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

7-05
5 October 2005

DRAFT ASSESSMENT REPORT

PROPOSAL P291

REVIEW OF NOVEL FOOD STANDARD

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 25 January 2006
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

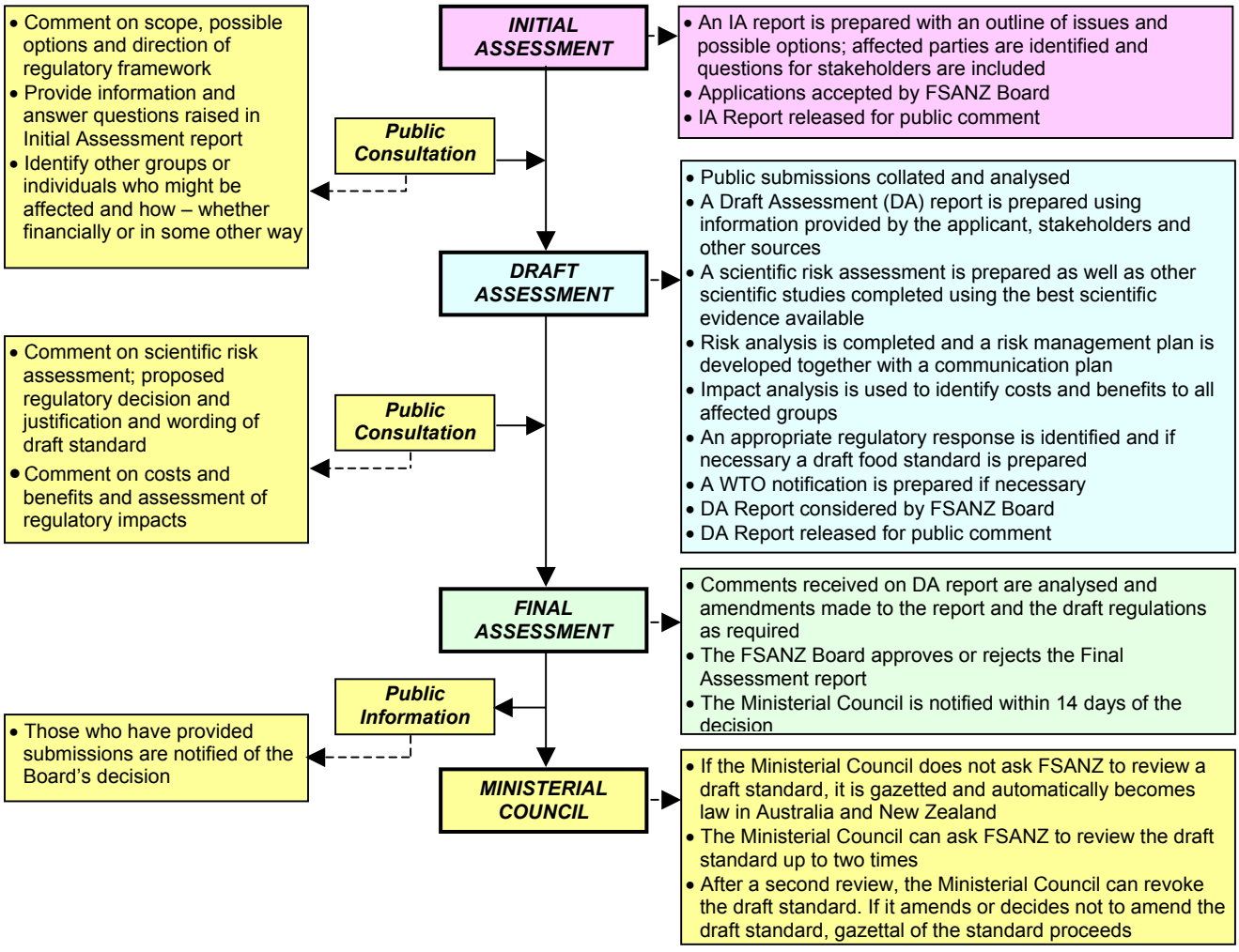
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Australian Government; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Australian Government, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Australian Government, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared a Draft Assessment Report of Proposal P291; and prepared a draft variation to the *Australia New Zealand Food Standards Code* (the Code).

FSANZ invites public comment on this 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 for 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) 25 January 2006.

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.

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Executive Summary and Statement of Reasons

FSANZ received policy guidance on novel foods from the Ministerial Council in December 2003. The policy guidance recommends that FSANZ review Standard 1.5.1 – Novel Foods, of the Code, while giving consideration to the higher order principles and specific principles of that policy guidance and to a number of issues raised during consultation on policy development. As a result, FSANZ raised this Proposal to review the regulation for novel foods. In accordance with the policy guidance, FSANZ established a Standard Development Advisory Committee (SDAC) to assist FSANZ during the review of the Standard. The role of the SDAC is to provide advice to FSANZ on matters related to the review, rather than to endorse any regulatory option.

Standard 1.5.1 introduces a risk-based assessment process to ensure the safety of novel foods before they are offered for sale in Australia and New Zealand. There is general support for the purpose of the Standard, namely that novel foods undergo a risk assessment to ensure their safety prior to sale, and it is seen as fulfilling a valid role in the protection of public health and safety.

Some stakeholders have viewed the current definitions in Standard 1.5.1 as broad and subjective and it is believed that this has lead to some inconsistency in the application of the Standard. One of the key issues that has been considered during this review is improving the definitions. It has been acknowledged that some degree of subjectivity is unavoidable due to the broad nature of novel foods. The definitions have been revised to provide more clarity.

Consideration has also been given to the process of determining novelty. A guidance tool for determining novelty has been proposed for inclusion in the revised guidelines for novel foods. This guidance tool will provide additional transparency to the process of determining novelty and will be applied by the Novel Foods Reference Group. Other proposed changes to the guidelines include revised categories of novel foods that can be used as a guide for applicants, revised data requirements for novel foods and separating the so called outcome views with respect to novelty of food from the guidelines document to give it more status and improve its accessibility.

Data protection has been recognised during this review as an issue for industry in that the current assessment process does not protect confidentiality, which may enable competitors to develop similar products, and the applicant would lose any commercial advantage. The provisions in the FSANZ Act in relation to confidential commercial information (CCI) can be used where certain information is requested by an applicant to be treated as such and this is agreed by FSANZ in accordance with the Act. Specific details on the method of production or the source material is the type of information for which CCI status is often sought and granted in relation to novel foods. Where appropriate, novel food applications can be assessed under section 36 of the FSANZ Act, allowing for only one round of public comment and a shortened assessment time, thereby protecting the commercial advantage of the applicant to some extent. Other options for addressing the issue of data protection are outside of the scope of this review and will be considered by the FRSC steering committee addressing the FSANZ assessment and approval process.

The review of novel foods is broad with a number of issues being considered and there are a large number of potential regulatory and non-regulatory initiatives that could address the Ministerial Policy Guidelines at least partially.

The regulatory option of amending Standard 1.5.1 and the operating procedures (Option 3) is the preferred option because it affords a clear benefit to consumers, public health professionals and government. When compared with other regulatory options this option provides increased clarity around the definitions. It is also the only regulatory option that allows FSANZ to adequately address and implement the Ministerial Council Policy Guideline on novel foods.

Proposed amendments to Standard 1.5.1, particularly with respect to the definitions, will provide additional clarity and assist in improving consistency in the application of the Standard. The introduction of a guidance tool, in combination with proposed amendments to the guidelines for novel foods, will provide additional transparency to the process of determining novelty.

Decision

FSANZ recommends that an amended Standard 1.5.1 – Novel Foods, be retained to provide regulation for novel foods. The main proposed amendments to Standard 1.5.1 are revised definitions for 'non-traditional food' and 'novel food'. The process for determining novelty should continue but be refined, with the adoption of a revised guidance tool for determining novelty based on the definitions in the Standard.

Statement of Reasons

Based on the review of the Novel Foods Standard, FSANZ recommends that an amended Standard 1.5.1 be retained to provide regulation for novel foods for the following reasons:

- There is general support from stakeholders for the purpose of the Standard, that novel foods undergo a risk-based assessment to ensure their safety prior to sale.

- To ensure consistency with the specific objectives of this Proposal, particularly, to ensure: (i) the safety for human consumption of novel foods; (ii) that regulations are complementary with inter-related standards in the Code; and (iii) that there is implementation of the Ministerial Policy Guidelines as far as possible.

- To address the higher order and specific policy principles of the Ministerial Policy Guideline, specifically: (i) to ensure priority is given to the protection and improvement of public health and safety in relation to food matters; (ii) to draw on the best elements of international regulatory systems and be responsive to future trends and developments; and (iii) to ensure that public and industry confidence in the food system is maintained and to ensure consumers are not mislead by novel foods or food ingredients which appear similar to existing foods but may differ in terms of nutrition or function.

- The purpose of the regulation for novel foods in Australia and New Zealand is consistent with the purpose of similar regulatory frameworks for novel foods in Canada and the EU.

FSANZ recommends that Standard 1.5.1 should continue to contain definitions for both 'non-traditional food' and 'novel food' (albeit, revised definitions) for the following reasons:

- The concept of *absence of history of safe use* is important for inclusion in the regulation for novel foods as it assists in the process of determining novelty. A revised definition for 'non-traditional food' has been retained to include this sentiment rather than incorporating it into the definition for novel food as the latter would likely result in a more cumbersome definition of novel food. This aims to ensure simplicity and clarity in the definitions for both 'non-traditional food' and 'novel food'.

- It is accepted that there will be some subjectivity associated with the definitions for 'non-traditional food' and 'novel food', however, the revised definitions omit the terms that were seen as ambiguous. An Editorial note is proposed to provide notes on the interpretation of the definitions.

- These revisions to the definitions address the Ministerial Policy Guidelines, specifically, that the subjectivity and scope of the current definitions should be considered and addressed as far as possible. The revisions to the definitions also address the specific objectives of this Proposal, particularly to ensure: the safety for human consumption of novel foods; and that the regulations are readily enforceable.

FSANZ recommends that the process for determining novelty should continue but be refined, with the adoption of a guidance tool for determining novelty and amendments to the guidelines for novel foods for the following reasons:

- The proposed amendments to the guidelines for novel foods will provide greater clarity and transparency for stakeholders as to how the process for determining novelty is undertaken.

- The introduction of the proposed guidance tool for determining novelty will increase the level of rigour applied to the process of determining novelty. The guidance tool is consistent with the proposed decision-making mechanism of developing a decision-tree as proposed during the policy development process.

- These proposed changes are consistent with the Ministerial Policy Guidelines, specifically, that the user guide be reviewed to include any amendments to the novel food definition and to provide greater clarity about the process for determining if a food is novel or not.

The proposed drafting for amendment to Standard 1.5.1 is at Attachment 1 of the Draft Assessment Report.

1. Introduction

FSANZ has prepared this Proposal to review the regulations for novel foods, namely Standard 1.5.1 – Novel Foods. 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 and to a number of issues raised during consultation on policy development. The policy guidance also recommends that FSANZ use a reference group comprising representatives of enforcement agencies to provide advice during the review.

The main issues covered in the review include:

- The purpose of the Standard, as stated in the purpose clause of the current Standard 1.5.1.
- The definitions for both 'non-traditional' and 'novel' in the current Standard 1.5.1 and the process by which determinations in relation to novelty have been made in accordance with the definitions.
- General history and operation of the Standard including enforcement by jurisdictions.
- The scope of the existing Standard 1.5.1, including the potential to capture food derived from new technologies.
- The information provided to the public with respect to determinations made in accordance with the Standard.
- The costs and benefits associated with the current Standard.
- Data requirements for novel foods to be assessed in accordance with the Standard including protection of data.
- Examination of inter-relationships with other projects, other existing Standards and the foods-therapeutic goods interface.
- Comparison with the regulation of novel foods in other countries.

The focus of the review is to examine the regulatory framework for novel foods and the decision-making mechanisms that determine whether a food is subject to the regulations for novel foods. It is not the intent of the review that existing individual permissions for novel foods be revisited or that applications for the approval of novel foods being undertaken during the review in accordance with the existing Standard be affected.

In order to assist in the review of novel foods, the FSANZ Board established a Standard Development Advisory Committee (SDAC) to provide advice to FSANZ. The SDAC has met twice, prior to the development of the Initial Assessment Report on 23 September 2004, and then prior to the development of this Draft Assessment Report (DAR) to discuss submissions received in response to the Initial Assessment Report on 21 June 2005.

Further procedural details regarding the SDAC such as the formation, terms of reference, guidelines, timelines and membership are provided in section 8.1 of this Report. Issues raised at these meetings is incorporated under the relevant issues headings in section 5 of this Report.

2. Regulatory Problem

During the time between which the Novel Foods Standard was established (December 1999) and when clause 2 of the Standard, which prohibits the sale of novel foods unless included in the table to that clause, came into full effect (June 2001), some determinations were made with respect to novelty.

At this stage of implementation of the Standard, the criteria and process for determining whether a particular food was novel within FSANZ and the then Senior Food Officer forum was still developing and being articulated. There was some criticism from the industry sector at the time about the lack of clarity on how the potential novelty of a food was assessed. These criticisms formed part of the impetus for the inclusion of the regulation of novel foods on the Ministerial Policy Guidelines work program.

This review provides a timely opportunity to consider the operation of the Standard since its establishment.

2.1 Current Standard

Novel foods and novel food ingredients are currently regulated by Standard 1.5.1 – Novel Foods – of the Code. The current Standard 1.5.1 is at Attachment 2. 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 deemed 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.

2.1.1 Determinations with respect to novelty

The determination as to whether or not a food or food ingredient is novel is made in accordance with the current definitions for 'non-traditional' and 'novel' in the Standard.

In Standard 1.5.1:

> **non-traditional food** means a food which does not have a history of significant human consumption by the broad community in Australia or New Zealand.
>
> **novel food** means a non-traditional food for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account -
>
> (a) the composition or structure of the product; or

(b) levels of undesirable substances in the product; or
(c) known potential for adverse effects in humans; or
(d) traditional preparation and cooking methods; or
(e) patterns and levels of consumption of the product.

The determination of novelty is made in conjunction with the Senior Food Officers in Australian State and Territory jurisdictions and in New Zealand, and the Australian Quarantine and Inspection Service (AQIS). Some stakeholders have expressed dissatisfaction with both the outcomes of these determinations and the process by which these determinations are made. Some stakeholders are of the view that what they see as flawed determinations with respect to novelty has contributed to applications to amend the Table to clause 2 of Standard 1.5.1 being unnecessarily made and assessed.

3. Objective

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.

The specific objective of this Proposal is to review the regulations for novel foods and amend as appropriate to ensure the:

- safety for human consumption of novel foods;
- regulations are readily enforceable;
- regulations are complementary with inter-related standards in the Code;
- regulations do not unnecessarily place a burden on industry innovation and are able to be consistently applied;

- implementation of the Ministerial Policy Guidelines as far as possible; and
- other issues raised by stakeholders are considered and covered as far as possible.

4. Background

4.1 Development of Standard 1.5.1

In 1996, the then Australia New Zealand Food Authority (ANZFA) released a discussion and options paper entitled 'The safety assessment of novel foods and novel food ingredients'. At this time, the number, variety and increasing use of non-traditional foods raised the question of public health and safety with respect to these foods.

This paper discussed: the characteristics of a food which may suggest novelty; some examples of novel foods; the need for a formal safety assessment and what would need to be considered; the options of pre-market approval and pre-market notification; and relevant international regulations. There were 33 submissions received in response to this paper and all except one were in support of a standard, which facilitated a risk-based assessment process.

Proposal P168 – Novel Foods, was raised to formally consider the need to regulate novel foods in Australia and New Zealand. Twenty-four submissions were received during the first round of public comment and a further 19 submissions were received during the second round of public comment. It was recommended that novel foods be considered a sub-set of non-traditional foods and definitions were proposed. A pre-market assessment process was favoured over a pre-market notification scheme. Risk evaluation guidelines were also developed and included in assessment reports for public comment. The proposed standard was intended to introduce a more formal safety assessment system than was available previously to allow any potential concerns to be addressed before the sale of the food.

The new Standard A19 of the now revoked Australian *Food Standards Code* (also known as Volume 1) and Standard 1.5.1 of the Code, then known as Volume 2, were gazetted in December 1999. Clause 2 of the Standard, which prohibits the sale of novel foods unless included in the table to that clause, came into effect on 16 June 2001. Between the gazettal of the Standard and 16 June 2001, industry had the opportunity to submit data to ANZFA for the assessment of novel foods while these remained on the market.

4.1.1 Supporting documents for potential applicants

To coincide with the gazettal of Standard A19/Standard 1.5.1, ANZFA developed documentation to assist industry in interpreting the Standard. These two documents were made available on the then ANZFA website and these have subsequently been updated. These documents were provided as attachments to the assessment reports for P168 and amended during the course of the review in response to public comments received. These are:

- 'Format for applying to amend the Code – Novel Foods' which contains a template which can be used when making an application for permission to use a novel food (Attachment 3); and

- 'Guidelines to assist in applying to amend the *Australia New Zealand Food Standards Code* – Novel Foods' which provides details of the operation of the standard, descriptions of the likely categories of novel foods, a decision tree for determining the novelty of a food, data requirements for the assessment of novel foods and a record of views formed in response to inquiries with respect to novelty.

The Guidelines document was completely reviewed and updated in early 2004 and a significant new inclusion was made – a table presenting a record of views formed in response to inquiries with respect to novelty. The table presents the outcome view with respect to whether a particular food or food ingredient is: a) traditional or non-traditional; and b) novel or not novel, with respect to the definitions in Standard 1.5.1. Prior to this update, the only way of finding out this information was for an inquiry to be made directly to FSANZ and the information would be made available on a case-by-case basis.

The guidelines for novel foods have been reviewed as part of this Proposal and amendments are discussed in section 5 of this Report.

4.2 Purpose of Standard 1.5.1

The Standard for novel foods was intended to introduce a more formal safety assessment system than was available previously to allow any potential concerns to be addressed before the sale of the food. As stated in the Purpose Clause of Standard 1.5.1,

> *The purpose of the Standard is to ensure that non-traditional foods which have features or characteristics which raise safety concerns will undergo a risk-based safety assessment before they are offered for retail sale for direct consumption in Australia and New Zealand*.

4.3 Use of Standard 1.5.1

The following novel foods have been assessed and approved (in some cases with conditions of use) in accordance with the Novel Foods Standard and permission, with any conditions of use, is given in the table to clause 2 of that Standard:

- Docosahexaenoic acid (DHA) – rich dried marine micro-algae (*Schizochytrium* sp.);
- Docosahexaenoic acid (DHA) – rich oil derived from marine micro-algae (*Schizochytrium* sp.);
- Docosahexaenoic acid (DHA) – rich micro-algal oil (*Ulkenia* sp.);
- α-Cyclodextrin;
- γ-Cyclodextrin;
- Diacylglycerol oil;
- Phytosterol esters (in certain specified foods);
- D-Tagatose;
- Tall oil phytosterols (in certain specified foods); and
- Trehalose.

In addition, FSANZ has completed the assessments for the applications listed below and recommended that they be approved for use as novel foods. FSANZ has undertaken a first review of these Applications in response to a request by the Ministerial Council.

- Application A433 – Phytosterol esters as ingredients in breakfast cereal;
- Application A434 – Phytosterol esters in low fat milk and low fat yoghurt; and
- Application A508 – Tall oil phytosterols in low fat milk.

4.4 Assessment of novel foods

4.4.1 Risk assessment

The purpose of undertaking a risk assessment for a novel food is to confirm that there is a reasonable certainty that no harm will result from the intended use of the food. The risk assessment also determines whether or not the novel food offers the same basic level of safety that is expected for all foods. Where a food is produced using a new or novel process, the purpose of a risk assessment is to confirm that the food has an equivalent level of safety to its traditional counterpart. This approach will have limited application to the safety of novel foods since most, by definition, will not have a traditional counterpart.

The risk assessment comprises the following steps: hazard identification; hazard characterisation; exposure assessment; and risk characterisation.

The hazard identification and hazard characterisation of novel foods is undertaken by considering a variety of toxicological and nutritional issues together with information on the chemistry and dietary intake of the product. Such evaluations differ somewhat from the traditional evaluation techniques that have been applied to food additives and contaminants both in the type and variety of information. Due to the much larger anticipated daily intake of foods compared to food additives, studies in animals have limited usefulness. This is because the larger intakes are likely to cause physiological, morphological or biochemical changes, which reflect an altered nutritional status rather than an indication of a toxic response. Human studies are more likely to offer relevant data. The exact data requirements depend on the type of novel food being considered.

A detailed description of the risk assessment process for a novel food is at Attachment 4.

4.4.2 Risk management

Standard 1.5.1 of the Code, in the Table to clause 2, makes provision for conditions of use for a particular novel food to be specified in column 2 of that table, associated with permission for that novel food. Conditions of use may be specified where a particular public health and safety risk is identified for either the general population or an identified population sub-group. Such conditions of use may be referred to as risk management strategies and include:

- limiting the maximum level of use of the novel food or novel food ingredient;
- limiting the categories of foods to which the novel food ingredient may be added;
- limiting the level of natural toxicants in the novel food;
- requiring statements to be provided on novel foods that advise against consumption by particular sub-groups;
- requiring the novel food to carry information about the appropriate use of the novel food and/or preparation instructions.

Other non-regulatory risk management options could be employed such as:

- provision of educational material (e.g. pamphlets) to consumers or industry; and
- encouraging industry to disseminate information about their products and any necessary preparation.

4.5 Food Regulation Standing Committee consideration of Standard 1.5.1

The development of policy guidelines for novel foods was identified as one of the several priority issues for the first year of the Ministerial Policy Guidelines work program. This work was considered a high priority because of problems with particular foods during the introduction of the new Novel Foods Standard, specifically during the 18 month transition period between the gazettal of the new Standard and the commencement of the clause which prohibited on the sale of novel foods unless permitted in that Standard. The concerns related to how determinations were made as to the novelty of these particular foods, and the subsequent need to undertake a risk assessment.

In addition, the Ministerial Council raised issues relating to treating information supplied by potential applicants as commercial-in-confidence. The issues, which arose during the transition period, with the introduction of the Standard, have largely been resolved.

The novel foods working group produced a policy options paper on novel foods, which was endorsed by FRSC and released for public consultation in February 2003. The policy options paper discussed five policy options for regulating novel foods under the Code and two mechanisms for decision-making with respect to novelty. Submitters were invited to nominate their preferred policy option(s) and decision-making tool. A total of 20 submissions were received. An analysis of stakeholder comments was prepared by the novel foods working group (Attachment 5).

The final draft policy guideline was considered by FRSC in September 2003 and it was agreed that this draft policy guideline would be provided to the Ministerial Council in December 2003. The final draft policy guideline did not directly reflect any of the policy options or decision-making mechanisms put forward in the options paper but rather recommended a review of the Standard itself. The rationale for this was that the detailed concerns expressed by both consumer and industry groups indicated that the main problems appear to stem from the broad definitions in the current Standard and difficulties with some of the language used, allegedly resulting in inconsistency and subjectivity in the application of the Standard. As such, a review of the regulation of novel foods would be an appropriate approach for addressing these issues.

4.6 Policy Guidance on Novel Foods

The Ministerial Council endorsed policy guidelines for novel foods and agreed to refer the policy guidelines for novel foods to FSANZ in December 2003. The policy guidelines are at Attachment 6. The policy guidelines consist of higher order principles, specific principles and policy guidance. The higher order principles can be summarised as follows:

The regulation for novel foods should:

- give priority to improvement of public health and safety;
- ensure consumers have sufficient information to enable informed and healthy food choices;

- be consistent with national policies on nutrition and health promotion;
- draw on the best elements of international regulatory systems and be responsive to future developments; and
- be timely, cost effective, transparent, consistent with minimum effective regulation, encourage fair trade, industry growth, innovation and international trade.

The specific principles can be summarised as follows:

The regulation of novel foods should:

- ensure that public and industry confidence in the food system is maintained;
- provide an assessment process that aims to protect commercially sensitive information and recognise industry's intellectual property to the maximum extent possible; and
- ensure consumers are not mislead by novel foods which appear similar to existing foods but may differ in terms of nutrition or function.

The main elements of the policy guidance are that FSANZ:

- prepare a proposal to review Standard 1.5.1 – Novel Foods, of the Code.
- recognise that the standard is there to ensure the safety of new foods coming on to the market and that the standard reflects a risk based approach.
- use a reference group that includes representatives from relevant Australian Government, New Zealand and State and Territory enforcement agencies to provide advice in reviewing the Standard.
- consider, as part of the review process, the issues raised by stakeholders during FRSC consultation including subjectivity, scope of the definition, protection of information, and level of assessment to be commensurate with level of risk; and
- review the user guide to reflect any amendments made as a result of the review. The user guide should give greater clarity about the process FSANZ takes in determining if a food is a novel food.

4.7 International regulations for Novel Foods

4.7.1 European Union

Between 1997 and 2003, novel foods and genetically modified food and feed were covered under the same regulation, Regulation No 258/97 – Novel Food and Novel Food Ingredients. Since late 2003, genetically modified food or feed has been covered by a separate regulation, Regulation 1829/2003. New regulation for genetically modified food and feed was separated from the regulation for novel foods to set up an EU system to trace genetically modified organisms, introduce the labelling of genetically modified feed, reinforce the existing labelling rules for genetically modified food and establish an authorisation procedure for genetically modified organisms in food and feed and their deliberate release into the environment.

Regulation 258/97 applies to the placing on the market within the Community of novel foods or novel food ingredients which have not been used for human consumption to a significant degree within the Community since the introduction of the Regulation in 1997 and which fall under the following categories:

(a) foods and food ingredients with a new or intentionally modified primary molecular structure;

(b) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;

(c) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating and breeding practices and having a history of safe food use; and

(d) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

Novel foods and novel food ingredients are subject to a safety assessment prior to placement on the market within the Community. A simplified notification procedure is available for those novel foods that are purported to be substantially equivalent to existing foods.

For products on the market before the entry into force of Regulation No 258/97, those responsible for their placement on the market had six months after the date of application of that regulation to notify the Commission of the date on which they were first placed on the market in the Community.

A number of novel foods have been approved for sale in the EU such as oil rich in DHA, noni juice, certain products with added phytosterol esters (e.g. yellow fat spreads, milk and yoghurt type products), coagulated potato proteins and hydrosylates, salatrim, trehalose, phospholipides from egg yolk, and pasteurised fruit-based preparations produced using high-pressure pasteurisation.

The Commission has refused the marketing of both Nangai nuts (*Canarium indicum* L.) and *Stevia rebaudiana* (plant and dried leaves).

The EU regulations for novel foods are currently being reviewed. It is anticipated that a proposal will be presented to Parliament and Council in 2006. The objectives of the review are to secure public health by assessing the safety of foods entering the market after the introduction of the regulation in 1997, to secure the functioning of internal market for foods, and to achieve legal clarity by making necessary changes and updating legislation. The areas to be addressed in the review include the definition for novel foods, the authorisation procedure, the resolution process, authorisations made under the novel food regulation, transparency and public consultation and labelling of novel foods.

4.7.2 United Kingdom

The UK Advisory Committee on Novel Foods and Processes (ACNFP) is a non-statutory, independent body of scientific experts that advises the UK Food Standards Agency on any matters relating to novel foods (including genetically modified foods) and novel processes (including food irradiation).

The ACNFP operated for a number of years, prior to the EU Regulations, providing advice to the UK government. It undertakes evaluations and provides advice to the UK Food Standards Agency on novel foods or process submitted for approval under the EC Novel Food Regulation. The reports of these evaluations and the minutes of the ACNFP meetings are published.

4.7.3 Canada

In Canada genetically modified foods are included in the definition of 'novel food' and as such, both GM foods and non-GM foods are regulated in the same way and subject to the same requirements.

The definition of 'novel food' as defined in the Food and Drug Regulations – [Amendment (Schedule No. 948), as published in the 'Canada Gazette Part II' – October 27, 1999] is:

a) a substance, including a microorganism, that does not have a history of safe use as a food;
b) a food that has been manufactured, prepared, preserved or packaged by a process that

    1. has not been previously applied to that food, and
    2. causes the food to undergo a major change;

c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that

    1. the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
    2. the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
    3. one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.

The regulation requires that notification be made to the Health Products and Food Branch by the company who wants to sell the product prior to the marketing or advertising of a novel food. Pre-market notification permits Health Canada to conduct a thorough safety assessment of all novel foods to demonstrate that a novel food is safe and nutritious before it is allowed on the Canadian market. The vast majority of assessments undertaken in accordance with this regulation are genetically modified foods. The non-GM novel foods that have been assessed include: DHASCO® and ARASCO® oils as sources of docosahexaenoic acid (DHA) and arachidonic acid (ARA) in human milk substitutes; and apple cider and juice treated with UV light using CiderSure 3500.

4.7.4 United States

In the United States, the Food and Drug Administration (FDA) regulates foods which would be regarded as novel in Australia and New Zealand as food additives under existing law, the principal law being the Federal Food, Drug and Cosmetic Act. The 'Generally Recognised as Safe' or GRAS concept is the bench mark by which all foods, including novel foods, are assessed.

GRAS substances are: substances used before 1958 (excluding prior sanctioned food ingredients); and substances for which there is scientific evidence of safety as determined by competent experts and by published and available safety information.

A substance that will be added to food is subject to pre-market approval by the FDA unless its use is GRAS. Any person may notify the FDA of a determination, by that particular person, that a particular use of a substance is GRAS. The GRAS notification is required to include relevant documents and information, for example, toxicological data, compositional data, and an estimate of exposure. The FDA evaluates each submitted notice as to whether it provides a sufficient basis for a GRAS determination or whether information in the notice or otherwise available to FDA raises issues that lead the agency to question whether use of the substance is GRAS. Following this evaluation, FDA responds to the notifier by letter. In general, FDA's response has been in one of three categories:

1. The agency does not question the basis for the notifier's GRAS determination;
2. The agency concludes that the notice does not provide a sufficient basis for a GRAS determination (e.g., because the notice does not include appropriate data and information or because the available data and information raise questions about the safety of the notified substance); or
3. The response letter states that the agency has, at the notifier's request, ceased to evaluate the GRAS notice.

Some GRAS notices that are or may be considered non-traditional and/or novel foods in Australia and New Zealand are as follows:

- tomato lycopene extract (pending);
- α-cyclodextrin (pending);
- conjugated linoleic acid (pending);
- algal oil (*Schizochytrium* sp.) (FDA has no questions);
- grape seed extract and grape pomace extract (FDA has no questions);
- diacylglycerol oil (FDA has no questions);
- phytosterols (FDA has no questions);
- DHA-rich oil from tuna and arachidonic acid-rich oil from *Mortierella alpina* (pending);
- D-ribose (notice does not provide a basis for a GRAS determination);
- D-tagatose (FDA has no questions);
- DHASCO (docosahexaenoic acid-rich single-cell oil) and ARASCO (arachidonic acid-rich single-cell oil) (FDA has no questions);
- β-cyclodextrin (FDA has no questions);
- trehalose (FDA has no questions); and
- hempseed oil (notice does not provide a basis for a GRAS determination).

5. Relevant Issues

5.1 Purpose of Standard 1.5.1

As described in section 4.2 of this Report, the purpose of the Standard as stated in the purpose clause is to ensure that non-traditional foods which have features or characteristics which raise safety concerns will undergo a risk-based safety assessment before they are offered for retail sale for direct consumption in Australia and New Zealand.

The purpose clause is not in the operative part of the Standard. However, enforcement agencies do use the wording of the purpose clause as a guide when considering taking enforcement action.

The Standard for novel foods introduces a risk-based assessment process to ensure the safety of novel foods before they are offered for sale in Australia and New Zealand. Both the EU and Canada have regulations for novel foods with similar intent.

Stakeholders have indicated general support for the purpose of the Standard, that novel foods undergo a risk-based assessment to ensure their safety prior to sale. A suggestion for wording for inclusion in the purpose clause was put forward in the Initial Assessment Report and those submitters who commented generally supported the suggestion. The suggested wording was as follows:

> *The purpose of this Standard is to ensure that novel foods will undergo a risk-based safety assessment before they are offered for retail sale for direct consumption in Australia and New Zealand.*

This proposed wording would form only part of the purpose clause. Some specific comments on the purpose clause made by submitters and/or SDAC members include:

- The terms 'direct consumption' and 'retail sale' were questioned. It was suggested that the current wording, because of the inclusion of these terms, may exclude wholesale supply. It was also pointed out that it should be the sale of novel foods that is regulated and not the consumption, consistent with the Food Acts of relevant jurisdictions.
- The concept of a risk-based approach based on a safety concern should be reflected in the purpose clause.

5.1.1 Consideration and outcome

The following wording is incorporated into the purpose clause (second paragraph) instead of the wording proposed in the Initial Assessment Report.

> *The purpose of this Standard is to ensure that novel foods will undergo a risk-based safety assessment before they are offered for sale in Australia and/or New Zealand.*

5.2 Definitions in Standard 1.5.1

5.2.1 General definitional issues

The evaluation of submissions received in response to the FRSC policy options paper, as prepared by the novel foods working group, indicated that the main problems appear to stem from the broad definitions in the current Standard and the language used. It is also suggested that problems with the definitions have resulted in inconsistency and subjectivity in the application of the Standard. As an example of one of the difficulties, some products that are already on the market as foods in Australia and New Zealand, albeit for a small time (i.e. only for a couple of years and clearly not one generation) such as non-culinary herbs, for which there are safety concerns, may not be captured by the current definition for 'non-traditional food' by virtue of the fact that they are on the market. Clarity around the definitions is required in order for the Standard to operate effectively.

FSANZ has considered the elements of international regulatory systems for novel foods, consistent with the Ministerial Council Policy Guidelines. There appear to be difficulties associated with all of the definitions for novel food. For example, there are difficulties interpreting the term 'history of safe use' used in the EU definition of novel food. The EU regulations for novel foods are being revised and a key aspect of this review will be examining the definition for novel food. Because of the broad nature of potential novel foods, a certain level of subjectivity in the definitions is unavoidable.

FSANZ has given consideration as to whether there is a need for definitions for both 'non-traditional food' and 'novel food' in the Novel Food Standard. If 'non-traditional food' is not defined in Australia and New Zealand, the definition for 'novel food' would need to incorporate the element of an absence of history of safe use.

A number of submitters were of the view that there is no need to define 'non-traditional food' as the definition for novel food can accommodate the intent of absence of history of safe use. It was suggested that a decision-tree could incorporate questions that will address the extent to which a potential novel food has been consumed. However, some submitters believed there is value in revising and maintaining a definition for 'non-traditional food'. Since the concept of absence of history of safe use should still be incorporated in the definition for novel food, the subjectivity would simply be moved from the definition of 'non-traditional food' to 'novel food'. Feedback received from a recent Nordic Council workshop on the risk assessment principles for novel fruits and vegetables indicated that the concept of a food being non-traditional on a regional level is helpful.

Specific questions related to the definitions, particularly the need for and interpretation of the definition for 'non-traditional food' were asked in the Initial Assessment Report. Some specific suggestions made in submissions to the Initial Assessment Report were:

- Tradition of use could be defined as three or more generations. This would be consistent with the approach taken by the Therapeutic Goods Administration.
- The Macquarie dictionary definition of 'generation' could be used.
- A food that has been consumed by broad communities outside Australia and New Zealand should not be considered as a novel food.
- Food could be considered to be significantly consumed by the broad community when it is freely available.

- Extensive use is difficult to define, but could be considered as weekly use by 50% of the population.
- Broadening of the Australian cultural base should be taken into account for the whole population. The context of the food use (e.g. ceremonial verses daily consumption) should be considered.

At the second meeting of the SDAC the following specific points were made:

- Determining whether a food is traditional or not has been a relatively easy determination to make and is a useful first step in the decision-making process. Factors considered in determining whether a food is traditional or not could be incorporated into a decision-tree. At least some elements of determining tradition of use should remain.
- The history of previous considerations with respect to novelty is what really gives an idea of what may be subject to the Standard.
- The issue of 'creep' onto the market place (i.e. products being on the market for a short period of time not being deemed to be non-traditional by virtue of their presence, even though there may be safety concerns) should be addressed in revising the definitions.

5.2.2 Foods produced from processes not previously applied to food

In the Initial Assessment Report, FSANZ discussed the range of new technologies that are being employed in the food industry. New breeding technologies were also discussed. Some examples include:

- using ozone as a food disinfectant;
- plasma technology using free radicals to increase shelf-life;
- electron beam treatment of packaging;
- high pressure pasteurisation of juices;
- pulsed electric fields for vegetative cells;
- UV light processing of juices;
- ultrasound for enzyme deactivation;
- pressure shift freezing for cooked vegetables;
- carbon dioxide and other gases in modified atmospheres;
- nanotechnology; and
- combinations of the above.

Some detail was provided on high pressure pasteurisation of juices in the Initial Assessment Report. Foods produced using new technologies are regulated as novel foods by Canada and the EU if the resultant food has altered characteristics. Canada has approved apple cider and juice treated with UV light using CiderSure 3500 and, in the EU, pasteurised fruit-based preparations produced using high-pressure pasteurisation have been approved.

The EU definition for novel food includes:

> *Foods and food ingredients to which a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.*

The Canadian definition for novel food includes:

> *A food that has been manufactured, prepared, preserved or packaged by a process that has not been previously applied to that food, and causes the food to undergo a major change.*

The current 'Guidelines to assist in applying to amend the *Australia New Zealand Food Standards Code* – Novel Foods' acknowledge that foods produced using new technologies may be captured by the existing Standard 1.5.1 as follows:

> *There is also potential under this Standard to consider the safety of foods that have been prepared using new technologies (other than irradiation or gene technology, since foods prepared using these technologies are regulated by other Standards). Food produced using traditional breeding techniques, where the nature of the food has been significantly changed from the traditional variety, could be considered under this Standard.*

There is some ambiguity as to whether food produced using any of the aforementioned new technologies would be captured by the existing Standard 1.5.1 as the guidelines are not enforceable and the Standard has never been used to assess food derived from a process not previously applied to food.

Submitters to the Initial Assessment Report expressed a range of views, but overall, it was clear that it is the resultant food that would potentially require assessment and not the process itself. Most submitters from the industry sector believe that it is not necessary to regulate new technologies or foods produced from new technologies unless the resultant food is considered novel. Some submitters indicated that there is a need to regulate foods produced using new technologies in all circumstances. Only one submitter indicated a preference for separate horizontal standards to regulate foods produced using new technologies based on safety, all other submitters indicated that if there is a need to regulate the resultant food (i.e. because it has novel characteristics) then it should be addressed in the regulation for novel foods.

It has been noted that there may be some consumer wariness about foods produced using processes not previously applied to food. There was considerable discussion about foods derived from new technologies at the second meeting of the SDAC. The following points were made:

- The Standard should only capture foods produced using new technologies that have altered characteristics <u>if these raise safety concerns</u>. Reviewing every new technology would not be feasible. Contrary to that argument, it was questioned how it would be possible to determine whether a food that has altered characteristics is safe if it has not been assessed.

- Consideration needs to be given to how to define or refer to new technologies as some of the technologies are well established and not new, although new food applications have been developed.

- Altered characteristics as a result of applying a new technology are reflected by: removal of a component; addition of a component; or alteration of a component. If something is removed, then there should not be any safety issue, if something is added or altered then it may be novel. Whether it is novel or not will depend on the level of change, the nature of the change and the context of use.

5.2.2.1 Consideration and outcome

FSANZ has considered a number of points in developing the revised definitions, including:

- Comments made by stakeholders during the FRSC consultation relating to subjectivity and ambiguity associated with the definition.

- The policy principles, including an investigation of the best elements of international regulatory systems and the capacity to be responsive to future trends and developments.

It is proposed that a definition for non-traditional food will be retained in the Novel Foods Standard. It is important to retain some elements of the tradition of use as this assists the process of determining novelty. Although, it was suggested that these elements could be incorporated into the definition for novel food, this would likely result in a more cumbersome definition for novel food. The proposed definition for non-traditional food has been tightened in comparison with the previous definition.

While the terminology 'new technologies' was used in the Initial Assessment Report, the term 'process' is now being used in this Report as it was noted that many of the technologies being referred to are not in fact new, but the food applications are new. Foods produced using a process that has not previously been applied to food will be captured under the revised definition if the resultant food is non-traditional and may be unsafe. Foods produced from a new source, where there is no history of human consumption of that food or the source, will potentially be captured in the revised definition if there is the potential for it to be unsafe.

The revised definitions are as follows:

Non-traditional food means –

(a) a food that has not been generally available to a broad cross-section of consumers in Australia or New Zealand; or
(b) a substance derived from a food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food; or
(c) any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand.

Novel food means a non-traditional food that may be unsafe having regard to –

(a) the composition or structure of the food; or
(b) the potential for adverse effects in humans; or
(c) patterns and levels of consumption of the food; or
(d) the process by which the food has been prepared; or

(e) the source from which it is derived; or
(f) any other relevant matters.

It is accepted that there will likely be some subjectivity associated with the definitions, however, the revised definitions omit the terms that were seen as ambiguous. An editorial note is proposed to be included to provide notes on the interpretation of the definitions.

5.3 Determining novelty

5.3.1 Current approach

Prior to an application to amend the Code being assessed by FSANZ, a determination as to whether the potential novel food is 'non-traditional' and 'novel' is made in accordance with the definitions in the current Standard 1.5.1. This determination is made in conjunction with the Senior Food Officers in Australian State and Territory jurisdictions and in New Zealand and the Australian Quarantine and Inspection Service (AQIS).

The internal FSANZ Novel Foods Reference Group (NFRG) makes an initial consideration and this is reported and/or discussed with jurisdictions with varying levels of involvement depending on the complexity. Over 100 potential novel foods or novel food ingredients have now been examined by the NFRG, sometimes in conjunction with jurisdictions. This experience provides an extensive experience base for revision of the Novel Foods Standard, and in particular, the definitions provided within that Standard.

Considerable effort has been made towards ensuring consistency in the determinations with respect to novelty and the subsequent communication of these determinations. Since January 2004, considerations with respect to novelty (prior to receipt of an application) have been made publicly available on the FSANZ website (in the document, 'Guidelines to assist in applying to amend the *Australia New Zealand Food Standards Code* – Novel Foods') and any updates to this information are reported to jurisdictions. The outcome view in relation to some of these is pending receipt of further information and these are not reported in the table in the guidelines document on the FSANZ website. FSANZ also reports to jurisdictions quarterly providing an alphabetical listing of potential novel foods considered and the justification for deeming a food to be either novel or not novel by the NFRG.

Submitters to the Initial Assessment Report and SDAC members have indicated that the inclusion of determinations with respect to novelty on the FSANZ website have been helpful but suggestions for improvement have been made. These are discussed in section 5.4 of this Report.

Making a determination with respect to novelty involves a significant amount of background research, which is in effect a small-scale risk assessment that could be classified as risk profiling. Although FSANZ requests information from the inquirer, this risk profiling is resource-intensive standards related work. FSANZ acknowledges that it is difficult to make initial considerations as to the potential novelty of a food and there is a degree of subjectivity to many considerations. The Novel Foods Standard, and the definitions for 'non-traditional' and 'novel' contained within are broad and this was considered to be necessary due to the varied nature of novel foods, but has contributed to some of the difficulties in determining novelty.

Standard 1.5.1 is consistent with minimum effective regulation as highlighted by the fact that over 100 potential novel foods have been considered and only approximately 25% have been deemed to be subject to the pre-market requirements of the Standard.

5.3.2 Decision-tree

A decision-tree was put forward as a decision-making mechanism in the FRSC policy options paper. There was support from both submitters to the Initial Assessment Report T and SDAC members for the development of a comprehensive decision-tree to assist in making determinations with respect from novelty, to assist potential applicants and reduce the number of inquiries. Having considered more than 100 inquiries with respect to novelty, the NFRG has extensive experience from which to examine emerging patterns to use in the development of a decision-tree. It was suggested by submitters that the decision-tree should not be too prescriptive and novelty should not be based on one characteristic, but the sum of characteristics.

5.3.2.1 Consideration and outcome

FSANZ has developed a guidance tool for determining novelty. The tool provides step-wise guidance in decision-tree format as well as listing a number of questions that may be asked in relation to each step. A straight decision-tree format would have resulted in a highly complex decision-making tool, given the number of factors considered and the number of potential branches to such a tree. The guidance tool is intended to assist the NFRG and Senior Food Officers in determining whether a food or food ingredient is subject to the Novel Foods Standard. This tool may not be exhaustive of all the possible questions that could be asked relating to novelty. Accordingly, judgement will be needed in the application of the guidance too. The guidance tool is intended to be as simple as possible. It should not be interpreted as giving a definitive 'yes' or 'no' outcome and the NFRG should still play an important role in determining novelty.

This guidance tool for determining novelty is presented in the proposed revised guidelines at Appendix 1 to Attachment 7. The proposed revised guidelines (Attachment 7) will be placed on the FSANZ website at the completion of this review. Until such times as the review is completed, the current guidelines will remain on the FSANZ website with regular updates to be made to reflect new outcome views, as is the current situation.

Please provide comments on the proposed guidance tool for determining novelty at Appendix 1 to Attachment 7.

5.3.3 Expert panel

An expert panel was put forward as another decision-making mechanism in the FRSC policy options paper. There was limited support from submitters for the establishment of an expert panel to assist in making novel food determinations. One of the reasons for this limited support is that the panel would need to be large to adequately address the diverse range of novel foods. Such a panel would likely be logistically difficult to manage and resource intensive, using significantly more resources than the current system. Some submitters supported the establishment of an expert panel only if necessary in the future (e.g. if clear definitions and a decision-tree prove ineffective).

There is extensive experience within FSANZ and the NFRG is appropriate as a panel for giving the first consideration in determining novelty. It was also noted that the idea behind suggesting this decision-making mechanism was to improve transparency and the justifications for all determinations should be clearly explained to the inquirer.

5.3.3.1 Consideration and outcome

FSANZ believes the establishment of an expert panel is not currently justified. It would require a broad range of experts and would be unlikely to meet as regularly as the NFRG currently does. The organisation of such a panel would require significant resources to manage on an ongoing basis. However, experts in any particular field could be approached if necessary on an ad-hoc basis. If a comprehensive decision-tree and clear definitions prove ineffective tools for determining novelty, an expert panel could be considered further in the future. FSANZ has also further articulated the role of the NFRG in the revised guidelines for novel foods at Attachment 7.

5.4 Guidelines for novel foods

As discussed in section 5.3, the guidelines for novel foods have been revised as part of this review process and include a number of amendments discussed throughout section 5 of this Report. The proposed revised guidelines are at Attachment 7. The proposed revised guidelines will be placed on the FSANZ website at the completion of this review. Until such times as the review is completed, the current guidelines will remain on the FSANZ website with regular updates to be made to reflect new outcome views, as is the current situation.

5.4.1 Accessibility of guidelines and determinations with respect to novelty

FSANZ has received feedback that the inclusion of considerations with respect to novelty on the FSANZ website has been helpful. It has generated greater awareness and assists prospective applicants in determining whether a food falls within the scope of the Standard. However, some submitters felt that the information is difficult to locate on the website and needs to be more widely publicised. FSANZ suggested that there may be a case for having this table of considerations as a separate document on the website, rather than at the back of the novel food guidelines – this would make the information more accessible and give it more status.

At the second meeting of the SDAC it was suggested that in addition to listing the determinations alphabetically, they could be split into those deemed to be novel and those deemed not to be novel. It was also suggested that including the justification for determinations, i.e. the reasons for a food being deemed to be novel or not novel, would be helpful. This would also be consistent with the policy guideline that advocates transparency. At present, a justification is only provided where it is specifically requested. This is in accordance with the arrangement made with then Technical Advisory Group members in October 2003 for the provision of outcome views. It was agreed at the time that the rationale surrounding the outcome view would not be provided, as it can be complicated due to the complexity of some potential novel food issues. The arguments against including a justification are that there is sometimes limited information, the issues are often complex and it is not possible to give an adequate description of the context of use while maintaining simplicity of the table. However, without such details, considerations could be misconstrued and applied more broadly than intended or in unsuitable contexts by members of public.

FSANZ approached Senior Food Officers in jurisdictions asking them to consider the implications of providing justifications to accompany outcome views with respect to novelty of food that are made publicly available on the FSANZ website. Those Senior Food Officers in jurisdictions who responded indicated support for providing the justifications to accompany outcome views. Some members suggested that the provision of justifications be reviewed in approximately 12 months time.

It should be noted that in some cases inquirers request that the information they supply be treated as confidential. FSANZ is bound by obligations under its Act to protect confidential commercial information from disclosure and these requirements do not only apply to applications, but also to information provided to FSANZ in other contexts, such as inquiries regarding novelty. In situations where the information meets the definition of commercial confidential information under the Act, this information cannot be supplied as part of the justification.

5.4.1.1 Consideration and outcome

FSANZ has developed a separate document containing the outcome views for inclusion on the FSANZ website upon finalisation of this review. It is hoped that this will make the information more accessible. The information has been re-ordered such that outcome views are listed alphabetically and also according to whether they are deemed to be novel or not. In addition, the justification for each outcome view will also be included. An illustration of the format of this document containing the outcome views and justifications is at Attachment 8. Hyperlinks will be provided in both the guidelines for novel foods and the outcome views to the other document. Until this review is finalised, the outcome views will remain at the end of the current guidelines document and regular updates to the table will continue to be made.

5.4.2 Categories of novel foods

FSANZ has revised the current categories of novel foods that are referred to in the guidelines document. It was noted that the categories of foods are helpful however, they may be able to be updated given the nature of inquiries received in relation to the Standard since its introduction. Submitters to the Initial Assessment Report indicated that the reference to categories is more helpful and appropriate in the guidelines rather than in regulation itself. In this way, information for applicants as to the nature of the information that would be required with an application for any particular type of category of novel food could be provided. Another reason supporting the reference to categories of novel foods in the guidelines rather than in regulation is that not all potential novel foods would necessarily be captured by one of the categories.

The current categories of novel foods recognized in the guidelines are:

- dietary macro-components;
- whole foods;
- extracts of plants, animals or micro-organisms; and
- viable micro-organisms.

The detailed record of considerations in relation to Standard 1.5.1 that FSANZ maintains was used as a guide to a revised set of categories. There are over 100 potential novel foods that have been considered by the NFRG (in conjunction with jurisdictions). This provides an extensive basis for considering any revisions to the categories.

The revised categories suggested based on this exercise are similar to the current categories, however seven rather than four categories are proposed. The suggested revised categories are as follows:

- plants or animals and their components;
- plant or animal extracts;
- herbs (both non-culinary and culinary) including extracts;
- dietary macro-components;
- single chemical entities;
- micro-organisms (including probiotics); and
- foods produced from new sources, or by a process not previously applied to food.

A description of these seven categories is included in the revised guidelines at Attachment 7. An editorial note for inclusion in Standard 1.5.1 is proposed that will make reference to the categories of novel foods in the guidelines.

5.4.3 Data requirements for making a novel food application

The current guidelines for novel foods contain information on required data for the safety assessment of novel foods. This provides a guide for applicants about what general, toxicological and nutritional data would be required. Data requirements for novel foods generally and for the newly revised categories for novel foods have been revisited however, this work is not yet finalised and further progress will be made before the Final Assessment. This information is in the revised guidelines for novel foods at Attachment 7. As previously mentioned in section 5.3.2, the proposed revised guidelines (Attachment 7) will not be placed on the FSANZ website until the completion of this review.

5.4.4 Assessment issues

FSANZ has considered whether the approach of substantial equivalence could be used to assess a novel food derived from a novel source and potentially, whether the approval process could be simplified. The EU regulations for novel foods allow for a simplified notification procedure for those novel foods that are purported to be substantially equivalent to existing foods. It could be argued that such an application for a novel food, for which the risk assessment could be completed using the approach of substantial equivalence, raises issues of minor significance or complexity only and could be assessed under section 36 of the FSANZ Act and be released for one round of public comment only. It would not be possible to apply this approach to all novel foods, particularly whole foods.

The issue was raised in the Initial Assessment Report and there was good support from submitters for using the approach of substantial equivalence as this would reduce the assessment time, may require only one round of public consultation, and would also assist in helping to protect sensitive commercial information and a legitimate market advantage.

The approach of substantial equivalence would involve mainly a comparison of the specifications for two different novel food ingredients. However, an application for a novel food ingredient derived from novel source may affect overall consumption of that novel food ingredient and a dietary exposure assessment should still be undertaken.

If a new novel food is argued to be substantially equivalent to a previously assessed novel food and the application for the previously assessed novel food had data submitted and accepted as confidential commercial information, then this data would not be able to be used in the new application process.

5.4.4.1 Conclusion and outcome

It is possible for an application for a novel food from a novel source or produced using a new technology that raises issues of minor significance or complexity only to be assessed under section 36 of the FSANZ Act and be released for one round of public comment only. This would allow for safety and dietary exposure assessments to be undertaken and the application progressed in a potentially shortened timeframe without specifically referring to the approach of substantial equivalence. It has been articulated in the revised guidelines for novel foods at Attachment 7 that certain novel food applications may be assessed under section 36 of the FSANZ Act.

5.4.5 Uptake of existing permissions/post-market monitoring

The importance of monitoring novel foods, once approved, to determine market trends following release into the food supply has been identified. FSANZ has stated in its guidelines for novel foods that, for approved novel foods, FSANZ will seek cooperation from the food industry to obtain post-market monitoring data. Such data should provide additional reassurance regarding long-term safety of products, as well as their impact on the food supply. Data on the sale of novel foods and novel food ingredients and the nature of the final product sold on the market in Australia and New Zealand is valuable for informing both the review of novel foods and also the assessment of future applications. This type of data can potentially inform the dietary exposure assessment.

Specific data which may be useful in this context includes:

- identification of product categories which contain the novel food;
- the level of the novel food in each product category;
- an estimate of market share for product categories containing novel foods; and
- provision of a report on the notification of adverse reactions/complaints received by the manufacturer(s).

FSANZ has very limited data on most approved novel foods and this was presented in the Initial Assessment Report. FSANZ sought information from submitters on the uptake of existing permissions for novel foods by industry including quantitative data on sales and market share, however no additional information was provided.

There is currently no process for removing an approved novel food from the list once it has been used extensively. FSANZ could consider reviewing the approved novel foods, for example, every 10 years, so long as sufficient data is obtained. However, removal of a novel food permission from the Standard would have no real advantage as the novel food would have already undergone pre-market assessment and removal of a permission would also necessitate removal of its consideration as novel from the outcome views in relation to novelty of food on the FSANZ website.

FSANZ is seeking views from submitters on the merits of establishing a review process for those novel foods already approved for use in Australia and New Zealand (e.g. 10 years following approval), subject to receipt of sufficient data on extent of use.

FSANZ is also seeking information on the use of approved novel foods currently on the market in Australia or New Zealand, including quantitative data on sales and market share.

5.5 Data protection

Currently, all relevant information needs to be provided to FSANZ to support an application for a novel food. This includes the nature of the novel food or novel food ingredient, any specific target population sub-group, the proposed food uses and the proposed levels of use to inform the dietary exposure assessment. The general method of production of the novel food is also assessed and presented in a food technology report. This information is all publicly available by virtue of reports released for public comment and public access to the public register for that application, unless certain information is requested to be considered as confidential commercial information (CCI) and this is agreed by FSANZ in accordance with the Act.

Specific details on the method of production or the source material is the type of information for which CCI status is often sought and granted in relation to novel foods. Toxicological data, the proposed food uses and the proposed levels of use are not normally granted CCI status in accordance with the Act. In some cases, mock-up samples are provided to enable FSANZ to assess whether they would appeal to a non-target population sub-group or a population sub-group for which there may be a greater public health and safety concern.

During the policy development for novel foods, stakeholders, specifically industry stakeholders, raised concerns about the protection of commercially sensitive information, including the proposed food uses and the proposed levels of use. As a result of these issues raised, the Ministerial Council policy guidelines on novel foods requests that FSANZ consider, as part of the review process, the issue of protection of information. One of the specific policy principles 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.*

Not all novel foods would be protected by a patent and more commonly, the method of production/technology used to produce the novel food would be patented rather than the novel food itself. Patents are expensive, although a one-year provisional patent is cheaper than a full patent and generally not issued until the company makes a decision as to whether to apply for a full patent or not.

The information made available to the public through the course of an application can be used by a viable competitor to develop a similar product to coincide with the gazettal of the approval for that novel food.

In this case, the competitor 'rides on the back' of a generic permission without having invested resources into the compilation of data for the application, liaising with FSANZ during the course of assessment of the application, or paying for the application to be assessed under workgroup 3. This, in effect, removes the commercial advantage of the applicant. It was acknowledged that the issues were raised previously through consideration of Health Claims. CCI provisions provide some protection to industry stakeholders, however, these provisions alone do not prevent a competitor from developing a similar product to coincide with the gazettal of a permission for a novel food.

Submitters to the Initial Assessment Report echoed 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 (discussed in section 5.4.4).
- Partial assessment could be completed and then the applicant informed early of the likelihood that it would undergo a full assessment (this would allow the applicant to withdraw if there was unlikely to be a favourable outcome for the application).

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, however, some circumstances were discussed in section 5.4.4.

Other options for addressing the issue of data protection are outside the scope of this review. The FRSC steering committee addressing the FSANZ assessment and approval process is considering the protection of confidential commercial information.

5.5.1 Consideration and outcome

Where appropriate, novel food applications will be assessed under section 36 of the FSANZ Act, allowing for only one round of public comment and a shortened assessment time, thereby reducing the likelihood of a competitor being in a position to 'ride on the back' of a generic permission. The CCI provisions in the Act will continue to be used where applicable. Other options for addressing the issue of data protection will be considered by the FRSC steering committee addressing the FSANZ assessment and approval process.

5.6 Inter-relationships with this review and other work

5.6.1 Inter-relationships with existing standards

The Novel Foods Standard is inter-related to a number of other Standards within the Code. Some examples are as follows:

- Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations – is relevant because advisory statements are required as a condition of use for some novel foods.

- Standard 1.2.6 – Directions for Use and Storage – is relevant because directions for preparation of some foods may still be necessary even if the food is considered 'traditional' and therefore not captured by the definition for 'novel food' or the requirements of the Standard (e.g. cassava).

- Standard 1.3.4 – Identity and Purity – is relevant because specifications for novel foods are included in this Standard and it is a requirement that approved novel foods comply with those specifications.

- Standard 1.4.4 – Prohibited and Restricted Plants and Fungi – is relevant because some plants and plant extracts could be considered novel foods.

- Standard 1.5.2 – Food Produced Using Gene Technology and Standard 1.5.3 – Irradiation of Food are the other Standards requiring food subject to these Standards to have a pre-market assessment. Genetically modified foods are considered as novel foods under regulations in some countries.

- Standard 2.6.2 – Non-alcoholic beverages – is relevant because beverages containing potentially novel ingredients that may be sold in other countries are often the subject of novel food inquiries.

- Standard 2.6.4 – Formulated Caffeinated Beverages – is relevant because beverages containing caffeine may also contain potentially novel ingredients, particularly products sold in other countries. These products are often the subject of novel food inquiries.

- Standard 2.9.4 – Formulated Supplementary Sports Foods – is relevant because products targeted to sports people may also contain potentially novel ingredients.

The implications of any amendment to the Novel Foods Standard for these related Standards has been considered in the development of this Report. Because the proposed changes to the Standard are minimal and intended to provide additional clarity in relation to what is deemed to be a novel food, implications for other Standards have not been identified.

5.6.2 Inter-relationships with other projects

The work of the FRSC Sub Group considering the addition to food of substances other than vitamins and minerals with a view to developing a policy guideline on the addition of these substances is relevant to this review. The scope of what is intended to be considered by the Sub Group is broad and will likely include substances such as non-culinary herbs and extracts thereof (e.g. ginkgo, echinacea), nutritive substances other than vitamins and minerals (e.g. amino acids), substances that may promote health (e.g. conjugated linoleic acid) or enhance performance (e.g. creatine), probiotics and disease risk-modifying substances (e.g. phytosterols, nucleotides). A number of these substances could currently be considered as novel food ingredients. Excluded from the scope of the considerations are substances added to foods for a technological purpose, vitamins and minerals, whole foods and special purpose foods.

An issues consultation paper was released for public comment in February 2005 and a stakeholder workshop was held on 1 March 2005. It is anticipated that the final policy guideline will be finalised in 2006.

It is not clear how these anticipated policy guidelines would interact with the Novel Foods Standard. A number of substances currently considered to be novel that are also included in the scope of what is being considered by the FRSC Sub Group may need to be addressed based on any such policy guidance.

5.6.3 Inter-relationships with the foods-therapeutic goods interface

5.6.3.1 Regulations for foods and therapeutic goods

In Australia, products are regulated as either foods in accordance with the Code or as therapeutic goods, including complementary medicines, as regulated by the Therapeutic Goods Administration (TGA).

In New Zealand, products are currently regulated as foods in accordance with the Code, as dietary supplements in accordance with the New Zealand *Dietary Supplements Regulations 1985* (NZDSR), or as medicines in accordance with the Medicines Act 1981. Products manufactured in accordance with the NZDSR include both therapeutic-type and food-type (i.e. food form such as beverage) dietary supplements. Most therapeutic-type dietary supplements manufactured to the NZDSR would be considered complementary medicines in Australia. Under the Trans-Tasman Mutual Recognition Arrangement (TTMRA), food-type dietary supplement products can be legally imported from New Zealand into Australia without meeting the compositional and labelling requirements of the Code, provided they comply with the Dietary Supplements Regulations in New Zealand.

The New Zealand and Australian Governments have agreed to establish a trans-Tasman therapeutic products agency. From 2006, the joint agency will replace the Australian TGA and New Zealand's Medsafe. New legislation that will cover regulation of therapeutic products in both countries will be introduced. The Joint Scheme will introduce risk-based regulation of complementary medicines as therapeutic products for the first time in New Zealand. Consideration is currently being given, through different fora, to the ongoing management of the interface between foods and therapeutic goods in Australia and New Zealand.

5.6.3.2 Foods-therapeutic goods interface

A number of foods contain bioactive ingredients and are presented in a manner that places them at the interface of regulations relating to foods and therapeutic goods. Currently, many products manufactured to the NZDSR and imported into Australia under the TTMRA raise questions as to whether they are foods or therapeutic goods. In particular, some food-type dietary supplements manufactured to the NZDSR may contain substances that are not present in the food supply in Australia or not widely consumed. Such substances may be considered 'traditional' in New Zealand but 'non-traditional' in Australia. It is ambiguous whether such substances could be considered under the Novel Foods Standard even if there were sufficient concerns about safety to otherwise consider the food 'novel'.

Some potential novel foods have characteristics of products that sit at the interface between foods and therapeutic goods, particularly complementary medicines. Plant and herbal extracts are increasingly being used in the food supply, some of which may be considered novel, and may also be used in complementary medicines/dietary supplements.

In other cases, the physical presentation of a potential novel food may more closely resemble a therapeutic form, e.g. a tablet intended to be crushed and consumed with another food such as cereal.

5.7 Consideration of Ministerial Council Policy Guidelines

In developing and varying standards, FSANZ must also have regard to any written guidelines formulated by the Ministerial Council. In developing this Report, FSANZ has attempted to address the Ministerial Council Policy Guidelines as far as possible and our response to the guidelines has been discussed with SDAC members. The way in which FSANZ has addressed the guidelines is described below.

In response to the higher order principles:

- Retaining regulation for novel foods with a risk-based approach for pre-market assessment ensures the protection of public health and safety.

- Consumers would have access to sufficient information to enable informed choice through any labelling information specified in the conditions of use for novel food permissions and through general labelling requirements.

- The purpose of regulation for novel foods is to provide a framework for the risk-based assessment of new foods to ensure their safety prior to sale. Since the focus of this regulation is on safety, it is not inconsistent with (though also not directly relevant to) national policies and legislation including those relating to nutrition and health promotion.

- FSANZ has considered other relevant regulations for novel foods, namely in the EU and Canada and has discussed these regulations with members of the SDAC, in revising the definitions in Standard 1.5.1.

- The revised guidelines assist in increasing transparency by way of more information about the process for determining novelty and the inclusion of a guidance tool for determining novelty. Transparency is also increased by the separation of the outcome views with respect to novelty from the guidelines document. Where appropriate, applications for novel foods could be assessed in accordance with section 36 of the FSANZ Act while other issues related to timeliness of the regulatory environment are being addressed by the FRSC steering committee addressing the FSANZ assessment and approval process. Standard 1.5.1 is consistent with minimum effective regulation as highlighted by the fact that over 100 potential novel foods have been considered and only approximately 25% have been deemed to be subject to the pre-market requirements of the Standard. The revised definitions should encourage fair trade by increasing the consistency of determining novelty. Industry growth, innovation and international trade may be encouraged by the increased availability of information regarding the novel food regulations in the guidelines and outcome views documents, and by any education undertaken which raises awareness of the regulations.

In response to the specific principles:

- The maintenance of public and industry confidence in the food system was considered in the impact analysis of the regulatory options and in increasing transparency with respect to determining novelty.

- Commercially sensitive information is protected to the extent possible under the FSANZ Act. Where appropriate, novel food applications will be assessed under section 36 of the FSANZ Act, allowing for only one round of public comment and a shortened assessment time. Other options for addressing the issue of data protection will be considered by the FRSC steering committee addressing the FSANZ assessment and approval process.

- Conditions of use for novel foods can be specified to provide consumers with appropriate information on novel foods or novel food ingredients that may assist them in understanding the novelty or functionality of the ingredients. This provision coupled with the general labelling requirements including full disclosure of the name of the novel food ingredient should ensure that consumers are not mislead by novel foods or novel food ingredients which appear similar to existing foods but may differ in terms of nutrition or function.

In response to the policy guidance:

- FSANZ is reviewing Standard 1.5.1 through a Proposal.

- FSANZ has held discussions with stakeholders, including jurisdictions, on the purpose of the Standard and also sought views from submitters. There was support for the purpose of the standard – that novel foods undergo a risk-based assessment to ensure their safety prior to sale.

- A SDAC was established to provide advice to FSANZ during the review comprising members representing industry, consumers, public health and government. The government enforcement agencies represented include New South Wales Food Authority, South Australian Department of Health, Queensland Health, the Australian Quarantine and Inspection Service and New Zealand Food Safety Authority.

- Consideration has been given to the subjectivity and scope of the definitions (section 5.2), protection of information (section 5.5) and level of assessment to be commensurate with level of risk (section 5.4.4), the issues raised by stakeholders during the FRSC consultation.

- FSANZ has reviewed the guidelines for novel foods and these are included at Attachment 7. Amendments to the guidelines include further articulation of the process by which novelty is determined including a description of the NFRG, a guidance tool for determining novelty, an update reflecting the amendments to Standard 1.5.1, revised categories of novel foods and data requirements, and a description of when it may be appropriate for a novel food application to be assessed under section 36 of the FSANZ Act.

6. Regulatory Options

The review of novel foods is broad with a number of issues being considered and there are a large number of potential regulatory and non-regulatory options. In the Initial Assessment Report, the most feasible options were presented. These options covered both regulatory and non-regulatory initiatives. FSANZ sought views of submitters to the Initial Assessment Report on preferred options and any additional options or initiatives that should be covered. One suggestion was made for an additional regulatory option, which was to consider the implementation of a notification procedure similar to the US GRAS system. A notification procedure was considered in the development of Standard 1.5.1 however, it was not feasible under the FSANZ Act.

One of the options put forward in the Initial Assessment Report was to have no specific regulation for novel foods (Option 4). This option involved:

- Removal of the current Standard 1.5.1.
- Removal of the document 'Format for applying to amend the Code – Novel Foods' from the website as this would no longer be relevant.
- Removing or substantially narrow the guidelines document to reflect that there is no specific regulation for novel foods.
- Regulating novel foods through relevant generic standards in the Code.

There was some support from industry submitters to the Initial Assessment Report for this Option on the basis that the Food Acts adequately ensure the sale of safe food. However, this Option is not seen by as affording adequate protection for public health and safety. This option cannot satisfy the objectives of the FSANZ Act or the specific objectives of this proposal and therefore it is not feasible. On this basis, Option 4 has been dismissed and is not put forward in this Report.

Three options are put forward (essentially Options 1, 2 and 3 put forward in the Initial Assessment Report) with only minor modifications in comparison with those put forward in the Initial Assessment Report. The Options for this review are:

6.1 Option 1: Retain the *status quo*

- Retain the current Standard 1.5.1 – Novel Foods.
- Retain the current assessment process for novel foods.
- Retain the current supporting documents on the website but continue to update the considerations by the NFRG in the guidelines as is the case currently.
- Retain the current operation for determining novelty i.e. NFRG working in conjunction with jurisdictions.

6.2 Option 2: Retain the current standard but amend operating procedures

- Retain the current Standard 1.5.1 – Novel Foods.
- Retain the current assessment process for novel foods.
- Amend the supporting documents as required, particularly the guidelines. Review the classes of novel foods referred to in the guidelines and develop data requirements for each of the identified classes.

- Amend operating procedures for determining novelty by developing a decision-tree to assist the NFRG.
- Undertake education for stakeholders in response to demand that may assist in reducing the load on the NFRG.

6.3 Option 3: Amend Standard 1.5.1 and operating procedures

- Maintain the intent of the current Standard but review the wording of the purpose clause and the definitions for 'non-traditional food' and 'novel food'.
- Amend the definition for novel foods to capture foods produced using new technologies that have altered characteristics.
- Amend the supporting documents as required, particularly the guidelines. Review the classes of novel foods referred to in the guidelines and develop data requirements for each of the identified classes.
- Amend the guidelines to indicate that it is possible for an application for a novel food from a novel source or produced using a new technology that raises issues of minor significance or complexity only to be assessed under section 36 of the FSANZ Act and be released for one round of public comment only.
- Amend operating procedures for determining novelty by developing a decision-tree to assist the NFRG.
- Undertake education for stakeholders in response to demand that may assist in reducing the load on the NFRG.

7. Impact Analysis

7.1 Affected Parties

1. Consumers of novel foods or novel food ingredients in Australia and New Zealand including: those consumers interested in discerning the difference between novel foods and similar appearing traditional foods which may differ in terms of composition; the indigenous populations; target population sub-groups where appropriate (e.g. consumers of phytosterol esters wishing to lower their blood cholesterol levels); and non-target population sub-groups which may consume novel foods (e.g. children).

2. 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.

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

4. 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.

7.2 Data Collection

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. FSANZ has sought advice from the SDAC on the possible costs and benefits associated with each option, however, it was widely acknowledged that quantitative data is difficult to obtain due to the limited number of novel foods on the market in Australia and New Zealand. There was no quantitative information provided on the potential costs and benefits associated with the regulatory options by submitters to the Initial Assessment Report.

7.3 Impact Analysis

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 9.

FSANZ is seeking input from stakeholders on the potential impacts on each of these identified regulatory options.

Option 1 (status quo) affords a high level of protection of public health and safety, however some costs have been identified for all affected parties that should be further considered and addressed if possible.

Option 2 provides a benefit to all affected parties in comparison with Option 1 due to greater clarity around determining novelty and the operating procedures generally. Under this Option, the operating procedures would be amended and a decision-tree included in the guidelines, providing increased clarity to all affected parties. Stakeholders would benefit from any education undertaken in response to demand. However, this Option would not allow the review of the regulations for novel foods including the definitions and the asserted subjectivity associated with the definitions would not be addressed.

Option 3 affords a clear benefit to consumers, public health professionals and government in comparison with Option 2 due to the opportunity to provide increased clarity around the definitions in addition to the process for determining novelty. Increased clarity around definitions would increase industry confidence in determining which foods are captured by the Standard and improve the efficiency of government enforcement agencies. Regulation of foods produced using new technologies would benefit consumers and public health professionals, and any cost to industry is likely to be minimal since only those foods with altered characteristics would be deemed to be novel. Option 3 is the only option that allows FSANZ to adequately address and implement the Ministerial Council Policy Guideline on novel foods.

Overall, Option 3 is the preferred regulatory Option.

8. Consultation

8.1 Consultation

There is a keen interest in the review of the novel foods standard, particularly from industry and government enforcement agencies. There is also some interest from public health/nutrition stakeholders in Applications assessed against the existing Standard. There is less interest from the broader community in the regulation of novel foods. Therefore, FSANZ has developed a targeted consultation strategy to seek views of key stakeholders.

8.1.1 Standard Development Advisory Committee

The policy guidance issued by the Ministerial Council on novel foods requested that FSANZ use a reference group that includes representatives from relevant Australian Government, New Zealand and State and Territory enforcement agencies to provide advice in reviewing the Standard. Nominations were sought for representatives from industry, public health and consumer groups to participate on the SDAC in addition to government representatives. The FSANZ Board established the SDAC and agreed to the Terms of Reference.

Guidelines for members were prepared to support the Terms of Reference and provide further details regarding the nature of issues for which input will be sought and the anticipated timelines. The membership of the SDAC and its terms of reference and guidelines are at Attachment 10. The Kahui (Maori Reference Group) was represented and FSANZ also approached OATSI seeking an indigenous representative however, no nomination was put forward.

The first meeting was held on 23 September 2004. Australian members attended the FSANZ office in Canberra and New Zealand members attended the FSANZ office in Wellington. Key staff members from FSANZ were also present as observers. Outcome notes were circulated to members the following day. The issues raised in discussions throughout the meeting and since the meeting were incorporated into the relevant issues sections of the Initial Assessment Report. SDAC members were also provided with a draft version of the Initial Assessment Report to provide comment on but not endorsement.

The second meeting was held on 21 June 2005, again with Australian members attending the FSANZ office in Canberra and New Zealand members attending the FSANZ office in Wellington. Submissions received in response to the Initial Assessment Report were discussed and the agenda was divided into regulatory issues, guidelines issues and operational issues. Outcome notes were circulated to members the following day. The issues raised at the meeting have been incorporated into this Report and have also informed the proposed direction being taken in the review. SDAC members were provided with a draft version of this Report to provide comment on but not endorsement.

8.1.2 Initial assessment

There were 15 submissions received in response to the Initial Assessment Report, 13 from Australia and two from New Zealand. The majority of submissions received were from the industry sector (8), followed by government (5), public health/nutrition (1), and individual (1). Six of the submissions received were from agencies/industry bodies or associations represented on the SDAC.

The remaining 11 SDAC representatives did not submit. A full summary of submissions including a list of submitters is at Attachment 11 and issues raised in submissions have been addressed in relevant sections of this Report, however a short summary of the main issues is provided here.

8.1.2.1 Regulatory options

Overall, Option 3 was most strongly supported (amend Standard 1.5.1 and amend the operating procedures), with 8 submitters favouring this option, followed by Option 4 (no specific standard for novel foods) favoured by 5 submitters.

8.1.2.2 Purpose of the Novel Foods Standard

The majority of submitters supported the purpose of the Standard, that novel foods undergo a risk-based assessment to ensure their safety prior to sale.

8.1.2.3 Definitions for 'non-traditional' and 'novel'

A number of submitters were of the view that there is no need to define 'non-traditional food' as the definition for novel can accommodate the intent of absence of history of safe use. It was suggested that a decision-tree could incorporate questions that will address the extent to which a potential novel food has been consumed. Some submitters stated that there is value in revising and maintaining a definition for 'non-traditional food' in the Novel Foods Standard.

8.1.2.4 Regulation of foods produced using new technologies

Some submitters indicated there is a need to regulate food produced using new technology. Others indicated that there is a need to regulate foods produced using new technologies only if the resultant food falls within the definition of novel food or there is evidence that the resultant food has significantly altered characteristics. Still other submitters did not support regulation of foods produced using new technologies as there is already a requirement to produce safe food.

8.1.2.5 Categories of novel Foods

All submitters who commented agreed that categories of novel foods are appropriate and helpful in the guidelines for novel foods but not appropriate to include in regulations for a variety of reasons. It was recommended that that the categories of foods currently referred to in the guidelines be revised based on experience since the introduction of the Standard.

8.1.2.6 Decision-tree

There was overwhelming support for the development of a comprehensive decision-tree and a more structured approach to determining novelty. Submitters suggested that a decision-tree would assist potential applicants and reduce the number of enquiries, and therefore, the workload of the Novel Foods Reference Group.

8.1.2.7 Expert panel

There was limited support for the establishment of an expert panel to assist in novel food determinations. Some submitters supported the establishment of an expert panel only if necessary in the future (e.g. if clear definitions and a decision-tree prove ineffective).

8.1.2.8 Education for industry

There was some support for education of stakeholders, including industry, in order to reduce the number of inquiries. However, there was also a view that clear definitions, a decision-tree and referral of previous determinations with respect to novelty would be just as effective.

8.1.2.9 Data protection

There was general agreement amongst submitters that the current assessment process does not protect confidentiality, which may enable competitors to develop similar products. A number of suggestions were made for addressing this issue, though the consideration of some may not be within the scope of this project.

8.1.2.10 Assessment process

There was support for considering the adoption of the approach of substantial equivalence for novel foods if appropriate (i.e. if a full safety assessment had been conducted on a similar food). This would result in shorter approval time, help protect sensitive information, and would be consistent with minimum effective regulation. However, it would have limited application for novel foods and some submitters were opposed outright to the approach.

8.1.3 Draft Assessment

FSANZ is now seeking comment in relation to this Draft Assessment Report. Comments received in response to this Report will be used to assist in the development of a Final Assessment Report.

Submitters are invited to provide comments in relation to:

- the issues discussed in section 5 of this Report;
- specific input sought in sections 5.3.2 and 5.4.5 of this Report;
- the proposed definitions for ‘non-traditional food’ and ‘novel food’;
- regulatory options and potential impacts in relation to these regulatory options;
- the proposed guidance tool for determining novelty; and
- the revised guidelines for novel foods.

8.2 Communication strategy

Although FSANZ identified a targeted group of stakeholders with which consultation is occurring, it is also beneficial to communicate the nature of the review and timelines 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 the novel foods standard. This interested parties group has been provided with updates in relation to the review on three occasions.

FSANZ included some information on the review of novel foods in *Food Standards News* in September 2004 and will continue to provide updates during the course of the review.

8.3 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 European Commission is currently reviewing the EU regulations for novel foods. Although the Standard currently covers a broad range of foods and captures a number of imported foods, amending the Code in relation to the regulation of novel foods is unlikely to have a significant effect on international trade. The proposed amendments to Standard 1.5.1 are intended to clarify the definition for novel foods and it is not anticipated that the range of foods that are subject to the Standard will vary significantly from what is captured currently. Therefore, the proposed amendments to Standard 1.5.1 will not be notified to the WTO under either the Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) agreements as the amendments are unlikely to significantly effect trade.

9. Conclusion and Recommendation

Decision

FSANZ recommends that an amended Standard 1.5.1 – Novel Foods, be retained to provide regulation for novel foods. The main proposed amendments to Standard 1.5.1 are revised definitions for 'non-traditional food' and 'novel food'. The process for determining novelty should continue but be refined, with the adoption of a revised guidance tool for determining novelty based on the definitions in the Standard.

FSANZ recommends that an amended Standard 1.5.1 be retained to provide regulation for novel foods for the following reasons:

- There is general support from stakeholders for the purpose of the Standard, that novel foods undergo a risk-based assessment to ensure their safety prior to sale.

- To ensure consistency with the specific objectives of this Proposal, particularly, to ensure: (i) the safety for human consumption of novel foods; (ii) that regulations are complementary with inter-related standards in the Code; and (iii) that there is implementation of the Ministerial Policy Guidelines as far as possible.

- To address the higher order and specific policy principles of the Ministerial Policy Guideline, specifically: (i) to ensure priority is given to the protection and improvement of public health and safety in relation to food matters; (ii) to draw on the best elements of international regulatory systems and be responsive to future trends and developments; and (iii) to ensure that public and industry confidence in the food system is maintained and to ensure consumers are not mislead by novel foods or food ingredients which appear similar to existing foods but may differ in terms of nutrition or function.

- The purpose of the regulation for novel foods in Australia and New Zealand is consistent with the purpose of similar regulatory frameworks for novel foods in Canada and the EU.

FSANZ recommends that Standard 1.5.1 should continue to contain definitions for both 'non-traditional food' and 'novel food' (albeit, revised definitions) for the following reasons:

- The concept of '*absence of history of safe use*' is important for inclusion in the regulation for novel foods as it assists in the process of determining novelty. A revised definition for 'non-traditional food' has been retained to include this sentiment rather than incorporating it into the definition for novel food as the latter would likely result in a more cumbersome definition of novel food. This aims to ensure simplicity and clarity in the definitions for both 'non-traditional food' and 'novel food'.

- It is accepted that there will be some subjectivity associated with the definitions for 'non-traditional food' and 'novel food', however, the revised definitions omit the terms that were seen as ambiguous. An Editorial note is proposed to provide notes on the interpretation of the definitions.

- These revisions to the definitions address the Ministerial Policy Guidelines, specifically, that the subjectivity and scope of the current definitions be considered and addressed as far as possible. The revisions to the definitions also address the specific objectives of this Proposal, particularly to ensure: the safety for human consumption of novel foods; and that the regulations are readily enforceable.

FSANZ recommends that the process for determining novelty should continue but be refined, with the adoption of a guidance tool for determining novelty and amendments to the guidelines for novel foods for the following reasons:

- The proposed amendments to the guidelines for novel foods will provide greater clarity and transparency for stakeholders as to how the process for determining novelty is undertaken.

- The introduction of the proposed guidance tool for determining novelty will increase the level of rigour applied to the process of determining novelty. The guidance tool is consistent with the proposed decision-making mechanism of developing a decision-tree as proposed during the policy development process.

- These proposed changes are consistent with the Ministerial Policy Guidelines, specifically, that the user guide be reviewed to include any amendments to the novel food definition and to provide greater clarity about the process for determining if a food is novel or not.

10. Implementation and review

It is anticipated that the review of novel foods will not be completed until mid 2006 as a number of complex issues are being addressed, involving consultation with stakeholders.

The public comment period for this Report is longer than usual to allow submitters to comment on the complex issues that are raised and the proposed amendments to Standard 1.5.1. It is likely that the SDAC will meet again following receipt of submissions in response to this Report and prior to the completion of the Final Assessment Report.

Any amendments to the regulation for novel foods would be gazetted following notification of the Final Assessment Report to the Ministerial Council. Any changes to the supporting documents described in section 4.1.1 of this Report would be made public on the FSANZ website at the time of gazettal or before. FSANZ is considering education for stakeholders on a demand basis to coincide with the introduction of any amendments to the regulation for novel foods.

FSANZ has described a mechanism to track the uptake of permissions for novel foods by industry in the revised guidelines at Attachment 7. This includes gathering information on the nature and range of the final food products introduced to the market in Australia and New Zealand, the levels of the novel food used, sales and market share data. FSANZ will also consider how best to evaluate the relative effectiveness and workability of any amended regulations for novel foods.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Current Standard 1.5.1 – Novel Foods – of the Code
3. Format for applying to amend the *Australia New Zealand Food Standards Code* – Novel Foods
4. Risk Assessment for Novel Foods
5. Analysis of stakeholder comments to the FRSC policy options paper
6. Ministerial Council Policy Guidelines
7. [Revised] Guidelines to assist in applying to amend the *Australia New Zealand Food Standards Code* – Novel Foods
8. Outcome views with respect to novelty
9. Impact Analysis
10. Standard Development Advisory Committee Membership, Terms of Reference and Guidelines
11. Summary of submissions to the Initial Assessment Report

ATTACHMENT 1

Draft Variations 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 –*

[1.1] *omitting* the second paragraph of the Purpose*, substituting –*

The purpose of this Standard is to ensure that novel foods will undergo a risk-based safety assessment before they are offered for sale in Australia and/or New Zealand.

[1.2] *omitting clause 1, substituting –*

1. Definitions

In this Standard –

non-traditional food means –

(a) a food that has not been generally available to a broad cross-section of consumers in Australia or New Zealand; or
(b) a substance derived from a food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food; or
(c) any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand.

novel food means a non-traditional food that may be unsafe having regard to –

(a) the composition or structure of the food; or
(b) the potential for adverse effects in humans; or
(c) patterns and levels of consumption of the food; or
(d) the process by which the food has been prepared; or
(e) the source from which it is derived; or
(f) any other relevant matters.

[1.3] *omitting the* Editorial note *after clause* 1, *substituting –*

Editorial Note:

Novel food includes novel foods used as ingredients in another food.

Possible categories of novel foods are described in the Authority's guidelines. Categories of novel foods may include, but are not limited to: plants or animals and their components; plant or animal extracts; herbs, including extracts; dietary macro-components; single chemical entities; micro-organisms, including probiotics; foods produced from new sources, or by a process not previously applied to food.

ATTACHMENT 2

STANDARD 1.5.1

NOVEL FOODS

Purpose

This Standard regulates the sale of novel food and novel food ingredients. This Standard prohibits the sale of these foods unless they are listed in the Table to clause 2, and comply with any special conditions of use in that Table. The specific permission may impose conditions relating to matters such as the need for preparation or cooking instructions, warning statements or other advice, or the need to meet specific requirements of composition or purity.

The purpose of this Standard is to ensure that non-traditional foods which have features or characteristics which raise safety concerns will undergo a risk-based safety assessment before they are offered for retail for direct consumption in Australia and/or New Zealand.

The Authority will assess the safety for human consumption of each novel food prior to its inclusion in the Table. The safety assessment will be performed in accordance with the Authority's safety assessment guidelines.

Foods produced using gene technology and foods which have been irradiated are regulated in Standards 1.5.2 and 1.5.3 respectively.

Table of Provisions

Clauses

1 Definitions

In this Standard –

non-traditional food means a food which does not have a history of significant human consumption by the broad community in Australia or New Zealand.

novel food means a non-traditional food for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account –

(a) the composition or structure of the product; or
(b) levels of undesirable substances in the product; or
(c) known potential for adverse effects in humans; or
(d) traditional preparation and cooking methods; or
(e) patterns and levels of consumption of the product.

Editorial Note:

Novel food includes novel foods used as ingredients in another food.

2 Sale of novel foods

A novel food must not be sold by way of retail sale as food or for use as a food ingredient unless it is listed in column 1 of the Table to this clause and complies with the conditions of use, if any, specified in column 2.

Table to clause 2

Column 1	Column 2
Novel Food	**Conditions of Use**
α-cyclodextrin	The name 'alpha cyclodextrin' or 'α-cyclodextrin' must be used when declaring the ingredient in the ingredient list, as prescribed in Standard 1.2.4.
Diacylglycerol oil (DAG-Oil)	'Diacylglycerol oil' is a prescribed name. Notwithstanding clause 4 of Standard 1.2.4, diacylglycerol oil must be declared in the statement of ingredients using the prescribed name.
Docosahexaenoic acid (DHA) – rich dried marine micro-algae (*Schizochytrium* sp.)	
Docosahexaenoic acid (DHA) – rich oil derived from marine micro-algae (*Schizochytrium* sp.)	
Docosahexaenoic acid (DHA) – rich oil derived from marine micro-algae (*Ulkenia* sp.)	
γ-cyclodextrin	The name 'gamma cyclodextrin' or 'γ-cyclodextrin' must be used when declaring the ingredient in the ingredient list, as prescribed in Standard 1.2.4.
Phytosterol esters	The requirements in clause 2 of Standard 1.2.3. The name 'phytosterol esters' or 'plant sterol esters' must be used when declaring the ingredient in the ingredient list, as prescribed in Standard 1.2.4. May only be added to food - (1) according to Standards 1.3.4 and 2.4.2; and (2) where the total saturated and trans fatty acids present in the food is no more than 28% of the total fatty acid content of the food.
D-Tagatose	

Table to clause 2 (continued)

Column 1	Column 2
Novel Food	**Conditions of Use**
Tall oil phytosterols	The requirements in clause 2 of Standard 1.2.3. The name 'tall oil phytosterols' or 'plant sterols' must be used when declaring the ingredient in the ingredient list, as prescribed in Standard 1.2.4. May only be added to food - (1) according to Standards 1.3.4 and 2.4.2; and (2) where the total saturated and trans fatty acids present in the food is no more than 28 % of the total fatty acid content of the food.
Trehalose	

Editorial note:

Novel Foods must meet the requirements of Standard 1.3.4 – Identity and Purity.

The Table to Clause 2 contains conditions relating to novel foods. Nothing contained in this Code permits the mixing of phytosterol esters and tall oil phytosterols.

ATTACHMENT 3

Format for applying to amend the *Australia New Zealand Food Standards Code* – Novel Foods

updated June 2005

PART 1 GENERAL INFORMATION

1.1 Applicant

You should give details of:

(a) Company/organisation name;
(b) Address (street and postal);
(c) Contact (name/s, telephone and facsimile numbers); and
(d) Nature of your business (for example, manufacturer of additive/agent of manufacturer/food processor etc.).

1.2 Nature of application

You should state whether your application is:

(a) to develop a new Standard or vary an existing Standard;
(b) being made on behalf of a single company or organisation, or on behalf of the food industry, a sector of the food industry, or other companies or organisations; or
(c) a co-application being made on behalf of more than one company or organisation. If it is, you must provide the names and addresses of all parties to the application.

PART 2 SPECIFIC INFORMATION

2.1 Details of the application

(a) brief description of the nature of the novel food;

(b) the proposed name the product will be marketed under; and

(c) a list of the products that are likely to include the food.

PART 3 SAFETY ASSESSMENT CONSIDERATIONS

FSANZ assesses the safety of foods in accordance with internationally accepted risk-based principles as described in the paper *Framework for the assessment and management of food-related health risks* which is available from Info@foodstandards.gov.au. It is currently being updated and will be available from the web in due course. The factors which need to be considered in the safety assessment of novel foods will vary depending on the nature of the food and may change over time as better information becomes available. Further details on the safety assessment are provided in the next section.

Where a novel food has been approved by another national or international body, FSANZ will give due regard to this assessment in consideration of approval in Australia and New Zealand.

Generally, the information provided should cover the following:

3.1 Product information

You should identify:

(a) nature and purpose of the novel food;
(b) preparation methods /specifications, if appropriate;
(c) use overseas or by population sub-groups;
(d) stability in cooking and processing; and
(e) any requirement for processing or cooking before consumption.

3.2 Dietary intake

You should identify:

(a) proposed pattern of use;
(b) predicted exposure level for average and extreme consumers;
(c) predicted exposure level for any special target group.

3.3 Nutritional data

In general, nutritional data is sought to ensure that the nutritional status of the consumer is not compromised by the use of a novel food or by substitution of presently used food by a less nutritious food. See the accompanying safety assessment guidelines in the next section.

3.4 Toxicological data

The necessity for toxicological assessment will depend on the nature of the novel food and in some cases, both in vitro and in vivo studies may be required. See the accompanying safety assessment guidelines in the next section.

PART 4 OTHER TECHNICAL INFORMATION

4.1 Energy values

The determination of energy values will only be necessary if there is to be a low energy claim associated with the novel food. This would generally be the case only for dietary macro-components. Guidelines for the determination of energy values are provided at the end of this document.

PART 5 REGULATORY/LEGISLATIVE IMPLICATIONS

5.1 Other approvals

You should provide details of the following:

(a) any approvals that have been granted by overseas bodies which may be relevant to the proposed use of the food.
(b) whether approval has been rejected or withdrawn by any regulatory body.

5.2 Regulatory Impact Statement

In most cases, it is now mandatory for FSANZ to prepare a Regulatory Impact Statement (RIS) when considering applications to vary the Code. A RIS seeks to identify and assess any social, economic and/or environmental impacts of an application. Please identify the economic implications associated with your application. Relevant quantitative and qualitative information FSANZ requires could include:

- cost implications
- profit implications
- market share implications
- price implications
- trade implications
- employment implications.

PART 6 STATUTORY DECLARATION - AUSTRALIA

The information provided in Parts 1 to 3 must be attested to by a statutory declaration in some suitable form along the following lines:

STATUTORY DECLARATION

Statutory Declarations Act 1959

I, [*Name, address and occupation of person making the declaration*]

make the following declaration under the *Statutory Declarations Act 1959*:

1. the information provided in this application fully sets out the matters required
2. the information provided in this application is true to the best of my knowledge and belief
3. no information has been withheld that might prejudice this application, to the best of my knowledge and belief

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the *Statutory Declarations Act 1959*, and I believe that the statements in this declaration are true in every particular.

[*Signature of person making the declaration*]

Declared at [*place*] on [*day*] of [*month*] [*year*]
Before me,

[*Signature of person before whom the declaration is made*]*
[*Full name, qualification and address of person before whom the declaration is made (in printed letters)*]

* A statutory declaration must be made before a prescribed person under the *Statutory Declarations Act 1959*, available online at http://www.frli.gov.au/.

PART 6 STATUTORY DECLARATION – NEW ZEALAND

The information provided in Parts 1 to 3 must be attested to by a statutory declaration in some suitable form along the following lines:

STATUTORY DECLARATION

Oaths and Declarations Act 1957

I, [*name*] of [*place of residence and occupation*] solemnly and sincerely declare that:

1. the information provided in this application fully sets out the matters required; and
2. the information is true to the best of my knowledge and belief; and
3. no information has been withheld which might prejudice this application to the best of my knowledge and belief.

And I make this solemn declaration conscientiously believing the same to be true and by virtue of the *Oaths and Declarations Act 1957*.

Declared at [*location*] this [*date*]

Signature

Declared before me* .....…

*A statutory declaration must be made before a person authorised to take a statutory declaration under the *Oaths and Declarations Act 1957*, available online at http://www.legislation.govt.nz.

Application to develop or vary the *Australia New Zealand Food Standards Code*

Novel Foods Checklist

PART 1 General information	**Data provided**	**Data Not provided**	**Omission explained**
1.1 Applicant (a) Name (b) Address (c) Contact (d) Business **1.2 Nature of application** (a) New or variation (b) Sole or joint (c) Co-applicants			
PART 2 Specific information			
2.1 Details of application (a) Nature of the novel food (b) Proposed marketing name (c) List of products likely to contain the novel food			
PART 3 Safety Assessment considerations			
3.1 Product information (a) nature and purpose of the novel food; (b) preparation methods /specifications, if appropriate; (c) use overseas or by population sub-groups; (d) stability in cooking and processing; and (e) any requirement for processing or cooking before consumption. **3.2 Dietary intake** (a) proposed pattern of use; (b) predicted exposure level for average and extreme consumers; (c) predicted exposure level for any special target group. **3.3 Nutritional data** **3.4 Toxicological data**			
PART 4 Other technical information			
4.1 Energy values			
5.1 Other approvals (a) any approvals that have been granted by overseas bodies which may be relevant to the proposed use of the food. (b) whether approval has been rejected or withdrawn by any regulatory body. **5.2 Regulatory Impact Statement**			
PART 6 Statutory declaration			

ATTACHMENT 4

Risk assessment for novel foods

The purpose of undertaking a risk assessment for a novel food is to confirm that there is a reasonable certainty that no harm will result from the intended use of the food. The risk assessment also determines whether or not the novel food offers the same basic level of safety that is expected for all foods. Where a food is produced using a new or novel process, the purpose of a risk assessment is to confirm that the food is equivalent to its traditional counterpart. This concept is referred to as substantial equivalence, but will have limited application to the safety of novel foods since most, by definition, will not have a traditional counterpart. The risk assessment comprises the following steps: hazard identification; hazard characterisation; exposure assessment; and risk characterisation.

The safety evaluation of foods involves consideration of a variety of toxicological and nutritional issues together with information on the chemistry and dietary intake of the product. Such evaluations differ somewhat from the traditional evaluation techniques that have been applied to food additives and contaminants both in the type and variety of information. Due to the much larger anticipated daily intake of foods compared to food additives, studies in animals have limited usefulness. This is because the larger intakes are likely to cause physiological, morphological or biochemical changes, which reflect an altered nutritional status rather than an indication of a toxic response. Human studies are more likely to offer relevant data. The exact data requirements depend on the type of novel food being considered.

Hazard identification

Hazards identification involves gathering information in order to identify any hazards of concern in the food. The information is gathered from sources such as: toxicological and nutritional data and evaluations, published literature, clinical studies, epidemiological studies and reports of adverse reactions. Because of the nature of novel foods, identified hazards could include the presence of a natural toxin, a safety concern if the food is not appropriately prepared, gastrointestinal effects with novel carbohydrates, or physiological effects such as altered metabolism.

Hazard characterisation

Hazard characterisation describes the nature and severity of any adverse health effects that result from the identified hazard. The following factors may influence the conclusions about the safety of novel foods:

- toxicity studies in animals;
- clinical, epidemiological or other studies in humans or observations in humans;
- source and composition of the novel food;
- evidence of previous human exposure;
- the level of consumption and extent of use, where the food has been used in other communities or in a different context (e.g. use in complementary medicines);
- the specifications for the ingredient;
- metabolic and toxicokinetic data;

- toxicity of any related substances or foods; and
- any known cases of adverse effects in humans.

Novel foods have the potential to affect the composition of the diet and the nutritional status of the general population. Adverse effects of novel foods might arise indirectly as a result of displacing traditional foods and ingredients from the diet, or directly by affecting the bioavailability of existing nutrients. Nutritional factors that may need to be considered include:

- the composition of the food including the levels of nutrients and anti-nutritional factors;
- the potential for the novel food to effect the absorption of other nutrients (this may involve using animal models);
- the potential for the novel food to displace other traditional foods in the diet (e.g. dietary macrocomponents); and
- an evaluation of the energy factor for the food (e.g. poorly absorbed carbohydrates), where necessary and requested.

Because of the nature of novel foods (i.e. complex mixtures or whole foods), in most cases there will be no reference health standard such as an acceptable daily intake (ADI) and it would not be appropriate to determine any.

Exposure assessment

A dietary exposure assessment is conducted for a novel food in order to predict the potential exposures to that novel food in Australia and New Zealand if it were to be approved for use and used at the proposed levels. A dietary exposure assessment is conducted for the general Australian and New Zealand populations and generally, for certain sub-groups of the population considered at potential risk from higher exposures (e.g. young children). Food consumption data are derived from the 1995 Australian National Nutrition Survey (NNS) and the 1997 New Zealand NNS. For certain novel foods where there is an acute affect associated with consumption of the food, the dietary exposure assessment may include an estimation of the bolus dose, which could be used as an indication of consumption at a single meal.

Risk characterisation

Risk characterisation of novel foods involves integrating the conclusions of the hazard characterisation and the predicted levels of exposure for that novel food. This is an estimation of the probability of occurrence and severity of an adverse effect for the general population and/or for a certain population sub-group. Because of the complex nature of novel foods, there is generally no reference health standard and it would not normally be appropriate to determine one. As such, it is not normally possible to characterise the risk posed by a novel food by comparing the estimated exposure for each population group to a reference health standard. In characterising the risk of a novel food it is necessary to take into account any uncertainties in the data, the strengths and weaknesses of the data, specific population sub-groups that may be at risk and the severity of any adverse effects that are noted (e.g. gastrointestinal effects compared with the potential for cancer).

ATTACHMENT 5

Analysis of stakeholder comments to FRSC policy options paper

The Food Regulation Standing Committee released a public consultation document on the issue of policy guidance for novel foods in February 2003. A summary of the policy options canvassed and the stakeholder responses is outlined below.

Five policy options and two decision making tools were proposed for consultation. Policy options:

1. Retain existing novel foods standard, process and definitions, accompanied by updated User Guide.
2. Introduce a more prescriptive, categories based definition for novel food, with the same assessment process to apply to all categories.

3a. Introduce greater flexibility into the assessment process, so that the level of assessment can be adjusted to the level of risk – *requires legislative changes to amend current practice.*

3b. Introduce greater flexibility into the assessment process, so that the level of assessment can be adjusted to the level of risk – *relying on administrative changes to amend current practice.*

No specific standard for Novel Foods. Delete the novel foods standard and rely on other provisions in the Code.

Decision making tools:

1. The 'decision tree' tool which would consist of a structured questionnaire that could be used in determining the novelty of a food as well assessing its risk and making judgements about information requirements. This would aim to provide robust guidance to administrative personnel.

2. Expert Panel to determine 'novelty'. The objective of the expert panel would be to provide a recognised, central point of advice regarding whether or not a food is novel.

Summary of submissions received

Australia

<u>Consumers and Dietitians</u>

2 submissions received.

On the whole, the submissions in this category supported the draft policy principles. In particular, consumer groups stated that they were pleased with the emphasis that had been placed on the interests of consumers. One submission stated that the policy principles were 'somewhat confusing' and suggested ways to clarify them.

All groups in this category supported option 2, stating that this option will provide clearer guidance on the definition of a novel food, which will assist industry and ensure public health and safety is protected. It was also stated in one submission that this is the only option to protect consumers to any extent.

Option 1 was not supported. Option 3a was supported by one group with conditions, while the other opposed it. It was stated that the potential risks to consumers of simplifying the assessment process would outweigh potential benefits, and it would reduce the level of public consultation. Similar comments were made regarding option 3b. Option 4 was opposed by one group on the grounds that it would result in a gap in regulation where novel foods could escape the pre-assessment process, while the other group did not comment.
Both submissions supported the decision tree model, with one group suggesting that the decision tree be category based, and the other suggesting it be used in combination with the expert panel model.

Industry

10 submissions received.

The groups that commented on the draft policy principles were overall supportive. Some made suggestions for changes of wording preferences. Suggestions were also made about reordering some of the specific principles to become high order principles, essentially resulting in the high order principles becoming more generic and the specific principles becoming more specifically applicable to novel foods.

On the whole, industry groups appear to favour option 4, with 3b being cited as a second preference. Reasons for preferring option 4 are the emphasis on safety, the possibility of foods being assessed under other existing standards, and the placement of responsibility on manufacturers and suppliers.

3a is also supported for similar reasons given in support of option 3b, but is not the preferred option because of the time and expense involved. Some groups oppose option 3a for this reason. Where industry groups commented, they opposed options 1 and 2. Option 1 was opposed because it is too subjective and does not allow for streamlining of the application process. Option 2 was seen as risking having categories that are too narrow or too broad, and it is seen to be in conflict with government policy of minimum effective regulation.

The decision tree is the preferred decision making model, with some groups supporting an expert panel in combination with a decision tree and other groups opposing it outright. The expert panel is seen to be inappropriate for use with option 4, the preferred policy option. One group has proposed a draft decision tree which has some support from other groups.

Government

One submission received.

This submission stated that the current situation where FSANZ is solely responsible for decision making is unacceptable. A preference for any particular option was not specified and the submission proposed a decision making model which incorporates aspects of both the decision tree and the expert panel models.

Other

One submission received.

This submission supported the policy principles and would like to see the increasing use of scientific risk assessment in food, as they believed this would result in less subjective decision making and interpretation.

This submission stated a preference for option 3a, as it adjusts assessment and approval processes according to risk, and gives more certainty for food and food ingredient innovation. Given the time necessary to achieve option 3a, option 3b was supported as second preference. Options 1, 2 and 4 were not commented on.

The preferred decision making model was stated to be the decision tree as it allows innovators to judge whether a product is likely to be novel and thus require assessment. Support was also stated for the expert panel in developing and maintaining the decision tree.

New Zealand

Consumers and Dietitians

One submission received.

This submission supported all principles, being particularly pleased with those relating to consumers.

In contrast to the Australian consumer groups, the preferred option was option 1. It was seen as the only option to ensure the protection of public health and safety, and consumer access to information to make informed choices. Option 3b was also supported with caveats, namely the inclusion of a provision to ensure that consumers are not misled by substantially similar foods, and that they have access to information. The other options were not commented on.

The decision tree model was supported as a streamlined approach to determine novelty of a food, while the expert panel model was viewed as being more appropriate to assess a formal application to FSANZ at the next stage of the pre-market assessment procedure.

Industry

3 submissions received.

The industry groups that commented on the policy principles supported them, while making some suggestions for minor changes to wording preferences.

Two groups support option 3a as a risk based approach, combined with the decision tree model. One group opposes this option as it would be time-consuming to set up. There is more support for option 3b combined with the decision tree model, as it is politically and legally expedient, has a flexible, risk based approach and is seen as the best option to meet the needs of industry and consumers.

Two groups oppose option 1 on the grounds that it does not allow streamlining of application where is a food is novel but does not present a health and safety risk, while the other group did not comment. The same groups opposed option 2 because there is a risk of subjectivity entering the decision making process, and an inability to streamline the application process where there are no health and safety concerns.

The comments regarding option 4 were mixed, with one group opposing it on the grounds that it could result in over-regulation of innovative products that are not truly novel and under-regulation of products that are novel but do not fit elsewhere in the existing regulatory framework. Another group supported this option, but had concerns that there would be a lack of support given the current environment concerning 'untraditional' foods.

All groups supported the decision tree model, with two groups commenting that the decision tree should be incorporated into the User Guide, and that an expert panel could have a role in developing and/or monitoring the decision tree.

Other

2 submissions received.

One submission supports the policy principles as outlined, while the other urges they be reconsidered.

One submission favours options 3a and 3b. The reason stated for support is that lower risk foods will not be subjected to the same rigorous level of assessment. The other submission supports only option 3a.

One submission opposes option 1 as taking too long to process a low risk application, while the other did not comment. Option 2 is opposed as possibly being too broad and risking public health and safety or too narrow and allowing foods that do not fit the definition to escape assessment. Option 4 is not supported because it is seen as likely to result in over-regulation of products that are novel but do not fit within the existing regulatory framework.

Both submissions supported the decision tree model as being least costly, easy to modify in the future, and transparent and consistent. One group recommended that it be reviewed at six-monthly intervals. The expert panel model is not supported by one group, and was not commented on by the other.

ATTACHMENT 6

Ministerial Council Policy Guidelines

Endorsed 12 December 2003

High Order Principles

- To ensure that priority is given to the protection and improvement of public health and safety in relation to food matters.

- To ensure that consumers have access to sufficient information to enable informed and healthy food choices.

- Be consistent with and complement Australian and New Zealand national policies and legislation including those relating to nutrition and health promotion.

- To draw on the best elements of international regulatory systems for (i.e. protocols, standards, guidelines, assessment processes) and be responsive to future trends and developments (i.e. CODEX, WHO/FAO).

- To provide a regulatory environment that is timely, cost effective, transparent and consistent with minimum effective regulation, and which encourages fair trade, industry growth, innovation and international trade.

Specific Principles

- To ensure that public and industry confidence in the food system is maintained.

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

- To ensure consumers are not misled by novel foods or food ingredients, which appear similar to existing foods but may differ in terms of nutrition or function.

Policy Guidance

ANZFRMC requests that FSANZ:

1. Raise a proposal to review Standard 1.5.1 of the *Australia New Zealand Food Standards Code.*
2. Recognise that the standard is there to ensure the safety of new foods coming on to the market and that the standard reflect a risk based approach.
3. Use a reference group that includes representatives from relevant Australian Government, New Zealand and State and Territory enforcement agencies to provide advice in reviewing the Standard.
4. Consider, as part of the review process, the following issues as raised by stakeholders during the FRSC consultation:

a) Subjectivity – the current definition in the standard tends to be too open to subjective interpretation as to whether a food is novel or not. In particular, stakeholder feedback indicates concern with the use of the words 'non-traditional' and 'insufficient knowledge in the community to enable safe use'. In each of these components of the novel food definition this wording is seen to be contradictory or open to interpretation.

b) Scope of the definition – the scope of the novel foods definition needs to be refined and particular attention given to the identification of the appropriate triggers of a pre-market assessment of novel foods.

c) Protection of information - to provide an assessment process that aims to protect commercially sensitive information and recognise industry's intellectual property to the maximum extent possible.

d) Level of assessment to be commensurate with level of risk – the use of a decision tree approach to determine if an application/pre-market assessment is required should be considered. A decision tree should provide industry and enforcement agencies with clear guidance in such a determination.

5. Review the user guide to include the above changes to the novel foods definition. In addition the guide should provide greater clarity about the process that FSANZ undertakes in determining if a food is a novel food. These revisions should be developed with industry, government and consumer input to ensure that the revised guide appropriately meets their needs.

ATTACHMENT 7

Guidelines assist in applying to amend the *Australia New Zealand Food Standards Code* – Novel Foods *Revised*[1]

1 Operation of the Standard

1.1 Purpose of the Standard

Standard A19 - Novel Foods (of the superseded Australian *Food Standards Code*) came into effect on 16 December 1999[1]. Standard 1.5.1 – Novel Foods of the *Australia New Zealand Food Standards Code* ('the Code') replaced Standard A19. The Standard prohibits the retail sale of novel foods as foods or for use as food ingredients, unless they are listed in the Table to clause 2 and comply with any conditions of use specified in that Table. The Standard is available at Standard 1.5.1.

The Standard for novel foods introduces a risk-based assessment process to ensure the safety of novel foods before they are offered for sale in Australia and New Zealand.

1.2 Determining novelty

Prior to an application to amend the Code to approve a novel food being assessed by FSANZ, a determination as to whether the potential novel food is 'non-traditional' and 'novel' is made in accordance with the definitions in Standard 1.5.1. The definitions are as follows:

Non-traditional food means –

(a) a food that has not been generally available to a broad cross-section of consumers in Australia or New Zealand; or
(b) a substance derived from a food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food; or
(c) any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand.

Novel food means a non-traditional food that may be unsafe having regard to –

(a) the composition or structure of the food; or
(b) the potential for adverse effects in humans; or
(c) patterns and levels of consumption of the food; or
(d) the process by which the food has been prepared; or
(e) the source from which it is derived; or
(f) any other relevant matters.

[1] The revised guidelines will be placed on the FSANZ website at the completion of Proposal P291 – Review of the Novel Food Standard. Until the review is completed, the current guidelines will continue to be updated regularly to reflect new outcome views formed.

Novel foods are a subset of non-traditional foods. The Guidance tool for determining novelty discussed in section 2 provides assistance.

The overall process for considering potential novel foods is detailed in Figure 1. A flow chart for determining novelty is provided in Figure 2 and a guidance tool for determining novelty is at Attachment 1.

1.3 Novel Foods Reference Group

Questions regarding the novelty or otherwise of a food or food ingredient under Standard 1.5.1 are generally directed to FSANZ. These questions are considered by an internal FSANZ group referred to as the novel foods reference group (NFRG). The group comprises members with expertise in different areas including toxicology, food technology and nutrition. The NFRG examines the available information on the food in relation to the definitions provided in Standard 1.5.1 and considers:

- whether or not the food or food ingredient appears to be traditional or non-traditional; and
- if the food or food ingredient is non-traditional, whether or not it is also novel according to the definition in the Standard. In some cases, this may require additional information to be sought from the inquirer or from other sources.

The NFRG will make an initial consideration in accordance with the guidance tool for determining novelty.

1.4 Role of the Senior Food Officers

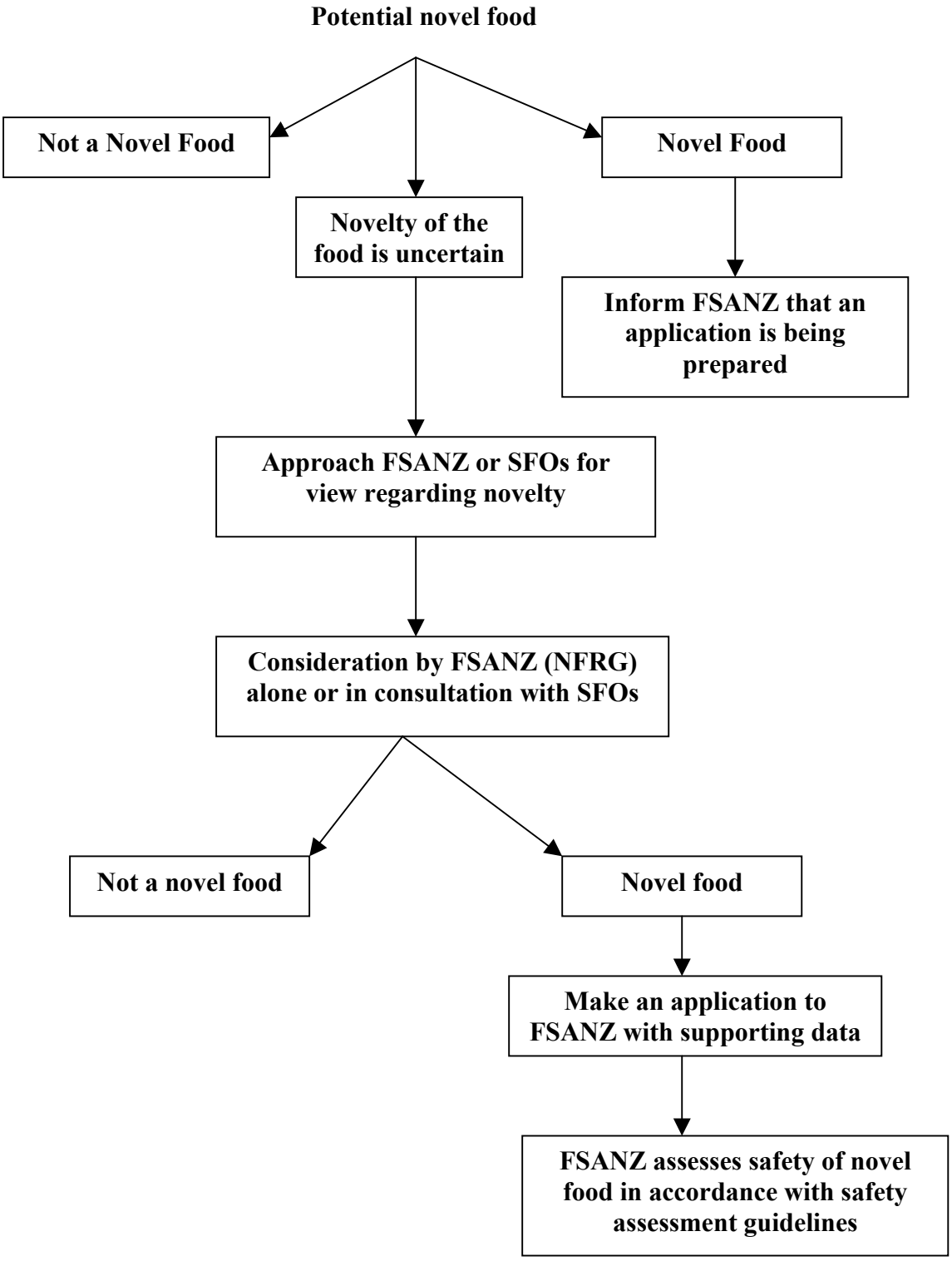
Enforcement of the Code is the responsibility of the Australian, State, Territory and New Zealand Governments. Considerations relating to the novelty of food, therefore, need to be made in close consultation with the Senior Food Officers (SFOs) of the Australian, States, Territories and New Zealand as well as the Australian Quarantine and Inspection Service (AQIS).

Where, in the view of the NFRG, a food or food ingredient is clearly novel or not novel, this information is reported to SFOs in the State, Territory and New Zealand Governments and AQIS. When a food or food ingredient is clearly novel, an application to FSANZ to amend Standard 1.5.1 needs to be made and approved for the food or food ingredient to be lawfully sold in Australia and New Zealand. Where the novelty of a food is less clear, a consensus view may be sought by consultation with the SFOs at their regular meetings.

1.5 Consultation with FSANZ and SFOs

Individual or companies considering marketing a non-traditional food are encouraged to consult with FSANZ regarding whether the food may or may not fall within the novel food standard. The process for considering such foods is shown below in Figure 1:

Figure 1: PROCESS FOR CONSIDERING POTENTIAL NOVEL FOODS



2. Identifying novel foods

2.1 Factors influencing the novelty of a food

The Standard defines a novel food as 'a non-traditional food that may be unsafe having regard to –

(a) the composition or structure of the food; or
(b) the potential for adverse effects in humans; or
(c) patterns and levels of consumption of the food; or
(d) the process by which the food has been prepared; or
(e) the source from which it is derived; or
(f) any other relevant matters.'

Each of these factors is discussed in further detail below:

The composition or structure of the food

Food ingredients that have a new or changed molecular structure are likely to fall within the Standard because such foods do not have a history of human consumption in Australia or New Zealand. In this regard, a compound such as olestra (a mixture of sucrose esters), which is marketed in the USA, would be regarded as a novel food. Other compounds used to replace fats or carbohydrates in foods are likely to also be regarded as novel foods.

Similarly, new substances added to food that are not nutrients and do not meet one of the functions of a food additive might be regarded as novel foods.

Foods that may be consumed by particular population sub groups (who may or may not be located overseas) but which are non-traditional in Australia or New Zealand (because they have not been generally available to a broad cross-section of consumers in Australia or New Zealand) may contain naturally occurring toxins or anti-nutrients at potentially harmful levels. Population sub-groups who are familiar with the risks involved can manage this risk either by limiting intake or by treating the food to reduce the level of the hazardous substance. Risk management strategies available to FSANZ could include:

(i) specifying a maximum level for a hazardous substance;
(ii) labelling advice regarding the appropriate level of consumption; or
(iii) labelling advice regarding appropriate preparation methods.

The potential for adverse effects in humans

Foods that are non-traditional in Australia or New Zealand may be widely consumed in other countries. In some cases, there are reports in the scientific literature of adverse effects associated with consumption of these foods. Such foods may warrant assessment, particularly as consumption patterns of these foods may be different in other countries and the foods may or may not be accompanied by dietary advice.

Patterns and levels of consumption

With the increasing interest in promoting the positive benefits of certain foods over and above their normal nutritional benefits, food components and food extracts are being used in ways that significantly increase their level of dietary intake compared to the levels normally associated with a balanced diet. In some cases, this could have unexpected consequences and the potential health risks of a changed pattern of intake need to be considered. Use of a food in such a way that there is a significant change to the pattern or level of its consumption is likely to require it to be considered under this Standard.

The process by which the food has been prepared

The potential exists for processes that have not normally been applied to foods to be introduced. There may be little known about the processes or their application in the food industry. The use of traditional breeding techniques where the nature of the food has been changed from the traditional variety could raise safety concerns. If the process by which a food has been prepared raises questions related to its safety on the basis of altered characteristics of the final food, its safety may need to be established by consideration under this Standard.

The source from which it is derived

It is possible for a food or food ingredient to be produced from a source that in itself is not normally consumed as food. The potential exists for such a 'non-traditional' source to contain low levels of toxic contaminants or undesirable substances. Non-traditional sources may include algal species or micro-organisms that have not traditionally been used in food production. In some cases, a specification for the novel food may be necessary to ensure its safety. The source may be new or uncharacterised such that its safety for human consumption has not been established. Such foods, derived from non-traditional sources may require consideration under Standard 1.5.1.

Any other relevant matters

The relevance of the matter is governed by the scope of the other listed matters. It could potentially capture matters that almost, but not strictly, fall within those other factors for consideration.

2.2 Categories of novel foods

Foods regarded as novel are likely to, but do not necessarily, fall into one of the following categories:

- plants or animals and their components;
- plant or animal extracts;
- herbs (both non-culinary and culinary) including extracts;
- dietary macro-components;
- single chemical entities;
- micro-organisms, including probiotics; and
- foods produced from new sources or by a process not previously applied to food.

Plants or animals and their components

This category includes:

- plants or animals which are consumed in their entirety either alone or as ingredients in other foods;
- components of plants such as fruit, nuts, or seeds, either alone or as ingredients in other foods;
- components of animals such as meat or milk products that are non-traditional, consumed either alone or as ingredients in other foods;
- grains, used either alone or as ingredients in other foods;
- oils or similar products derived from plants, animals and their components.

These may be foods from other parts of the world or traditional indigenous foods or new foods. While there are many new foods on the market, it is likely that only those where there is some evidence of potential adverse effects would be considered novel. Plants or animals and their components, including whole foods, may be considered as novel because of the level of undesirable substances in the product, known potential for adverse effects in humans and/or the use of traditional preparation and cooking techniques.

Plant or animal extracts

This category includes components of plants or animals that have been deliberately extracted using specific technology and added to other foods for a nutritional or functional purpose. This includes phytosterol esters, isoflavones, and docosahexaenoic acid (DHA) from marine algal sources. Increasingly, extracts of plants or animals are being added to other foods for either a functional or nutritional purpose. This category is separated from the first since such extracts have the potential to concentrate hazardous substances and additional data would be required in relation to the method of extraction.

Extracts may also be used to provide a function normally associated with a food additive. Food additives require positive permission for use and are normally accompanied by specifications that ensure identity and purity. If the intent of adding an extract were to provide a technological purpose, then the extract would be regarded as a food additive and must meet the relevant requirements. While the distinction between a food, an extract and a food additive is not clear in all cases, the purpose of adding the substance to food must be a consideration.

Plant or animal extracts may be considered as novel because of the level of undesirable substances in the products, the potential for adverse effects in humans and/or their pattern and level of consumption.

Herbs, including extracts

This category includes both culinary and non-culinary herbs, both of which could potentially be considered novel, although the majority are likely to be non-culinary. Both the whole herb and an extract of an herb would be considered. Increasingly, herbs are being added to foods, particularly juices for a functional purpose.

Although herbal material could be considered under either of the previous two categories depending on the nature of its presentation, the uniqueness of the issues associated with herbs is a valid reason for considering herbs as a category in its own right. Herbs may be considered as novel because of undesirable substances in the products, the potential for adverse effects in humans and/or their pattern and level of consumption.

Dietary macro-components

This category includes novel carbohydrates, proteins, fats or fibre that are intended to be added to foods in such a way that they will be present in significant quantities, either replacing existing traditional macro-components, or being used in addition to these. Many of these substances are used to fully or partially replace fats or carbohydrates, in some cases to produce a low fat or low energy product. Examples include olestra, salatrim, and diacylglycerol oil. Dietary macro-components may be considered as novel foods because of the composition and structure of the product, the potential for adverse effects in humans and/or their pattern or level of consumption.

Single chemical entities

This category covers substances or compounds that may be defined by a chemical name or formula and are usually synthesized. Examples include alpha-lipoic acid and glucosamine sulphate. This is a relatively small category with only five potential novel food considerations however, this is also a category for which there may be more interest in the future. Single chemical entities may be considered as novel foods because of the potential for adverse effects in humans and/or their pattern or level of consumption.

Micro-organisms, including probiotics

Micro-organisms are being developed as ingredients of food products which may contribute to the intestinal microbial balance. This category includes new strains of probiotics as well as novel micro-organisms that do not have a probiotic function. The safety of new strains of micro-organisms needs to be established before use in widely consumed foods.

Micro-organisms may need to be considered as novel foods because of levels of undesirable substances in the product and/or known potential for adverse effects in humans.

Foods produced from new sources or by a process not previously applied to food

The potential exists for a number of new technologies, or new food applications of existing technologies to be employed in the food industry. If these technologies result in altered characteristics in the resultant foods, then safety may need to be established before use in widely consumed foods. Foods produced using traditional breeding techniques, where the nature of the food has been significantly changed from the traditional variety, could be also be considered as novel. Food ingredients obtained from novel sources may also be a cause for concern since these could inadvertently contain low levels of toxic contaminants. Non-traditional sources may include algal species or micro-organisms that have not traditionally been used in food production.

2.3 Novel foods flow diagram

Figure 2 presents a flow diagram that sets out the stages involved in determining novelty and also what action is taken by FSANZ if a food or food ingredient is deemed to be novel. It does not provide detail on the factors considered at each stage. This level of detail is provided in the guidance tool for determining novelty discussed in the next section.

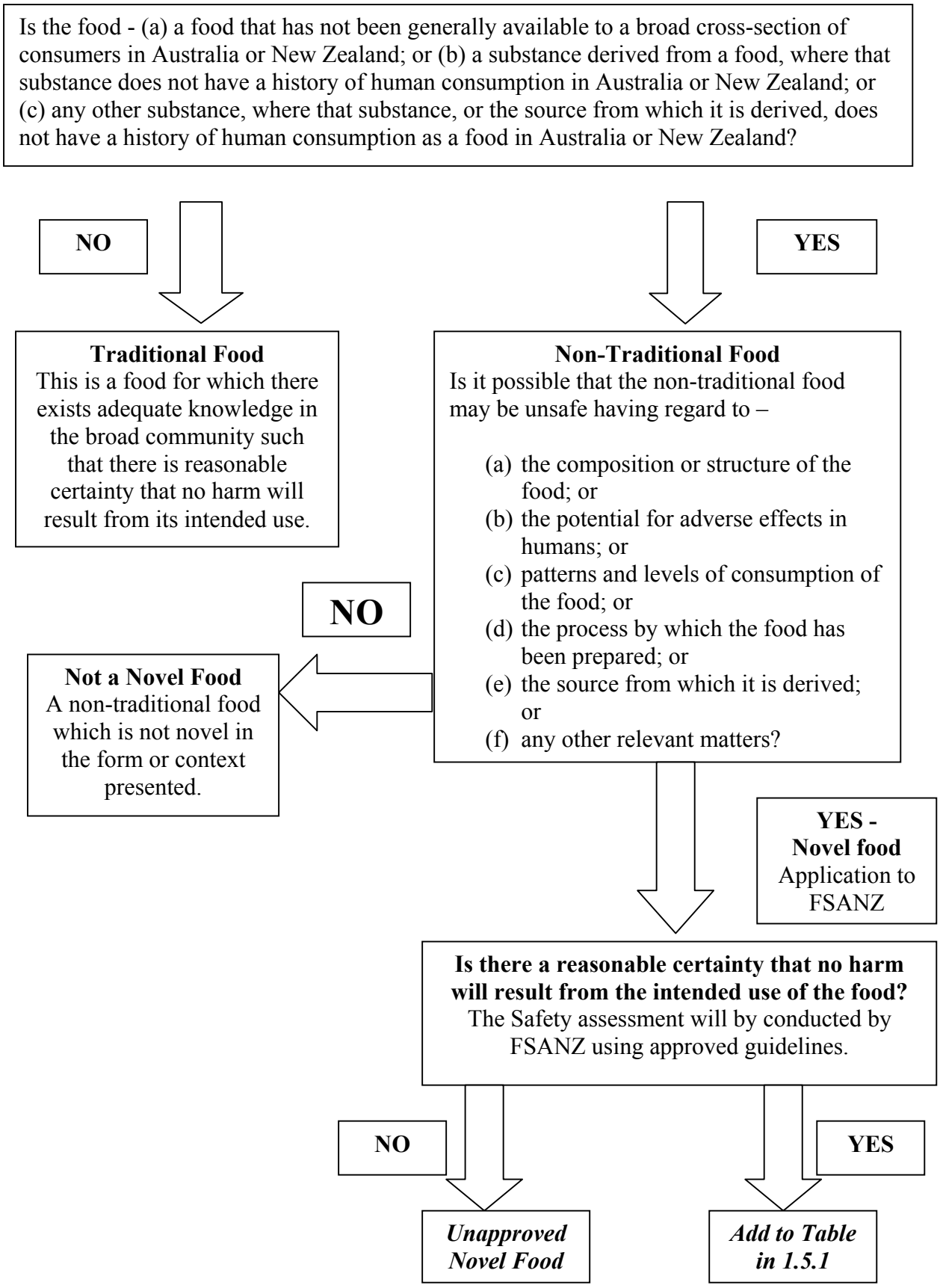
2.4 Guidance tool for determining novelty of food

A guidance tool for determining novelty has been developed to assist the NFRG and SFOs in determining whether a food or food ingredient is subject to the Novel Foods Standard. A number of factors are considered in determining novelty and accordingly, a degree of judgement will be required in the application of the guidance tool. The tool outlines that main steps taken in determining novelty and combines a decision-tree approach with specific questions that may be asked in undertaking each of the steps. The guidance tool for novelty is at Appendix 1.

2.5 Outcome views with respect to novelty of food

A record of views formed by the NFRG in conjunction with jurisdictions in response to inquiries is available from [insert hyperlink]. The outcome views are presented in a table that lists foods and food ingredients with views as to their status as non-traditional/novel foods.

Figure 2: NOVEL FOOD FLOW DIAGRAM



3. DRAFT Guidelines for the safety assessment of novel foods

(These guidelines will be finalised prior to the release of the Final Assessment Report)

3.1 Regulatory framework

The safety of food is addressed in the broad provisions of State, Territory and New Zealand Food and Health Acts require that food must be safe and suitable. Under these Acts, the responsibility for the safety of food lies with the food industry, however, compliance with Standard 1.5.1 – *Novel foods* provides reasonable assurance that the food will be safe for the vast majority of the population.

Historically, foods have been regarded as natural, beneficial and necessary, and presumed safe unless a significant hazard has been identified. Thus, those foods regarded as traditional foods are considered safe because over time either there has been no evidence of adverse effects, or adequate knowledge has been acquired in the community to address any identified hazard. In general, the majority of traditional foods consumed in Australia and New Zealand are considered safe i.e. there is a reasonable certainty that no harm will result from their intended use. Many non-traditional foods can also be considered safe because they represent a relatively minor variation from traditional foods or their nature and proposed use do not raise any safety questions.

For those non-traditional foods that are regarded as 'novel' under the definition in the Standard, a safety assessment needs to be undertaken to identify any potential risks and to ensure that those risks are managed before the food is made available for sale. When making an application for the approval of a novel food, it is the responsibility of the applicant to present appropriate studies to enable FSANZ to undertake a safety assessment to establish the safety of the food. The following guidelines indicate the types of data that can assist in this process.

3.2 General safety issues

The purpose of a risk assessment for a novel food is to establish whether there is a reasonable certainty that no harm will result from the intended use of the food. In this regard, the novel food should offer the same basic level of safety that is expected for all foods.

Factors that are considered when evaluating the safety of a novel food may include:

- the source and process by which the food has been prepared;
- the composition of a novel food, or the structure and specifications of a novel ingredient;
- the history of use (whether in a particular population group or as a component of traditional foods);
- the level of consumption or extent of use (current and proposed);
- data on the metabolism of novel ingredients;
- data from toxicity studies in animals;
- the toxicity of any related substances or foods; and
- any known cases of adverse effects on humans.

The evaluation of the safety of novel foods and ingredients involves consideration of a variety of toxicological and nutritional issues together with information on chemistry and dietary intake of the product. Such evaluations may differ somewhat from the traditional evaluations that have been applied to food additives and contaminants, both with respect to the type and variety of information considered. For example, in relation to traditional feeding studies in animals, the much larger anticipated daily intake of most foods compared to food additives means that they are likely to cause physiological, morphological or biochemical changes before any evidence of toxicity. The usefulness of animal studies is thus more limited for the safety assessment of whole foods. Studies in humans may offer data more relevant to a safety evaluation.

In some cases, particularly where a new production process is involved, a novel food may be assessed for its safety by a comparison to the benchmark of a commonly consumed traditional food. This concept is referred to internationally as the *comparative approach* and means that the biochemical or compositional identity is within the limits of natural diversity of the traditional counterpart. However, as many novel foods will not have traditional counterparts, this concept will have limited application to the safety assessment of novel foods.

A guide to the type of information that might be useful in assessing the safety of a novel food is presented in **Table 1**. The exact data requirements will depend on the type of novel food being considered. Specific information that may be required for each of the seven different categories of novel foods is presented following Table 1. However, the data requirements for each food will need to be considered on an individual basis and it is ultimately the responsibility of the applicant to present appropriate data to establish the safety of the novel food.

3.3 Safety data (This section (previously 'Toxicology Data') has been substantially shortened. It is anticipated that the information previously in this section will be included in the new sections on the data required in Table 1).

The nature and extent of the data used to assess the potential risk associated with a novel food depends largely on the nature of the novel food. In some cases, information on the origin, production, composition, nutritional characteristics, history of previous human exposure and anticipated use of the material as a novel food may be sufficient to conclude that the food is safe. On the other hand, where the safety assessment involves consideration of a novel ingredient for which there is no prior exposure, it is likely that some animal toxicity studies will be required.

Studies in humans are likely to have a significant role in assessment of the safety of novel foods. Provided the *in vivo* animal studies demonstrate no adverse effects, human studies may be considered to complement animal data. For example, human studies can confirm the safety established by animal studies where the expected human exposure is high and the margin between animal studies and potential human exposure is low.

Experiments conducted to determine the safety of a novel food should be performed in accordance with sound scientific concepts and principles. Regard should be given to relevant quality assurance guidelines and internationally accepted protocols (i.e. approved methodology and Good laboratory Practice). Primary data should be submitted to FSANZ whenever possible.

3.4 Nutritional data (This section has been cut down. It is anticipated that the information previously in this section will be included in the new sections on the data required in Table 1)

Some novel foods and novel food ingredients have the potential to affect both the composition of the diet and the nutritional status of the general population. In some instances this could be beneficial, while in others, there could be potential adverse effects.

Beneficial effects of novel foods could include improved organoleptic qualities, enhanced nutritional profiles which meet particular nutritional needs and reduced energy density of the diet. Adverse effects of novel foods might arise indirectly as a result of displacing traditional foods and ingredients from the diet, or directly by affecting the bioavailability of existing nutrients. For example, novel foods may alter the absorption or utilisation of other dietary constituents through the alteration of colonic microflora, gut transit time or novel food-nutrient interactions.

The nature of the nutritional data required will depend on the nature of the novel food. In general, information would be sought to assess whether the nutritional status of the consumer is likely to be compromised by the substitution of less nutritious food varieties or by the presence of constituents that may interfere with nutrient absorption or introduce an increased level of anti-nutritional factors in the food supply. Generally, this can be assured by careful compositional analysis of nutrients and potential anti-nutritional factors. In some cases, it may be necessary to examine nutrient bioavailability using animal models. The impact of the consumption of the novel food on total dietary intakes of essential nutrients or other biologically active substances may need to be considered, taking into account the quantity and bioavailability of the nutrients or other substances in the novel food.

3.5 Dietary exposure (This section will be expanded in the revised guidelines)

A reasonable margin between the maximum level of a substance shown to be without harm in animal and human studies and the estimated daily intake needs to be identified as part of the dietary exposure assessment. Information on the potential uses of the novel food and an estimate of potential dietary exposure are required to make a decision on its safety under the conditions of use. An assessment of aggregate exposure can provide further information on potential exposure.

The use of the food in other countries may be taken into consideration. However, detailed dietary modelling will usually be conducted by FSANZ using consumption data from the Australian and New Zealand populations.

3.6 Data requirements (This section will be expanded in the revised guidelines)

The basic information that may form part of the data package for the assessment of a novel food or novel food ingredient is presented in **Table 1** and discussed in further detail below. This list is not exclusive and further data requirements and considerations for each of the categories of novel food are presented following Table 1. Not all information described will be relevant in every case. This represents a general guide only as the exact data requirements will depend on the novel food or ingredient being assessed and will need to be considered on a case-by-case basis.

Applicants are encouraged to consult with FSANZ prior to submission of an application, to clarify what information may be needed.

Product information

Guidance on the type of information required to establish the following points (from Table 1) will be developed:

- Identity of the novel food / macro-component / micro-organism
- Method of preparation / process
- Purpose of use in food
- Compositional information / specifications for identity and purity
- Use overseas and by population subgroups
- Stability in cooking and processing

Dietary exposure data

Guidance on the type of information required to establish the following points (from Table 1) will be developed:

- Proposed pattern of usage
- Dietary exposure for average and extreme consumer
- Dietary exposure for special groups

Toxicological and nutritional data

Guidance on the type of information required to establish the following points (from Table 1) will be developed:

- Nutrient content
- Effect on bioavailability of other nutrients
- Levels of anti-nutrients
- Levels of natural toxins
- Potential for allergenicity
- Relevant animal studies (e.g. 90-day rodent studies)
- Genotoxicity studies
- Human toleration studies

Table 1. Data that may assist in the safety assessment of novel foods

Basis data requirements	
Product information	Identity of the novel food / macro-component / micro-organism Method of preparation / process Purpose of use in food Compositional information / specifications for identity and purity Use overseas and by population subgroups Stability in cooking and processing

Dietary exposure data	Proposed pattern of usage Dietary exposure for average and extreme consumer Dietary exposure for special groups
Toxicological & nutritional data	Nutrient content Effect on bioavailability of other nutrients Levels of anti-nutrients Levels of natural toxins Potential for allergenicity Relevant animal studies (e.g. 90-day rodent studies) Genotoxicity studies Human toleration studies

In addition to the information specified above (summarised in Table 1), where possible, specific information requirements for each of the seven categories of novel foods will be developed.

Plants or animals and their components (section under development)

These types of products will generally be considered as novel foods only where there is a potential safety concern. For example for foods traditional to only a small community which are now being presented to the broad community, it will be important to identify any inherent hazards that might require attention. If there is any requirement for processing or cooking before consumption, this should be made clear. Otherwise, the information on the product, the proposed pattern of usage and dietary exposure, and toxicological and nutritional information listed in Table 1 will generally be adequate to address safety.

Plant or animal extracts (section under development)

Additional data is required for plant or animal extracts compared to the previous category, as hazardous substances present in the source organism may be concentrated in the extract. Therefore, in addition to the basic production information, dietary exposure data and toxicological and nutritional data listed in Table 1, the following points may need to be taken into consideration.

Plant extracts may often be standardised on the basis of a particular active component and may be quite variable in relation to other components. This may or may not be of concern depending on the toxicological properties of the other components. The part of the plant from which the extract is sourced may also be a consideration. The method of extraction will also form part of the safety assessment of these products.

For a new plant extract, genotoxicity and short-term feeding studies can provide a basic level of information to ensure safety. Studies on metabolism/toxicokinetics and long-term rodent studies may be required.

The nature and variety of toxicity studies required will need to be commensurate with the level and extent of human exposure. Any previous assessment of the novel food or ingredient by FSANZ, may be taken into consideration. For example, for a substance such as DHA, which can be derived from a variety of sources and has been assessed a number of times by FSANZ, an application for DHA from a source not previously considered by FSANZ should focus on the safety of the source and the extraction process.

Herbs, including extracts (section under development)

Much of the data required for herbs and herbal extracts will be similar to that required for plant extracts. However, there may be additional unique data requirements for herbs and their extracts due to the presence of undesirable substances and pharmacologically active compounds. Information on the part of the plant used, geographical origin, the stage of growth and storage conditions may be important. Studies on the metabolism/toxicokinetics of any bioactive component and long-term rodent studies may be required.

Dietary macro-components (section under development)

In the case of dietary macro-components such as fat- and sugar-substitutes that are to be used in large amounts in foods, extensive animal toxicity data may be required. Data on metabolism/toxicokinetics, bioavailability, fate of unabsorbed material and effects of fermentation in the gut will also be considered.

Information on nutrient content, levels of natural toxins and potential for allergenicity may not be required.

Single chemical entities (section under development)

In the case of a single chemical entity, a chemical specification would normally be required. For the assessment of single chemical entities, it will be relevant to conduct studies on the metabolism and toxicokinetics of the product. Feeding studies in rodents may also provide information on these products. Studies on nutrient content and levels of natural toxins and antinutrients are less likely to be relevant.

Micro-organisms, including probiotics (section under development)

Novel micro-organisms are a somewhat different category of novel food. In most cases, the general toxicological and nutritional studies in Table 1 may not be appropriate (i.e. levels of antinutrients and natural toxins, potential for allergenicity, traditional animal studies and genotoxicity studies). Issues to consider will include the potential pathogenicity of the novel micro-organism and related organisms. Similarly, evidence that the novel micro-organism does not produce any toxins will form an important part of the safety assessment.

There is a potential for adverse effects associated with colonisation of the gastrointestinal tract. Animal studies where the gut has been recolonised with human gut microflora might be useful in this instance. The traditional 90-day feeding study might also provide useful information if appropriate parameters are measured and nutritional imbalances are avoided.

Foods produced from new sources or by a process not previously applied to food (section under development)

The safety of a novel food is based on the food product rather than the process, however there may be circumstances where a novel process applied to foods will mean that the food product is considered novel. In this case, a full description of the novel process will be required as this can guide the safety assessment.

Processing and preparation techniques can result in potential microbiological, toxicological, allergenicity or nutritional concerns and these will need to be addressed. Compositional analysis and comparison with similar existing products will form part of the safety assessment.

4. Risk management for novel foods

Standard 1.5.1 of the Code, in the Table to clause 2, makes provision for conditions of use for a particular novel food to be specified in column 2 of that table, associated with permission for that novel food. Conditions of use may be specified where a particular public health and safety risk is identified for either the general population or an identified population sub-group. Such conditions of use may be referred to as risk management strategies and include:

- limiting the maximum level of use of the novel food or novel food ingredient;
- limiting the categories of foods to which the novel food ingredient may be added;
- limiting the level of natural toxicants in the novel food;
- requiring statements to be provided on novel foods that advise against consumption by particular sub-groups;
- requiring the novel food to carry information about the appropriate use of the novel food and/or preparation instructions.

Other non-regulatory risk management options could be employed such as:

- provision of educational material (e.g. pamphlets) to consumers or industry; and
- encouraging industry to disseminate information about their products and any necessary preparation.

4.1 Applications that raise issues of minor complexity or significance only

Section 36 of the FSANZ Act allows FSANZ to simplify an application procedure if the application raises issues of minor significance or complexity only. Use of section 36 of the FSANZ Act would allow FSANZ to undertake a simplified and/or shortened assessment process, including one round of public comment. Novel food assessments would rarely be sufficiently simple to consider under section 36, particularly whole foods. However, it may be possible for foods deemed to be novel because they are derived from a non-traditional source or foods produced using a process not previously applied to food to be assessed under section 36. In most cases it would probably still be necessary for FSANZ to undertake a full safety assessment and dietary exposure assessment. FSANZ will consider the possibility of assessing an application under section 36 of the FSANZ Act on a case-by-case basis.

4.2 Post-market information

For approved novel foods, FSANZ will seek cooperation from the food industry in providing post-market monitoring data. The data to be provided will depend on the nature of the novel food and may be more extensive for some classes e.g. dietary macro-components. Such data will provide additional reassurance regarding long-term safety of products, as well as their impact on the food supply. This type of data can potentially inform dietary exposure assessments.

Specific data which may be useful in this context includes:

- identification of product categories which contain the novel food;
- the level of the novel food in each product category;
- an estimate of market share for product categories containing novel foods; and
- provision of a report on the notification of adverse reactions/complaints received by the manufacturer(s).

However, post-market monitoring is not a substitute for a rigorous risk assessment and novel foods with a large degree of uncertainty around human health effects will not be permitted until further information to demonstrate safety is provided.

5. Guidelines for determining the energy value of a novel food

The term 'energy factor' describes the average amount of energy from a specific food component that is available for total (whole body) heat production and for body gains (retained energy) in humans. For some novel foods or food ingredients, particularly macronutrient substitutes, determination of the energy value will be important.

Guidelines for determining the energy value of a novel food are available at Energy Factors.

6. Attachments

1. Guidance tool for determining novelty

APPENDIX 1

GUIDANCE TOOL FOR DETERMINING NOVELTY

The purpose of regulating novel foods is to apply a risk-based approach to ensuring the safety of new foods coming onto the market. This guidance tool is intended to assist the Novel Foods Reference Group, Senior Food Officers and industry, including potential applicants, in determining whether a food or food ingredient is subject to the Novel Foods Standard. A number of factors are considered in determining novelty, including consistency with previous determinations for similar foods or food ingredients. This tool may not be exhaustive of all the possible questions that could be asked relating to novelty. Accordingly, judgement will be needed in the application of the guidance tool.

Step 1 – Identity of the food or food ingredient[2]

Prior to making any determination as to whether a food or food ingredient is non-traditional or novel, it is important that the identity of that food or food ingredient is known and understood. The following questions may be applicable.

1. What is the name of the food/food ingredient?
2. What are the specifications for the material?

Botanical characterisation may involve the following questions:

1. What is the common and botanical name of the plant?
2. What part of the plant is used or intended for use?
3. What is the form of the final food/food ingredient (e.g. does the final food product contain the plant itself, a ground up preparation such as a powder, or an extract)?

Step 2 – Determining whether a food or food ingredient is non-traditional[3]

(a) Has the food been generally available to a broad cross-section of consumers in Australia or New Zealand?

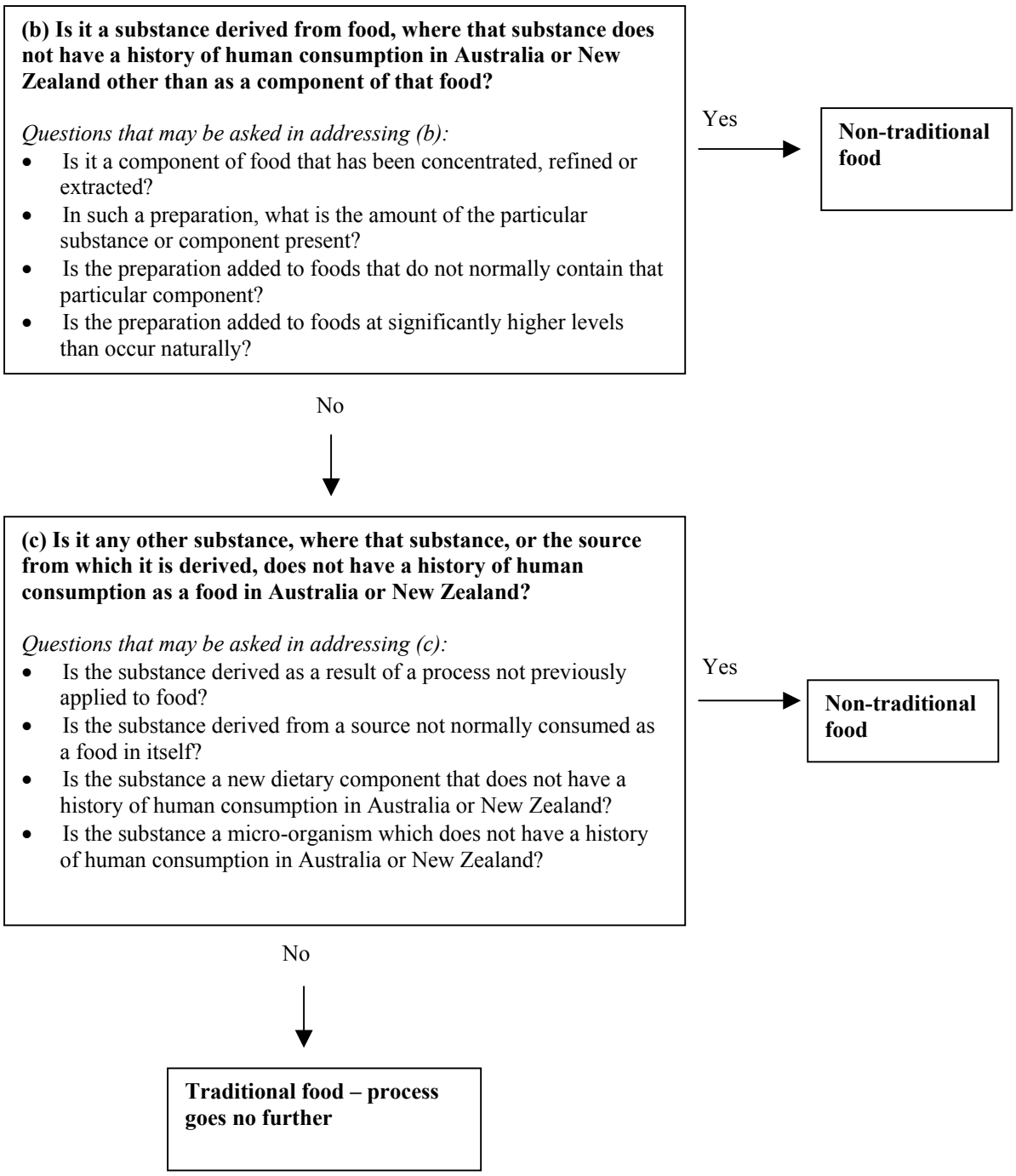
Questions that may be asked in addressing (a):

- Is the food or food ingredient recognised worldwide, regionally, or in isolated populations?
- How long has the food or food ingredient been available?
- Has it been used in the food context or has it been used for other purposes in addition to or instead of food use (e.g. traditional medicine)? If it has been used for medicinal purposes, what are the conditions for which it has been used and are there maximum levels prescribed?
- Has it been used as part of the regular diet or only at certain times (e.g. during famine or for ceremonial purposes)?

No → **Non-traditional food**

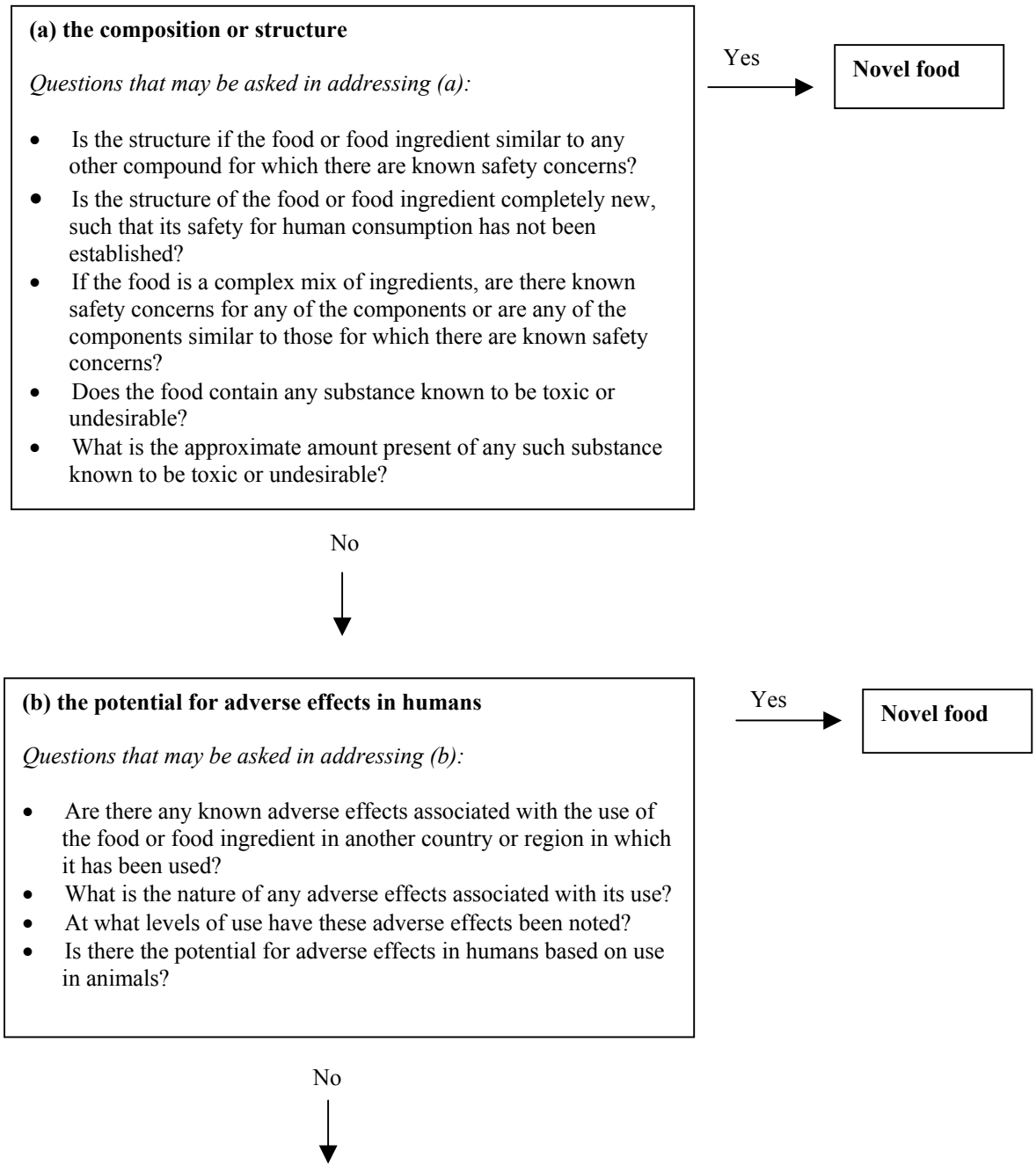
Yes ↓

[2] Step 1 is performed for all inquiries in relation to potential novel foods
[3] Step 2 is performed for all inquiries in relation to potential novel foods


(b) Is it a substance derived from food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food?
Questions that may be asked in addressing (b):
Is it a component of food that has been concentrated, refined or extracted?
In such a preparation, what is the amount of the particular substance or component present?
Is the preparation added to foods that do not normally contain that particular component?
Is the preparation added to foods at significantly higher levels than occur naturally?
Yes
Non-traditional food
No
(c) Is it any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand?
Questions that may be asked in addressing (c):
Is the substance derived as a result of a process not previously applied to food?
Is the substance derived from a source not normally consumed as a food in itself?
Is the substance a new dietary component that does not have a history of human consumption in Australia or New Zealand?
Is the substance a micro-organism which does not have a history of human consumption in Australia or New Zealand?
Yes
Non-traditional food
No
Traditional food – process goes no further

Step 3 – Determining novelty[4]

Does the potential exist that the non-traditional food may be unsafe taking into account (a-f)–



[4] Step 3 is performed only for those foods/food ingredients for which the outcome for step 2 was non-traditional food

(c) patterns and levels of consumption of the food

Questions that may be asked in addressing (c):

- What is the expected level of intake of the food or food ingredient?
- For a food ingredient, in what food commodities is it proposed to be used and at what levels?
- Is the food or food ingredient intended to be marketed to the general population or a specific target sub-group of the population?
- How does the proposed level of intake compare with any traditional use in any other country or region in which it has been used?

Yes → **Novel food**

No ↓

(d) the process by which the food has been prepared

Questions that may be asked in addressing (d):

- Is the food produced by a process which has not previously been applied to food?
- Is the structure or composition of the final food or food ingredient altered?

Yes → **Novel food**

No ↓

(e) the source from which it is derived

Questions that may be asked in addressing (e):

- Is the food or food ingredient produced from a source that in itself is not normally consumed as part of the diet?
- Is the source itself known to contain toxic or undesirable substances?
- Is the source new or uncharacterised such that its safety for human consumption has not been established?

Yes → **Novel food**

No ↓

(f) any other relevant matters

The relevance is governed by the scope of the other listed matters (a-f)

Yes → **Consideration – may be Novel food**

No ↓

If the answers to all points (a) – (f) inclusive is 'no' – the food or food ingredient is **not novel**

ATTACHMENT 8

Outcome views with respect to novelty of food

An example of the format of the document[5]

Prior to an application to amend Standard 1.5.1 – Novel Foods – of the *Australia New Zealand Food Standards Code* (the Code) being assessed by FSANZ, a determination as to whether the potential novel food is 'non-traditional' and 'novel' is made in accordance with the definitions that Standard. This determination is made in conjunction with the Senior Food Officers in Australian State and Territory jurisdictions and in New Zealand and the Australian Quarantine and Inspection Service (AQIS).

The internal FSANZ Novel Foods Reference Group (NFRG) makes an initial consideration and this is reported to jurisdictions or discussed with members of the forum with varying levels of involvement depending on the complexity.

Further information on the operation of the Novel Foods Standard can be obtained from [insert hyperlink].

Table 1 gives a record of views formed by the NFRG in conjunction with jurisdictions in response to inquiries. The table lists foods and food ingredients with views as to their status as non-traditional/novel foods. The outcome views with respect to novelty are divided into those foods deemed to be novel and those foods deemed not to be novel and are also listed alphabetically within each part of Table 1. Other foods and food ingredients not included in the table have been considered in response to inquiries. However, the NFRG has not formed a view in relation to these items pending receipt of further information requested from the inquirer.

Enforcement of the Code is the responsibility of the Commonwealth, State, Territory and New Zealand Governments. Accordingly, the interpretation and application of Standard 1.5.1, including decisions about the novelty of a food or food ingredient, is ultimately the responsibility of those jurisdictions.

Important Notice

The composition, form and way in which a product is presented, as well as the information available in relation to a product, may vary and this may affect the status of the product under Standard 1.5.1. Therefore, the information in the following tables should only be treated as a general guide, and you should not expect that a view reached about a food or food ingredient listed in the table will always apply in relation to apparently similar products. The views indicated may be subject to review and amendment.

[5] This is not the final document that is posted on the FSANZ website. It is intended to provide an illustration of the format and content of such a document. It is anticipated that the final outcome views with respect to novelty of food will be posted on the FSANZ website at the completion of Proposal P291 – Review of the Novel Foods Standard.

Record of views formed by the FSANZ Novel Foods Reference Group in response to inquiries as at June 2005

Table 1: Foods deemed to be novel

For all entries in this table, the outcome view with respect to the food or food ingredient is that it is 'non-traditional' and 'novel'.

Food or food ingredient	Justification	Comment
Ackee fruit (*Blighia sapida*) – sourced from Jamaica	Significant safety concerns if consumed unripe or improperly prepared	No application received
Agaricus blazei murill mushroom	Insufficient knowledge in community to enable safe use	No application received
Alpha Lipoic acid (also known as thiotic acid)	Safety not established for proposed pattern and level of use	No application received
L-Arginine alpha-ketoglutarate	Safety not established for proposed pattern and level of use	No Application received
Citrin (5-hydroxycitric acid)	Safety concerns based on potential for adverse effects in humans	No application received
Conjugated linoleic acid (CLA)	Safety concerns based on structure and proposed pattern and level of use	No Application received
α-Cyclodextrin	Safety not established for proposed pattern and level of use	Application to FSANZ (A494). Permission in Standard 1.5.1.
γ-Cyclodextrin	Safety not established for proposed pattern and level of use	Application to FSANZ (A438). Permission in Standard 1.5.1.
Docosahexanoic acid (DHA) sourced from *Schizochytrium* sp. marine algae	Safety of source from which DHA is derived is not established – potential for presence of undesirable substances.	Application to FSANZ (A428). Permission in Standard 1.5.1.
Diacyl glycerol (DAG) oil	Safety concerns based on structure and proposed pattern and level of use	Application to FSANZ (A505). Permission in Standard 1.5.1.
Garcinia cambogia (source of 5-hydroxycitric acid)	Safety concerns based on potential for adverse effects in humans	No application received
Hawthorn-berry (*Cratagegus oxyacantha*) based jam	Safety concerns based on potential for adverse effects in humans	No application received
Hemp (*Cannabis* spp.)	Safety not established	Application (A360) assessed. Rejected by ministers.
Isoflavones from red clover (*Trifolium pratense L.*)	Safety not established for proposed pattern and level of use.	No application received
Korean supplement drink (2) including *Angelica Keiskei*, *Artemisia princes*, *Ganoderma lucidum*, and *Cordyceps*	Safety concerns based on potential for adverse effects in humans	No Application received
D-Mannose	Safety not established for proposed pattern and level of use	No application received
Manuka plant (*Leptospermum scoparium*) – extract of New Zealand Manuka plant for use in alcoholic beverages	Safety concerns based on composition and potential for adverse effects (impaired mineral and protein absorption)	No application received

Phytostanols derived from tall oils	Safety not established for proposed pattern and level of use	No application received
Phytosterol esters derived from vegetable oils	Safety not established for proposed pattern and level of use	1. Application to FSANZ (A410) - Permission in Standard 1.5.1. 2. Application to FSANZ (A433). 3. Application to FSANZ (A434).
Phytosterols - Free phytosterols derived from tall oils	Safety not established for proposed pattern and level of use	1. Application to FSANZ (A417) - Permission in Standard 1.5.1. 2. Application to FSANZ (A508).
Phytosterol/phytostanol mixture derived from vegetable or tall oils	Safety not established for proposed pattern and level of use	Application to FSANZ – subsequently withdrawn by applicant.
Quorn	Safety concerns based on the composition. Potential for adverse effects in humans (e.g. allergenicity)	No application received
Rhodiola crenulate	Safety not established	No application received
Scaevola spinescens	Potential for adverse effects in humans	No application received
Slipper elm bark powder (*Ulmus fulva*)	Safety not established for proposed pattern and level of use	No application received
Stevia (crushed leaf)	Potential for adverse effects in humans	Stevioside and stevia extract considered as a food additive. Previous applications for stevioside (A397 & A457) as a food additive have previously been submitted but there have been deficiencies in some of the safety data. Both applications were withdrawn.
D-Tagatose	Safety not established for proposed pattern and level of use	Application to FSANZ (A472). Permission in Standard 1.5.1
Trehalose	Safety not established for proposed pattern and level of use	Application to FSANZ (A453). Permission in Standard 1.5.1.

Table 2: Foods deemed not to be novel

For some entries in this table, the outcome view will be that the food is a 'non-traditional food' but not a 'novel food'. For other entries in this table, the outcome view will be that the food is a traditional food.

Food or food ingredient	Outcome view	Justification	Comment
Acerola (*Malpighia glabra L*) – frozen fruit pulp	• Non-traditional food • Not novel	History of safe consumption in other countries. No safety concerns identified.	
Aloe vera (juice and juice concentrate)	• Non-traditional food • Not novel	Small established market for beverages in Australia and New Zealand	
Amaranth seed (*Amaranthus* sp)	• Non-traditional food • Not novel	No safety concerns identified	
Apple polyphenol extract	• Non-traditional food • Not novel	No safety concerns identified based on specifications provided	
Arachidonic acid (ARA) sourced from Fungus *Mortierella alpina*	• Traditional food for infants • Not novel	Traditional food for infants with no safety concerns identified based on this use	No application required for use as a food ingredient in infant formula
Argan oil (derived from the fruit kernels of *Argania spinosa*)	• Non-traditional food • Not novel	History of safe use in other countries. Chemical composition consistent with other vegetable based edible oils.	
Berries from palm fruit Acai (*Euterpe oleracea*) sourced from Brazil	• Non-traditional food • Not novel	History of safe use in South America. No safety concerns identified.	
Birds' nests (as produced by swiftlets in south-east Asia from saliva)	• Non-traditional food • Not novel food	History of safe use in Asian countries. No adverse health effects observed. No harmful substances identified.	Relevant quarantine requirements exist.
Boab fruit (otherwise known as boab nuts, from the Boab tree, *Adansonia*)	• Non-traditional food • Not novel food	Limited history of safe use in indigenous communities. No safety concerns identified. No concerns regarding composition.	
Camu camu fruit (*Myrciaria dubia*)	• Non-traditional food • Not novel food	No safety concerns identified. No concerns regarding composition.	
Cashew (*Anacardium occidentale L*) – frozen fruit pulp	• Non-traditional food • Not novel food	History of use in South America. No safety concerns identified. No concerns regarding composition.	
Cassava (*Manihot esculenta* Crantz)	• Traditional food (tapioca and cassava chips) • Not novel food	Traditional food, however knowledge about appropriate preparation required to ensure safe consumption.	Requirement for preparation instructions in Standard 1.2.6 – Directions for Use and Storage
Chia seed (*Salvia hispanica L*)	• Non-traditional food • Not novel	No safety concerns identified	

Colostrum (bovine, pre-milk produced by the cow's mammary glands in the first 72 hours after birth of the calf)	• Traditional food for infants • Not novel food	Non-traditional food in the population in Australia and New Zealand (excluding infants). No safety concerns identified.	
Damiana (*Turnera diffusa* or *Turnera aphrodisiaca*, same species) – non-culinary herb	• Non-traditional food • Not novel food when used in beverages at less than 100 mg/100 ml	No safety concerns identified at low levels of use.	No application required when in beverages at less than 100 mg/100 ml. Current relevant Proposal being assessed, Proposal P260 – Non-culinary herbs.
DHA sourced from algae *Crypthecodinium cohnii*	• Traditional food for infants • Not novel	Traditional food for infants with no safety concerns identified based on this use	No application required when used as a food ingredient in infant formula.
Evening primrose seed	• Non-traditional • Not novel	No safety concerns identified at the proposed levels of use.	
Fresh bamboo shoots	• Traditional food • Not novel food	Traditional food (particularly of canned product), however knowledge about appropriate preparation of fresh product required to ensure safe consumption.	Requirement for preparation instructions in Standard 1.2.6 – Directions for Use and Storage
β-Glucan derived from barley and produced by enzymatic starch hydrolysis at elevated temperature with ethanol precipitation	• Non-traditional • Not novel	No safety concerns identified with the production method employed.	
(High) β-Glucan cereals	• Non-traditional food • Not novel food	Natural variety sourced from a cereal fraction with high natural levels of β-glucan. No safety concerns identified.	
Grape pomace extract	• Non-traditional food • Not novel food	No concerns regarding composition or safety	
Grapeseed extract	• Non-traditional food • Not novel food	No concerns regarding composition or safety	
Graviola (*Annona muricata L*) – frozen fruit pulp	• Non-traditional food • Not novel food	Limited tradition of safe use in some population sub-groups. No concerns regarding composition or safety.	
Hu-hu grub (*Prionoplus reticularis*)	• Traditional food • Not novel food	Traditional of safe use – eaten as a delicacy in Maori populations in New Zealand.	
Konjac (100% konjac in elastic, thermo-irreversible gel rather than as an additive)	• Non-traditional food • Not novel food	History of safe use in Japan and other Asian countries with no known adverse effects.	

Korean supplement drink (containing lotus seeds and root (*Nelumbo nucifera* syn. *Nelumbium speciosum*), sea tangle or kelp (*Laminaria japonica*), jew's marrow (*Corchorus olitorius*))	• Non-traditional foods • Not novel food	No safety concerns at the proposed low level of use of ingredients	
Lavender (*Lavendula angustifolia*)	• Traditional food • Not novel food	Traditional use for purpose of flavouring. No safety concerns at proposed low level of use.	
Long neck turtle (*Chelodina longicollis*)	• Non-traditional food • Not novel food	Limited history of use in population sub-groups with safety concerns identified based on this use.	The sale of the meat of long-neck turtles is not covered by the Code and would require permission for human consumption under State or Territory law.
Luo han guo extract (*Siraitia grosvenorii*, otherwise known as Momordica P.E.)	• Regulate as a food additive	Extract contains a high level of mogroside, an intense sweetener.	No Application for approval of extract as an intense sweetener received.
Lycopene-enriched tomato extracts	• Non-traditional food • Not novel food	No safety concerns identified. Composition comparable to tomato paste products.	
Maca powder (*Lepidium meyenii*)	• Non-traditional food • Not novel food	History of safe use in South America. No concerns regarding composition.	
Melaleuca (*Melaleuca quinquenervia*) isolates	• Regulate as a food additive	Intended purpose is as a preservative.	No application received for approval as a food additive.
Nata de Coco (a fermented coconut-gel dessert)	• Traditional food • Not novel food	Fermented coconut extract with tradition of use as a food and no safety concerns identified.	
Passionflower (*Passiflora incarnata*)	• Traditional food • Not novel food	No safety concerns identified at proposed low levels of use.	
Pigeon pea (*Cajanus cajan* (L.) Millsp.)	• Traditional food • Not novel food	Tradition of use as food with no safety concerns identified.	
Pine bark extract	• Non-traditional food • Not novel when used as a surface treatment for cut fruit.	Intended use will have a minimal impact due to: the small amount used on cut fruit; and the small number of products anticipated on the market. Other food applications of pine bark extract would be considered novel.	No application required when used as a surface treatment agent for cut fruit.
Plant ingredients in fruit drink – *Garcinia mangostena*	• Traditional food • Not novel food	No safety concerns identified	
Quinoa (grain sourced from South America)	• Non-traditional food • Not novel food	No safety concerns identified. No concerns regarding composition.	

Salvia columariae	• Traditional food • Not novel food	No safety concerns identified	
Schizandra (*Schizandra chinensis*) – non-culinary herb	• Non-traditional food • Not novel food when used in beverages at less than 100 mg/100 ml	No safety concerns identified at low levels of use.	No application required when used in beverages at less than 100 mg/100 ml. Current relevant Proposal being assessed, Proposal P260 – Non-culinary herbs.
Sheep's placenta	• Non-traditional food • Not novel food	No safety concerns identified.	
Tempeh (fermented food made from soybeans) and Kefir (cultured milk beverage)	• Traditional foods • Not novel food	Traditional foods with no safety concerns identified	
Tequila worm in lollipops	• Traditional food • Not novel food	History of safe consumption based on use in alcoholic beverages. No safety concerns identified.	
Yacon (*Smallanthus sonchifolius*)	• Non-traditional food • Not novel food	History of safe use in other countries. No concerns regarding composition.	
Yuzu (Citrus Junos Siebold ex Tanaka)	• Non-traditional food • Not novel food	Tradition of safe use in Japan of the peel and oil in foods. No safety concerns identified. No concerns based on composition.	

ATTACHMENT 9

Impact Analysis

Option 1: Retain the *status quo*

- Retain the current Standard 1.5.1 – Novel Foods, of the Code.
- Retain the current assessment process for novel foods.
- Retain the current supporting documents on the website but continue to update the considerations by the NFRG in the guidelines as is the case currently.
- Retain the current operation for determining novelty i.e. NFRG working in conjunction with jurisdictions.

Option 2: Retain the current standard but amend operating procedures

- Retain the current Standard 1.5.1 – Novel Foods, of the Code.
- Retain the current assessment process for novel foods.
- Amend the supporting documents as required, particularly the guidelines. Review the classes of novel foods referred to in the guidelines and develop data requirements for each of the identified classes.
- Amend operating procedures for determining novelty by developing a decision-tree to assist the NFRG.
- Undertake education for stakeholders in response to demand that may assist in reducing the load on the NFRG.

Option 3: Amend Standard 1.5.1 and operating procedures

- Maintain the intent of the current Standard but review the wording of the purpose clause and the definitions for 'non-traditional food' and 'novel food'.
- Amend the definition for novel foods to capture foods produced using new technologies that have altered characteristics.
- Amend the supporting documents as required, particularly the guidelines. Review the classes of novel foods referred to in the guidelines and develop data requirements for each of the identified classes.
- Amend the guidelines to indicate that it is possible for an application for a novel food from a novel source or produced using a new technology that raises issues of minor significance or complexity only to be assessed under section 36 of the FSANZ Act and be released for one round of public comment only.
- Amend operating procedures for determining novelty by developing a decision-tree to assist the NFRG.
- Undertake education for stakeholders in response to demand that may assist in reducing the load on the NFRG.

Option 1

<u>Consumers</u>

The identified benefits are as follows:

- The current standard offers a high level of protection to consumers in requiring that all novel foods undergo a pre-market safety assessment prior to sale on the Australian and New Zealand market.
- Appropriate risk management strategies are employed if the risk assessment indicates that a particular novel food may pose a public health and safety concern to any population sub-group.

The identified costs are as follows:

- Some consumers may desire quicker access to certain novel foods than is achievable under the current process.
- In some cases it may be difficult for consumers to differentiate between a traditional food and a novel food that is similar in appearance but which has different nutrient content or a different function.

Public health professionals

The identified benefits are as follows:

- The current standard offers a high level of protection to public health professionals that may be recommending novel foods to clients.
- Because risk management strategies are put in place for certain novel foods if required, public health professionals can readily identify population sub-groups that the novel food should not be recommended to.

The identified costs are as follows:

- It may be difficult for public health professionals to identify the differences between a traditional food and a novel food that is similar in appearance but which has a different nutrient content or a different function.

Industry

The identified benefits are as follows:

- The pre-market assessment process for novel foods provides certainty and assurance for industry.
- The Standard is reasonably successful in supporting minimum effective regulation. For example, more than 100 inquiries have been received in relation to the Standard with approximately 25% of these being deemed to be novel and therefore subject to the pre-market assessment requirements of the Standard.

The identified costs are as follows:

- Because of the broad nature of the standard, it may not be clear to industry which foods are captured by the standard and therefore subject to the pre-market assessment requirements.
- Applicants incur a resource and monetary cost in applying to FSANZ to amend the Code to permit a novel food.

- Competitors in the industry sector can take advantage of a novel food permission once gazetted and therefore remove the commercial advantage of the applicant.

Government

The identified benefits are as follows:

- The Standard prohibits the sale of novel foods unless they are have undergone a pre-market safety assessment and are permitted. This allows enforcement agencies to take action in relation to a food if it is deemed to be non-traditional and novel.

The identified costs are as follows:

- Because of the broad nature of the Standard and the definitions contained within, it may be unclear to enforcement officers whether a food would be considered novel or not.
- If a food is already on the market in Australia or New Zealand, particularly in the more mainstream shops, it may be difficult to argue that the food is non-traditional even though there may be safety concerns. If the food is traditional, it cannot be captured by Standard 1.5.1 and enforcement officers cannot take any action if they cannot argue it is non-traditional.
- Making determinations as to the novelty of a food is resource intensive for government agencies – both FSANZ and enforcement agencies.

Option 2

Consumers

The potential costs and benefits to consumers listed for Option 1 apply to this Option. The amendment of the operating procedures e.g. inclusion of a decision-tree, would give greater clarity as to how determinations regarding novelty are made and this would be reflected in the guidelines. This potentially provides an additional benefit to consumers in comparison with Option 1 if the time taken to determine novelty is reduced and novel foods are available on the market earlier.

Public health professionals

The potential costs and benefits to public health professionals listed for Option 1 apply to this Option. The amendment of the operating procedures may provide an additional to benefit public health professionals because of greater clarity as to how determinations regarding novelty are made.

Industry

In comparison with Option 1, amending the operating procedures would benefit industry by providing greater clarity as to determinations with respect to novelty are made and data requirements. The incorporation of a decision-tree for determining novelty into the guidelines would assist industry in judging whether or not an application is required. An education initiative targeted toward industry would provide an additional benefit.

Government

Amending the operating procedures and the development of a decision-tree for incorporation into the guidelines would benefit government in comparison with Option 1 by providing greater clarity. Some input would likely be required by representatives from jurisdictions in developing the decision-tree and potentially also in education for stakeholders, having an initial impact on resources, however, it is expected that in the long-term these mechanisms will provide a benefit to government.

Comments on Option 2

This Option provides a benefit to all affected parties in comparison with Option 1 due to greater clarity around determining novelty and the operating procedures generally.

Option 3

Consumers

Option 3 provides the additional benefit to consumers in comparison with Option 2 in that the amended definitions will provide further clarity. Improved clarity in the definitions may decrease the time taken to determine novelty in comparison with only amending the operating procedures.

Consumers may benefit from a shortened assessment process in accordance with section 36 of the FSANZ Act where appropriate, in that those foods may be available on the market earlier. On the other hand, some consumers may have reduced confidence in the system to protect public health and safety. Overall, the use of section 36 of the FSANZ Act would have limited application for novel foods and thus there will be minimal impact on consumers.

Regulating foods produced using new technologies that have altered characteristics where necessary and appropriate could benefit consumers in providing them with additional confidence in relation to public health and safety. The potential cost to consumers under this option is that some foods may not be available on the market as early.

Public health professionals

As for consumers, Option 3 provides the additional benefit to public health professionals of improved clarity in comparison with Option 2. The regulation of foods produced using new technologies could also potentially benefit public health professions by providing additional confidence in relation to public health and safety.

Industry

Industry has difficulties with the current definitions. Improving the definitions will benefit industry in making an initial determination as to whether or not a food is novel and requires pre-market assessment. Clear and workable definitions with less ambiguity will also provide increased confidence to the industry sector.

Progressing an application in accordance with section 36 of the FSANZ Act where appropriate would benefit industry by offering a shortened assessment process allowing for earlier access to the market and also reduced risk of a competitor developing a similar product for release upon gazettal of the permission.

Regulating foods produced using new technologies that have altered characteristics would likely be viewed as a cost to industry in terms of resources required for submission of an application and delayed access to the market in Australia and New Zealand. A potential benefit for industry is that the mechanism would provide assurance and protection (credibility in the view of the consumer) regarding the public health and safety of foods produced using new technology.

Government

Enforcement agencies would also clearly benefit from clear and workable definitions, in combination with a clear process for determining novelty. Officers would have greater confidence in enforcement decisions and actions and would be able to act quicker if the definitions were less ambiguous.

Progressing applications in accordance with section 36 of the FSANZ Act may benefit the government because the time required to assess such an application would be reduced, thus freeing up resources for other tasks. However, if the circumstances under which an application could be assessed using this approach are not made clear, this could result in ambiguity as to how it is determined that issues of minor significance or complexity only are raised. As noted previously, the use of section 36 of the FSANZ Act would have limited application for novel foods and thus there will be minimal impact on

Including foods produced using new technologies that have altered characteristics would have an impact on government resources in relation to both enforcement and assessment. A clear description of what should be captured by any requirement to regulate foods produced using new technologies would be necessary to avoid a further question that would need addressing prior to assessment (i.e. should this food produced using a new technology be subject to pre-market assessment requirements?) further impacting on resources. Regulating foods produced from new processes if necessary would provide confidence in assuring public health and safety, benefiting government.

Comments on Option 3

Option 3 affords a clear benefit to consumers, public health professionals and government in comparison with Option 2 due to the opportunity to provide increased clarity around the definitions in addition to the process for determining novelty. Option 3 should benefit industry in comparison with Option 2 in most regards, specifically in relation to increased clarity around definitions. However, the introduction of regulation for foods produced from new technologies with altered characteristics may be viewed as a cost. Option 3 is also supports the implementation of the Ministerial Council Policy Guidelines.

Conclusion

Option 1 (*status quo*) affords a high level of protection of public health and safety, however some costs have been identified for all affected parties, that should be further considered and addressed if possible.

Option 2 provides a benefit to all affected parties in comparison with Option 1 due to greater clarity around determining novelty and the operating procedures generally. Under this Option, the operating procedures would be amended and a decision-tree included in the guidelines, providing increased clarity to all affected parties. Stakeholders would benefit from any education undertaken in response to demand. However, this Option would not allow the review of the regulations for novel foods including the definitions and the asserted subjectivity associated with the definitions would not be addressed.

Option 3 affords a clear benefit to consumers, public health professionals and government in comparison with Option 2 due to the opportunity to provide increased clarity around the definitions in addition to the process for determining novelty. Increased clarity around definitions would increase industry confidence in determining which foods are captured by the Standard and improve the efficiency of government enforcement agencies. Regulation of foods produced using new technologies would benefit consumers and public health professionals, and any cost to industry is likely to be minimal since only those foods with altered characteristics would be deemed to be novel. Option 3 is the only option which allows FSANZ to adequately address and implement the Ministerial Council Policy Guideline on novel foods.

Overall, Option 3 is the preferred regulatory Option.

ATTACHMENT 10

Standard Development Advisory Committee Membership, Terms of Reference and Guidelines

SDAC Membership

Ms Melanie Fisher (Chair)	FSANZ
Dr Leanne Laajoki	FSANZ
Mr Michael Apollonov	NSW Food Authority
Ms Joanne Cammans	South Australian Department of Human Services
Mr Michael Skinner	Queensland Health
Ms Jan Cristofani	Australian Quarantine and Inspection Service
Mr John van den Beuken	New Zealand Food Safety Authority
Dr Karl Skewes	Office of Complementary Medicines, Therapeutic Goods Administration
Ms Brigid Hardy	Department of Agriculture, Fisheries and Forestry
Ms Catherine Gay	Department of Health and Ageing
Mr Kim Leighton	Australian Food and Grocery Council
Mr Eric Wilson	New Zealand Food and Grocery Council
Ms Melanie McPherson	Australian Chamber of Commerce and Industry
Mr Allan Crosthwaite	Complementary Healthcare Council
Ms Linda Hodge	Dietitians Association of Australia
Ms Julie Woods	Public Health Association of Australia
Ms Amber Strong	New Zealand Dietitians Association
Ms Belinda Allen	New Zealand Consumers Institute
Ms Bella Tuau	Maori Reference Group

Terms of Reference for the Standard Development Advisory Committee on Novel Foods

The proposed Terms of Reference of the SDAC is to provide advice to FSANZ regarding:

1. the review of Standard 1.5.1 – Novel Foods in accordance with:

    a. the requirements of the *Food Standards Australia New Zealand Act 1991*; and
    b. the Australia and New Zealand Food Regulation Ministerial Council Policy Guideline on Novel Foods; and

2. any scientific, technical, policy, regulatory/enforcement, cost benefit or other information that may be relevant to the review process.

Conflict of interest

> **Standard Development Advisory Committee member** includes officers and employees of the Standard Development Advisory Committee.

1. All Standard Development Advisory Committee members are required to disclose at the start of each meeting, whether they believe they have a financial or non-financial conflict of interest with respect to any agenda item for that meeting. The Committee will determine whether such a conflict of interest exists.

2. If, during a meeting of the Standard Development Advisory Committee a conflict of interest arises, or appears likely to arise, the Standard Development Advisory Committee member agrees to:

    a. immediately make full disclosure of all relevant information relating to the conflict, or potential conflict to the Standard Development Advisory Committee; and
    b. take such steps as the Standard Development Advisory Committee may reasonably require to resolve, or otherwise deal with the conflict.

3. A Standard Development Advisory Committee member must not, unless the Standard Development Advisory Committee otherwise determines:

    a. be present during any deliberation of the Standard Development Advisory Committee with respect to the matter in relation to which a conflict has been determined to exist; or
    b. take part in any decision of the Standard Development Advisory Committee with respect to that matter.

4. If a Standard Development Advisory Committee member fails to make a full disclosure of the conflict, or potential conflict to FSANZ, or is unable or unwilling to resolve or deal with the conflict as reasonably required, FSANZ may terminate membership to the Standard Development Advisory Committee.

5. Without limiting the circumstances in which a conflict of may be found to exist, a conflict of interest exists if a member:

a. has made, or is preparing to make an application to FSANZ in relation to a matter;
b. is a board member of an organisation which has an interest in a matter;
c. is an adviser to a consultancy and/or a market research business which has an interest in a matter
d. intends to bid for a project commissioned by FSANZ in relation to which they have provided developmental input and have therefore gained inside knowledge of the project that would advantage them relative to other potential bidders.

Confidentiality

Confidential Information means all information that:

(a) by its nature is confidential;
(b) is designated by FSANZ as confidential;
(c) a Standard Development Advisory Committee member knows or ought to know is confidential; or
(d) is confidential commercial information as defined under section 3 of the *Food Standards Australia New Zealand Act 1991.*

Standard Development Advisory Committee member includes officers and employees of the Standard Development Advisory Committee.

1. Obligations

Standard Development Advisory Committee members agree to:

a. keep Confidential Information confidential;
b. only use or copy the Confidential Information as strictly necessary for Standard Development Advisory Committee meetings;
c. not disclose the Confidential Information to any other person without written approval by FSANZ; and
d. immediately notify FSANZ if the Standard Development Advisory Committee member becomes aware that any of the Confidential Information:

i. has been used, copied or disclosed other than in accordance with paragraph (c); or
ii. is required to be disclosed by law.

2. Exceptions

The obligation of confidentiality does not apply to information that is:

a. in the public domain;
b. independently developed or acquired by a Standard Development Advisory Committee member; or
c. required to be disclosed by law.

3. Return or destruction of Confidential Information

Standard Development Advisory Committee must return to FSANZ, or destroy all copies or delete electronic forms of Confidential Information, within 14 days of receiving a written request from FSANZ.

Guidelines for members

These guidelines for members have been developed to support the Terms of Reference for the Standard Development Advisory Committee (SDAC). The guidelines for members provide additional details about what role the SDAC fulfils as part of the review and what tasks they are being requested to contribute towards and the expected timelines for the engagement.

Purpose

The purpose of the SDAC is to provide advice to FSANZ on issues related to the review of Standard 1.5.1 – Novel Foods – of the *Australia New Zealand Food Standards Code* (the Code) including:

19. The current operation of the Standard from the enforcement, industry, public health and consumer perspective.
20. The current definitions for 'non-traditional food' and 'novel food' and any proposed revised definitions relating to novel foods.
21. The scope of the existing Standard 1.5.1 and the scope of any proposed revised regulation for novel foods.
22. The information provided to the public currently as to the novelty or otherwise of foods considered against the Standard and any proposed revision to this provision of information.
23. The costs and benefits associated with the operation of the Standard.

Have input into:

24. The development of an Initial Assessment Report on the review of novel foods, to be prepared by FSANZ for public consultation, including the regulatory and any non-regulatory options and the associated costs and benefits. A draft version of the Initial Assessment Report, and subsequently draft versions of the Draft Assessment Report and the Final Assessment Report, will be distributed to SDAC members for comment prior to consideration by the FSANZ Board. The SDAC members will be asked to comment on these draft versions but will not be endorsing the Reports.
25. Consideration of issues raised in submissions in response to the Initial Assessment Report in order to progress the development of the Draft Assessment Report and any proposed draft amendments(s) to the Code relating to novel foods.
26. Consideration of issues raised in submissions in response to the Draft Assessment Report in order to progress the development of the Final Assessment Report and any proposed amendments(s) to the Code relating to novel foods.

Timelines

An initial meeting is proposed for August/September 2004. It is anticipated that the Initial Assessment developed on the basis of this input will be subject to public consultation in December 2004. Further advice may be required based on issues raised in public submissions during 2005.

ATTACHMENT 11

Summary of Submissions to the Initial Assessment Report

There were 15 submissions received in response to the Initial Assessment Report for Proposal P291 – Review of the Novel Foods Standard, 13 from Australia and two from New Zealand. The majority of submissions received were from the industry sector (8), followed by government (5), public health/nutrition (1), and consumers (1). Six of the submissions received were from agencies/industry bodies or associations represented on the Standard Development Advisory Committee (SDAC). The remaining 11 SDAC representatives did not submit. A full list of submitters is at attachment 1.

Preferred regulatory options

The four options put forward in the Initial Assessment Report were:

Option 1 – Retain the *status quo*
Option 2 – Retain the current standard but amend operating procedures
Option 3 – Amend Standard 1.5.1 – Novel Foods, and operating procedures
Option 4 – No specific regulation for novel foods

Overall, Option 3 was most strongly supported, with 8 submitters favouring this option, followed by Option 4, favoured by 5 submitters. Of the submissions received from government, all supported Option 3. Whereas, of the submissions received from industry, most (5/8) supported Option 4 with an amended Option 2 nominated as the second preference. The submission received from the public health nutrition sector (Dietitians Association of Australia) also supported Option 3.

Some of the main issues that submitters commented on are discussed briefly below.

Purpose of the Novel Foods Standard

The majority of submitters supported the purpose of the Standard, that novel foods undergo a risk-based assessment to ensure their safety prior to sale.

Definitions for 'non-traditional' and 'novel'

A number of submitters were of the view that there is no need to define 'non-traditional food' as the definition for novel can accommodate the intent of absence of history of safe use. It was suggested that a decision-tree could incorporate questions that will address the extent to which a potential novel food has been consumed. Some submitters stated that there is value in revising and maintaining a definition for 'non-traditional food' in the Novel Foods Standard.

Regulation of foods produced using new technologies

Some submitters indicated there is a need to regulate food produced using new technology. Others indicated that there is a need to regulate foods produced using new technologies only if the resultant food falls within the definition of novel food or there is evidence that the resultant food has significantly altered characteristics.

Still other submitters did not support regulation of foods produced using new technologies as there is already a requirement to produce safe food.

Categories of novel Foods

All submitters who commented agreed that categories of novel foods are appropriate and helpful in the guidelines for novel foods but not appropriate to include in regulations for a variety of reasons. It was recommended that that the categories of foods currently referred to in the guidelines be revised based on experience since the introduction of the Standard.

Decision-tree

There was overwhelming support for the development of a comprehensive decision-tree and a more structured approach to determining novelty. Submitters suggested that a decision-tree would assist potential applicants and reduce the number of enquiries, and therefore, the workload of the Novel Foods Reference Group.

Expert panel

There was limited support for the establishment of an expert panel to assist in novel food determinations. Some submitters supported the establishment of an expert panel only if necessary in the future (e.g. if clear definitions and a decision-tree prove ineffective).

Education for industry

There was some support for education of stakeholders, including industry, in order to reduce the number of inquiries. However, there was also a view that clear definitions, a decision-tree and referral of previous determinations with respect to novelty would be just as effective.

Data protection

There was general agreement amongst submitters that the current assessment process does not protect confidentiality, which may enable competitors to develop similar products. A number of suggestions were made for addressing this issue, though the consideration of some may not be within the scope of this project.

Assessment process

There was support for considering the adoption of the approach of substantial equivalence for novel foods if appropriate (i.e. if a full safety assessment had been conducted on a similar food). This would result in shorter approval time, help protect sensitive information, and would be consistent with minimum effective regulation. However, it would have limited application for novel foods and some submitters were opposed outright to the approach.

Full summary of submissions

The submissions are summarised in accordance with the questions asked in the Initial Assessment Report, as this is the way in which the majority of submitters structured their responses. Headings correspond to the headings used in the Initial Assessment Report under which questions were included.

5.1 General History and Operation of Standard 1.5.1

1. Has the inclusion of considerations with respect to novelty on the FSANZ website been helpful?

Nine submitters responded to this question and all stated that the inclusion of considerations with respect to novelty on the FSANZ website has been helpful, at least to some extent. It has generated greater awareness and assists prospective applicants in determining whether a food falls within the scope of the standard. However, some of these submitters stated that the inclusion of these considerations needs to be more widely publicised and is difficult to locate on the website.

2. Are there other strategies that can be employed to assist?

Submitters listed clear definitions, editorial notes and an effective decision-tree as strategies that will assist in determining novelty.

3. Are there any other comments on the general history and operation of the Standard, including determinations with respect to novelty?

Submitters from the industry sector primarily responded to this question and argued that there has been confusion associated with the standard and further clarity is required around the definitions and enforcement. One submitter asserted that FSANZ has 'misinterpreted the definitions and operation of the standard with respect to protecting public health and safety.'

4. Is there support for the development of a more comprehensive decision-tree, which draws on the experience of addressing a large number of inquiries in relation to the novel foods standard?

There was overwhelming support from submitters (all of the nine that specifically addressed this question) for the development of a comprehensive decision-tree and a more structured approach. Submitters stated that a decision-tree would assist potential applicants and reduce the number of enquiries and therefore, workload of the Novel Foods Reference Group. One submitter suggested that the decision-tree should not be too prescriptive and novelty should not be based on one characteristic, but the sum of characteristics. Industry submitters suggest that industry should have input into the development of this decision-tree.

5. Is there any support for investigating the establishment of an expert panel to assist in making determinations?

There was limited support for the establishment of an expert panel to assist in making determinations. Reasons stated include the diverse range of novel foods, necessitating a panel reflecting this diversity and therefore, large in numbers. Some supported the use of an expert panel, but in only if necessary in the future (e.g. if clear definitions and a decision-tree prove ineffective). Only three submitters supported the establishment of an expert panel outright and these submitters suggested that it should include representatives from dietetics, food science, medical and social sciences and that changing food consumption patterns in the population should be considered.

6. Is there support for investigating education for industry on the regulations? Is this likely to reduce the number of inquiries received in relation to the Standard? Are there suggestions as to how such an education initiative could be handled most effectively?

There was some support for education for stakeholders, including industry, on regulations as this may reduce the number of enquiries. Suggestions include workshops, user guides and education kits. However, some submitters believe that it is not necessary to hold targeted education for industry as clear definitions, a decision-tree and referral of previous determinations with respect to novelty would be just as effective. It was also noted that smaller companies may be more difficult to reach.

5.2 Purpose of the Standard

7. What are your views on the purpose of regulating novel foods, i.e. a risk-based assessment process to ensure the safety of novel foods prior to sale in Australia and New Zealand?

The majority of submitters support the purpose of the Standard, that novel foods undergo risk-based assessment to ensure their safety prior to sale. Submitters indicated that there is a need to protect the consumer and this is appropriately done through a risk-based process with maintenance of confidence in the food supply. Only one submitter did not support the purpose of regulation of novel foods, arguing that public health and safety is protected by the general requirements of the Code.

8. Does the current Standard support this purpose?

The majority of submitters that responded to this question agreed that the current Standard does support the purpose. One submitter argued that FSANZ fails to interpret the Standard according to its purpose. Another submitter argued that the current Standard does not support the purpose and implementation would be enhanced by the clarification of definitions.

9. Would you support the suggested wording, or something similar (depending on the outcomes of the review), for inclusion in the purpose clause of the Standard?

The suggested wording was "The purpose of this Standard is to ensure that novel foods will undergo a risk-based safety assessment before they are offered for retail sale for direct consumption in Australia and New Zealand."

The majority of submitters supported the suggesting wording for inclusion in the purpose clause of the Standard, however, some stated that comment could not be made until the outcome of the review is known.

10. Do you have any alternative suggestions for the wording of the purpose clause?

Two suggestions were made:

- The proposed wording be expanded to ensure the standard captures foods produced by new technologies including breeding, where safety concerns are known.

- The word 'retail' be removed such that it reads "the purpose of this Standard is to ensure that novel foods will undergo a risk-based safety assessment before they are offered for sale for direct consumption in Australia and New Zealand."

5.3 Definitions for 'non-traditional' and 'novel' in Standard 1.5.1

11. Is there a need to define 'non-traditional food' or is it sufficient to define 'novel food' and incorporate the element of the absence of a history of safe use into that definition?

A number of submitters had the view that there is no need to define non-traditional as the definition for novel can accommodate the intent of absence of history of safe use. The idea of a non-traditional food could be included in the factors determining novelty. It was noted that the Canadian and EU definitions for novel food contain aspects of the current definition for non-traditional food. It was suggested that the decision-tree and guidelines could incorporate questions on whether the food has been consumed in Australia and New Zealand. However a small number of submitters believed that there is value in revising and maintaining a definition for 'non-traditional food' as it incorporates the elements of varied diets and multicultural populations.

12. What does 'history of significant consumption' mean in the definition for 'non-traditional food'? Could either, or a combination, of the following be used as a guide:

- **a specified number of generations (e.g. 1-3) of use?**
- **a specified number of sub-groups within a population?**

How could a 'generation' be defined?

Approximately half the submitters that responded to this question argued that if the definition for 'non-traditional food' was removed, these questions would not need to be addressed. Some suggestions were made:

Tradition of use could be defined as three or more generations. This would be consistent with the approach taken by the Therapeutic Goods Administration.
The Macquarie dictionary could be used to provide guidance in determining a generation.

It was noted that there is a difficulty in determining whether there was a significant consumption of certain foods given the current data available. As a guide, subgroups of the population should be considered.

13. What does 'broad community in Australia or New Zealand' mean in the definition for 'non-traditional'? To what extent is use by indigenous or immigrant populations taken into account? What level of use would constitute extensive use by those population sub-groups?

As with question 12, some submitters believed that these questions would not be relevant if the definition for 'non-traditional food' is removed, and advocated for its removal. Some suggestions include:

A food that has been consumed by broad communities outside Australia should not be considered as a novel food.

Food should be considered to be consumed by the broad community when food is freely available. The extent to which a food is consumed should contribute to the safety assessment. A food would not be considered to be consumed by the broad community if it is unlikely to be consumed outside small indigenous groups or immigrant populations.

All groups likely to consume the food should be considered. Extensive use is difficult to define, could be considered as weekly use by 50% of the population.

Broadening of the Australian cultural base should be taken into account for the whole population. The context of the food use (e.g. ceremonial verses daily consumption) should be considered.

14. There may be varied interpretations of 'insufficient knowledge in the broad community to enable safe use' as included in the definition for novel food. There may be a need to distinguish between documented knowledge (e.g. in the form of recipes) from anecdotal reports of knowledge.

There was some agreement that uncertainty surrounds the interpretation of 'insufficient knowledge in the broad community to enable safe use' and that improvements in the definitions and the guidelines for assessing this knowledge in the community needs to be developed. The extent of knowledge in the broad community will need to be determined on a case-by-case basis. It is important in making risk management decisions and the extent of knowledge will be related to severity of risks associated.

15. Is there support for developing a decision-tree, based on experience since the introduction of Standard 1.5.1 and advice from SDAC members, to support the definition(s)?

There was clear support for developing a decision-tree to support the definitions. Industry expressed a desire to have input. Submitters believed that a decision-tree would introduce more transparency into the decision process for determining novelty.

16. Is there support for addressing foods requiring specific preparation in Standard 1.2.6 – Directions for Use and Storage – of the Code and making this clear in the regulation for novel food?

The majority of submitters who responded to this question supported the inclusion of preparation instructions for novel foods in the Novel Foods Standard rather than Standard 1.2.6. There was some support for addressing foods requiring specific preparation in Standard 1.2.6, though this decision would have to be made on a case-by-case basis. Most submitters stated that if the food is novel, then it is appropriate to include specific preparation requirements as a condition of use in the Novel Foods Standard. The Novel Foods Standard already allows a variety of risk management options and can readily accommodate preparation instructions. If specific preparation instructions for novel foods are included in Standard 1.2.6, a cross-reference would need to be included in the Novel Foods Standard.

17. What other issues are relevant to improving the clarity of the definition(s)?

The only additional issue mentioned was that consideration should be given to foods produced by technology that substantially change the characteristics. This is poorly captured in the Standard, unlike in the guidelines.

18. Question primarily for enforcement agencies: Are there any particular issues unique to enforcement agencies that are important for consideration when reviewing the definitions?

No additional issues were stated by enforcement agencies.

5.4 Scope of novel foods regulation

19. Do submitters have information about the safety of any of these new technologies?

- Ozone treatment is used as an antimicrobial agent in bottled water.
- Carbon dioxide and other gases are processing aids.
- Modified atmosphere storage is an old technology.
- The resultant food product is important, not the type of processing.

20. Is there a need to regulate the foods produced from these new technologies?

There were a variety of views expressed. Some submitters (4) indicated that there is a need to regulate food produced using new technologies. Other submitters (3) indicated that there is a need to regulate foods produced using new technologies only if the resultant food falls within the definition of novel food or there is evidence of substantial differences. The application of a new technology should not automatically trigger an assessment of the resultant food. Two submitters did not support regulation of foods produced from new technologies as there is already a requirement in the Code to produce safe food.

21. If there is a need to regulate the resultant foods, is it appropriate to consider these within the Novel Foods Standard or is it preferable to introduce specific standard(s) for different processes based on an identified safety concern?

The clear majority of submitters supported the regulation of foods produced using new technologies under the Novel Foods Standard if there is a need for their regulation (i.e. if there are differences introduced by the application of the technology and they meet the definition of novel). The introduction of specific standards for different technologies was seen to be contrary to the principle of minimum effective regulation. Only one submitter supported the introduction of specific standards.

22. Do submitters agree that any reference to classes or categories of novel foods is more appropriately included in the guidelines rather than the regulation?

All submitters who responded to this question agreed that categories of novel foods is appropriate to include in the guidelines but not appropriate to include in regulation (the Novel Foods Standard). Reasons given include:

- Not all foods will fit within designated categories.

- Inclusion of categories in EU and Canadian legislation has given rise to difficulties.
- Inclusion of categories in regulations would be confusing.
- Guidelines are more easily amended than regulation and there will likely be a need to amend categories in the future.
- Inclusion of categories in regulations would be contrary to minimum effective regulation.

It was suggested that an editorial note could be included in the Novel Foods Standard referring to the guidelines.

23. Are the current classes in the guidelines helpful?

All submitters who responded to this question agreed that the inclusion of categories in the guidelines is helpful to potential applicants. It was suggested that these categories need to be kept updated and should be reviewed, perhaps with industry input. It was also suggested that examples would be helpful.

24. FSANZ will consider the current classes identified in the guidelines and use the inquiries dealt with by the NFRG as a guide. Are there any comments on appropriate classes that could assist FSANZ in this exercise?

There was little comment in response to this question and submitters felt that more detail was needed before they could provide input. One submitter suggested including reference to foods produced by new breeding and processing technologies.

5.6 Data protection for industry

25. What are your views on issues related to data requirements and data protection that are relevant to the assessment of novel foods?

There was general agreement amongst submitters that the current assessment process does not protect confidentiality, which may enable competitors to develop similar products, or 'ride on the back' of a permission. The processing of applications in a transparent way conflicts with confidentiality. Some suggestions for addressing this issue were:

- An amendment to the Act may be necessary to address this.
- A more streamlined approach based on substantial equivalence (this would only be possible in a small number of cases).
- Partial assessment be completed and then the applicant be informed early of the likelihood that it would undergo a full assessment.
- The GRAS approach of the US should be considered.
- Provisional patent for a year to enable industry to gain lead-time and included in information supplied for application.

There was some support for the current approach of all information being made public unless there is a patent or other legal constraints.

5.7 Assessment process for novel foods

26. What are your views on applying the approach of substantial equivalence in undertaking a risk assessment for certain novel foods, where appropriate?

There was fairly strong support for considering the approach of substantial equivalence further, with seven submitters providing outright support or indicating it was worth considering. Reasons given in support were that it is consistent with minimum effective regulation, shorter approval time, and it would help protect sensitive commercial information and a legitimate market advantage. However, further clarification of the circumstances under which it would be appropriate to consider substantial equivalence is needed. It was suggested that it only be applicable if an applicant is seeking approval of a similar food for which the safety has been assessed. Two submitters from the industry sector argued that if a food is shown to be substantially equivalent, then it is not a novel food. Two submitters opposed the approach of substantial equivalence outright.

5.11 Uptake of existing permissions for novel foods

27. Is there any additional information relevant to the uptake of existing permissions for novel foods by industry including quantitative data on sales and market share?

There was little information provided in response to this question. One submitter suggested that the uptake of existing permissions for novel foods has been slow because it is extremely difficult, expensive and time-consuming to launch a novel food because the novel foods process is so unpredictable with respect to timing that plans cannot be made to meet a trade launch date until the novel food is actually approved. Any competitive advantage that a company may have had initially is eroded over time, to the extent that some companies do not see this as a worthwhile exercise.

Another submitter stated that due to the limited data on novel foods, it is imperative that such data on sales and market share be provided by sections of industry to receive the benefits of approval. Another submitter suggested that because FSANZ has limited data on approved novel foods, a 1800 hotline to obtain more accurate data (on adverse reactions and complaints) would assist.

6 Regulatory options

28. Are there any additional regulatory options that should be considered?

Only one addition regulatory option was put forward, to consider a system of GRAS such as in the US.

29. Are there any additional non-regulatory initiatives that could be considered?

It was noted that there is useful information on the website but it is not easy to follow and should be reviewed, other tools such as this could be useful.

30. If an education program was implemented to assist industry in understanding the regulations for novel foods, who should conduct this (FSANZ, FSANZ and enforcement agencies, or enforcement agencies alone) and what industry sectors would benefit most?

As with question 6, support for an education initiative was varied with some submitters believing that education is not warranted. It was suggested that any education initiative could be through industry and agency conferences and targeted to companies interested in functional foods. It was suggested that FSANZ and enforcement agencies would be best placed to conduct a program. However, it was noted that there is limited public funded resources in the enforcement area and if industry is likely to benefit from such an initiative, then they should equally contribute.

31. Would industry benefit from such an initiative?

It was generally stated that industry would benefit, but some industry submitters did not support this, arguing that a clear definition and guidelines would be equally helpful.

7 Impact analysis

32. What are the current and potential costs and benefits associated with each of the regulatory options proposed for each of the affected parties?

There was no quantitative information provided on potential costs and benefits associated with the regulatory options. The limited qualitative information provided supports the costs and benefits suggested in the impact analysis in the Initial Assessment Report.

33. What is your preferred regulatory option? Please provide reasons.

Option 3 was most strongly supported, with 8 submitters favouring this option, followed by Option 4, favoured by 5 submitters. Of the submissions received from government, all supported Option 3. Whereas, of the submissions received from industry, most (5/8) supported Option 4 with an amended Option 2 nominated as the second preference. The submission received from the public health nutrition sector (Dietitians Association of Australia) also supported Option 3. Option 1 was not supported. One submitter suggested a further option, the GRAS status used in the US.

Reasons given in support of Option 3:

- Best option for addressing ministerial policy guideline.
- Provides assurance of public health and safety and allows to maintain obligations under the FSANZ Act.
- Allows amendments of both the Standard and the operating procedures.
- Will enable clearer definitions to be developed, protecting industry confidence.
- Will consider data protection and substantial equivalence.
- Option is consistent with areas the Technical Advisory Group and the Novel Foods Reference Group have agreed need improvement.
- Clarification of definitions and development of an improved decision-tree will assist enforcement agencies.
- Enable consideration of foods produced using new technologies.

Reasons given in support of Option 4:

- Consider the current provisions for industry to sell safe food are sufficient to ensure public health and safety and there is no need for a specific novel food standard.

List of submitters to the Initial Assessment Report

Australia

Public Health

Dietitians Association of Australia, Ms Sue Cassidy

Government

Department of Human Services Victoria, Mr Victor Di Paolo
Department of Agriculture, Fisheries and Forestry, Mr Richard Souness
West Australian Food Advisory Committee, Mr Paul Van Buynder
Queensland Health, Mr Gary Bielby

Industry

Food Technology Association of Victoria Inc., Mr David Gill
Unilever Australia, Ms Julie Newlands
Sanitarium Health Food Company, Ms Alison Tickle
Dairy Australia, Ms Janine Cornel
George Weston Foods Limited, Ms Fiona Fleming
Cadbury Schweppes Pty Ltd, Mr Neil Smith
Australian Food and Grocery Council, Mr Kim Leighton

Consumer/Private

Mr Gary Bilton

New Zealand

Government

New Zealand Food Safety Authority, Ms Carole Inkster

Industry

New Zealand Food and Grocery Council, Ms Brenda Cutress