem

2.1 Exclusive permissions for novel foods

One of the specific principles of the Ministerial Policy Guideline on novel foods is as follows:

> *To provide an assessment process that aims to protect commercially sensitive information and recognise industry's intellectual property to the maximum extent possible.*

Discussions about this specific principle led to consideration by the FRSC working group on the review of FSANZ's assessment and approval processes and treatment of commercial information. This subsequently resulted in requests from FRSC and the Ministerial Council that FSANZ consider the capacity to include a provision for exclusivity of use for novel foods for a period of 15 months in Standard 1.5.1, after which an exclusive permission would revert to a generic permission.

The impact of such an amendment would be to provide clarity that an applicant for a novel food is able to apply for a variation to the Standard for a specific brand and class of food. The specific brand may be applied to the class of food as a whole or to a particular product(s) within the class of food. The applicant would need to clearly state the brand and class of food, they are seeking exclusivity for.

When an approval for exclusive permissions is sought, and if approved, Standard 1.5.1 would need to be amended to provide exclusivity for the brand and class of food requested for 15 months and then revert to a generic approval for that specific class of food. An applicant seeking exclusive permissions would be required to advise FSANZ at the time of submitting the application that exclusivity is being sought.

Applicants would still be able to seek generic approvals for novel foods and such applications can be paid (in order to expedite the process) or unpaid (and placed on the FSANZ Work Plan) as is currently the case.

Standard 1.5.1 does not currently have a specific provision for exclusive permissions for approved novel foods. FSANZ has prepared Proposal P305, having regard to the recommendations of the Ministerial Council and FRSC, to investigate the capacity for including a specific provision for exclusivity of use for novel foods in the Standard.

3. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives (in descending priority order), which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

For the purposes of this Proposal, FSANZ also had regard to the intention of protecting commercially sensitive information to the maximum extent possible as addressed in a specific principle of the Ministerial Policy Guideline for novel foods.

KEY ISSUES

At Initial/Draft Assessment, FSANZ outlined the capacity for exclusive permissions for novel foods to be incorporated into the Standard. FSANZ has recognised a number of key issues, both in response to public submissions to the Initial/Draft Assessment Report and in preparation of the Final Assessment report. These key issues are discussed below:

4.1 Process for considering applications for exclusivity

4.1.1 Multiple applications for exclusivity of the same novel food and class of food

The Impact Analysis section of the Initial/Draft Assessment report indicated the provision for exclusive permissions in Standard 1.5.1 would not prohibit other companies making an application to FSANZ for approval of an exclusive permission of their brand of the same food. Public submissions to the Initial/Draft Assessment sought clarification on whether this inferred that multiple applications could be submitted for approval of exclusive permissions for the same novel food ingredient in the same class of food, with the brand being the only differentiating feature. It is possible that this situation could occur.

However, the following example may arise if similar applications for approval of exclusive permissions were submitted to FSANZ.

	Applicant A	**Applicant B**
Application received by FSANZ	1 March 2008	1 August 2008
Gazettal of exclusive permission	1 February 2009	1 July 2009
Period of exclusivity expires	1 May 2010	1 October 2010
Reverts to general permission	1 May 2010	1 May 2010
Effective period of Exclusivity	**15 months**	**10 months**

In the example in the table above, Applicant A and Applicant B have both submitted applications requesting the approval of an exclusive permission for the same novel food in the same class of food. Applicant B submitted an application five months after Applicant A. If both applications are approved and exclusive permission is granted for the same novel food in the same class of food for each applicant, there is an overlap in that the period of exclusivity for Applicant B would actually be less than 15 months.

The exclusive permission for Applicant A reverts to a general permission five months before the exclusive permission for Applicant B is scheduled to expire. Therefore, despite Applicant B having an approved exclusive permission, they will not realise the benefits of the entire 15-month period of exclusivity provided for in the approval of the application. Given the potential for a reduced period of exclusivity, it would be up to industry in the market place to assess the costs and benefits of submitting an application for approval of an exclusive permission that is similar to a previous application submitted by a competitor.

4.1.2 Safety assessment of novel foods

FSANZ must have regard to the need for standards to be based on risk analysis using the best available scientific evidence in reviewing variations to food regulatory measures[1]. All applications for approval of a novel food are required to undergo a pre-market safety assessment in accordance with FSANZ's risk analysis framework. Due to an exclusive permission reverting to a general permission for a novel food in a particular class of food, an application requesting exclusive permission for a novel food will be required to undergo a safety assessment of the novel food in the context of the particular class of food (not just the brand) for which exclusivity is sought.

The identity of the applicant, or the brand that would be associated with the exclusive permission, is not associated with the content of the safety assessment of the applications. The purpose of the brand reference is to identify the holder of the permission and identify the actual product to which the exclusive permission applied. The brand associated with the exclusive permission is merely an identifying feature for inclusion in the variation to the standard and to assist with enforcement of the exclusive permission.

[1] s18(2)(a) of the *Food Standards Australia New Zealand Act, 1991*

4.2 Impact on competition in the market

Some submitters to the Initial/Draft assessment commented that exclusive permissions for novel foods may restrict the trade of competitors. If approved, a novel food exclusive permission will provide the applicant with exclusive access to the market for products within a particular class of foods that contain the approved novel food ingredient. During the period of exclusivity, competitors will be limited to selling products within a specific class of food that do not contain the approved novel food ingredient.

Industry is generally very supportive of an explicit provision for exclusivity of use for novel foods in the Standard. An exclusive permission for an approved novel food is intended to provide a benefit to an applicant that has expended considerable resources into the development of a potential novel food. An exclusive permission for a novel food is one way for an applicant to recoup some of the initial cost of product research and development.

The explicit provision for exclusivity of use for novel foods in the Standard provides an incentive for industry to innovate and invest in research and development. At present, if an application for approval of a novel food is approved and an amendment to the Standard is subsequently made, the amendment has general application to all foods of that type. The effect is, if one applicant makes an application to FSANZ to have the Standard amended then competitors benefit from a 'free-rider' effect. Once the changes have been made to the Standard competitors can then take advantage of such changes.

Through the explicit provision for exclusivity of use for novel foods, industry recognises that there is a potential avenue to recoup some of the investment in research and development through an exclusive permission, rather than the outcomes of the current process.

One submission to the Initial/Draft Assessment indicated that an explicit provision for exclusivity of use for novel foods has the potential to stimulate product differentiation and competition, which is a very important feature of the marketplace. Rather than creating a monopoly and stifling competition, it is viewed as stimulating product differentiation and competition with like-products in a similar category that do not incorporate the novel food component. The issue of a 'monopoly' permission is overcome by limiting the exclusive permission to a period of 15 months, after which it reverts to a general permission.

4.3 World Trade Organization

Some submitters to the Initial/Draft assessment expressed concern that overseas competitors could be denied access to the Australian or New Zealand markets for 15 months if another company had obtained an exclusive permission through the approval of a novel food application by FSANZ, and that this would breach WTO requirements.

However, it should be noted that an international competitor would be in the same situation as a domestic competitor insofar as a domestic competitor would also not be permitted to sell a novel food in a particular class of food if there was an exclusive permission in the Standard. A competitor, whether domestic or international, may apply to FSANZ for approval of an exclusive permission for their brand of food or wait until the exclusive permission becomes a generic permission after the 15-month period of exclusivity expires.

At present, if a food is considered novel, an application to amend Standard 1.5.1 is required, before that novel food can be legally sold in Australia and New Zealand. If a novel food has not undergone a pre-market safety assessment as part of the application process and been approved, it cannot be sold as a food in Australia and New Zealand, even if it is approved for use in other countries.

At Initial/Draft Assessment, FSANZ notified the World Trade Organization (WTO), under the Technical Barriers to Trade Agreement, given that exclusive permissions for novel foods in Australia and New Zealand may have an effect on trade. FSANZ did not receive any comment from WTO members on this Proposal.

4.4 Protection of confidential commercial information

FSANZ recognises that the explicit provision for exclusivity of use for novel foods in the Standard does not specifically address the protection of confidential commercial information. FSANZ considers it is crucial to maintain transparency in relation to risk assessments for novel foods. The assessment of a novel food application requires a full pre-market safety assessment, which is open to public comment. The assessment process is the same for all novel food applications (for exclusive and generic permissions) in that a pre-market safety assessment will be conducted by FSANZ.

A provision for exclusivity is intended to provide a benefit to an applicant that has expended considerable resources into the development of a potential novel food, rather than providing any additional protection of information than that afforded in the FSANZ Act and other potential avenues available in general law.

Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure. An applicant can identify material that they believe should be treated in-confidence by FSANZ. However, the meaning of confidential commercial information in the FSANZ Act is narrow and does not necessarily pertain to the majority of the information that is required for an assessment for approval of a novel food.

4.5 Period of exclusivity

A number of submitters requested that the period of exclusivity be extended from 15 months to 18 or 24 months to allow sufficient time for product development after gazettal of an exclusive permission and to take into account the seasonal nature of some food products. The 15-month time period is based on advice received from industry during earlier consultations by FRSC. FSANZ, in having regard to the request of the Ministerial Council and earlier advice from industry, is maintaining the 15-month period of exclusivity.

4.6 Increased cost of products

There is a potential disadvantage for consumers if product costs increase because an exclusive permission is being relied upon. However, it would not be in industry's interests to increase product costs when industry has invested considerably to obtain an exclusive permission (to a level that it is not affordable or competitive with alternative products).

Even if this did occur, the reversion to a generic permission after the 15-month period of exclusivity expires would allow competitors to sell similar products, introducing competition which may well have the effect of reducing prices if the original product has been marketed at an inflated price.

4.7 Provision of brand name at time of application to FSANZ

Some submitters commented that the brand name of the product an applicant is seeking an exclusive permission for may not be determined at the time an application is submitted to FSANZ. FSANZ recognises that the development of a brand name may occur later in the development of a product and that the inclusion of 'brand' in the Standard 1.5.1 is for the purpose of identifying the brand that will be associated with the exclusive permission. The brand is not integral to the risk assessment process. However, FSANZ would require the name of the brand that will be associated with the exclusive permission before a draft variation to the standard is developed.

FSANZ prefers that the information relating to the brand is provided at the time the application is received. However, it is apparent that in some circumstances this is a marketing task that may continue after the application has been received. In that case, FSANZ would encourage the applicant to provide the brand information prior to the public consultation stage of the assessment.

4.8 Identification of market

At Initial/Draft Assessment, FSANZ referred to the need for the market to be defined in an application. FSANZ now recognises that defining a market does not add clarity in assessing an application. Rather, the application would be required to define only the novel food and the class of food for which the applicant is seeking approval.

4.9 Relationship with health claims

It is possible that an applicant requesting the approval of a novel food may also submit an application to FSANZ in regard to high level health claims that may be associated with that novel food. The assessment process for novel foods is separate and distinct from the consideration of high level health claims. The assessment of a novel food application requires a full pre market safety assessment, which is open for at least one period of public comment. At the completion of the assessment process and if the application has been approved, an applicant requesting exclusive permission will have 15 months' exclusive access to the market for their brand and class of food.

An application to consider a new high level health claim is proposed to be confidential throughout the application process with no public comment. However, at the completion of the assessment process the high level health claim, if approved, is permitted generally and may be used by anyone. An application for a high level health claim must be for a food or food ingredient/component that is already legally able to be sold as a food/food ingredient in accordance with the Code.

4.10 Ministerial Council reviews

It was suggested that requests for review by Ministerial Council for an initial application for approval of a particular novel food may delay the assessment process so that if the novel food is eventually approved, a competitor would potentially have a more rapid path for approval of a subsequent application for approval of the same novel food. It was also suggested that a review request by the Ministerial Council should only be permitted where a Jurisdiction's comments made in submissions have not been fully addressed.

While Ministerial Council review request processes are beyond FSANZ's capacity to influence, FSANZ assesses the safety of a novel food based on the best scientific evidence available at the time and presents a recommendation, through the FSANZ Board, to the Ministerial Council for consideration.

4.11 Enforcement

An exclusive permission in the Standard will clearly state the brand and class of food that the novel food ingredient is permitted to be added to. Enforcement of an exclusive permission for a novel food ingredient should be a straightforward matter of assessing compliance with the entry in Standard 1.5.1 for that particular novel food ingredient. This is similar to the enforcement of novel foods currently permitted in the Standard. Imported foods would continue to be enforced by the Australian Quarantine and Inspection Service in accordance with the Imported Food Inspection Scheme.

4.12 Other issues

Submitters also raised the following issues:

- Some submitters requested clarification around the priority of novel food applications being assessed by FSANZ.

Applications to amend the Standard can be either paid or unpaid. An unpaid application is entered on the FSANZ Work Plan and FSANZ begins its assessment of the application when it has reached the front of the queue of unpaid applications. FSANZ begins the assessment of a paid application upon receipt of the fees. This is the current process used to determine priorities for the assessment of any application. The process for considering multiple applications for exclusivity is discussed in section 4.1.1.

- An applicant may request an exclusive permission with no intent to market a novel food product. This may be a strategy to block competitors from marketing a novel food product in a particular class of food for the period of exclusivity.

It should be noted that applications for exclusive permission must be paid and that employing such a strategy is a business decision and is not something that FSANZ has control over in assessing an application for approval of a novel food.

- A submitter suggested that applications for approval of novel foods should not be placed on the publicly available FSANZ Work Plan, but should still be released for public comment; as well as requesting that FSANZ clarify how it will ensure that there are no health or safety risks associated with the application.

All applications for approval of a novel food will be placed on the FSANZ Work Plan and will be subject to at least one period of public consultation. While only limited details of an application will be placed on the FSANZ Work Plan after an application is accepted by FSANZ, the information included in the application will be placed on a public register file (subject to confidential commercial information provisions). As discussed in section 4 of this Report, all applications for approval of novel foods are required to undergo a pre-market safety assessment by FSANZ and this safety assessment will be published as part of the public comment period.

- A submitter suggested that the draft variation to the Standard should not include the column titled 'brand' (Column 2) in the Table to clause 3. It was suggested that this would provide some additional confidentiality to the manufacturer and flexibility to change the proposed brand name, if needed, during the product development and launch phase.

The purpose of the brand reference is to identify the holder of the permission and identify the actual product to which the exclusive permission applied. The brand associated with the exclusive permission is important as an identifying feature for inclusion in the variation to the standard and will assist with enforcement of the exclusive permission. Section 4.7 of this Report includes discussion of the appropriate time for providing details of the brand in the application process.

- Clarification was sought from submitters that an exclusive permission would apply to a class of food and not just a specified brand and whether an applicant could apply for an exclusive permission across different classes of foods in one application.

An exclusive permission, if approved, would be included in the Table to clause 3 of the Standard. Inclusion in the Table to clause 3 of Standard 1.5.1 will require details of the novel food, the brand, the class of food and any additional conditions of use. Therefore, an exclusive permission will apply to the approved novel food, the brand and a specific class of food. An application submitted to FSANZ for approval of a novel food may request approval for more than one class of food.

RISK MANAGEMENT

5. Options

5.1 Option 1: Amend Standard 1.5.1 to include a provision for exclusive permissions where sought

Include in the Standard a provision for exclusive permissions for novel foods, relating to a specific brand within a specific class of food, for a period of 15 months, followed by the reverting of this exclusive permission to a generic permission.

5.2 Option 2: Do not amend Standard 1.5.1 to include a provision for exclusive permissions where sought

Do not include in the Standard a provision for exclusive permissions for novel foods, relating to a specific brand within a specific class of food, for a period of 15 months, followed by the reverting of this exclusive permission to a generic permission.

6. Impact Analysis

6.1 Affected Parties

1. Those sectors of the food industry wishing to market foods which may be considered non-traditional and novel and as such, currently subject to the requirements of the Standard, including small business and importers of novel foods.

2. Government agencies, particularly those involved in enforcing the regulation for novel foods including the Commonwealth, New Zealand, and Australian State and Territory jurisdictions.

3. Consumers of novel foods or novel food ingredients in Australia and New Zealand, and public health professionals who provide advice to clients and may refer to some novel foods, for example, those novel foods which replace dietary macro-components and thus offer the potential for a food with a reduced energy value or fat content.

6.2 Benefit cost analysis and comparison of options

An analysis of the advantages and disadvantages of Option 1 in comparison with 2 has been undertaken. FSANZ currently has limited quantitative data in relation to the impacts on the various affected parties of each of the regulatory options put forward, though some qualitative information has been made available. This section presents a summary of the analysis of the costs and benefits for each of the affected parties for each of the Options. The detailed impact analysis is at Attachment 2.

Option 1 provides a clear mechanism in the Code for the implementation of the capacity in the FSANZ Act for exclusive permissions for novel food products and places a 15-month time limit on exclusive permissions, after which exclusive permission reverts to a general permission. This option also affords a clear benefit to industry wishing to capture the commercial benefit of an innovative novel food, removing the 'free-rider effect'.
Other companies also have the opportunity to market any such novel food which has had an exclusive permission after the exclusive permission reverts to a generic permission (after 15 months) or they may apply to FSANZ to capture an exclusive benefit for their own brand.

There is a potential disadvantage for consumers if the cost of products increases where there is an exclusive permission. However, it would not be in industry's interests to increase the cost of a product for which they have invested considerably in to obtain an exclusive permission to a level that it is not affordable to consumers or competitive with alternative products. Even if this did occur, the reversion to a generic permission after the 15-month period of exclusivity expires would allow competitors to sell similar products, introducing competition which may well have the effect of reducing prices if the original product has been marketed at a significant premium.

Option 2 does not provide a clear mechanism in the Novel Foods Standard for the implementation of the capacity in the FSANZ Act for exclusive permissions for a particular brand and class of food. Option 2 also does not provide a clear mechanism in the Standard for limiting the period of time an exclusive permission may apply for and therefore if and how an exclusive permission may revert to a generic permission.

Additionally, Option 2 does not enable industry to capture the commercial benefit of an innovative novel food. In summary, Option 1 is favoured over Option 2.

COMMUNICATION AND CONSULTATION STRATEGY

7. Communication

Over a period of two years, the FRSC Working Group on FSANZ's assessment and approval processes has consulted with other Australian Government agencies, State and Territory Governments, the New Zealand Government, and key stakeholders on a number of proposed measures, including the capacity for exclusive permissions for novel foods.

FSANZ identified a targeted group of stakeholders with which consultation occurred in the preparation of the Initial/Draft Assessment for Proposal P305. It was also beneficial to communicate the nature of the Proposal with a broader group identified as 'interested parties'. The group is made up of submitters to all applications that have been assessed in accordance with Standard 1.5.1. This interested parties group was invited to comment on the Initial/Draft Assessment when it was released for public comment.

FSANZ also provided information on this Proposal to the Standards Development Advisory Committee (SDAC) for Proposal P291. The SDAC had also discussed exclusive permissions for novel foods at an earlier meeting before Proposal P305 was prepared.

8. Consultation

FSANZ decided, pursuant to section 36 of the FSANZ Act to omit to invite public submissions in relation to the Proposal prior to making a Draft Assessment. FSANZ released the Initial/Draft Assessment Report for public consultation in July 2007 and has had regard to submissions received in preparation of the Final Assessment.

The Initial/Draft Assessment Report was advertised for public comment from 13 July 2007 to 10 August 2007. Sixteen submissions were received, 13 from Australia and three from New Zealand. The majority of submissions received were from the industry sector (10), followed by government (5) and individual (1).

A summary of submissions and list of submitters to the Initial/Draft Assessment is at Attachment 3. The FSANZ response to the issues raised in submissions can be found in section 4 of this Report.

8.2 World Trade Organization (WTO)

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

There is no international standard for regulating novel foods, however, the EU and Canada have a similar approach to regulating novel foods as Australia and New Zealand. The proposed amendment to the Standard to permit exclusive permissions for novel foods in Australia and New Zealand may have an effect on trade.

An approved novel food in another country could potentially be restricted access to the Australian and New Zealand markets on the basis that a company has exclusive rights under Standard 1.5.1 for a similar product. However, this situation is also faced by domestic competitors in Australia and New Zealand and is not unique to international competitors. Despite this, at Initial/Draft Assessment, FSANZ notified the WTO under the Technical Barriers to Trade Agreement.

Some submitters to the Initial/Draft assessment expressed concern that overseas competitors could be denied access to the Australian or New Zealand markets for 15 months if another company had obtained an exclusive permission through the approval of a novel food application by FSANZ. This issue is further discussed in section 4.3 of this Report.

CONCLUSION

9. Conclusion and Decision

Decision

Standard 1.5.1 – Novel Foods be amended to include a specific provision for exclusive permissions to be granted for a specific brand and class of food for a period of 15 months, after which the exclusive permission would revert to a general permission in the Standard.

Reasons for Decision

- This provides a clear mechanism in the Code for the implementation of the capacity for exclusive permissions for novel food products and places a 15-month time limit on exclusive permissions.

- This provides an incentive to industry for innovation and provides a benefit to an applicant that has expended significant resources into the development of a potential novel food.

- It is one of the measures presented in a report to the Australia and New Zealand Food Regulation Ministerial Council in October 2005 in response to the Review of FSANZ assessment and approval processes and treatment of confidential commercial information, and agreed to by Ministers.

10. Implementation and Review

It is proposed that the draft variation come into effect on the date of gazettal. The Ministerial Council has requested that FSANZ undertake a review of the advantages, disadvantages and impact of this recommendation within three to five years of implementation. This is noted in an Editorial note in the draft variation to the Standard.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Impact analysis
3. Summary of Submissions to Initial/Draft Assessment

Attachment 1

Draft Variation to the *Australia New Zealand Food Standards Code*

Section 94 of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunsetting

To commence: on gazettal

[1] ***Standard 1.5.1*** *of the Australia New Zealand Food Standards Code is varied by inserting after clause 2 –*

3. Exclusive use of novel foods

1. Despite clause 2, the novel food listed in column 1 of the Table to this clause may be sold as food or for use as a food ingredient for an exclusive period in the brand of food listed in column 2, in the class of food listed in column 3 and subject to the novel food complying with the conditions of use, if any, listed in column 4.

2. The exclusive period commences on gazettal of the variation of this Standard to the Table to this clause.

3. At the end of the exclusive period the novel food listed in column 1 of the Table to this clause, in the class of food listed in column 3 and the conditions of use, if any listed in column 4 is taken to continue as a novel food under clause 2 of this Standard.

4. For the purpose of this clause**,** 'exclusive period' means the period of 15 months' exclusive use of the novel food listed in column 1 of the Table to this clause in the brand listed in column 2 and the class of food listed in column 3.

Table to clause 3

Column 1	Column 2	Column 3	Column 4
Novel Food	**Brand**	**Class of Food**	**Conditions of Use**

Editorial note:

Clause 3 of this Standard will be reviewed after 3 years and before 5 years from gazettal of this Standard in accordance with the request of the Ministerial Council on 4 May 2007 for review under section 33 of the *Food Standards Australia New Zealand Act 1991*.

Under subclause 3 the exclusive use permission reverts to a general permission under clause 2, after the 15 months period (exclusive period) has expired. The Table to clause 2 and the Table to clause 3 will be updated to reflect the operation of subclause 3. Note that the class of food and conditions of use, if any in the Table to clause 3 will be inserted in column 2 of the Table to clause 2.

For information purposes only, the exclusive period for the following novel foods listed in column 1 of the Table to clause 3 are as follows:

Novel food + gazettal commencement date + 15 months/end date

Attachment 2

Impact Analysis

Option 1: Amend Standard 1.5.1 to include a provision for exclusive permissions where sought

- Include in the Standard a provision for exclusive permissions for novel foods, relating to a specific brand within a specific class of food, for a period of 15 months, followed by the reverting of this exclusive permission to a generic permission.

Option 2: Do not amend Standard 1.5.1 to include a provision for exclusive permissions where sought

- Do not include in the Standard a provision for exclusive permissions for novel foods, relating to a specific brand within a specific class of food, for a period of 15 months, followed by the reverting of this exclusive permission to a generic permission.

Option 1

Advantages

- This option provides a clear mechanism in the Code for the implementation of the capacity in the FSANZ Act for exclusive permissions for novel food products and places a 15-month time limit on exclusive permissions.

- This option provides an incentive to innovate for both small and large companies, although requiring all such applications to be paid applications places limitations on small companies.

- This option provides a clear mechanism for applicants who seek to capture the commercial benefit of a novel product. Exclusive access to the market provides a commercial benefit to the applicant for a period of 15 months.

- This option does not restrict public consultation in the assessment of approval of a novel food, which is considered critical in the area of novel foods.

- If an applicant applied to have exclusivity apply for a particular product or products, a generic permission would subsequently apply, allowing other companies to market the novel food. However, this generic permission would still only apply to the relevant class of food and any additional conditions of use specified in the original exclusive permission.

- Applicants will still be able to seek generic approvals for novel foods, as is currently the case. Applicants will continue to have the choice of either paying (in order to expedite the process) or not paying to have such applications assessed by FSANZ.

- It is not envisaged that there will be any additional impact on enforcement agencies.

Disadvantages

- The effect of exclusive permissions, if implemented, could be to potentially restrict the use of foods to particular companies, such that it would confer a monopoly right for particular foods to be manufactured for the period of exclusivity. However, the provision for exclusive permissions in the Standard would not prohibit other companies making an application to FSANZ for approval of an exclusive permission of their own brand. In addition, the issue of a 'monopoly' permission is overcome by limiting the exclusive permission to a period of 15 months, after which it reverts to a general permission.

- The cost to consumers of novel foods could increase, particularly for the period of exclusivity, reflecting additional costs of paid applications or as a consequence of a monopoly-like situation. However, there is no evidence to suggest that the current paid application option has increased the cost of foods in general.

Option 2

Advantages

- Maintains the status quo and does not require an amendment to be made to the Standard. Applicants will still be able to seek generic or product specific approvals for novel foods, as is currently the case. Applicants will continue to have the choice of either paying (in order to expedite the process) or not paying to have such applications assessed by FSANZ.

Disadvantages

- An applicant may still apply for exclusive permissions under section 16(2) of the FSANZ Act (formerly section 9(2)). This option does not provide a clearly understood mechanism in the Standard for the implementation of the capacity in the FSANZ Act for exclusive permissions for a particular brand and class of food.

- This option does not provide a clear mechanism in the Standard for automatically limiting the period of time that an exclusive permission may apply for in relation to Novel Foods. Nor does it provide a clear mechanism in the Standard for the reversion of an exclusive permission to a generic permission.

Conclusion

Option 1 provides a clear mechanism in the Code for the implementation of the capacity in the FSANZ Act for exclusive permissions for novel food products and places a 15-month time limit on exclusive permissions, after which and exclusive permission reverts to a general permission. This option also affords a clear benefit to industry wishing to capture the commercial benefit of an innovative novel food, removing the 'free-rider effect'. Other companies also have the opportunity to market any such novel food which has had an exclusive permission after the exclusive permission reverts to a generic permission (after 15 months) or they may apply to FSANZ to capture an exclusive benefit for their own brand.

There is a potential disadvantage for consumers if the cost of products increases where there is an exclusive permission. However, it would not be in industry's interests to increase the cost of a product for which they have invested considerably in to obtain an exclusive permission to a level that it is not affordable to consumers or competitive with alternative products.

Option 2 does not provide a clear mechanism in the Novel Foods Standard for the implementation of the capacity in the FSANZ Act for exclusive permissions for a particular brand and class of food. Option 2 also does not provide a clear mechanism in the Standard for limiting the period of time an exclusive permission may apply for and therefore if and how an exclusive permission may revert to a generic permission.

In summary, Option 1 is favoured over Option 2.

Attachment 3

Summary of submissions to the Initial/Draft Assessment

The public consultation period on the Initial/Draft Assessment Report commenced on 13 July 2007 and closed on 10 August 2007.

Overview of submissions received

Total number of submissions	**16**
Total from Australia	**13**
Total from New Zealand	**3**
Food Industry & Business	**10**
Consumers	**1**
Government	**5**

A full list of submitters is attached.

Summary of key points raised in submissions

The two options put forward in the Initial/Draft Assessment Report were:

Option 1 – Amend Standard 1.5.1 to include a provision for exclusive permissions where sought.
Option 2 – Do not amend Standard 1.5.1 to include a provision for exclusive permissions where sought.

Thirteen submitters were generally in favour of Option 1, although of these, one submitter who represented an industry group was divided in its opinion, with the majority of committee members supporting the Proposal and a minority who expressed concern in relation to a variety of issues. Two submitters opposed the Proposal, while one submitter did not indicate a preferred option.

Submitters opposing the Proposal cited concerns such as inconsistency with trade practices legislation, restriction of international trade, limiting consumer choices of the novel food/ingredient and increased prices for consumers.

Of those submitters that supported the Proposal, six submitters considered that the 15-month exclusivity period was insufficient and should be extended to at least 18 months, and preferably 24 months. It was considered that a longer period of exclusivity was necessary to recoup the significant investment dollars made by manufacturers in the development and launch of a novel food.

Submitters also raised comments in relation to a range of issues including, but not limited to: the protection of confidential commercial information (CCI); the processes for dealing with similar applications seeking exclusivity and for exclusive versus 'generic' applications; consistency with WTO obligations, trade practices legislation and the FSANZ Act objectives; enforcement, drafting and cost-benefit analysis. These issues are discussed in detail below.

Full summary of submissions

Similar Applications Seeking Exclusivity

Several submitters felt that further clarification should be provided with respect to similar applications seeking exclusivity for a novel food. It was suggested that the Standard should clarify that the granting of an exclusive permission to one applicant does not preclude another applicant from obtaining an exclusive permission for a similar product or ingredient but for a different brand. The following specific questions were also raised:

- how will priority be determined if two applications are received for the same novel product and the same class of foods?
- will equivalent applications be considered in parallel in the event that one application may fail?
- will an exclusive permission also be granted to the failed application if two applications are essentially equivalent?

One submitter also suggested that FSANZ considers changing the terminology from 'exclusivity' to 'explicit permission' as it more accurately reflects that the permission granted is explicit to the applicant and the brands or products requested.

Process for Considering Applications – Exclusive and Generic

Two submitters sought clarification on the process for considering applications for novel foods involving both exclusivity and unpaid generic applications. Specifically, the question was raised as to whether a paid application for a novel food seeking exclusivity for a brand and class would receive priority over a previous unpaid application seeking generic permission for that class of food.

Consistency with World Trade Obligations, *Trade Practices Act 1974* and FSANZ Act Objectives

Three submitters commented with respect to the implications of the 15-month period of exclusivity for novel foods on international trade. These submitters questioned whether prohibiting entry to Australia of competing overseas products would mean a breach of WTO obligations and whether protection of commercial interest is permissible under the TBT.

Two submitters questioned whether the proposal is a contravention of the *Trade Practices Act 1974* while one submitter questioned whether FSANZ would be meeting its objectives under the FSANZ Act of the promotion of fair trading and the promotion of consistency between domestic and international food standards. It was also noted that P305, if accepted, will fundamentally change the principles in the Code that food can be generally sold by all, without restriction, if the food is safe and adequately labelled.

Protection of Confidential Commercial Information

Two submitters commented that the Proposal does not adequately address the issue of protection of CCI that is required to support a novel foods application.

It was noted that if there is no increased protection available for material provided to support these applications, there is still potential for competitors to use this information to their advantage, to facilitate their entry into the market at the expiration of the 15-month time period, notwithstanding the period of exclusivity.

Period of Exclusivity

Six submitters commented on the period of exclusivity, suggesting that the period of exclusivity should be extended to at least 18 months, and preferably 24 months. It was considered that a longer period of exclusivity was necessary to recoup the significant investment dollars made by manufacturers in the development and launch of a novel food. The following arguments were put forward by submitters to support an 18 to 24 months period of exclusivity:

- Product formulations and design and development of marketing material cannot be finalised until the novel food is gazetted.
- A development timeframe of 6-9 months is required to plan all elements of a product launch, including: product development and stability testing; consumer testing; development of marketing plan including advertising, point of sale, media buying, label development etc; presentations to customers; production and packaging trial; ingredient purchasing and delivery. In practical terms, therefore, the exclusive period has already been reduced to 6-9 months.
- Many products are seasonal, therefore manufacturers could be forced to launch a product out of season to get a short period of exclusivity.
- Launch dates may be restricted as acceptance of a new product by leading food store companies is limited to a small number of windows during the year.
- Competitors will have 15 months' notice of the expiration of the 15-month exclusivity period. They will be in a position to launch their products with the new novel food on this date or commence advertising of their product before the expiration of the exclusivity period. This significantly reduces the effective exclusivity period available to the original applicant.

One submitter suggested that the period of exclusivity could commence from the point at which the business undertakes marketing of the product, provided such marketing occurs in a reasonable timeframe (e.g. within 6 months of approval of the Standard). This submitter also suggested that where an applicant fails to commence marketing the product within a reasonable or expected timeframe, the period of exclusivity should be rescinded so there is no unnecessary impediment to the Australian food industry.

By comparison, one submitter who did not support the Proposal believed that food businesses have sufficient time from product concept through the development phase and application period to gazettal, to plan and/or partner with other businesses to capture the benefits of innovation.

Clarification of Brand, Class of Foods, Product and Market

One submitter sought clarification on a number of issues relating to the brand, class of foods, product and market as follows:

- The Proposal must clarify that an exclusive permission will apply to a class of food and not just a specified brand.
- The classes of foods should be defined.
- The reference to defining the product and the market in clause 4.2, fourth paragraph should be removed, and for consistency, should instead refer only to defining the brand and class of foods.
- Whether a company can apply for a brand across different classes of foods and whether this can be treated as one application.
- How the brand name can be dealt with if it is not known at the time of application.
- Whether an exclusive permission automatically applies across Australia and New Zealand.

Another submitter stated that it is unclear why the market needs to be defined for exclusivity purposes (sections 4.2 and 4.3 of the report). An applicant may simply produce a list of all possible markets and this could stifle innovation in the food industry.

Interaction with Health Claims

One submitter commented on the potential interaction between Proposal P305 and Proposal P293 – Nutrition, Health & Related Claims. It was noted that the amendments to the FSANZ Act will enable applications for high level health claims to be kept confidential until the application is approved, in order to protect the applicant's first to market advantage. Therefore, in the absence of the amendments proposed in P305, the making of an application for a novel product may undermine the benefit to the company of making an application for a high level health claim if competitors can immediately bring to market a like product based on the information that has been made available during the novel foods application process.

Ministerial Council Review

One submitter commented that the 'first to market' advantage afforded by the 15-month exclusivity may be undermined with appeals or requests for review by the Ministerial Council. For example, if a first application suffers lengthy delays but is eventually approved, it provides an easier and more rapid path for approval of an application by a competitor. This submitter therefore suggested that jurisdictions should only have the right to request a review at Ministerial Council where their comments or concerns made in submissions have not been fully addressed.

Enforcement

Two submitters commented in relation to enforcement of the exclusivity period. One submitter questioned how the importation of novel foods would be monitored and enforced, particularly where the novel food product is an ingredient. This submitter considered that the exclusivity period may not be enforced by jurisdictions as food authorities lack the specialist skills in commercial law and also suggested that jurisdictions may wish to allocate their resources in areas that directly impact on public health and safety. This submitter also questioned whether it was the role of enforcement agencies to expend resources to assist businesses to maintain commercial competitive advantage.

Another submitter suggested that breaches of exclusivity should be very clear cut, therefore there should be no 'interpretation' required by enforcement agencies.

Draft Variations

Two submitters provided comments in relation to the draft variations to the Standard. One submitter recommended that the brand name be removed from the Table to clause 3 in the draft variations, noting that this would provide some additional confidentiality to the manufacturer and flexibility to change the proposed brand name, if needed, during the product development and launch phase.

One New Zealand submitter suggested that the draft variations should specify the extent to which the New Zealand 28-day rule will be factored into the 15-month period. The 28-day rule means that approval of the product on the New Zealand market would not apply until 28 days after gazettal in New Zealand.

Risk Assessment and Cost-Benefit Analysis

It was noted by one submitter that the exclusive right to use a novel food is already legislated for, through commercial options such as copyrights, patents, licensing, intellectual property and trade secrets. It was also noted that the Ministerial Council requested that FSANZ 'consider the capacity for including a specific provision for exclusivity of use for novel foods in Standard 1.5.1' and did not direct that a specific provision be developed. Clarification was sought on why these alternate mechanisms are inadequate, what other options have been examined and whether consumers actually stand to benefit from exclusivity.

Additional Questions/Issues Raised

A number of additional questions and issues were raised by submitters during the public consultation process as follows:

- Can a company apply for exclusivity in a food class that it does not currently produce but intends to manufacture and make use of the novel material?
- If a company is awarded exclusivity for a certain food class and either does not have the capacity or the intention to launch the product, will it still be able to keep the exclusive right for that period?
- What provision would be included in the Standard to prevent companies using the legislation as a blocking strategy to prevent launch of a particular novel food in a competing category?
- How could we distinguish between a blocking strategy and a genuine intention to enter a new category?
- Would an individual or applicant with exclusive permission be able to sell their exclusive brand to another person or company for financial gain?

One submitter expressed concern that the drafting of Standard 1.5.1 does not directly reflect the intent of the Standard, that is, to restrict foods to which approved novel food ingredients can be added. It was recognised, however, that to address this issue is outside the scope of Proposal P305.

One submitter stated that they support a recommendation to not include the entering of novel foods applications in the Work Plan.

However, they did not support the proposal that these applications be held in total confidence without an opportunity for public consultation and requested that FSANZ clarifies how it will ensure that there are no health or safety risks associated with the application.

List of Submitters to the Initial/Draft Assessment Report

Australia

Government **4**

Department of Health, South Australia, Ms Joanne Cammans
Department of Human Services Victoria, Mr Victor Di Paola
NSW Food Authority, Dr David Cusack
Queensland Health, Mr Gary Bielby

Industry **8**

Australian Beverages Council, Ms Melanie McPherson
Australian Food and Grocery Council, Mr Kim Leighton
Cadbury Schweppes, Mr Neil Smith
Coca-Cola South Pacific, Mr Jim Moshovellis
Coles Group Limited, Mr Neil McSkimming
Dairy Farmers, Ms Jo Davey
Food Technology Association of Victoria Inc., Mr David Gill
Unilever Australasia, Ms Julie Newlands

Consumers **1**

Mr Dean McCullum

New Zealand

Government **1**

New Zealand Food Safety Authority, Ms Carole Inkster

Industry **2**

New Zealand Food and grocery Council, Ms Brenda Cutress
New Zealand Juice and Beverage Association, Mr John Robertson

Total = 16 submissions received