Documents for Public Comment as of 13 July 2007

Public comment is invited on the following documents.

> Helpful hint: Opening or downloading a PDF document.

You are invited to make written submissions to FSANZ on the following Applications and Proposals. These items reflect information from current Notification Circular .

DRAFT ASSESSMENT – PROPOSALS

Closing date for written submissions for is by **6pm (Canberra time) 10 August 2007**:

> **Proposal P305 – Permission for Exclusivity of Use of Novel Foods**:

How to make a submission

Please contact slo@foodstandards.gov.au if you have difficulty in opening the document.

Proposal P305 – Permission for Exclusivity of Use of Novel Foods

Initial/Draft Assessment Report - 13 July 2006 [word | pdf 140kb]

FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

4-07
13 July 2007

INITIAL/DRAFT ASSESSMENT REPORT

PROPOSAL P305

EXCLUSIVITY OF NOVEL FOODS

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 10 August 2007
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

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) has prepared Proposal P305 – Exclusivity of Novel Foods - in response to requests from the Food Regulation Standing Committee (FRSC) and the Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council). FSANZ has been 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 has also been 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 – Novel Foods – of the Code. The Standard prohibits the sale of novel foods unless they are listed in the Table to clause 2 of the Standard 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 of the Novel Foods Standard to include the novel food or novel food ingredient before it can be sold in Australia and New Zealand. Standard 1.5.1 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 the transparent FSANZ process. That is, a competitor is able to see the information provided by the applicant and undertake product development to coincide with the gazettal of an approved novel food, thus removing the benefit for the applicant.

The impact of amending the Novel Foods Standard to include specific provision for exclusive permissions would be to make clear that an applicant for a novel food is able to apply for a variation to the Novel Foods 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; a decision that is up to the applicant. The applicant would need to clearly state the brand and class of food, or product(s) within a class of food, they are seeking exclusivity for.

When an approval for exclusive permissions is sought, and if approved, the Novel Foods Standard would need to be amended such that the Standard would 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.

Proposal P305 is being progressed in parallel to Proposal P291 – Review of Novel Foods. 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 to amend or not amend Standard 1.5.1, to include the facility within the Standard for exclusive permissions for the brand and class of food combination for a novel food. An exclusive permission for novel foods affords a clear benefit to industry wishing to capture the commercial benefit of an innovative novel food, and promotes innovation in the food industry.

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. In summary, amending Standard 1.5.1 to include the facility within the Standard for exclusive permissions for the brand and class of food combination is the preferred option.

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 of the Code.

Preferred Approach

FSANZ recommends that 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, if sought by an applicant, after which the exclusive permission would revert to a generic permission.

Reasons for Preferred Approach

- It more clearly addresses one of the specific policy principles for novel foods, that is, to provide an assessment process that aims to protect commercially sensitive information and recognise industry's intellectual property to the maximum extent possible.

- 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.

Consultation

FSANZ decided, pursuant to section 36 of the FSANZ Act, to omit to invite public submissions in relation to this Proposal, prior to making a Draft Assessment, due to the previous consultation undertaken during the FRSC Working Group's review of FSANZ's assessment and approval processes. However, FSANZ now invites written submissions for the purpose of the Final Assessment under s.17(3)(c) of the FSANZ Act and will have regard to any submissions received.

CONTENTS

INVITATION FOR PUBLIC SUBMISSIONS

FSANZ invites public comment on this Initial / Draft Assessment Report based on regulation impact principles and the draft variation to the Code for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Final Assessment of this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 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.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions need to be received by FSANZ by 6pm (Canberra time) 10 August 2007.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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 Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council) has subsequently requested FSANZ consider an amendment to the novel food standard that would limit the period of exclusive approval as a novel food for a particular brand for up to 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 – Exclusivity of Novel Foods in response to these requests.

In 2004, the Food Regulation Standing Committee (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, suggesting amendments to the *Food Standards Australia New Zealand Act, 1991* (the FSANZ Act) may be required, which were intended to protect commercially valuable information.

It was initially considered that the FSANZ Act would need to be amended to allow for 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 are 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 of the Standard 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 of the Novel Foods Standard 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 the Novel Foods Standard and permission, with any conditions of use given in the table to clause 2 of that Standard.

1.2 Review of the Novel Foods Standard

FSANZ received policy guidance on novel foods from the Ministerial Council in December 2003. This policy guidance recommends that FSANZ review Standard 1.5.1 while giving consideration to the higher order principles and specific principles of that policy guidance.

FSANZ prepared Proposal P291 – Review of the Novel Foods Standard in response to this policy guidance, 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 addressing the perceived ambiguity of the definitions of 'non-traditional food' and 'novel food' in Standard 1.5.1, in addition to examining the process for determining whether a food is novel or not.

Proposal P305 is being 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 the Review of Novel Foods may unnecessarily delay the progress of Proposal P291. Therefore, Proposal P305 will consider the capacity for including a specific provision for exclusivity of use for novel foods in Standard 1.5.1.

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 an amendment to the novel food standard to include a provision for exclusivity of use for novel foods for a period of 15 months, 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 Novel Foods 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, or product(s) within a class of food, they are seeking exclusivity for.

When an approval for exclusive permissions is sought, and if approved, the Novel Foods Standard would need to be amended such that the Standard would 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.

The Novel Foods Standard does not currently have a provision for exclusive permissions for approved novel foods. FSANZ has therefore prepared Proposal P305 to consider the requests from FRSC and the Ministerial Council to amend Standard 1.5.1 to include provision for exclusive permissions for novel foods.

3. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 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 has also given specific regard to the intention of protecting commercially sensitive information to the maximum extent possible as addressed in a specific principle of the Ministerial Policy Guidance for novel foods.

4. Exclusive permissions for novel foods

4.1 Industry issues in relation to current novel foods assessment process

Data protection for industry and streamlining of the FSANZ assessment process were identified as issues for consideration by stakeholders commenting on the policy options paper on novel foods released by FRSC for public comment in February 2003.

The issue was discussed at the first Proposal P291 Standards Development Advisory Committee (SDAC) meeting with some members stating that due to FSANZ's transparent process, competitors can have access to the details of an application and undertake product development to coincide with the gazettal of an approval, removing the benefit for the applicant.

A couple of solutions were suggested – shortening the assessment process to one round of public comment to reduce the time a competitor has available to undertake product development; and allowing a quarantine period of use to the applicant following gazettal. It was noted that neither of these options were feasible at that point in time.

Submitters to the Initial Assessment Report for Proposal P291 reiterated that the current assessment process for novel foods does not protect confidentiality, which may enable competitors to develop similar products, and the applicant would lose any commercial advantage. A couple of suggestions for addressing this situation were raised:

- A one-year provisional patent may, in some circumstances, be a cost-effective way for industry to gain some lead-time.

- A more streamlined approach (one round of public comment) where appropriate. This would include only those applications that could be considered under section 36 of the FSANZ Act, i.e. those which raise issues of minor significance or complexity only. An example is an application for a novel food derived from a novel source where that resulting food is argued to be substantially equivalent to another generally available food or a previously assessed novel food.

In response to these comments from submitters, the Draft Assessment Report for Proposal P291 stated that novel food assessments would rarely be sufficiently simple to consider under section 36 of the FSANZ Act and thus allow for only one round of public comment, although it would be utilized where possible. It was also noted that other options for addressing the issue of data protection were outside the scope of this review and that the FRSC Working Group established to address the FSANZ assessment and approval process and treatment of confidential commercial information were considering the protection of confidential commercial information.

During consultation on the FRSC review of FSANZ's assessment and approval processes and treatment of confidential commercial information, industry restated these concerns in relation to novel foods as follows:

- when FSANZ receives an application, the application is entered on the Work Plan which is made publicly available. This potentially provides a signal to competitors about the proposed amendment being sought by the applicant;

- the information provided to FSANZ in support of the application is disclosed to the public through the FSANZ assessment reports; and

- if an application gains FSANZ approval and an amendment to the standard is subsequently made, the amendment to the standard has general application to all foods of that type, unless the permission sought was for a proprietary product. The effect of this is that if one applicant makes an application to FSANZ to have a standard amended then others benefit from a 'free-rider' effect. Once the changes have been made to the standard others can then take advantage of such changes.

Industry was particularly concerned that there does not appear to be adequate protection for the large quantities of information that they would consider to be 'commercially valuable' in relation to novel foods.

While there is capacity for confidential commercial information (CCI) to be protected, the nature of material that could be granted CCI protection is limited by the meaning of CCI in the FSANZ Act. Industry has noted that, while they are able to innovate within an existing standard, the features of the current food regulatory system can inhibit research and innovation into new products because there is limited capacity for industry to exclusively capture the benefits of the innovation. This is because there are limited protections for new food products in general law (particularly where the innovation relates only to a new combination of existing ingredients) and because once a standard has been amended anyone can sell the product without the need to seek separate approval to do so (the 'free-rider' effect).

For example, a company may choose to develop a novel food product. If the manufacturer wishes to sell the product, then the manufacturer needs to seek an amendment to the standard. The manufacturer's application will be subject to public consultation and the process of assessment takes 12 months.

During this time, competitors have information about the manufacturer's innovation and may have sufficient time to develop a similar product. Unless the novel food product is protected by a patent, by the time the standard has been amended (enabling the food to be supplied), the innovator's competitors could also be able to release similar products. This eliminates the 'first market advantage' of the innovating manufacturer.

4.2 Exclusive permissions

It is proposed that an applicant would be able to apply for a variation to the Novel Food Standard for a specific brand of food within a specific class of food (for example, breakfast cereals). 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; a decision that is up to the applicant. The applicant would need to clearly state the brand and class of food, or product(s) within a class of food, they are seeking exclusivity for.

The applicant may request that the Standard be amended such that, if FSANZ approves the novel food, the amendment to the Standard would only apply to the specific brand of novel food approved within specified classes of food (the draft variation to the Code is at **Attachment 1**). In essence this means that the novel food included in the Standard (i.e. approved) would be brand and product specific.

If the Novel Food Standard is amended in this way, the Standard will provide exclusivity for the brand within a class of food for 15 months. The period of exclusivity is to commence from the date when the approval is given. After that the Standard is to revert to a generic permission for that specific class of food.

If the Novel Food Standard is amended to provide exclusivity, if sought by an applicant, for the brand and class of food for 15 months, the applicant would need to define the product(s) and market they are seeking exclusivity for. For example, if an application seeks approval for the use of a novel food ingredient in breakfast cereal, and for that approval to apply exclusively to the brand and class of food combination, the applicant should specify whether the novel food ingredient is intended for use in one particular existing product, a new product under development or a range of products. This information will assist FSANZ in its assessment of the novel food but also in defining the parameters for exclusivity.

In order to enable applicants to apply to FSANZ for an amendment to the Standard that would only apply to them and to the specific class of food(s), or specified product(s) within a class of food, for which approval is sought, this option would comprise the following elements:

(a) if approved by FSANZ, the standard would be amended such that the approval applied only to the brand within a specific class of food or foods for which approval was sought for a set period of time, beyond which the amendment reverted to generic application for the specific class of food; and
(b) if applicants chose to seek an approval of this type (as opposed to a general amendment to a standard) applicants would be required to pay for the assessment. Such paid applications would be expedited by FSANZ (as is currently the case).

It should be noted that under the proposed FSANZ Act amendments, the default stream for applications (general procedure) will involve an early bird notification, one round of public comment and a nine month time frame will apply. It is anticipated that most novel food applications will fall into this stream.

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.

Over the past two years, consultation has been undertaken with other Australian Government agencies, State and Territory Governments, the New Zealand Government, and key stakeholders on all of these proposed changes. There is broad support amongst these stakeholders for the proposed measures.

4.3 Period of Exclusivity

An exclusive novel food approval, if sought by an applicant and approved, will apply only to the specific brand within the specific class of food requested and will be included in the Table to clause 3 of the Standard upon gazettal (clause 3 of the Draft Variation to the Standard (**Attachment 1**) relates to the exclusive use of novel foods). As indicated in section 4.2 of this Report, due to an exclusive permission being brand specific within a class of food, if an application requests exclusive permission for a novel food, the applicant would need to define the product and market they are seeking exclusivity for.

It is proposed that at the end of the 15 month period of exclusivity, the novel food permission is to automatically revert to a generic permission for that specific class of food. Therefore, the assessment of the application for exclusive use will need to consider the safety of the novel food in the context of the class of food specified (not just the brand of food) in order for the reversion to a generic permission to be automatic and not reliant upon further assessment of safety. The generic permission would be limited to the same class of food as the exclusive permission and continue to be subject to any conditions of use associated with the approval of the exclusive novel food. Only the reference to a specific brand, within the class of food, would be removed for the reversion to a generic permission and the Tables to clause 2 and 3 would be updated. An editorial note has been included after clause 3 in the draft variation to the Standard to provide some guidance on the operation of the reversion to a generic permission.

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 Standard 1.5.1 of the Code, 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

An analysis of the advantages and disadvantages of Option 1 in comparison with 2 has been undertaken.

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

6.2.1.1 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.

6.2.1.2 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.

- 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.

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

6.2.2.1 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.

6.2.2.2 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.

6.3 Comparison of Options

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.

COMMUNICATION AND CONSULTATION STRATEGY

7 Communication and consultation strategy

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. However, FSANZ now invites written submissions for the purpose of the Final Assessment under s.17(3)(c) of the FSANZ Act and will have regard to any submissions received.

FSANZ made its decision under section 36 because it was satisfied that omitting to invite public submissions prior to making a Draft Assessment would not have an adverse effect on the interests of anyone. Over the past 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. There is broad support for the proposed measures.

Section 63 of the FSANZ Act provides that, subject to the *Administrative Appeals Tribunal Act 1975*, an application for review of FSANZ's decision to omit to invite public submissions prior to making a Draft Assessment, may be made to the Administrative Appeals Tribunal.

8. 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 Standard 1.5.1 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. Therefore, FSANZ will notify the WTO under the Technical Barriers to Trade Agreement.

CONCLUSION

9. Conclusion and Preferred Approach

FSANZ has considered the costs and benefits associated with the option of including a specific provision for exclusive permissions for novel foods in Standard 1.5.1. The inclusion in the Standard of a specific provision provides a clear mechanism in the Code to implement the capacity in the FSANZ Act for exclusive permissions for novel food products. There appears to be a clear benefit to those sectors of the food industry that have an interest and capability in marketing novel foods. The cost of investing in the development of a novel food and the preparation of an application to seek an exclusive permission may be prohibitive for small companies even if they have an interest in this market. Smaller companies may benefit only after an exclusive permission reverts to a generic one.

The potential benefit for consumers of allowing exclusive permissions for novel foods is unclear, depending on how such products are priced. However, the option of exclusive permissions for novel foods is a measure agreed to by Ministers and it does address one of the specific policy principles for novel foods. As such, FSANZ proposes to amend Standard 1.5.1 to include a specific provision for exclusive permissions for novel foods to be granted.

Preferred Approach

FSANZ recommends that 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, if sought by an applicant, after which the exclusive permission would revert to a generic permission.

9.1 Reasons for Preferred Approach

- This more clearly addresses one of the specific policy principles for novel foods, that is, to provide an assessment process that aims to protect commercially sensitive information and recognise industry's intellectual property to the maximum extent possible.

- 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.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*

Attachment 1

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

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